Risk Assessments – Global Requirement
Is there a major difference in the Risk Assessments done in North America and Europe?

Summary

This risk assessment white paper guides you through answering the questions of what is a risk assessment, is it mandatory, how does it help me comply with the local and global compliance requirements, what does the risk assessment process involve, is it a one time or a continuous process, what are some of the risk reductions techniques, does following the risk assessment standards help my bottom line? Many of your questions will be answered in this educational document to assist you in making intelligent decisions when it comes to Risk Assessments and designing your machine and applications to meet the machine safety compliance requirements with the goal of increasing productivity in a safer manner, globally.

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Safety is a double-edged tool in that, it not only protects plant personnel, but it also increases productivity and provides cost savings. On top of that, companies who implement safety functions perform functional safety evaluations, and implement safety in manufacturing processes by following the guidelines stated in the machine safety standards and complying with their requirements, find benefits that go straight to the bottom line.

There are other financial benefits to implementing safety standards. For example, meeting safety specifications is globally understood and respected, which can in turn open up more global opportunities. Another factor is insurance companies have started to recognize machine safety compliance and its benefits, which can have a positive influence on insurance premiums.

When it comes right down to it, safety provides a safer and a more efficient work environment. Let’s face it, every year there are just over 4,600 employee deaths in industry, with another 50,000 that die from illnesses caused by exposure to workplace hazards, according to the U.S. Occupational Safety and Health Administration (OSHA). On top of that, six million workers suffer nonfatal workplace injuries. The annual cost to U.S. businesses ends up being more than $125 billion, according to OSHA.

Safety can truly be the source of a competitive advantage because it can reduce the total cost of goods and the total cost of risk. It can impact productivity along with image and reputation.

But before a manufacturer can reap any benefits, they should understand just which machine standard or standards to follow. That is why when making a risk assessment you should be able to analyze and understand the differences between ISO 12100 and ANSI B11.0.

Benefits of Risk Assessment

Before looking at the differences between the risk assessment standards, a user should understand just what a risk assessment brings to the table.

For one, to ensure compliance with the essential health and safety requirements, a risk assessment should be performed for machinery and partially completed machinery. Risk assessment is an essential part of the required technical documentation. Failure to perform one can result in a design error and/or incorrect instructions. In addition, an assessment protects against allegations of negligent or even culpable action and, in some cases, against possible consequences under criminal law. Transparency of processes, decisions, and results helps to defend against liability claims. Also, if applied correctly, a risk assessment can result in additional cost savings. So following risk assessment standards is a major step in overcoming liability issues and a step forward to increasing productivity.
Now, a formal process will allow for an evaluation of risk potentials throughout all modes and operations of a given machine. This process identifies risk levels that could end up injuring anyone that has to deal with a machine from the operator, maintenance worker or even people just walking by. The person, or team, conducting the risk assessment must undergo training and understand how machinery operation and production are affected by applicable codes and standards.

Here are important factors to take into account during a risk assessment:
- Severity of foreseeable injuries
- Probability of occurrence
- Frequency of exposure to hazard
- A list of actions required to meet applicable standards

By evaluating the machine and the environment around it for safety, a risk assessment keeps an end user aware of changes that need to occur to meet applicable codes. It also severely lowers the risk to machine operators. If an injury occurs, OSHA in the United States will ask what the employer did to make the area safe.

A risk assessment shows that the employer took steps to understand and correct any associated safety violations.

**Working with Standards**

In terms of performing a risk assessment, the international standard ISO 12100:2010, “Safety of machinery – General principles for design – Risk assessment and risk reduction” and the North American-centric ANSI B11.0-2010, “Safety of Machinery; General Requirements and Risk Assessment” are similar in many ways, but they also differ.

ANSI B11.0 is a significant document for machinery safety and for end users. The scope of the standard focuses on new, modified or rebuilt 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.

The ISO 12100 standard is geared more toward OEMs, while the B11.0 series covers not only machine builders, but also end users. So that means there may be some subtle terminology in ANSI B11.0 geared for end users that may not have a direct correlation with the ISO standards. Other than that, the risk assessment principals and requirements documentation are really almost the same or very similar.

The ANSI B11.0 standard references the similarities between the two: “This standard has been harmonized with international (ISO) and European (EN) standards by the introduction of hazard identification and risk assessment as the principal method for analyzing hazards to personnel to achieve a level of acceptable risk. This standard integrates the requirements of ANSI/ISO 12100 parts 1 and 2, and ISO 14121(now combined into a single standard – ISO 12100), as well as selected U.S. standards. Suppliers meeting the requirements of this ANSI B11.0 standard may simultaneously meet the requirements of these ISO standards.”

One major difference is ANSI is purely North American and that will place limitations on machine builders. Along those lines the European Union does not recognize ANSI. Only the European Standards (EN) end up recognized in Europe. Conversely, in North America, OSHA does not recognize EN standards or ISO standards.

So what ends up happening is there is an equivalency between the two standards. If a builder designs a machine to ANSI B11.0 and ships it to Europe or any non North American country, it would, for all practical purposes, have met ISO 12100 or EN ISO 12100 requirements because of the similarities. The same is true for North America. They are both globally recognized as equivalent type of standards. In the end, the builder may need to make a few changes, but they are not significant changes.

The differences come into play when you look at it from the legal standpoint. Legally, you can’t use ANSI B11.0 in Europe or other countries such as Brazil.

As mentioned, ANSI B11.0 includes requirements for suppliers and users of machinery. The standard states that machinery suppliers and users have responsibilities for defining and achieving acceptable risk. The standard provides additional details and descriptions of the responsibilities for users and suppliers in the standard. They entail: Prepare and set limits of the assessment; identify tasks and hazards; assess initial risk; reduce risk; assess residual risk; residual risk acceptable; validate solutions, and results/documentation.

The primary performance requirement of the standard is that the risks associated with the operation, maintenance and dismantling and disposal of machinery will reduce down to an acceptable level. This requirement applies to the supplier, user, installer, and the integrator/modifier/rebuilder of the machinery.

While understanding nothing in the manufacturing environment can be totally hazard free, the standard provides an assessment process that can achieve acceptable risk. In addition, B11.0 includes clauses on specific risk reduction and safeguarding methods, information for use, and training.
Going Global

Like ANSI B11.0, ISO 12100 is an A-level standard and it has seven clauses and three annexes.

The first three clauses address scope, normative references, and terms and definitions. Clause 4 addresses risk assessment and reduction strategy. Clauses 5 and 6 discuss risk assessment and risk reduction. Clause 7 describes documentation for the activities of clauses 5 and 6.

Another difference between ISO 12100 and ANSI B11.0 is the explicit assignment of responsibilities within clause 4 of ANSI B11.0. Duties are typically delegated within the ANSI standard to the general categories of supplier and user. Within ISO 12100, another standard ends up being referenced (ISO/TR 14121-2) that provides specific methods for systematic hazard identification.

During risk estimation, ISO 12100 specifically cautions about the possibility of defeating or circumventing protective measures in four situations:

1) The protective measure slows down production or interferes with another activity or preference of the user.
2) The protective measure is difficult to use.
3) Persons other than the operator are involved.
4) The protective measure is not recognized by the user or not accepted as being suitable for its function.

Updated Information

The ISO 12100 relies upon 20-year-old information where ANSI B11.0 comes from more recent updated information. It may seem confusing, but like its ANSI counterpart, ISO 12100 published in 2010. But that is as new as this international standard gets.

Without getting into all the political ramifications behind the standard, essentially three standards – EN 292-1 terms and hazard identification, EN 292-2 risk reduction, and EN 1050 risk assessment and then later ISO 12100-1, 12100-2, and ISO 14121 – came together in Europe in the late 1990s.

With the revision of the Machinery Safety Directive, these individual standards needed an update and that process started around 2004.

By 2008, the three individual ISO standards would editorially combine with no technical changes. This editorial combination melded together into the new ISO 12100 and the committee published it in 2010. This was a major accomplishment in the standards world, but at the end of the day, it took almost a decade to combine the standards into one, but there were no changes made to the actual content.

While both standards are solid, if the user is looking for the most current techniques and technology usage and information, they will end up better served looking to the B11.0 standard rather than the ISO 12100 standard.

Performing a Risk Assessment

The supplier and the user can, either separately or jointly identify hazards, assess risks, and reduce risks to an acceptable level as described in this standard.
The supplier and user shall use the related regulations and standards applicable to their work activity. This may include regulations and standards for a specific location and/or for a specific application.

When the supplier is not available to participate in the risk assessment for the machine tool, the user assumes that responsibility.

ANSI B11.0 does address some higher-level injury prevention techniques such as elimination and substitution. A term catching on in the Safety, Health and Environmental (SH&E) professional community is prevention through design (PTD).

Terms such as elimination by design, design out and substitution have equivalent meanings and are discussed in B11.0.

B11.0 contains nine clauses (or sections) and 11 annexes. The first four clauses have a similar format throughout the B11 series. These clauses deal with the scope, normative references, definitions and responsibilities. The fifth clause talks about the fundamental machinery requirement where suppliers and users must achieve acceptable risk.

In clauses 6 through 9, B11.0 addresses risk assessment, risk reduction, information for maintenance/ use and training. In the standard, a supplier is typically responsible for machine design and construction, as well as for providing information on machine operation and maintenance. The user is responsible for the machine operation and maintenance.
A key concept is suppliers and users should collaborate on safety and risk reduction as early in the process as possible. If a machine is modified during its lifecycle, the risk assessment/risk reduction process must be performed again. This shows that the risk assessment is not a one time thing but a continuous risk reduction process.

Risk Assessment Team

Like most things in manufacturing a risk assessment should not occur in a vacuum. A risk assessment team must consist of qualified personnel. The B11.0 standard calls for individuals of “technical competence” and “relevant skill set.” Operators, maintenance or engineering personnel may have the most to offer in this process.

Key ideas in the risk assessment process involve the terms residual risk and acceptable risk. The standard defines residual risk as “the risk remaining after risk reduction measures (protective measures) are taken” while acceptable risk is “a risk level achieved after risk reduction measures have been applied. It is a risk level that is accepted for a given task (hazardous situation) or hazard.” ANSI B11.0 talks about acceptable risk, where ISO 12100 talks about tolerable risk.

The differences between tolerable risk and acceptable risk can appear a bit confusing.

Tolerable can be a very subjective interpretation where it means different things to different people. An OEM may configure the machine to a tolerable level and sell it to an end user, but end users have other things they have to look at like moral and ethical responsibility, social responsibility and brand image. There may be tolerable risk, but not acceptable risk to them because of the other things that could play into their brand image.

After assessing what is acceptable, the risk assessment team identifies tasks and hazards. It needs to include all reasonably foreseeable hazards regardless of the existence of risk reduction measures. For example, the team must consider whether guards supplied with a machine are sufficient for hazards or whether supplemental protection is necessary. The team also must consider reasonably foreseeable misuse of equipment and protective measures, as well as machine malfunction.

When identifying tasks for risk assessment, the team should consider scenarios in addition to machine operation. Situations noted in B11.0 include packing and transportation; unloading/unpacking; systems installation and assembly; start-up/commissioning; setup/changeover; operation (all modes); maintenance; shutdown; lockout/tagout; recovery from jams; troubleshooting; cleaning; and decommissioning, dismantling and disposal. The standard also suggests several hazard categories and advises that all reasonably foreseeable hazards be included. Categories mentioned include mechanical hazards; energy sources; foreseeable hazards; slips and falls; hot surfaces; combustible atmospheres or media; sharp edges; and operational hazards.

Assessing initial risk is Step 3 in the risk assessment process. Risk is a function of severity of harm and probability of occurrence of that harm; also, an additional factor of frequency of exposure will apply. This frequency takes into account the fact an individual may not always suffer exposure to the risk under consideration. For example, the hazard may involve a maintenance procedure required only once per year. If frequency of exposure is a consideration, then it would have a different risk than a maintenance procedure required each day, even if the probability of occurrence of harm is the same.

From ANSI B11.0, a severity of harm that is moderate, coupled with a very likely probability of occurrence of harm, would fall in the high risk category. In this sample system, risk divides into high, medium, low and negligible risk.

Assigning severity and probability categories can come from these sample definitions:

Severity

- Catastrophic: Death or permanently disabling injury or illness (unable to return to work)
- Serious: Severe debilitating injury or illness (can return to work at some point)
- Moderate: Significant injury or illness requiring more than first aid (able to return to same job)
- Minor: No injury or slight injury requiring no more than first aid (little or no lost work time)

Probability

- Very likely: Near certain to occur
- Likely: May occur
- Unlikely: Not likely to occur
- Remote: So unlikely as to be near zero
If the residual risk calculated during risk assessment is greater than the acceptable risk, that risk must reduce down to the hazard control hierarchy. B11.0 lists risk reduction measures from most preferred to least preferred: Elimination or substitution (most preferred); guards and safeguarding devices; awareness devices; training and procedures; and Personal Protective Equipment (PPE) (least preferred). Once risk reduction measures are in place, the risk assessment repeats until residual risk reaches acceptable risk.

After risk is at an acceptable level, the user must then verify risk reduction. Those involved must ensure that such testing does not expose an individual to potential harm if the measures fail.

To complete the risk assessment process, B11.0 requires the following documentation:

- Machinery assessed
- Relevant assumptions made
- Information on which the assessment was based
- Names of risk assessment team members
- Date(s) of the risk assessment
- Tasks and hazards identified
- Initial risks associated with the machinery
- Risk reduction measures implemented to eliminate identified hazards or to reduce risk
- Residual risks associated with the machinery
- Validation of risk reduction measures, including information on the responsible individual and the date of validation
Risk Reduction in three levels:
Following risk assessment, a decision as to whether risk reduction measures have to be initiated must be made. Such risk reduction comprises design measures, technical protective equipment as well as training measures for users – and can be divided into three levels.

**Level 1: Safe Design**

Safe design can for example be ensured through the integration of safety in the machine (covers, fences, etc.). These measures take top priority within the scope of risk reduction.

They are to ensure the following:
- Avoidance of crushing points
- Avoidance of electric shock
- Concepts for machine shutdown in case of emergency
- Concepts for operation and maintenance

**Level 2: Technical protective measures**

A safety function has to be defined for each hazard which cannot be eliminated by means of design measures. As shown in the following example, such safety function can be executed by a safety system: “When the protective door is opened during normal operation, the motor has to be switched off.”

A safety system executes safety functions and is comprised of subsystems:
- Detecting (position switch, E-STOP, light curtain, etc.)
- Evaluating (fail-safe controller, safety relay, etc.)
- Reacting (contactor, frequency converter, etc.)

**Level 3: User Information on residual risks**

As a matter of fact, users have to be comprehensively informed of any possible residual risks. However, such information does not replace the request for safe design and technical protective measures, but is merely intended to supplement such measures.

User information for example comprises of:
- Warnings in the operating instructions
- Special work instructions
- Pictograms
- Note on the use of personal protective equipment

Vigilantly following the risk assessment standard, whether it is ANSI B11.0 or ISO 12100, and the risk reduction techniques will keep safety incidents to a minimum, plus it has a major impact on increasing productivity and will bring in additional cost savings.

There is no doubt, if companies employ safety functions, perform functional safety evaluations, and fully execute safety in manufacturing processes by following the guidelines mentioned in the machine safety standards and complying with their requirements, they will gain benefits that go straight to the bottom line.

For additional information on Machine Safety Standards and Risk Assessment information and services, visit www.usa.siemens.com/safety

(This document is just an educational overview, for more details, the ISO 12100:2010 & the ANSI B11.0:2010 standards, can be purchased at the ANSI Store, online: www.webstore.ansi.org)