

RISK ASSESSMENT IN THE REAL WORLD

BRUCE W. MAIN, PE CSP
design safety engineering, inc.
Ann Arbor, Michigan
www.designsafe.com

Abstract

This presentation examines the risk assessment process and how it has been applied in actual companies. A framework that describes how the risk assessment process can be integrated into a company's existing operations is presented. Several situations are discussed where risk assessment has been successfully used to develop effective solutions. Common themes are stressed such as: identifying hazards early in the development process, engaging engineers and end users in the risk assessment effort, and using the risk assessment process to make appropriate decisions on risk reduction options. Emphasis is placed on how the risk assessment process can be applied to better identify hazards associated with automated machinery, and subsequently reduce the risks to an acceptable level.

Overview of the Risk Assessment Process

Although many companies and industries use different risk assessment methods, the fundamentals of the risk assessment process are common:

- identify hazards,
- assess risk,
- reduce risk, and
- document the results.

The overall risk assessment process is illustrated in Figure 1 and comprises seven steps. Step by step descriptions for the risk assessment process and a detailed discussion of each step are contained in *Risk Assessment: Basics and Benchmarks* (Main, 2004). Readers new to this topic or those interested in more details should refer to that text and others listed in the References.

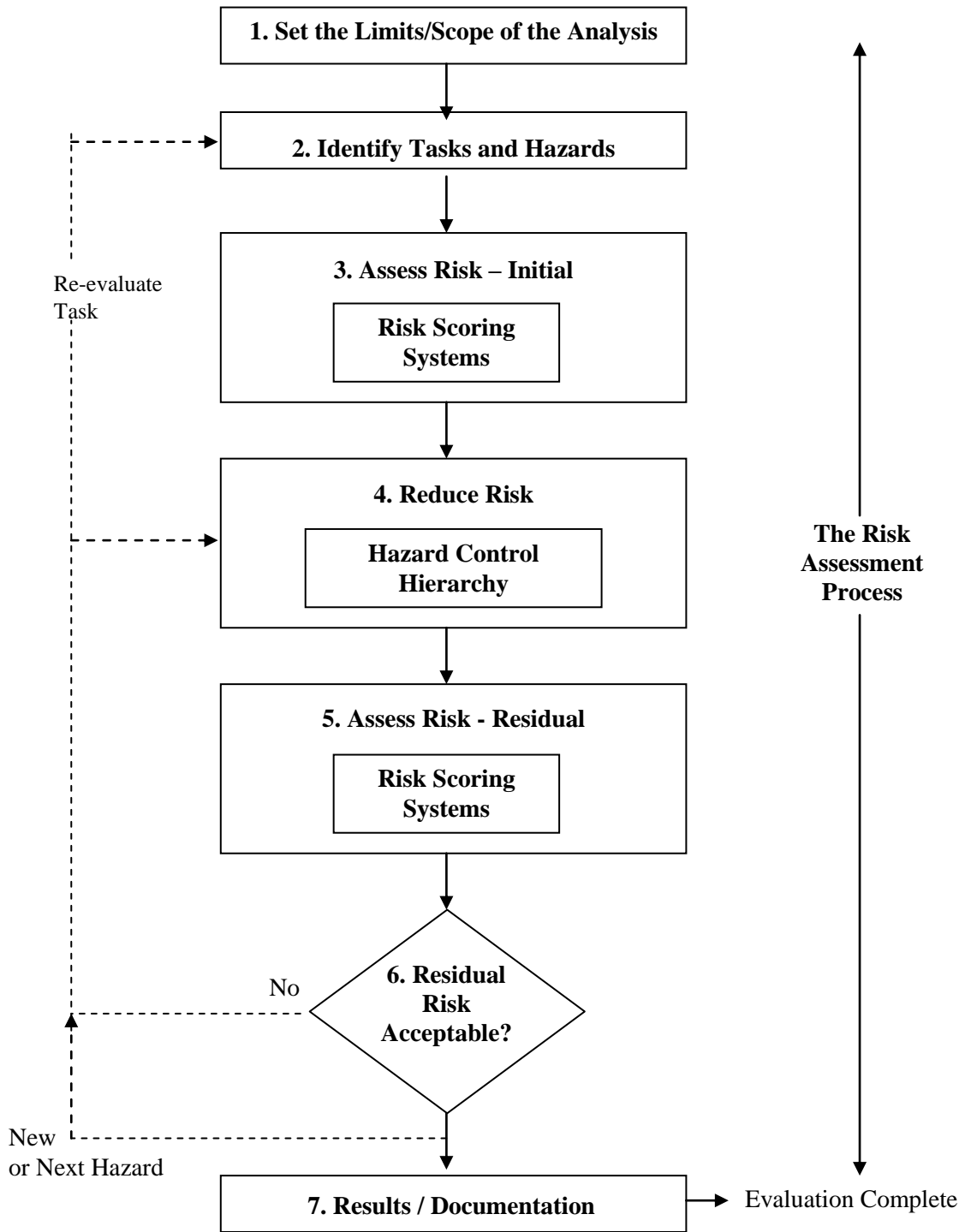


Figure 1 – The Risk Assessment Process
 From *Risk Assessment: Basics and Benchmarks (Main, 2004)*
 Used with permission

Benchmarks

Risk assessment methods following the general approach of Figure 1 are being deployed in many industries, and that momentum will likely continue. Risk assessment has been and is being written into industry standards and guidelines at both the national and international levels. Performance-based standards have been a key driver in the growth of risk assessments because they are the primary means to demonstrate that risks have been reduced to an acceptable level. Although the level of sophistication varies from industry to industry and within industries, the general risk assessment process applies across all industries and applications.

Some of the current benchmark methods are listed below and in the References:

- U.S. and Canadian robotics industries (ANSI/RIA R15.06, CSA Z434)
- U.S. Machine Tool Industry (ANSI B11 Technical Report #3)
- Packaging Machinery Industry (ANSI/PMMI B155.1)
- Automotive Industry
- Australia and New Zealand (AS/NZS 4360)
- Europe (ISO 14121)
- Control of Hazardous Energy - Lockout/Tagout (ANSI Z244)
- Chemical and Processing industries (ANSI/ISA S84)
- U.S. Military (MIL-STD-882D)
- Semiconductor Industry (SEMI S10)
- Medical Device Industry (ANSI/AAMI/ISO 14971)
- OSHA / personal protective equipment

Many of the differences in the approaches to risk assessment concern the way risks are scored. Manuele (2001) coined the term “risk scoring systems” to describe how risks are rated. A wide variety of risk scoring systems exist ranging from the qualitative to quantitative.

An extensive discussion of the benchmark methods falls beyond the scope of this article. Interested readers should review Main (2004) and Manuele (2003) for additional details.

Real World Applications

The risk assessment process can be applied to many different applications and industries. The process can be scaled from a very specific design or limited scope, to large scale operations. It applies to both product design and evaluating facilities. The following applications will be discussed in the presentation.

Automated Processing Line

A medium-sized automotive supplier company faced several safety concerns on an automated processing line including fall hazards, confined space, guarding, access, etc. Although the individual hazards were not all that complicated, the overall project was quite sizeable and raised questions of effective resource allocations. There were numerous opportunities to reduce risk, but limited resources required that a prioritized approach be used to addressing the hazards.

The risk assessment process was used to identify the tasks and hazards throughout the facility so that the risks could be appropriately assessed. Based on the initial risk levels, risk reduction options were identified to reduce risks to an acceptable level. Risks with the greatest levels were address first. In some instances such as fall hazards, engineered systems were developed to enable the tasks to be completed safely. In other types of hazards, procedures and warnings were determined to provide sufficient risk reduction.

In this application the company used the risk assessment process to logically develop answers to the safety related questions in a prioritized manner.

An OSHA Inspection

Following a near miss incident in a wood products manufacturing operation, an OSHA inspection resulted in requirements for several process changes. The changes were strictly based on perceived non-compliance with OSHA standards. The requested changes created substantial difficulties for the manufacturer due to the tightly integrated nature of the operation. To implement the OSHA changes would have created substantial problems for the manufacturer in terms of reorienting work flow, modifying equipment, and lost operations to make the changes.

As an alternate to the compliance assessment conducted by OSHA, the risk assessment process was used to better understand the particular hazards and evaluate options to reduce risks to an acceptable level. The risk assessment demonstrated that certain process changes OSHA required would increase overall risk, e.g., although egress risks would decrease, the ergonomic risks would greatly increase. The risk assessment also helped to identify alternate risk reduction methods that could be reasonably implemented by the company that addressed the underlying concerns raised by OSHA. In this instance, the risk assessment process moved the discussion from a compliance/non-compliance argument to a discourse on how to reduce the risks of particular hazards to an acceptable level for all parties. The risk assessment process was successful in this regard.

Consumer Electronics Manufacturer

A large consumer electronics manufacturer is successfully applying the risk assessment process to a new product development effort. Safety professionals lead the implementation effort and assist in identifying hazards. Design engineers participate in the process of identifying hazards and lead in reducing risks. Managers require risks to be reduced to an acceptable level before the design can advance to production.

In this application, products liability issues are a concern. Diligent efforts are being made by safety personnel and design engineers to prevent customer incidents while using the product. However, the manufacturer would likely be named in any potential litigation due to its size and resources. In this situation the risk assessment process is being used to help document decisions of risk and the risk reduction methods used to minimize risk knowing that the decisions may come under scrutiny in the future. The risk assessment process is helping to create the story that can be told about the design decisions and tradeoffs made during the development process. In the event of subsequent litigation, the story can be told as needed.

Prior to introducing the risk assessment process, engineers did not think in terms of hazards or risks. Now, engineers engage in discussions about hazards and specific risk reduction methods. They discuss alternate risk reduction methods and the impacts on the probability of injury, and whether the risk reduction methods reduce risk to an acceptable level. This constitutes significant progress.

Retail Bagel Store

A retail bagel store sought to determine if a slicing machine was safe for younger employees, or if additional risk reduction was required. The risk assessment process was used to identify the tasks and hazards, and to assess the risks associated with the tasks. Risk reduction methods included guarding systems, warnings, training and standard procedures. Based on the risk assessment, the machine was determined to afford an acceptably low level of risk for younger employees. A more complete discussion of this project and the resulting risk assessment appears in *Risk Assessment: Basics and Benchmarks*.

Sales Department

The sales department in an automated food packaging machinery manufacturer desired a smaller version of a packaging system. The engineers had a hand held prototype system that they had

used in developing the larger automated system that was offered for sale to customers. The smaller version did not leave the engineering laboratory. The sales department wanted to offer the smaller prototype system to potential customers so that they could “try before they buy” the larger system.

The system uses a hazardous gas to extend the shelf life of perishable goods. The engineers expressed great concern that the prototype did not have sufficient controls on the gas delivery system to allow potential customers to use it safely. As a result, the engineers expressed considerable reluctance to release the prototype system for external use.

In this situation the risk assessment process was used to identify the tasks and hazards necessary to properly use the hand held packaging system. Numerous issues were identified where customers could make errors that would result in unacceptable risk to the users or the prototype equipment. For example, the prototype system used an off-the-shelf pump that required adjustments depending on the food being packaged. If the adjustments were made incorrectly the pump would be damaged. Changes to the system design eliminated the need for pump adjustments thereby reducing risks of error, injury and damage. In addition, a new instruction manual was developed based on the risk assessment results.

With the many changes made to the prototype system through the risk assessment process, the engineers expressed confidence that the new system could be safely used by potential customers as the sales department desired.

Insurance Coverage

A small equipment manufacturer in the meat processing industry faced difficulty obtaining insurance coverage at reasonable cost. To improve its risk position in the insurance market, the company is turning to the risk assessment process to identify hazards and minimize risks. Although early in the process, the indications are that their risk position and insurance situation will improve at the renewal date due to the changes they will make through the risk assessment process.

Prototype System in the Automotive Industry

A manufacturer in the automotive industry was developing a prototype system for a production line that included robots and operator work stations. Questions arose concerning how to determine the most appropriate risk reduction methods between area scanners, light curtains or fixed guarding. Costs of each of these solutions vary, as does the feasibility of their effective use. To determine which solution provided the best risk reduction at reasonable cost, the company used the risk assessment process.

In the course of performing the risk assessment, the manufacturer also identified previously unknown hazards that had been designed into the system. For example, the system included overhead proximity sensors. The task-based risk assessment identified that these switches would need to be adjusted or replaced from time to time. At that point the team realized that there was no safe way that a maintenance person could work at height to perform that task. No tie-off anchor points were designed into the system, and the location precluded the use of man lifts. To perform this task would require the maintenance person to break the company rule of working at heights without fall protection. The changes to the prototype system included installing appropriate anchor points to the design.

Through the risk assessment process, this manufacturer was able to optimize spending on risk reduction devices, and also to identify previously unknown hazards.

Global Manufacturer

A global manufacturer operates a clean room used in the manufacturer of goods. The system includes proprietary processes for which specialty equipment is required. Because the manufacturer operates in several countries, the equipment must be able to ship anywhere in the

world. Therefore, the equipment in the room requires CE marking, which in turn requires a risk assessment. The manufacturer desired an in-house capability to perform risk assessments to accommodate its ongoing process and equipment improvements. The company management has set explicit requirements for implementing the risk assessment process against a specific time schedule.

In this situation, the risk assessment process is being used in the machinery design and process development to ensure both its safety and its ability to ship anywhere in the world. Safety professionals are engaged in leading the effort and design and maintenance engineers share ownership of the process. Management has set the criteria and all are working to meet these requirements.

Conclusion

The risk assessment process is gaining traction as companies seek to implement methods to maximize the use of safety and financial resources. The risk assessment process is flexible and scalable as shown in the real world applications discussed herein. Because the basics of risk assessment are common among the many different methods seen in standards, guidelines and technical reports, the risk assessment process is advancing quickly. These risk assessment principles assist companies in managing safety and health in their organizations.

References

- ANSI/AAMI/ISO 14971-2000. *Medical devices, risk management, Part 1: Application of risk analysis*. Association for the Advancement of Medical Instrumentation. www.aami.org.
- ANSI B11 Technical Report #3 (2000). *Risk Assessment - A guideline to estimate, evaluate and reduce risks associated with machine tools*. The Association for Manufacturing Technology. www.amtonline.org.
- ANSI/ISA S84-1996. *Application of safety instrumented systems for the process industries*. Instrumentation, Systems, and Automation Society. www.isa.org
- ANSI/PMMI B155.1-2000. *For packaging machinery and packaging-related converting machinery - safety requirements for construction, care and use*. Packaging Machinery Manufacturers Institute. www.pmmi.org
- ANSI/RIA R15.06-1999. *Safety requirements for industrial robots and robot systems*. Robotic Industries Association. www.robotics.org.
- ANSI Z244.1-2003 (final draft). *Control of hazardous energy – Lockout/tagout and alternative methods*. National Safety Council. www.nsc.org.
- AS/NZS 4360-1999. *Risk Management*. Standards Australia. www.standards.com.au.
- CSA Z434-03. *Industrial robots and robot systems - General safety requirements*. Canadian Standards Association. www.csa.ca.
- HB 203-2000. *Environmental risk management – Principles and process*. Standards Australia. www.standards.com.au.
- HSE. (2001). *Reducing risks, Protecting people: HSE's decision-making process*. Health and Safety Executive. www.hse.gov.uk.
- HSE. (1992). *Manual handling operations regulations*. www.ergonomics.org.uk/resources/newsinfo/hsenenews.htm.
- ISO 14121/EN 1050-1999. *Safety of machinery; risk assessment*. International Organization for Standardization. www.iso.ch.
- Main, B.W. (2004). *Risk Assessment: Basics and Benchmarks*. Ann Arbor, MI. design safety engineering, inc. www.designsafe.com
- Manuele, F. (2003). *On The Practice Of Safety, 3rd Edition*. New York: Van Nostrand Reinhold, New York, NY.
- Minter, S.G. (2003).
- Manuele, F.A. (2001). *Innovations in safety management - Addressing career knowledge needs*. New York: John Wiley & Sons.

- McNab, B. (2001). *Inspection, investigation and enforcement risk management through assessment and control*. A Framework for the Ministry of Agriculture Food and Rural Affairs, Draft Aug. 7. www.gov.on.ca/OMAFRA.
- MIL-STD-882D (2000). *Standard practice for system safety*. Department of Defense, U.S.A. www.defenselink.mil.
- NORSOK Standard Z-013. *Risk and emergency preparedness analysis*. Rev. 1, March 1998, and Rev. 2, 2001-09-01. Norwegian Center for Ecological Agriculture. www.norsok.no.
- Ontario Ministry of Agriculture Food and Rural Affairs. (2001). *Inspection, investigation & enforcement risk management through assessment & control; A framework for the ministry of agriculture food & rural affairs, Draft 7 Aug 2001*. www.gov.on.ca/OMAFRA/english/.
- SEMI S10 1103. (2003). *Safety guideline for risk assessment*. Semiconductor Equipment and Materials International. www.semi.org.

About the Author

Bruce W. Main, PE CSP, is president of design safety engineering, inc., in Ann Arbor, Michigan. Mr. Main holds mechanical engineering degrees from MIT and the University of Michigan. He serves on several industry risk assessment committees including the machine tool, packaging machinery, robotics, and semiconductor. He is a U.S. technical expert revising the ISO 14121 risk assessment standard. He is also the primary representative to the B11 Committee (machine tool industry) on behalf of the ASSE. Mr. Main has authored numerous articles, papers, and books including *Risk Assessment: Basics and Benchmarks*. He can be reached at www.designsafe.com