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Risk Assessments: Their Significance

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OBJECTIVES

- Inform on a relatively new international standard that requires making risk assessments and an updated American standard that includes similar requirements.
- Establish that safety professionals will be expected to have the knowledge and skills to make and advice on risk assessments and to give counsel in the design and redesign processes.
- Provide awareness of how risk assessments have been incorporated into selected standards and guidelines.
- Enlighten on the activities initiated by the American Society of Safety Professionals on risk assessments.
- Discuss risk assessment systems.
- Advice on how to adopt risk assessment systems.
- Overall, to establish that risk assessments have become more significant within a safety and health management system.

1.1 Introduction

In the first edition of this book, the purpose of the first chapter was to encourage safety professionals to recognize the trending throughout the world to include requirements for risk assessments in safety and health-related standards and guidelines. Further, the position was taken that it was logical to expect that having the capability to make risk assessments would eventually become a requirement for the safety and health position.

To support the positions taken, 35 subjects were included in Addendum A, which was titled "A List of Standards, Guidelines, and Initiatives That Require or Promote Making Risk Assessments – Commencing With the 2005 Year."

Since that list was prepared, the first international standard for occupational health and safety management systems was adopted by an entity with significant credentials – the International Organization for Standardization (ISO).

Risk Assessment: A Practical Guide to Assessing Operational Risks, Second Edition.
Georgi Popov, Bruce K. Lyon, and Bruce D. Hollcroft.

This standard, adopted in 2018, is identified as ISO 45001: *Occupational health and safety management systems – Requirements with guidance for use*. It is commonly referred to as 45001.

In the same year, approval was given to this international standard by the American National Standards Institute (ANSI) to become an American standard. Its designation is ANSI/ASSP/ISO 45001 – 2018, and the secretariat in the United States is the American Society of Safety Professionals (ASSP).

For safety professionals, there is now an international health and safety management systems standard and it requires that risk assessments be made.

Section 6.1.2,2 in 45001 (p. 13) is titled "Assessment of OH&S risks and other risks to the OH&S management system." Its opening sentence and the beginning of item (a) are as follows:

The organization shall establish, implement, and maintain a process(es) to:

a) "assess OH&S risks from the identified hazards."

In the previously mentioned Addendum A, item 34 was "ANSI/AIHA Z10-2012: a standard for *Occupational Health and Safety Management Systems*." This standard is now known as Z10. This, the second edition of Z10, also included a provision requiring that risk assessments be made.

A third version of Z10 was approved by the ANSI in August 2019. Since the ASSP is now the secretariat, the name of the standard was changed and is now known as "ANSI/ASSSP Z10.0 – 2019: Occupational Health and Safety Management Systems."

Section 8.2 in the most recent version of Z10 (p. 17) is titled "Identification of Hazards." Identification of hazards is necessary, first, in making a risk assessment. Section 8.3 (p. 18) is titled "Risk Assessment." It requires that an organization establish and implement a risk assessment process(es).

So, for safety professionals, there is also an American National Standard requiring that risk assessment procedures be established as an element within safety and health management systems.

Adoption of 45001 was a momentous development. It has international implications of considerable measure. Safety professionals in the United States should realize that there are two ANSI standards requiring that risk assessments be made and achieve the necessary knowledge and capabilities.

Working with design and operations personnel to assess risks and to give counsel in the decision-making to achieve acceptable risk levels adds an easily recognized value.

Imaginative safety professionals will recognize this opportunity to be additionally perceived as members of the management team and increase their value to their organizations.

1.2 What Is a Risk Assessment?

Two definitions, taken from standards, are presented here as illustrative. There are several others. "ANSI/ASSP Z690.3 – 2011 – *Risk Assessment Techniques,*" which is an adoption of "IEC/ISO 31010:2009," this is the statement given in the Introduction.

> Risk assessment is that part of risk management which provides a structured process that identifies how objectives may be affected, and analyzes the risk in terms of consequences and their probabilities before deciding on whether further treatment is required. Risk assessment attempts to answer the following fundamental questions:
>
> - What can happen and why (by risk identification)?
> - What are the consequences?
> - What is the probability of their future occurrence?
> - Are there any factors that mitigate the consequence of the risk or that reduce the probability of the risk?
> - Is the level of risk tolerable or acceptable and does it require further treatment?

ANSI/ASSP Z590.3 – 2011 is the standard *for "Prevention through Design: Guidelines for Addressing Occupational Hazards and Risks in Design and Redesign Processes."* This is its definition of risk assessment:

> **Risk Assessment**. A process that commences with hazard identification and analysis, through which the probable severity of harm or damage is established, followed by an estimate of the probability of the incident or exposure occurring, and concluding with a statement of risk.

Risk assessment is a fundamental component of the risk management process and an essential core competency for safety professionals.

To Install a Risk Assessment System Successfully – A Culture Change May Be Necessary
When safety professionals give advice on improving operational risk management systems, their overarching role is that of a culture change agent. If a risk assessment system is installed where there was no risk assessment systems previously, things will be then done differently. That means that a culture change is necessary.

Definitions of a change agent are numerous. This definition is a composite that fits well with the safety professional's position. It was taken from the third edition of *Advanced Safety Management: Focusing on Z10. 45001 and Serious Injury Prevention,* Chapter 3 – Safety Professionals as Culture Change Agents.

> A change agent is a person who serves as a catalyst to bring about organizational change. Change agents assess the present, are controllably dissatisfied with it, contemplate a future that should be, and take action to achieve the culture changes necessary to achieve the desired future.

Unfortunately, attempts at making culture changes are not always successful. Enter "Why culture changes are not successful" into an Internet search engine and many articles on the subject will be found.

Reflecting on this author's experience, a few suggestions on how to achieve success in attempting to have a culture change are recorded here. There can be many others depending on the culture in a particular organization.

1) Recognition must be given to the culture in place. Safety professionals must recognize the existing power structure and determine how to work within it.
2) Have the risk assessment system to be installed fits the needs of the organization. Avoid complexity if that can be done. It is better to have a noncomplex system that works than to have a complex system that does not.
3) The leadership and commitment necessary at sufficiently high levels to achieve the change must be obtained.
4) Determine how people who do the work are to be involved and how.
5) Align the risk assessment process with other stated organizational values.
6) Safety professionals, the change agents, must recognize the magnitude of the culture change they propose and be patient as they proceed.
7) Select risk assessments to be made, at first, where the outcomes will be beneficial and evident.
8) Team building – vital to success – must be sufficient.
9) To obtain the views of interested parties, consider holding an open house or establishing a focus group. These activities can have other payoffs as well.
10) Prepare for the typical resistance to change at all levels. Preparation must not come up short.

11) Communication to all personnel levels that would be affected by the change should be as thorough as needed.
12) Try to use the wording in presenting the risk assessment system and when introducing it to people who do the work that fits with their internal shorthand.
13) It is best to start with a limited number of clear objectives (say, three to five) and then expand the list over time. Keep your objectives simple initially, gain some early successes, and then build on them.
14) Measurable objectives should be consistent with the overall organizational mission and its policy.
15) Regularly communicate progress in achieving objectives to whom the safety professional reports, at staff meetings and throughout the organization, if appropriate.
16) Management personnel who are assigned responsibility for the change should be held accountable for progress by the people to whom they report.
17) Over time, the urgency and importance of the change may diminish and that should be anticipated and countered.
18) Be aware that it is typical for assumptions to be are made that a change in a process or a system has occurred when it actually has not. (This is called declaring victory too soon.)
19) Keep a tracking file suitable to the organization.

In the literature, some writers say that a change in a system or process should not be considered a success as a culture modification until the change has been in place for at least a year. It occurs too often that operators revert to previous methods or ignore the new system if supervision allows such regression.

Activities at the ASSP (Critiqued and approved By Tim Fisher at the ASSP)

In the late 1980s and early 1900s, organizations in the United States and throughout the world began to shift toward more risk-based decision-making to improve overall safety performance and reduce incidents of serious injuries, illnesses, and fatalities.

This was coupled with the fact that regulators in certain regions began adopting more risk-based approaches. The concept began to really pick up steam and move forward after 2010 as ASSP volunteers put their collective resources and expertise into high-caliber technical reports and standards.

For many decades in occupational safety and health, businesses and industries around the world were arguably more focused on regulatory compliance and task management centered instead of managing risks. As time went on and illnesses, injuries, and fatalities metrics plateaued, it was clear that something needed to change in order to achieve real progress.

As an example, data from the *Bureau of Labor Statistics* show that, from 2003 to 2016, the level of fatal occupational injuries maintained relatively steady. This indicates that there is still more work to do to educate safety professionals and business executives on the importance of identifying hazards and focusing on risk assessment, avoidance, and control.

A risk-based strategy serves many purposes, the foremost of which is identifying potential hazards and risks associated with an operation so that proper controls can be put in place. Once the risk is understood, organizations can develop a number of options for mitigating or eliminating hazards and risks. Safety professionals can play a key role in the process if they are able to facilitate the analysis and identify practical solutions.

A properly designed risk assessment will also effectively communicate to decision-makers the impact these risks could have on the organization, both from a safety standpoint and on the bottom line. Although progress has been made among safety professionals and business leaders in utilizing risk-based decision-making, many are still along the continuum of maturity from compliance to improved performance through risk assessment. To this day, the level of expertise about risk assessment and how risk is viewed varies from region to region.

1.2.1 Approach Taken at the ASSP

Several Occupational Safety and Health Professionals who were active in the ASSP recognized that requirements for risk assessment were more frequently included in safety-related standards and guidelines and that the ASSP should provide its members with educational opportunities through which the necessary skills could be acquired. A presentation on the subject was made at the ASSP/ASSP February 2013 Board of Directors meeting, the outcome of which was the creation of a Risk Assessment Institute and an ASSP Risk Assessment Committee.

One of the key issues leading to the formation of the committee was for its members to work on literature, videos, webinars, and other materials that could be presented at chapter meetings and at conferences. The significance of these activities is that increased awareness had developed among the leaders of ASSP, a professional and technical organization with an international scope that its members would be well served if they were provided means to acquire risk assessment skills. This is an important step forward for the practice of safety.

Risk assessment is a formal process for identifying hazards, evaluating and analyzing risks associated with those hazards, then either eliminating the hazards or controlling those risks that cannot be eliminated to minimize injury and illness potential. It is critical to proactively prioritize and mitigate risk in advance of injuries or catastrophes.

1.2.2 ASSP Risk Assessment Committee

Throughout, our Risk Assessment Committee (ASSP) has aimed to include risk assessment into an organizational risk process, allowing businesses to be proactive in prioritizing and mitigating risk in advance of injuries or catastrophes. By understanding and implementing risk-based approaches to safety management, injury/illness prevention, and employee well-being, occupational safety professionals help their organizations improve overall performance and position themselves as high-profile contributors who help organizations achieve their goals.

1.2.3 The Goals

Through its work and initiatives, the Risk Assessment Committee pursues four distinct goals:

1) **Educate executives, the business community, and occupational safety and health professionals** on the value of the risk assessment approach and ways to successfully implement risk assessment.
2) **Improve risk-related training and education for occupational safety and health professionals** so they can better understand the risk-based decision-making process and improve core risk assessment competencies.
3) **Provide a platform for the occupational safety community** to contribute to the development of new evidence-based risk-related policies, processes, and solutions. We seek ways to leverage the expertise of the occupational safety and health community in identifying and

quantifying risk, advance risk-related regulatory and legislative initiatives related to the management of risks, and identify relevant research related to understanding risks.

4) **Provide a center of excellence** for risk-related information and tools relevant to occupational safety and health professionals This involves collecting and disseminating relevant risk-related research, collaborating with the insurance, accounting, and financial risk management industries to promote an exchange of ideas, accessing real-world practical experiences and applications, and facilitating outreach and collaboration with global nongovernmental organizations and academia.

1.2.4 Core Risk-Related Competencies

There is a section on core competencies for risk management within ASSP's original paper on the Risk Management Institute and the most significant points are paraphrased here. Reference is made in that paper to several standards that contain relative definitions and descriptions. They are mentioned in this chapter – Z10, 45001, the 690 series, and Z590.3.

It is suggested that safety and health professionals know how to effectively implement and maintain a risk management system, for which guidance is given in this chapter. However, we know from member and stakeholder feedback that there is an ongoing need for training and development to effectively implement risk assessment systems.

Obviously, safety practitioners would have knowledge of relative principles, basic guidelines, and common risk assessment techniques. Be cautious here. Elsewhere in this chapter it is suggested that having knowledge of five risk assessment techniques would be sufficient for most, but not all, situations that safety professionals will need to consider. As this chapter is being written, a study is in progress that mentions, in detail, 49 risk assessment techniques. Some are exceptionally complex. Whatever risk assessment techniques a safety and health professional chooses to apply should meet the needs of the organization and not be overly complex if that can be avoided.

Hopefully, safety and health professionals will become involved with engineers in design reviews where the most effective and economical risk avoidance or control can be implemented.

Overall, safety and health professionals need to become more skilled so that they can provide counsel on analyzing risk assessments, establishing acceptable risk levels, utilizing a hierarchy of control system, identifying serious injury, illness and fatality potentials, monitoring the effectiveness of risk control measures, and prioritizing risks.

Throughout, communication would be critical for all affected in all four stages of the operational setting: (i) preoperational, (ii) operational, (iii) post incident, and (iv) post operation.

1.2.5 Risk Assessment Education

The ASSP is the preferred source for education among safety and health professionals, providing valuable training and education on a variety of safety topics. As an example, our Risk Assessment Committee has established a program for safety and health professionals to earn a Risk Assessment Certificate, where they will learn to:

1) Implement the steps of the risk assessment process.
2) Conduct a risk assessment leading to the identification and prioritization of an organization's hazards and controls.
3) Influence management to support risk reduction plans and efforts.
4) Measure the effectiveness of the risk assessment process and outcomes to support an organization's objectives.

The Risk Assessment Committee website can be accessed at https://www.assp.org/advocacy/risk-assessment-committee.

Programs Related to Risk Assessment Offered by ASSP as of 5 May 2020.

1) Prevention through Design
2) Risk Assessment
3) Manage Risk Not Safety
4) Essential Risk Assessment Tools for Safety Professionals
5) Three Keys to Improving Risk Management
6) Setting the Scope and Limits of a Risk Assessment

An Example of a Guideline That Gives Risk Assessment Due Recognition

Entering https://corporate.exxonmobil.com/en/energy-and-environment/tools-and-processes/risk-management-and-safety/operations-integrity-management-system into the Internet will lead to a brochure on ExxonMobil's "Operations Integrity Management System."

Within that brochure, on page 1, there is a depiction of its Operations Integrity Management System. An adaptation of it follows (Figure 1.1).

Element 1 in this 11-point outline is what would be expected – "Management Leadership, Commitment and Accountability," which is absolutely necessary. But note that "Risk Assessment & Management" follows item 1 immediately. That is an indication of the importance given to risk assessment within ExxonMobil operations.

And "Facilities Design & Construction" follows risk assessment immediately. That is another term for "Prevention through Design." In the design and redesign processes, risk assessments would be made continuously as needed.

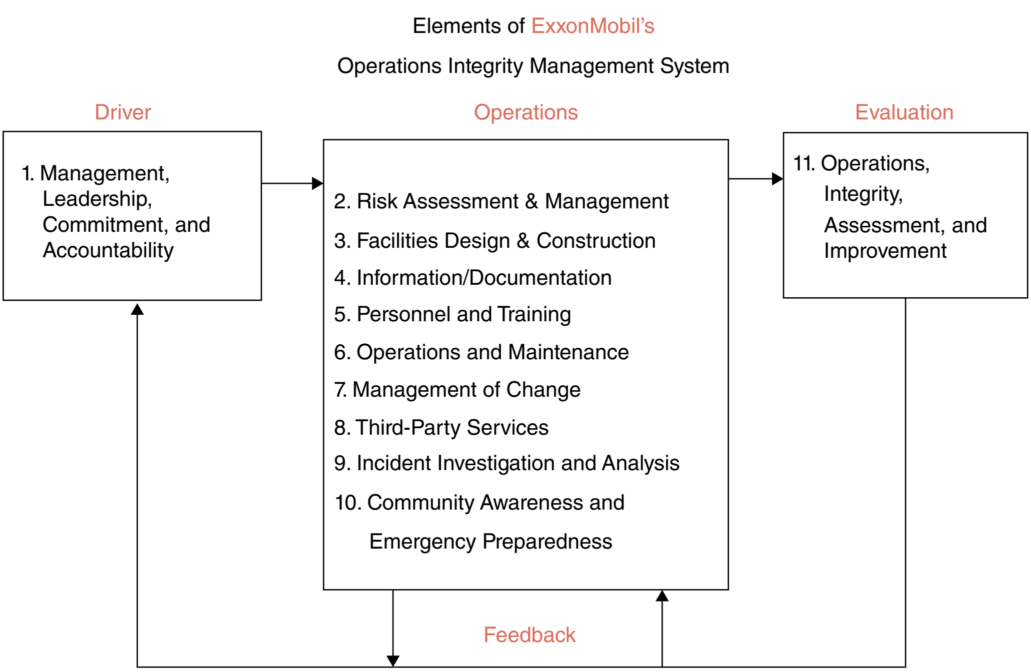

Figure 1.1 Elements of Exxon Mobil's OIMS.

Safety professionals should not be surprised if other companies produce similar outlines as greater recognition develops that the most effective and economical method to deal with hazards and risks is to address them in the design and redesign processes.

ExxonMobil's OIMS initiative pertains to all operational risks, including occupational, environmental, product, and public safety.

ANSI/ASSP Z590.3 – *Prevention through Design: Guidelines for Addressing Occupational Hazards and Risks in Design and Redesign Processes*.

This standard was previously mentioned in this chapter. It was approved by the ANSI on 1 September 2011. Activities have been commenced to update this standard. Georgi Popov is the chair of the committee and Bruce Lyon is the vice chair – both principal authors of this book.

The core of prevention through design is risk assessment. Making risk assessments early in the design and redesign processes and continuously as needed throughout the life cycle of the system or product reduces the potential for incidents occurring. Logic in support of that premise follows:

1) Hazards and risks are most effectively and economically avoided, eliminated, or controlled in the design and redesign processes.
2) Hazard analysis is the most important safety process in that, if that fails, all other processes are likely to be ineffective (Johnson – p. 245).
3) Risk assessment should be the cornerstone of an operational risk management system.
4) If, through the hazard identification and analysis and risk assessment processes, specifications are developed that are applied in the procurement process so as to avoid bringing hazards and their accompanying risks into a workplace, the potential for injuries occurring is reduced greatly.
5) The entirety of purpose of those responsible for safety, regardless of their titles, is to manage their endeavors with respect to hazards so that the risks deriving from those hazards are acceptable.

The practice of safety is hazards based. Thus, Johnson wrote appropriately that hazard analysis is the most important safety process. Since all risks in an operational setting derive from hazards and since the intent of an operational risk management system is to achieve acceptable risk levels and to avoid incidents and illnesses, it follows that risk assessment should be the cornerstone of an operational risk management system.

Figure 1.2 depicts the theoretical ideal. Prevention through Design is moved upstream in the design process. The intent is to have hazards and risks analyzed and dealt with in the Conceptual and Design steps. However, that requires unattainable perfection from the people involved. Hazards and risks will also be identified in the Build, Operation, and Maintenance steps for which redesign is necessary in a retrofitting process.

The Hazard Analysis and Risk Assessment Process is the longest section in the prevention through design standard. First, an outline of the hazard analysis and risk assessment process is given. That is followed by the "how" for each of its elements. The outline follows:

- Select a risk assessment matrix
- Establish the analysis parameters
- Identify the hazards
- Consider failure modes
- Assess the severity of consequences
- Determine occurrence probability
- Define initial risk
- Select and implement hazard avoidance, elimination, reduction, and control methods

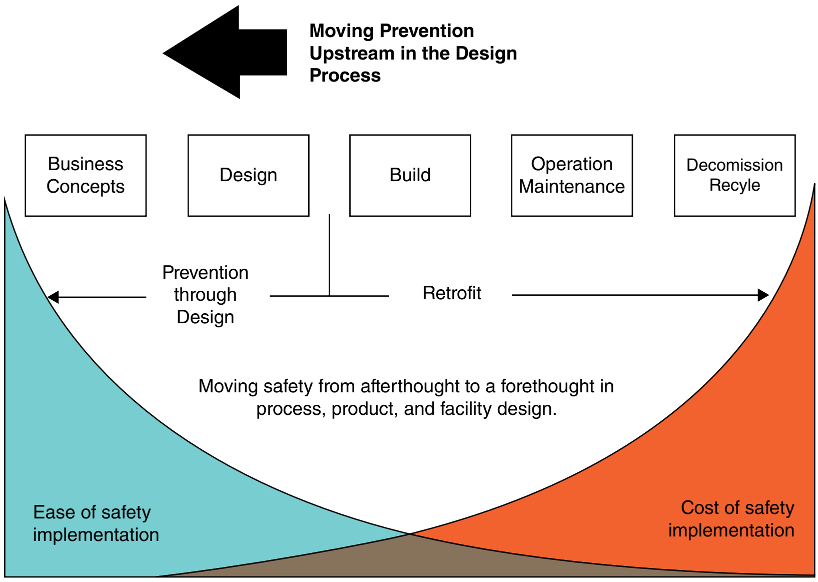

Figure 1.2 Prevention through Design. With permission. Hazards Limited.

- Assess the residual risk
- Risk acceptance decision-making
- Document the results
- Follow-up on actions taken

1.3 Risk Assessment Methods

One of the purposes of this book is to present a variety of risk assessment methods and they are described throughout the text. For many hazards, the proper level of acceptable risk can be attained without bringing together complex teams of people. Safety and health professionals and design engineers having the experience and education can reach the proper conclusions on what constitutes acceptable risk. As defined in Z590.3, acceptable risk is:

> **Acceptable Risk.** That risk for which the probability of an incident or exposure occurring and the harm or damage that may result are as low as reasonably practicable (ALARP) in the setting being considered.
> **ALARP – as low as reasonably practicable –** is defined as that level of risk which can be further lowered only by an increase in resource expenditure that is disproportionate in relation to the resulting decrease in risk. (p. 12)

For the more complex risk situations, management should have processes in place to seek the counsel of experienced personnel who are particularly skilled in risk assessment for the category of the situation being considered. More complex risk assessment methods may be necessary in such situations.

Sometimes, for what an individual considers obvious, achieving consensus on acceptable risk levels is still desirable so that buy-in is obtained for the actions to be taken.

It is suggested that the risk assessment method chosen fits the need. Sometimes, the method need not be complex. Information on a rather simplistic method follows. Its intent is to be illustrative.

Dated March 2020, NIOSH issued eNews Volume 17, Number 11, under the signature of the Director of NIOSH, Dr. John Howard. Its title is **Using Science to Assess Workplace Hazards: NIOSH Practices in Occupational Risk Assessment.** Content of this eNews follows:

What is *Risk Assessment?* Do you check for rain before deciding to carry an umbrella? Doing so is an example of risk assessment, which describes a process for answering three basic questions on a particular hazard.

What can happen? (It may rain today.)
How likely will it happen? (The Weather Channel says 70% chance of showers.)
What are the consequences if it happens? (I'll be soaked without my umbrella.)

The answers provide a foundation for preventing or lessening the threat imposed by the hazard (e.g. carry an umbrella to avoid getting wet if caught in the rain) known as *risk management*.

One can take the position that NIOSH was overly simplistic. However, if a person follows the procedure outlined in the foregoing, that person has made a risk assessment.

1.4 The ANSI/ASSP Z690 – 2011 Series

The ANSI/ASSP Z690 Risk Management Standards are the US national standards for applying risk management for occupational safety and health. They are the US adoption of the ISO 31000 Risk Management Standards.

The three ANSI Standards that constitute a set should be of interest to safety generalists who want to become familiar with risk assessment techniques. The ASSP is the secretariat. Comments on the three standards follow:

ANSI/ASSP Z690.1 – 2011: Vocabulary for Risk Management (National Adoption of ISO Guide 73:2009). This standard provides definitions of terms that, the originators hope, will be used in other standards.

ANSI/ASSP Z690.2 – 2011: Risk Management Principles and Guidelines (National Adoption of ISO 31,000:2009). The intent of this standard is to provide a broad-range primer on risk management systems that could be applied in any type of organization. The requirement for risk assessments is introduced in Section 5.4: Risk Assessment.

ANSI/ASSP Z 690.3 – 2011: Risk Assessment Techniques (National Adoption of IEC/ISO 31,010:2009). For safety generalists who want a ready reference on risk assessment concepts and methods, this standard is worth acquiring. It commences with a 15-page dissertation on risk assessment concepts and methods. Appendix A, in five pages, provides brief comparisons of 31 risk assessment techniques. Comments on the 31 techniques, covering Overview, Use, Inputs, Process, Strengths, and Limitations, are provided in Annex B which covers 79 pages.

ANSI/ASSP Z 690.3 – 2011, particularly, is a valuable resource. A list of the 31 risk assessment techniques follows. Some could be applied only by experienced safety professionals who had knowledge of system safety concepts and techniques. Other techniques would be used by probabilistic specialists. However, having knowledge of a few of them will serve for a huge percentage of the needs of a safety generalist.

B01	Brainstorming	B02	Structured or Semi-Structured Interviews
B03	Delphi	B04	Checklists
B05	Preliminary Hazard Analysis	B06	Hazard and Operability Studies
B07	Hazard Analysis and Critical Control Points	B08	Environmental Risk Assessment
B09	Structure – What if Analysis	B10	Scenario Analysis
B11	Business Impact Analysis	B12	Root Cause Analysis
B13	Failure Mode Effect Analysis	B14	Fault Tree Analysis
B15	Event Tree Analysis	B16	Cause and Consequence Analysis
B17	Cause-and-Effect Analysis	B18	Layer Protection Analysis
B19	Decision Tree	B20	Human Reliability Analysis
B21	Bow Tie Analysis	B22	Reliability Centered Maintenance
B23	Sneak Circuit Analysis	B24	Markov Analysis
B25	Monte Carlo Simulation	B26	Bayesian Statistics and Bayes Nets
B27	FN Curves	B28	Risk Indices
B29	Consequence/Probability Matrix	B30	Cost Benefit Analysis
B31	Multi-Criteria Decision Analysis		

In the Z590.3 standard, this statement is made (p. 23). "As a practical matter, having knowledge of three risk assessment concepts will be sufficient to address most, but not all risk assessment situations" (that safety professions will face). They are Preliminary Hazard Analysis and Risk Assessment; the What-If/Checklist Analysis Methods; and Failure Mode and Effects Analysis.

1.5 ANSI B11.0 – 2020: Safety of Machinery

This Is a Standard of Major Importance
Because of the breadth of its coverage, ANSI B11.0 – 2020 is of particular importance for machinery safety. Several parts of the standard are duplicated here with permission from B11 Standards Inc. As is said in the Forward,

> This standard specifies general safety requirements for the design, construction, operation and maintenance (including installation, dismantling and transport) of machinery and machinery systems. This standard also applies to devices that are integral to these machines. (p. 8)

This author believes that every safety professional who is involved in machinery safety should have a copy of this standard. It is supported by the standard known as ANSI B11.19-2019, the title of which is "Performance Requirements for Risk Reduction Measures: Safeguarding and other Means of Reducing Risk." This is a 231-page document that is devoted to means of risk reduction. This is the stated Purpose of B11.0-2020:

> This standard describes procedures for identifying hazards, assessing risks, and reducing risks to an acceptable level over the life cycle of machinery. (p. 9)

The objective of the B11 series of standards:

> Is to eliminate injuries to personnel from machinery or machinery systems by establishing requirements for the design, construction, reconstruction, modification, installation, set-up, operation and maintenance of machinery or machine systems. This standard should be used by suppliers and users, as well as by the appropriate authority having jurisdiction. (p. 9)

The standard includes an explicit requirement that machinery suppliers, reconstructors, modifiers, and users achieve acceptable risk levels.

ANSI B11.0 is the most comprehensive standard outlining the risk assessment process currently applicable to machinery for all of the operational categories just previously mentioned. Recognition is given to the Prevention through Design concept in the Forward.

> Prevention Through Design or PtD is a recent term in the industry; the objectives of risk assessment, risk reduction and elimination of hazards as early as possible are integral and not new to this standard. The phrase "Prevention Through Design" is used within the standard, as are other equivalent terms such as "elimination by design," "design out," and "substitution" to thoroughly address risk assessment and applying it to the lifecycle and operations of the machine. (p. 8)

Because many American makers of machinery sell their goods to other countries, there was a need for harmonization with other applicable standards. This sentence follows the caption Harmonization.

> 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.

That statement presents an interesting and weighty concept. If all safety professionals accept that hazard identification and analysis and risk assessment are the first steps in preventing injuries to personnel, a major concept change in the practice of safety will have been achieved.

This is how acceptable risk is defined in the standard – Definitions (p. 18):

> **Acceptable risk**: 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. For the purpose of this standard, the terms "acceptable risk" and "tolerable risk" are considered to be synonymous.
> ***Informative Note 1***: The expression "acceptable risk" usually, but not always, refers to the level at which further technologically, functionally and financially feasible risk reduction measures or additional expenditure(s) of resources will not result in significant reduction in risk. The decision to accept (tolerate) a risk is influenced by many factors including the culture, technological and economic feasibility of installing additional risk reduction measures, the degree of protection achieved through the use of additional risk reduction measures, and the regulatory requirements or best industry practice.
> ***Informative Note 2***: The user and supplier may have different level(s) of acceptable risk.
> ***Informative Note 3***: A similar phraseology used in some ISO standards is as follows: "the risk has been adequately reduced."

A particularly outlined risk assessment process is included on B11.0-2020. It is duplicated here to emphasize several purposes: it is illustrative although it differs from other outlines, it indicates that people involved in the process should be qualified, the scope of the risk assessment exercise is to be defined, hazards are to be identified and analyzed, initial risks are to be assesses, risks are to be reduced if necessary, and acceptable risk levels are to be achieved.

6 The Risk Assessment Process (p. 4)
- 6.1 General
  - 6.1.1 Quality personnel
  - 6.1.2 Goal
  - 6.1.2 Fundamental steps in the risk assessment process
- 6.2 Prepare for and set scope (limits) of the assessment
- 6.3 Identify tasks and hazards
  - 6.3.1 Identify affected persons
  - 6.3.2 Identify tasks
  - 6.3.3 Identify hazards and hazardous situations
  - 6.3.4 Similar machines
- 6.4 Assess initial risk
  - 6.4.1 Select a risk scoring system
  - 6.4.2 Assess risk
  - 6.4.3 Check for new hazards
- 6.6 Assess residual risk
- 6.7 Achieve acceptable risk
- 6.8 Validate and verify risk reduction measures
- 6.9 Document the process
  - 6.91 Content
  - 6.9.2 Document retention

"General Risk Assessment Requirements" are outlined in the following section of the standard. (p. 4)

ANSI B11.0-2020 is available for purchase at www.b11standards.org or www.ansi.org

1.6 Risk Scoring Systems

Note that 6.4.1 in The Risk Assessment Process is "Select a risk scoring system." Why do so? It is necessary in the management of risks to establish priorities for action. That can be done through a risk scoring system – risk levels being Low, Moderate, Serious or High, or a variation thereof. And it is important that the people involved in the risk assessment process understand what those terms mean and what action levels are implied by the terms used.

The risk assessment matrix shown in Figure 1.3 is a composite of matrices that include numerical values for likelihood and severity levels that are transposed into qualitative risk gradings. It was originally developed for people who prefer to deal with numbers rather than qualitative indicators. To provide a one-page tool that could be used by safety professionals who wanted to get shop floor personnel involved in risk assessments, extensions were made to include severity and likelihood descriptions and action levels.

In two instances, shop floor personnel said to safety professionals that relating numbers to each other first – such as 6–12 – was a big help in understanding whether the risk category was moderate or high-risk. If using a risk assessment matrix in which numbers are used to begin with to establish risk levels makes the process more understandable and acceptable for operating personnel, that should be encouraged.

It is important to understand that the numbers in Figure 1.3 were intuitively derived: they are semi-quantitative. Thus, the numbers have value only in relation to each other. And that is the case for all risk scoring systems that are not based on hard probability and severity numbers, which are rarely available.

Incident outcomes				Likelihood of occurrence				
Severity rating	**Health effects (people)**	**Property damage**	**Environment impact**	1 Very Unlikely	2 Unlikely	3 Possible	4 Likely	5 Very Likely
5	Death or permanent total disability	Catastrophic damage	Significant impact	5	10	**15**	**20**	**25**
4	Permanent partial disability; hospitalizations of three people or more	Severe damage	Significant, but reversible impact	4	8	12	**16**	**20**
3	Injury or occupational illness resulting in one or more days away from work	Significant damage	Moderate reversible impact	3	6	9	12	**15**
2	Injury or occupational illness not resulting in a lost work day	Moderate damage	Minimal impact	2	4	6	8	10
1	First aid only or no injuries or illnesses	Light damage	No impact	1	2	3	4	5

Very high risk: **15 or greater** High risk: **10 –14** Moderate risk: **5 – 9** Low risk: **1 – 4**

Figure 1.3 Risk matrix example.

Note that this Risk Assessment Matrix pertains to personal injury and illness, system loss or down time (from any source), and environmental release. Others may not be as inclusive.

1.7 European Union – Risk Assessment

In August 2008, The European Union launched a two-year health and safety campaign focusing on risk assessment. Their bulletin said:

> Risk assessment is the cornerstone of the European approach to prevent occupational accidents and ill health. If the risk assessment process – the start of the health and safety management approach – is not done well or not at all, the appropriate preventive measures are unlikely to be identified or put in place.

This bulletin, although exceptionally important, is no longer available on the Internet as a European Union Bulletin. It is available through "Prevention and Control Strategies – OSHWIKI" at https://oshwiki.eu/wiki/Prevention_and_control_strategies.

This author considers the statement made by the European Union as seminal. Consider its significance and huge implications. It specifically states that risk assessment should be the cornerstone of a safety and health system and that if risk assessment is not done well or not at all, the needed preventive measures are unlikely to be identified or taken.

The Europeans have been leaders in recognizing the importance of risk assessments and promoting their application. For example, employers in the United Kingdom have been required to make risk assessments by law since 1999. Indications of other European involvement follow:

EN ISO 12100-2010: Safety of Machinery. General principles for design. Risk assessment and risk reduction.

This standard, issued in 2010 by the ISO, has had an interesting history. It combines three previously issued ISO standards and replaces them. Note that "Risk assessment and risk reduction" are included in the title. That is significant as it separates the risk assessment process from the risk reduction process, as is the case in B11.0-2020. That is not always the case elsewhere.

ISO 12100-1 was titled *Safety of machinery – Basic Concepts, General Principles for Design-Part 1*. It presented general design guidelines and required that risk assessments be made of machinery going into a workplace. ISO 12100-2 was titled *Safety of machinery – Basic concepts, general principles for design – Part 2: Technical principles*. Part 2 gave extensive detail on design specifications for the "Safety of machinery." ISO 14121 was titled *Safety of machinery – Principles of risk assessment*. It set forth the risk assessment concepts to be applied. EN ISO 12100-2010 combines these three standards and retains their content.

EN ISO 12100-2010 is truly an international standard and has had considerable influence worldwide. Its existence implies that a huge majority of countries agree on the principal that hazards should be identified and analyzed and their accompanying risks should be assessed in the design and redesign processes for machinery.

The EN that precedes ISO in the title indicates that the origins of the standard were in the European Community. Several standards that were applicable in the European Community that had titles commencing with the EN designation became ISO standards.

The European Community standards have had considerable influence on manufacturers throughout the world. An example follows. Suppliers of products that are to go into a country that is a member of the European Community are required to place a "CE" mark on the products to indicate that all operable European Community directives have been met. Risk assessment provisions in EN ISO 12100-2010 are among those requirements.

STD-882E – 2012. The U.S. Department of Defense Standard Practice for System Safety. The base document for the Standard Practice for System Safety, MIL-STD-882, was issued in 1969. It was a seminal document at that time and has continued to be an important reference.

MIL-STD 882 has had considerable influence on the development of hazard identification and analysis, risk assessment, risk elimination, and risk control concepts and methods. Much of the wording on risk assessments and hierarchies of control in safety standards and guidelines issued throughout the world relate to what is in the several versions of 882. That is why considerable space is devoted to the standard in this chapter.

Four revisions of 882 have been issued over a span of 50 years. As is said in the Foreword for 882E: "This system safety standard practice identifies the DoD approach for identifying hazards and assessing and mitigating associated risks encountered in the development, test, production, use, and disposal of defense systems." (p. ii)

The last version of 882 was approved 11 May 2012. It is available, free, at https://www.dau.edu/cop/esoh/DAU%20Sponsored%20Documents/MIL%20STD%20882E%20Final%202012%2005%2011.pdf. This author strongly recommends that safety professionals obtain a copy of this Standard for informative purposes.

MIL-STD-882E extends the previous issue – 882D – considerably. For example, the 882D version, including addenda, had 26 numbered pages: the 882E version has 98 numbered pages. It replaces some of what was in 882C that was not included in 882D. In 882E:

- Achieving and maintaining acceptable risk levels dominates.
- Revisions were made in the system safety process that give additional emphasis to hazard analysis and risk assessment.
- The use of a risk assessment matrix is required.
- Noteworthy revisions are made in the design order of preference.
- Appropriate emphasis is given to managing High and Serious risk levels.
- A major section is devoted to software and software assessments.

Excerpts follow, some of which are modified to avoid governmental terminology. Section 4 in 882E is titled General Requirements. It sets forth the "requirements for an acceptable system safety effort." Section 4.3 outlines the eight elements in the system safety process, as follows:

Element 1: Document the System Safety Approach.
Element 2: Identify and Document the Hazards.
Element 3: Assess and Document Risk.
Element 4: Identify and Document Risk Mitigation Measures.
Element 5: Reduce Risk.
Element 6: Verify, Validate and Document Risk Reduction.
Element 7: Accept Risk and Document.
Element 8: Manage Life-Cycle Risk.

Because of its connotation, the concept outlined for 4.3.4 – Identify and document risk mitigation measures – is duplicated here.

Potential risk mitigation(s) shall be identified, and the expected risk reduction(s) of the alternative(s) shall be estimated and documented in the HTS. *The goal should always be to eliminate the hazard if possible*. (Emphasis added). When a hazard cannot be eliminated, the associated risk should be reduced to the lowest acceptable level within the constraints of cost, schedule, and performance by applying the system safety design order of precedence. The system safety design order of precedence identifies alternative mitigation approaches and lists them in order of decreasing effectiveness.

a) Eliminate hazards through design selection. Ideally, the hazard should be eliminated by selecting a design or material alternative that removes the hazard altogether.
b) Reduce risk through design alteration. If adopting an alternative design change or material to eliminate the hazard is not feasible, consider design changes that reduce the severity and/or the probability of the mishap potential caused by the hazard(s).
c) Incorporate engineered features or devices. If mitigation of the risk through design alteration is not feasible, reduce the severity or the probability of the mishap potential caused by the hazard(s) using engineered features or devices. In general, engineered features actively interrupt the mishap sequence and devices reduce the risk of a mishap.
d) Provide warning devices. If engineered features and devices are not feasible or do not adequately lower the severity or probability of the mishap potential caused by the hazard, include detection and warning systems to alert personnel to the presence of a hazardous condition or occurrence of a hazardous event.
e) Incorporate signage, procedures, training, and PPE. Where design alternatives, design changes, and engineered features and devices are not feasible and warning devices cannot adequately mitigate the severity or probability of the mishap potential caused by the hazard, incorporate signage, procedures, training, and PPE. Signage includes placards, labels, signs, and other visual graphics. Procedures and training should include appropriate warnings and cautions. Procedures may prescribe the use of PPE. For hazards assigned Catastrophic or Critical mishap severity categories, the use of signage, procedures, training, and PPE as the only risk reduction method should be avoided. 4.3.5 Reduce risk. Mitigation measures are selected.

For emphasis, it is said again that MIL-STD 882E is an excellent educational and resource document. Its base is hazard identification and analysis and risk assessment.

1.8 OSHA Requirements

OSHA's Rule For Process Safety Management Of Highly Hazardous Chemicals, 1910.119, issued in 1992, applies to employers at about 50 000 locations, many of which are not considered chemical companies. With respect to requirements for hazards analyses being included in standards, this OSHA standard merits a review by safety practitioners. The standard requires that:

> The employer shall perform an initial hazard analysis (hazard evaluation) on processes covered by this standard. The process hazard analysis shall be appropriate to the complexity of the process and shall identify, evaluate, and control the hazards involved in the process. The employer shall use one or more of the following methodologies that are appropriate to determine and evaluate the hazards of the process being analyzed:
>
> - What-If;
> - Checklist;
> - What-If/Checklist;
> - Hazard and Operability Study (HAZOP);

- Failure Modes and Effect Analysis (FMEA);
- Fault Tree Analysis; or
- An appropriate equivalent methodology.

Although affected employers are to make hazards analyses, the methodologies previously listed are risk assessment techniques. This author's recollection is that commenters on the standard prior to its promulgation expressed concern over having to use probability data – of which there is little that is statistically sound. OSHA responded favorably. This appears in the preamble to the standard.

> OSHA has modified the paragraph (editorial note – paragraph on consequence analysis) to indicate that it did not intend employers to conduct probabilistic risk assessments to satisfy the requirement to perform a consequence analysis.

However, all risks are not equal. Some require attention prior to others. And managements do assess and prioritize risks in their decision-making when determining which resources are to be allocated for individual projects.

1.9 EPA Requirements

The Environmental Protection Agency (EPA) and OSHA have different legal authority with respect to accidental releases of harmful substances. The concerns at EPA center on offsite consequences: that is, harm to the public and the environment. At OSHA, the legal authority pertains to on-site consequences.

On 19 August 1996, EPA issued rule 40 CFR Part 68, *Risk Management Programs for Chemical Accidental Release Prevention*. Risk Management Plans required of location managements by the rule were due by 21 June 1999. Although the provisions of the rule are extensive, only the specifications for hazards analyses will be addressed here.

Processes subject to this rule are divided into three groups, labeled by EPA as Programs 1, 2, and 3. Program levels relate to the quantities and extent of exposure to toxic and flammable chemicals. For locations qualifying for Program levels 1 and 2, those with lesser exposure, EPA will accept hazard reviews done by qualified personnel using suitable checklists.

Hazard reviews must be documented and show that problems have been addressed. In its literature, EPA comments on the desirability of using the "What If" hazard identification and analysis process. EPA also proposes the use of more involved analytical techniques if findings suggest that to be desirable.

Hazard review requirement for Program level 3 locations are more specific and extensive. But those locations that are compliant with the OSHA rule for Process Safety Management of Highly Hazardous Chemicals will need to do little new, although they do need to extend their hazards analyses to consider the probability of harm to the public or to the environment. As with OSHA, a team must complete the process hazards analyses required by EPA. One member of the team, at least, is to have experience with the process.

For American industry, EPA has obviously extended knowledge and skill requirements regarding hazard analysis techniques.

1.10 The Chemical Industry – The Extensive Body of Information

Completing hazards analyses was a common practice in the chemical industry many years before requirements for them were established by OSHA and EPA. Although the body of knowledge in the chemical industry on hazard analysis is extensive, reference will be made here to only one publication because of its particular significant.

The Center For Chemical Process Safety is a part of the American Institute of Chemical Engineers. One of its books is titled *Guidelines For Hazard Evaluation Procedures, Second Edition With Worked Examples*. Publication of the text by a chemically oriented group should not dissuade those who want an education in the following evaluation techniques. Their descriptions are generic.

Safety Review
Checklist Analysis

- Relative Ranking
- Preliminary Hazard Analysis
- What-If analysis
- What-If Checklist Analysis
- Hazard and Operability Analysis
- Fault Tree Analysis
- Event Tree Analysis
- Cause-Consequence Analysis
- Human Reliability Analysis

These techniques are dealt with broadly in the *Guidelines* within chapters titled "Overview of Hazard Evaluation Techniques" and "Using Hazard Evaluation Techniques."

1.11 Conclusion

The message is clear. Including provisions requiring hazards analyses and risk assessments in safety standards and guidelines has become ordinary. It is logical to assume that this trending will continue and that safety professionals will be expected to have the knowledge and skill necessary to give counsel on applying those provisions. Emphasis on practical applications of risk assessments is key.

References

ANSI B11.0-2020: Safety of Machinery. B11Standards, POB 690905, Houston, TX 77269, USA, 2020.

ANSI/ASSP Z10 – 2019 (2019). *Occupational Health and Safety Management Systems*. Park Ridge, IL: American Society of Safety Professionals.

ANSI/ASSP Z590.3 – 2011 (2011). *American National Standard: Prevention through Design: Guidelines Addressing Occupational Hazards and Risks in Design and Redesign Processes*. Park Ridge, IL: American Society of Safety Professionals (R2016).

ANSI/ASSP Z690 Series (2011). *Risk Assessment Techniques*. Park Ridge, IL: American Society of Safety Professionals.

ANSI/ASSP/ISO 45001 – 2018 (2018). *Occupational Health and Safety Management Systems – Requirements with Guidance for Use*. Park Ridge, IL: American Society of Safety Professionals.

ASSP Risk Assessment Institute and Committee. https://www.assp.org/advocacy/risk-assessment-committee

Bureau of Labor Statistics Reports on Occupational Fatalities, 2003 through 2016. Washington, DC: Bureau of Labor Statistics.

En ISO 12100-2010 (2010). *Safety of Machinery. General Principles for Design. Risk Assessment and Risk Reduction*. Geneva, Switzerland: International Organization for Standardization.

EPA: Risk Management Programs for Chemical Accidental Release Prevention. http://www.epa.gov/emergencies/content/lawsregs/rmpover.htm

EXXONMOBIL'S OIMS. https://corporate.exxonmobil.com/en/energy-and-environment/tools-and-processes/risk-management-and-safety/operations-integrity-management-system (accessed May 2020).

Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples. New York: Center for Chemical Process Safety of the American Institute of Chemical Engineers, 1992.

ISO 12100-1 (2003). *Safety of Machinery – Basic Concepts, General Principles for Design; Part 1. Basic Terminology, Methodology*. Geneva, Switzerland: International Organization for Standardization.

ISO 12100-2 (2003). *Safety of Machinery – Basic Concepts, General Principles for Design; Part 2. Technical Principles and Specifications*. Geneva, Switzerland: International Organization for Standardization.

ISO 14121 (1999). *Safety of Machinery – Principles for Risk Assessment*. Geneva, Switzerland: International Organization for Standardization.

Manuele, F.A. (2020). *Advanced Safety Management: Focusing on Z10. 45001 and Serious Injury Prevention*, 3e. Hoboken, NJ: Wiley.

MIL-STD-882E (2012). *Standard Practice for System Safety*. Washington, DC: Department of Defense. https://www.dau.edu/cop/esoh/DAU%20Sponsored%20Documents/MIL%20STD%20882E%20Final%202012%2005%2011.pdf

NIOSH: Howard, John, M.D. eNews Volume 17, Number 11. Science to Assess Workplace Hazards: NIOSH Practices in Occupational Risk Assessment, March 2020.

OSHA's Rule for Process Safety Management of Highly Hazardous Chemicals, 1910.119. Washington, DC: Department of Labor, Occupational Safety and Health Administration, 1992.

Prevention and Control Strategies. OSHWIKI at https://oshwiki.eu/wiki/Prevention_and_control_strategies.

Risk Management Programs for Chemical Accidental Release Prevention, 40 CFR Part 68. Washington, DC: Environmental Protection Agency, 1996.