Safe design—design that effectively minimizes the likelihood of process accidents and mitigates their consequences—has long been a priority in the process industries. Today, process industry companies need to be certain that their stakeholders have confidence in how they manage the environmental, health, and safety implications of industrial activities. A safe—and documented—design basis, together with a formal safety management system and safety practices, procedures, and training, is critical for providing that level of confidence required for risk management.

Risks cannot be completely eliminated from the handling, use, processing, and storage of hazardous materials. Instead, the goal of process safety management is to consistently reduce risk to a level that can be tolerated by all concerned—by facility staff, company management, surrounding communities, the public at large, and industry and government agencies. A systematic, risk-based approach to safety design can help eliminate hazards that pose intolerable risk from the process and mitigate the potential consequences of hazards.

To achieve a consistent, effective approach to risk reduction, designers must be able to define “tolerable” and “intolerable” risks. To meet the expectations of shareholders, employees, regulators, and the communities that surround process facilities, design engineers need to be able to document how risk is addressed in the design process.

At the same time, to meet the business needs of the company, the process safety solutions designers propose must be as cost-effective as possible. A risk-based approach to design safety enables designers to answer the needs of all process safety stakeholders without compromising on safety or spending too much on excessive prevention and mitigation measures.
The Concept of Risk

In chemical process safety design, risk is understood in terms of the likelihood and consequences of incidents that could expose people, property, or the environment to the harmful effects of a hazard. Hazards, as defined by the Center for Chemical Process Safety of the American Institute of Chemical Engineers, are potential sources of harm, including chemical or physical conditions or characteristics that can damage people, property, or the environment. Incident likelihood encompasses frequency and probability; consequences refers to outcomes and impacts.

It is always possible to identify scenarios that would be catastrophic for the system being designed. Process and emergency relief system (ERS) design does not necessarily need to address the worst scenario someone can identify. A line must be drawn (or a gray area defined) between likely scenarios and unlikely ones. For example, a process might use substance chloride, which is known to react vigorously with water. If water is not present at the site, there is no need to address that reaction scenario in ERS design. If water is on-site, but is not used in the same process as chloride there is still no need to address B in ERS design. If water is not used in the same process as chloride, but they share a storage facility, then, depending on the circumstances, it might make sense to include a chloride/water reaction scenario in ERS design.

Risk-based approaches to decision-making have gradually gained ground in process safety. In other business areas, risk analysis has been an important part of decision-making for some time. Risk-based approaches can benefit process safety environmental managers by supporting a clear, consistent approach to decision-making about risks and by providing about safety design choices that key stakeholders can understand. The technical nature of many aspects of process safety risk analysis has made this area something of a specialist’s preserve. With an approach to risk analysis that combines technical sophistication with outcomes that clearly communicate risks and choices, companies can achieve a greater degree of confidence about the management of process risk.

“Risk-based approaches to decision-making have gradually gained ground in process safety.”
Figure 1

Process Safety Design: Some Recent Regulatory Requirements and Industry Guidelines

In many cases, companies have been revisiting process design basis issues to meet recent regulatory requirements and industry guidelines. These include:

United States Regulations

Risk Management Program (RMP) Rule. The U.S. Environmental Protection Agency’s risk management program rule, published in final form on June 20, 1996 as part of the Clean Air Act Amendments of 1990, requires facilities with regulated substances to prepare a risk management plan. These substances include 77 toxic substances, 63 flammables, and certain high explosives. The program required by the RMP rule includes an emergency response program, a hazard assessment program, a prevention program, and an overall system for developing and implementing a risk management program.

Process Safety Management (PSM) Rule. The Occupational Safety and Health Administration’s PSM rule, issued in 1992, addresses the process safety management of highly hazardous chemicals. The rule’s process safety information, process hazard analysis, and pre-startup safety review elements address activities related to process design and documentation. Under the process hazard analysis element, for example, regulated facilities must conduct a process hazard analysis and establish priorities for implementing risk-reduction measures. But while the OSHA rule requires hazard evaluation and prioritization, it does not emphasize risk-based approaches to managing process hazards.

State Regulations. The OSHA PSM rule follows the regulatory lead taken by California, New Jersey, and Delaware for the management of process hazards. In California, facilities that store acutely hazardous materials (AHMs) must prepare a Risk Management and Prevention Program (RMPP) to document how AHMs are handled to minimize the possibility of a release. The RMPP law states that the RMPP “shall be based upon an assessment of the processes, operations, and procedures of the business, and shall consider the results of a HAZOP study . . . and an offsite consequence analysis.” From these studies, facilities develop risk assessments that guide risk mitigation and emergency response planning.

Regulations in European Countries

The Seveso Directives. Under the first Seveso Directive, passed by the European Community in 1982, specific industries are to meet safety requirements such as carrying out safety studies, providing hazard notification, develop, and maintaining emergency response plan. Seveso II, passed in 1984, covers the transport of hazardous wastes that cross national borders within the European Community.

Industry Guidelines

AIChE CCPS Guidelines. Since 1985, the Center for Chemical Process Safety, a part of the American Institute of Chemical Engineers, has worked to promote process safety among those who handle, use, process and store hazardous materials. CCPS publishes a series of publications covering the full range of technical and management issues in process safety and design, including the forthcoming — [Guidelines for Selecting the Design Basis for Process Safety Systems].

Responsible Care. Introduced in 1988, the Responsible Care program of the Chemical Manufacturers Association requires each member organization to establish six key program elements, including guiding principles, codes of management practice, and public advisory panels. Management practice codes include the Process Safety Code. Its four elements cover management leadership, technology, facilities, and personnel, emphasizing company objectives rather than specific prescribed standards.

API/CMA Recommended Practice 752. Issued in 1995, this recommended practice employs a risk-based approach for management of hazards associated with location of process plant buildings. Both flammable and toxic hazards are addressed as well as the frequency and consequences of hazardous material releases. The intent is that the relative risk of individual buildings should be identified and used in planning and projects that involve building changes.
A Systematic Approach

In designing a process, designers first address the mechanics of making the product. A core design is defined by heat and material balances and basic process controls. Once the core design is determined, engineers examine ways in which the system could break down. They look at issues concerning the reliability, safety, quality control, and environmental impact of the system. They try to determine what failures might occur, what effect these failures (“impact scenarios”) might have in terms of quality, safety, cost, and the environment would be, and how likely these scenarios are. As they answer these questions and proceed with system design, engineers are continually making risk-based decisions. But all too often, their decisions may not be based on measurements of risk—only perceptions. The process used may be neither systematic nor comprehensive.

Case Study

Reducing Mitigation Costs Using a Risk-Based Approach

A worldwide chemical manufacturer investigated “best available technology” options for risk reduction in two processes and found that optimal results would require a $2.5 million capital expenditure. Seeking a fresh angle on the technology and science of risk reduction, the company asked Arthur D. Little to help its technical staff explore cost-effective alternatives for reaching an equal—or superior—level of risk reduction. Working closely with the company’s scientists and process engineers, we used a risk-based approach to develop and rank risk-reduction measures and their costs. The approach, which included the evaluation of areas such as the design basis for pressure relief system sizing, drew on recent advances in emergency relief system and mitigation design.

After collaborating with the company team on the development of risk matrices for risk-reduction alternatives, we helped present the alternatives to their senior management. The matrices showed that the most significant risk reduction could be achieved at a cost of $200,000, and that almost no further reduction could be achieved by spending additional money. The company immediately benefited from this work by achieving optimal risk reduction in two processes for one-tenth of the original cost estimate. The study also provided documentation for meeting new U.S. process safety management regulations. Most important, the savings increased the capital available for technology upgrades and risk reduction in the company’s other processes.

“A core design is defined by heat and material balances and basic process controls.”
The approach presented here offers a disciplined, consistent thought process and flexible implementation options. When the process for selecting the design basis lacks consistency, it is difficult to know whether the same risk-management philosophy supports all of a company’s process safety and risk decisions. As a result, inconsistencies in approach can develop between different processes and facilities, and, in the case of large, complex design projects, different design engineers on the same project may be using different philosophies.

Ideally, safety should be a theme at each stage in a systematic design cycle—laboratory, pilot, production design, operations. But the most cost-effective solutions tend to emerge in the earliest design stage. A systematic approach does not necessarily mean a quantitative one. Quantitative analysis is most time- and cost-effective when it is used selectively. In many simple design situations, qualitative approaches are sufficient for selecting process safety system design bases. More complex design cases may occasionally require quantitative risk analysis. But even then, quantitative methods should only be used up to the point where a decision can be made.

For example, consider a company that has toxic-impact criteria limiting off-site vapor cloud concentrations to a specific, quantified level of concern. By performing vapor cloud dispersion calculations (through a quantitative characterization of the consequences of potential releases) the company can determine whether specific loss-of-containment scenarios associated with specific failures exceed the toxic impact criteria. If the scenario consequences do not exceed off-site toxic impact tolerability criteria, then there is no need to continue with an analysis of event likelihood or further risk quantification.

Case Study
Evaluating Risk Reduction Alternatives Using a Risk-Based Approach

A facility belonging to a large chemical manufacture was producing a family of chemicals that react vigorously with water, generating corrosive and toxic by-products. The production process utilized water-cooled heat exchangers for condensing and cooling the process streams. Given the hazard potential due to exchanger leaks, the facility had embarked of a program to reduce the risk of such an event. However, they needed a way to determine which risk reduction option or combination of measures was the most effective.

Working closely with the companies operations and design engineers, we utilized elements of a risk-based approach to determine the relative benefit of various risk mitigation alternatives. The approach involved a qualitative estimate of the consequences of exchanger leaks, since almost any size leak would result in an undesirable outcome. A quantitative determination of the likelihood of such events for different risk reduction measures, was also conducted to establish the relative benefit of the various options. The results were presented to a group of engineers and managers, to allow them to decide which option would meet their risk tolerability criteria. The company opted for the inherently safer solution of substituting a non-reactive coolant for water.

While the selected design approach was not the lowest capital cost alternative, there were offsetting operating cost benefits in terms of less maintenance cost, down-time, and administrative complexity.
Nine Steps to Cost-Effective Risk-Based Design

The technique outlined here derives from process design engineers’ characteristic problem-solving methods and can be applied to all design cases, from the simplest to the most complex. The technique provides for a disciplined thought process and flexibility in its application. It comprises a sequence of analysis and testing steps in the form of a decision tree.

1. **Identify failure scenarios.** When designers have established a core process design, they can address things that can go wrong—failure scenarios that might require a process safety system. Process hazard analysis techniques and past experience provide information on possible failure scenarios.

2. **Estimate the consequences.** In this step, designers establish the consequences of the failure scenarios identified in Step 1. These scenarios typically involve quality, safety, health, and environmental impacts. Consequences of interest include fires, explosions, toxic materials releases, and major equipment damage. Some potential consequences can be determined through direct observation, engineering judgment, or the use of qualitative consequence criteria. Other cases require experimentation or analytical approaches such as the calculation of maximum hazard distances of vapor cloud dispersion.

3. **Determine the tolerability of the consequences.** Answering this question requires guidance from established tolerability criteria. These include: company-specific criteria; engineering codes and standards; industry initiatives such as Responsible Care; and regulatory requirements. For ERS design, the focus of this Step is on comparing the potential rise in pressure to the mechanical limits of the equipment under consideration.
4. **Estimate likelihood and risks.** Estimates of likelihood rest upon an understanding of the mechanism and frequency with which failure scenarios such as those identified in Step 1 might occur. When historical data is available about equipment and processes, these data can be used to arrive at failure scenario frequency estimates. When data is lacking, methods such as fault tree analysis help in developing quantified estimates. Measures of risk are arrived at by combining risk and consequence estimates. A detailed review of methods for combining likelihood and consequence estimates to obtain risk measures can be found in Guidelines for Chemical Process Quantitative Risk Analysis. Some cases can be resolved through comparisons with similar systems or through the use of qualitative tools such as risk matrices. Others will require quantified approaches such as risk profiles and risk contours.

5. **Determine risk tolerability.** Determining risk tolerability means asking “Can we—and our stakeholders—tolerate this level of risk?” Guidance on tolerable levels of risk can be gained from established risk criteria. If the criteria, when applied, indicate a tolerable level of risk, then the design of the process or the emergency relief system is satisfactory from a risk standpoint. If the criteria indicate intolerable risk, the next step is to reduce risk through further design.

6. **Consider enhanced and/or alternative designs.** In the overall risk-based design sequence, this step is an opportunity to consider the entire process design and define changes that can reduce risk to a tolerable level. Risk reduction concepts have been classified by CCPS as inherently safer, passive, active, and procedural in declining order of reliability. In emergency relief system design, this step focuses on mitigation—lessening or controlling the consequences of an accidental release.

7. **Evaluate enhancements and/or alternatives.** A design change intended to reduce risk can introduce new failure scenarios and new risks. Therefore, the evaluation of design changes should treat these changes as an integral part of the process. Following Steps 1-4, the review should re-estimate process risk. The review should also estimate the cost of the proposed changes.

8. **Determine tolerability of risk and cost.** As in Steps 3 and 5, established risk criteria can provide guidance on risk tolerability. Cost becomes an issue in this step because, like all designs, process safety designs must meet business criteria. Coupling estimates of cost and risk reduction provides a basis for assessing the cost-benefit tradeoff of each alternative design or mitigation solution. The cost-benefit analysis can be qualitative or quantitative. A quantitative approach is especially useful when a large number of competing process safety systems are being considered. If the analysis yields tolerable risk and cost for a design option, the results should be documented (Step 9). If not, it may be necessary to consider further design enhancements and alternatives (Steps 6-8).

9. **Document results.** The failure scenarios and associated consequence, likelihood, and risk estimates developed during this process document the design basis for process safety systems and emergency relief systems. Documenting the process safety system and ERS design basis retains essential information that is extremely valuable for risk management situations such as hazard evaluations, management of change, and subsequent design projects. When the findings from Step 3 or Step 5 show that consequences and risk meet tolerability criteria, results still need to be documented. Doing so will cut down on needless repetitions of the analysis and ensure that design or operational changes reflect an understanding of the base-line risk of the design.
Guidelines for Risk Tolerability

Underlying this entire approach is the understanding that risk levels range along a continuum. In most cases, risks cannot be eliminated, only reduced to a level that everyone who has a stake in the activity or process finds acceptable when weighed against the advantages and benefits of the activity or process.

Because attitudes about the tolerability of risks are not consistent, there are no universal norms for risk tolerability. What your stakeholders view as a tolerable risk will depend upon a number of factors, including the following:

The nature of the risk. Is it a voluntary risk, one that those who are at risk accept as part of a choice? Or is it involuntary?

Who or what is at risks. Does it affect a single person or many people? What about the surrounding environment? Is it an industrial landscape already altered by past uses, or a pristine or prized natural setting? Are important water or other resources at risk? Residential neighborhoods? Schools?

The degree to which the risk can be controlled or reduced. Process safety design and especially emergency relief system design focus in large part on this issue. Making the case for a “tolerable” risk requires that the methods supporting the design basis be technically sound and defensible, clearly documented, and accurate.

Past experience. Uncertainty regarding the risk impact influences the risk takers tolerability. For example, the average person understands the risk of driving an automobile but is uncertain regarding the risk of nuclear power generation. Finally, attitudes toward risk change over time. Given all of these variables, how does a company establish risk tolerability criteria that can effectively contribute to decisions about the tolerability of certain consequences, likelihoods, and risks?

Companies that have successfully established risk criteria focus on providing consistency in their decisions about risk. These criteria typically represent levels of risk that the company believes will minimize impacts to continued operations. This approach does not explicitly mention specific stakeholder concerns such as protection of the surrounding environment and communities. However, risk decisions that protect operations are very likely to help reduce risk across the board— for facilities, employees, surrounding property, and the environment. Moreover, since demonstrably safe operations have become a cornerstone of a company’s franchise to operate in many places, well-thought-out risk criteria that make continued operation their objective will also address most other stakeholder concerns.

Risk criteria should also fit with a company’s philosophy and culture and match the type of analysis its engineers normally conduct in the design stage. The selection of appropriate risk criteria is a corporate responsibility and requires the involvement and support of senior management, as it establishes the levels and types of risks the company will tolerate.

Once a company has established specific risk criteria, they can be used to check outcomes throughout the design process, at Steps 3, 5, and 8 of the approach outlined above. This iterative approach builds consistency into the process and increases the likelihood of making risk-based choices early in design—where they
are often most cost-effective. Figure 4 provides examples of some accepted risk criteria.

**Figure 4:** Representative Risk Tolerability Criteria

*Release Limits* address the tolerability of potential release consequences by considering the amount of material that could be released. “Tolerable” quantities depend upon the physical states and hazardous properties of released materials. A hypothetical release limit for gasoline, for example, might be as much as 5,000 pounds, while for chlorine, it would be only 200 pounds.

*Threshold Impact Criteria for Fence or Property Line* employ standard damage criteria, such as toxicity, thermal radiation, or blast overpressure, together with consequence modeling, to determine whether potential impact at the facility’s fence or property line exceeds a tolerable threshold.

*Single versus Multiple Component Failures* provide a qualitative approach to how many component failures will be tolerated. For example, a company might choose to tolerate event scenarios that require three independent component failures; to conduct further analysis of event scenarios triggered by two failures, and not to tolerate events arising from single failures.

*Critical Event Frequency* addresses event scenarios with a defined high-consequence impact. Examples would be a severe injury, a fatality, critical damage to the facility, or impacts on the surrounding community. Companies often use a range of threshold frequencies for these scenarios, depending upon the extent and nature of potential worst-case consequences.

*Risk Matrix* criteria use qualitative and semiquantitative frequency and severity categories to estimate the risk of an event. Events with a low risk ranking are considered tolerable.

*Individual Risk Criteria* consider the frequency of the event or events to which an individual might be exposed, the severity of the exposure, and the amount of time for which the individual is at risk. While no consensus exists on appropriate thresholds, a maximum risk to the public of $1 \times 10^{-5}$ fatalities per year is not unusual among companies that use these criteria.

*Societal Risk Criteria* can be used instead of or in addition to individual risk criteria and provide a more detailed evaluation of the distribution of risk. In other words, societal risk criteria explicitly address both events with a high frequency and low consequence and events with a low frequency and high consequences. This class of criteria can be useful to companies that have recently experienced an adverse event and cannot tolerate another, no matter how small its likelihood.

*Risk Matrix and Cost Threshold* can account for the risk reduction level provided by a design enhancement and its cost. In cases where the benefit of a risk reduction step is large and its cost is small, the way forward is obvious. But most design situations are not that simple. For example, an enhancement or alternative that reduces a high risk to a medium risk and costs $15,000 may be considered feasible and effective, as might an alternative that costs $450,000 and reduced a high risk to a low risk. In these situations, a risk matrix and cost threshold with definite “rules” can help clarify decision-making.

“Risk managers and environmental managers at many companies face unremitting pressure to run their activities “lean” and control and justify costs.”

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Design Solutions: Understanding the Options

The purpose of the procedure described above is to enhance designers’ ability to make consistent choices about safe design and to introduce modifications where they can do the most good for the least cost. These design choices for safety system design are of four types. All of these approaches help to minimize risk. But they vary in terms of factors such as cost, reliability, and maintenance. Companies are in the best position to manage these design choices when they are prepared to follow consistent risk tolerability levels, understand how a specific facility or process fits into their overall business plan, and know what the cost limitations are for the safety component of a process.

When deciding among the hierarchy of mitigation options, designers should avoid the pitfall of ‘project mentality’, i.e., focusing only on minimizing capital cost. As Figure 5 suggests, inherently safer approaches may have higher initial investment, however, the cost of maintaining an active system to obtain an equivalent level of risk reduction can be significant. Therefore, the correct approach should be to consider the life-cycle cost of the design options, before making the final selection.

Figure 5  Inherently Safer Design

Inherently Safer design solutions eliminate or mitigate the identified hazard by using materials and process conditions that are less hazardous. For example, faced with the hazard posed by a flammable solvent, designers might seek to substitute water. When large inventories of hazardous “intermediates” increase risk levels, there may be a way to reduce or eliminate these inventories.

Passive design solutions offer a high level of reliability by operating without any devices that sense and/or actively respond to a process variable. Examples of passive design solutions include incompatible hose couplings for incompatible substances and process components, equipment designed to withstand internal deflagration and other very high-pressure hazards, and dikes that contain hazardous inventories with a bottom sloping to a remote impounding area.
Active design solutions employ devices that monitor process variables and activate to mitigate a hazardous situation. Active solutions, sometimes called engineering controls, are often less reliable than passive or inherently safer design solutions because they require more maintenance and more operating procedures. The following are characteristic active design solutions:

- A pressure safety valve or rupture disk that prevents vessel overpressure
- A high-level sensing device interlocked with a vessel inlet valve and pump motor to prevent overfilling
- Check valves and regulators

Procedural design solutions, also known as administrative controls, avoid hazards by requiring a person to take action. These actions might include reacting to an alarm, an instrument reading, a leak, a strange noise, or a sampling result and might involve steps such as manually closing a valve after an alarm sounds to prevent a vessel from overfilling or carrying out preventive maintenance to reduce the likelihood that equipment will fail. Involving a person in the safety solution means incorporating human factors in the analysis. These human factors, including an inappropriate division of tasks between machine and person and an unsupportive safety culture, contribute to making procedural solutions generally less reliable than other design solutions.

Choosing among these types of solutions is not simply a matter of selecting the most reliable approach. Inherently safer and passive solutions tend to offer high reliability and low operating costs, but may involve an initial cost that does not fit with the budget or business plan for the process. Active and procedural solutions cost less to begin with, but typically involve higher operating costs and are less reliable (See Figure 6).

Consider the case of a company that was handling a very energetic substance with a highly hazardous reaction. The company had faced incidents with the substance and was now reviewing two options for reducing the risk posed by the substance. The first, total containment of the substance in a vessel rated to withstand a maximum pressure level of 1,200 psi, was an inherently safer approach. However, the cost of this vessel was very high. Furthermore, using such a vessel meant having it sit continually within the facility at a very high pressure—a hazard in and of itself.

The second option was to construct a catch system and allow the reactor to activate an emergency pressure relief system. This required a reactor vessel with a lower pressure rating and a large vessel to be used as a catch/quench tank. While this approach was less expensive, it required the facility to deal with the potential of a hazardous effluent and to address the reliability of the release system. This option was found to provide a tolerable risk level and a lower cost of implementation.

In another case, a company was using water-cooled heat exchangers in a process that included a material that reacts violently with water, producing corrosive and toxic by-products. The company’s designers considered various combinations of passive solutions such as heat exchangers that use non-pressurized water, active solutions such as advanced leak-detecting sensors, and procedural solutions such as enhanced testing, inspection, and maintenance. All of the alternatives reduced risk levels, but none met the company’s risk tolerability criteria. Faced with the prospect of sustaining high operating costs and staff efforts for a less-than-satisfactory risk effort, management chose a design that substituted a compatible heat transfer fluid for water. This choice required a higher initial investment in equipment replacement but eliminated a host of maintenance and administrative complexities down the line.

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Next Steps in Cost-Effective Reduction

In recent years, industrial standards for tolerable risk have tended to become increasingly stringent. This trend reflects a convergence of public opinion, government regulations, and industry initiatives. The momentum for controlling and reducing risk is likely to continue, with leaders in the process industry setting standards for their companies that are well in excess of what is required.

Cost-Effective Risk Reduction

Incorporating systematic risk assessment in process safety design is sometimes viewed as an expensive way to achieve greater risk reduction. The reality, however, is that when risk assessment is left out of the design process, two problems are likely to occur. The system may be overdesigned, with safety protection costing more than it needs to, or the facility may be unprotected from significant, unidentified risks.

Systematic risk-based design helps companies more fully identify significant risks, rank them, and prioritize steps to address them. The result is that capital expenditures, operating expenses, staffing, and other resources are better allocated to risks, enabling companies to buy more risk reduction at a cost that is the same or less.

“The momentum for controlling and reducing risk is likely to continue.”
At the same time, risk managers and environmental managers at many companies face unremitting pressure to run their activities “lean” and control and justify costs. The ability to reach decisions about process safety design based on a clear understanding of both the risk reduction options and costs can greatly strengthen managers’ ability to meet the needs of internal and external stakeholders for process safety.

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