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Risk Management Practices

Cross-Agency Comparisons with Minerals Management Service

Lynn Scarlett, Igor Linkov, and Carolyn Kousky

1616 P St. NW
Washington, DC 20036
202-328-5000 www.rff.org

RESOURCES FOR THE FUTURE

Risk Management Practices: Cross-Agency Comparisons with Minerals Management Service

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Abstract

This paper reviews implementation of the risk management frameworks used by eight federal and foreign agencies—including the Minerals Management Service (MMS, now the Bureau of Ocean Energy Management, Regulation, and Enforcement, or BOEMRE)—and summarizes the features of a robust tolerable risk (TR) framework. A TR framework conceptually breaks risk into three categories—acceptable, unacceptable, and tolerable—separated by numerical boundaries. Most of the agencies surveyed in this review have adopted a TR or modified TR framework, but MMS (BOEMRE) generally has not (although the agency does use an Oil Spill Risk Model to assess spill probabilities and possible trajectories). The study argues that while numerical thresholds are not essential to risk management, they provide a transparent goal against which to benchmark practices, equipment, standards, and facilities, and would be a valuable tool for BOEMRE. We also recommend that BOEMRE develop better risk assessment and management guidance; identify and more systematically collect information for understanding and evaluating risks and safety performance; and strengthen performance-based risk management by adopting proven approaches, such as those used in Norway and the United Kingdom for offshore oil and gas development.

Key Words: tolerable risk, risk assessment, performance-based risk management, Minerals Management Service, Bureau of Ocean Energy Management, Regulation, and Enforcement

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Executive Summary

The *Deepwater Horizon* blowout killed 11 people and spilled millions of gallons of oil into the Gulf of Mexico. The spill affected the livelihoods of many people in Gulf Coast communities, and the natural resource damages have yet to be fully assessed. The catastrophe points to the risks, both to human safety and to the environment, from offshore oil and gas activities.

In the United States, since 1982, the Minerals Management Service (MMS, now restructured into the Bureau of Ocean Energy Management, Regulation and Enforcement, BOEMRE, which will become two bureaus—the Bureau of Ocean Energy Management and the Bureau of Safety and Environmental Enforcement) has been responsible for developing environmental and safety regulations for offshore oil and gas. The *Deepwater Horizon* disaster brings renewed focus to how MMS undertook those responsibilities and dealt with risk management.

* Lynn Scarlett, Visiting Scholar, Resources for the Future; Igor Linkov, U.S. Army Engineer Research and Development Center; Carolyn Kousky, Fellow, Resources for the Future.

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Current implementation of risk management processes differs across agencies but often relies on the concept of “tolerable risk.” This paper reviews implementation of the risk management frameworks used by eight federal and foreign agencies and summarizes the features of a robust tolerable risk framework. It draws extensively from an April 2008 workshop on tolerable risk sponsored by U.S. Army Corps of Engineers and several other federal agencies.

Findings

The National Research Council defines *risk assessment* as a process that involves hazard identification, hazard characterization or dose-response assessment, exposure assessment, and risk characterization. Traditional risk assessments evaluate the likelihood of a hazardous event and the likely adverse effects of that occurrence. *Risk management* applies society’s risk tolerance and preferences by identifying, selecting, and using specific risk-reducing strategies. Risk management recognizes that different levels of risk warrant different reactions. Some risks are high enough that action must always be taken to reduce their magnitude. Other risks are low enough that they can generally be considered negligible. Still other risks are high enough to warrant reductions but low enough that reductions should be undertaken only when considered reasonable in terms of project costs, other risks, and social preferences.

Risk assessment and risk management are often applied within a framework that includes thresholds for delineating different types or levels of risk and criteria for deciding which risk reductions are sufficient. The tolerable risk (TR) framework, first developed in the United Kingdom, has provided a basis for risk assessment in many agencies worldwide. The TR framework conceptually breaks risk into three categories—acceptable, unacceptable, and tolerable—separated by numerical boundaries. Under the TR framework, unacceptable risks are not allowed under any circumstances and, if identified, require that measures be taken to reduce the likelihood of harm. Acceptable risks are considered to have been reduced to levels that are below concern and require no further reductions. Tolerable risks, occupying the middle ground, are risks that society considers bearable, based on the benefits produced by incurring the risk, but nevertheless seeks to reduce within the limits of economic and technical feasibility. Under a TR framework, all risks within the tolerable region must be reduced to levels “as low as reasonably practicable” (ALARP), meaning they are reduced to the point at which costs or other feasibility concerns prohibit further reductions. The goal of risk management is to push risks from the unacceptable, through the tolerable, and into the broadly acceptable region using specific ALARP considerations.

Rather than rely on subjective judgment to determine the region in which a risk falls, agencies often use a TR framework to identify risk thresholds. Though there is currently no coordinated effort to adopt standardized risk management approaches across federal or international agencies, several trends can be seen. Most of the agencies surveyed in this review have adopted a TR or modified TR framework, specifying threshold values for the unacceptable and/or broadly acceptable regions. Threshold values for each agency are generally set to around 1 in 10,000 (deaths per year per capita) for the unacceptable region and 1 in 1,000,000 (deaths per year per capita) for the broadly acceptable region. The high similarity among threshold values is due to their popularization by the Food and Drug Administration and to a common derivation from socially acceptable risks and general background risks.

Many of the surveyed agencies have divided project risk into two or more categories, specifying different thresholds for individual risk, societal risk, and/or risk of project failure. Most surveyed agencies have also applied some sort of cost-benefit consideration to determine when risks are ALARP; exceptions are the Nuclear Regulatory Commission, which uses the more stringent constrained-risk approach, and the Food and Drug Administration, which often requires compliance with specific approved processes.

The planning and regulatory context for offshore (especially deepwater) oil and gas exploration and production involves both workplace safety hazards and the possibility of oil spills that will damage marine and coastal environments and human communities. Assessing and managing risks for offshore energy activities occur in two main clusters of activity: (1) the planning and leasing process; and (2) the regulatory process for establishing safety and environmental regulations.

Through its planning process, MMS (BOEMRE) identifies areas eligible for oil and gas leasing. Because of the uncertain nature of whether, when, and where an oil spill will occur and how significant it will be, the agency necessarily must use risk models to evaluate the likelihood of a spill's occurring and, if it occurs, the magnitude of environmental damage. The model that MMS (BOEMRE) uses to assess risk has three basic components: (1) estimates of the probability that a spill will occur; (2) simulated trajectories of spills to critical environmental resources; and (3) combined results of the first two elements to estimate the risks from potential oil development. The model uses historical records of oil spills, ocean currents, and wind patterns.

Modeling of oil spill occurrences is challenging. Though many small (less than 100 gallons) spills occur, high-volume, high-consequence spills are extremely infrequent. The infrequency of high-consequence events makes data-based estimations problematic. Nonetheless, even though a platform spill of the magnitude of the Macondo blowout had not previously occurred in the Gulf, the probability of the occurrence of such a spill was not zero.

The Oil Spill Risk Model has been subject to various technical and analytical critiques and has undergone numerous upgrades and periodic efforts to validate projections of spill trajectories and potential effects. Such efforts have been both regular and transparent. However, for purposes of understanding risk management in the offshore oil and gas context, our focus is on three broader institutional and decisionmaking issues: (1) what formal, regular, and transparent processes exist to periodically review, validate, and improve risk models used by the agency and industry; (2) how information generated by the model is used to inform decisionmaking, including decisions about risk mitigation; and (3) what standards, if any, are used as the benchmark or tolerable risk threshold for managing and mitigating risk.

Use of Models in Decisionmaking

Resource managers face two distinct but related questions: how to incorporate information about risk probabilities into planning and other resource impact analyses, and—the central, underlying policy decision—how to determine “how safe is safe enough.”

Impact analysis. Concern has persisted about how the oil spill risk model is used to inform decisionmaking. The initial estimate of extremely low probability of a spill has cascading effects on decisionmaking of resource managers. For the Macondo well, the risk model generated estimates of 4,600 barrels as the most likely size of a large spill and no more than 26,000 barrels of oil spilled over the entire 40-year life of production activity on six leases, including the Macondo well site. These estimates resulted in an environmental assessment determination of “no significant impact” from the project.

How safe is safe enough? Even if the Oil Spill Risk model is useful in estimating probabilities of a spill and projecting damages, a larger decisionmaking issue looms: how safe is safe enough? Risk models themselves do not establish what constitutes “acceptable” or “tolerable” risk or ensure transparent decisionmaking regarding tolerable risk thresholds.

Although numerical thresholds are not essential to risk management, they provide a transparent goal against which to benchmark practices, equipment, standards, and facilities. Risk analyses confront challenges of inadequate data and use of faulty assumptions. But quantitative goals nonetheless enable independent reviewers to evaluate whether a particular standard is likely to meet the specified safety threshold. Such goals also provide a clear benchmark against which industry can evaluate its own risk reduction practices and techniques. In general, MMS has not set numeric standards for unacceptable, tolerable, and acceptable risk.

Standard Setting and Regulations

The standard-setting aspect of risk management applies both to the offshore planning process and to the regulatory processes for establishing safety and environmental regulations. MMS (BOEMRE) looks at both quantitative and qualitative risk assessment but generally has favored qualitative approaches. The rationale for use of qualitative assessments relates, in part, to data quality. With poor data, quantitative assessments can be highly variable and even manipulated, depending on the assumptions and other criteria used.

Risk management involves three kinds of activity:

- administration, which comprises training, emergency planning, directives and supervision, inspections, communications, management of change, and related activities;
- engineering, which includes equipment design, monitoring, and related equipment issues; and
- operations, which include such matters as procedures, job safety analysis, and incident management.

In general, two regulatory approaches to risk management are available to agencies. In a risk-based accountability approach, companies or the regulating agency (or both) set a performance standard (or a tolerable risk threshold) and take actions to reduce risks to meet that standard. In a second, more prescriptive approach, a regulatory agency prescribes technologies and procedures deemed to represent best practices.

Risk-based performance regulations. Norway uses a risk-based, industry-accountability approach to offshore energy activities. The approach places responsibility on the operator (and contractor) to identify risks and hazards; develop controls, mitigation strategies, and systems to reduce risks to defined levels; and use identified risks as the basis for prioritizing decisionmaking. The United Kingdom takes a slightly different risk-based performance approach, requiring that each operator develop a “safety case” that identifies risks on an integrated, system-wide basis, including both technical and procedural (human behavior) issues, and describes how the operator will address risks and achieve specified safety levels.

Prescriptive regulations. In the more traditional risk management approach, a regulatory agency identifies equipment, technologies, and best practices deemed to contribute to safety and risk mitigation. The agency then prescribes use of these elements through regulations and undertakes inspections to affirm compliance. Noncompliance results in notices, fines, or other measures. The prescriptive approach as applied to offshore oil and gas activities presents at least three challenges: (1) prescribed regulations may lag behind development of new and safer equipment and procedures; (2) prescriptions may not cover all the behavioral and other actions that result in safe performance; and (3) regulators shoulder the primary responsibility for inspecting facilities and affirming that they are safe.

Recommendations

Several options for enhancing BOEMRE's risk management practices offer opportunities to strengthen transparency, accountability, and safety performance.

Risk Assessment and Management

- Adopt quantitative thresholds to specify unacceptable and tolerable risk levels, to enhance decisionmaking clarity and transparency.
- Develop (1) risk assessment guidance regarding information transparency, data validation, and analytic assumptions; and (2) risk management guidance on the use of risk assessment. The agency should consider including the five elements of risk management (metrics, threshold values, ALARP considerations, review timeframes, and applications) set forth in ISO 31000 and agency best practices, as well as guidance on risk communication.
- Identify and more systematically collect information for understanding and evaluating risks and safety performance.

Regulatory Processes for Risk Management

- Strengthen performance-based risk management by adopting proven approaches, such as those used in Norway and the United Kingdom for offshore oil and gas development. These approaches make firms more accountable for establishing tolerable risk (safety) standards (or applying agency standards), identifying all hazards, and showing how their equipment and practices will meet the established performance levels. The agency and industry share responsibility for developing and maintaining the standards.
- Define TR thresholds and use a structured decision framework to assess relevant factors as a part of the process. Tools of multicriteria decision analysis or other formal decision-analytic tools can be used for such evaluations.

Introduction

Risk management is a central function of agencies responsible for overseeing and regulating offshore oil and gas exploration, production, and transportation. How risks are identified, managed, and mitigated is fundamental to whether these offshore oil and gas activities are conducted safely and with minimal harm to humans and the environment.

The *Deepwater Horizon* blowout killed 11 people and spilled millions of gallons of oil into the Gulf of Mexico. The spill affected the livelihoods of many people in Gulf Coast communities, and the natural resource damages have yet to be fully assessed. Until the *Deepwater Horizon* event, the offshore oil and gas industry in the United States had experienced no platform spills greater than 1,000 barrels in 40 years. However, major spills have resulted from tanker accidents, such as the *Exxon Valdez* spill in Alaska in 1989, and numerous small spills have occurred over the past four decades. In addition, offshore oil and gas production in non-U.S. waters has experienced several major spills, including spills from platforms, and fatalities. These events included an explosion and fire on the U.K. production platform *Piper Alpha*, the capsizing of the Norwegian accommodation platform *Alexander Kielland* and the Canadian semisubmersible drilling rig *Ocean Ranger,* and the sinking of the Norwegian gravity-base structure *Sleipner A* (resulting in no injuries but generating major economic losses for the owner). Norway experienced a major spill from the 1977 *Bravo* blowout and over the past three decades has had three spills of more than 6,300 barrels each.[1] These events point to the risks, both to human safety and to the environment, from offshore oil and gas activities. Though the risk of large spills is small, when large-magnitude spills occur, they can cause catastrophic results—deaths and environmental damage.

In the United States, since 1982, the Minerals Management Service (MMS, now BOEMRE, which will become two bureaus—the Bureau of Ocean Energy Management and the Bureau of Safety and Environmental Enforcement) has been responsible for developing environmental and safety regulations for offshore oil and gas activities. The *Deepwater Horizon* accident raises questions about how MMS undertook those responsibilities and dealt with risk management.

[1] Norwegian Ministry of the Environment, *Integrated Management of the Marine Environment of the Norwegian Sea*, Report No. 37 (2008-2009) to the Storting. Available at: http://www.regjeringen.no/nn/dep/md/dok/regpubl/stmeld/2008-2009/report-no-37-2008-2009-to-the-storting/5/6/2.html?id=577943

This paper reviews implementation of the risk management frameworks of eight federal and foreign agencies and summarizes the features of a robust "tolerable risk" framework. It draws extensively from a March 2008 workshop on tolerable risk sponsored by USACE, the Federal Energy Regulatory Commission, and the Department of the Interior and attended by several federal and foreign agencies. Results of the workshop and thorough agency reviews are presented in Appendix A.

Risk-Based Decisionmaking

The Society for Risk Analysis defines risk as the "potential for realization of unwanted, adverse consequences to human life, health, property, or the environment."[2] Calculation of risk, especially in environmental settings, is conducted through *risk assessments* that place numerical values on the risk associated with a particular event or option. Understanding the risks associated with an activity requires evaluating the probability that disastrous events will occur and the likely effects if they do occur. In other words, risk is measured in terms of both the likelihood and the severity of the consequences. The National Research Council defines risk assessment as a process that involves hazard identification, hazard characterization, exposure assessment, and risk characterization.[3]

The risk assessment process requires many assumptions and often involves significant uncertainty, and the resulting risk levels are usually subject to interpretation, given specific project needs and stakeholder concerns. *Risk management* applies society's risk tolerance and preferences by identifying, selecting, and applying specific risk-reducing strategies.

All risks are not created equal, and risk management recognizes that different levels of risk warrant different reactions. Some risks are high enough that action must always be taken to reduce them. Other risks are low enough that they can generally be considered negligible. Still others are high enough to warrant reductions but low enough that reductions should be undertaken only when considered reasonable in the context of project costs, other risks, and social preferences. Risk management strategies often also vary across individual risk (which relates to one person's increased risk associated with the project or event), societal risk (which

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[2] Society for Risk Analysis, September 1, 2010 (accessed October 3, 2010, from Society for Risk Analysis, http://www.sra.org/resources_glossary_p-r.php).

[3] National Research Council, *Risk Assessment in the Federal Government: Managing the Process,* National Academy Press, Washington, DC, 1983.

aggregates individual risks to determine the total number of people who can be affected by a particular event), and project failure risk (which relates to the expected number of failures per project per year).

The components of risk management are (1) establishing the context and determining risk thresholds; (2) identifying and assessing the risks; (3) developing risk reduction and mitigation strategies; and (4) monitoring and reviewing the risks. Communication and consultation with internal and external stakeholders should take place at each stage of the process. By implementing these risk management strategies, public agencies can reduce or mitigate risk to socially acceptable levels. A general approach to risk management implementation has been standardized under ISO Standard 31000.[4]

Using the National Research Council's four-part definition of risk assessment (hazard identification, hazard characterization, exposure assessment, and risk characterization) in the context of offshore oil development requires evaluating the probability that a particular event (e.g., an oil spill or other accident) will occur and assessing its likely consequences.

Tolerable Risk Framework

However technically robust traditional risk assessments are, they give little insight into how trade-offs should be made between various risk management activities and whether the identified levels of risk are socially acceptable. Thus, agencies managing risks face challenges in estimating or calculating risks, establishing standards for risk thresholds, and developing strategies to prevent, detect, and mitigate risk.

The tolerable risk framework provides a structure for risk management and a basis for risk assessment in many agencies worldwide. The concept of tolerable risk (TR) was first conceived by the British Health and Safety Executive (HSE) during its work on the safety of nuclear power plants.[5] The TR framework conceptually breaks risk into three categories—acceptable, unacceptable, and tolerable—separated by numerical boundaries (Figure 1). A risk for which the probability of occurrence is so small or the consequences are so slight that individuals or groups are willing to accept the risk is an *acceptable risk.* Actions to further

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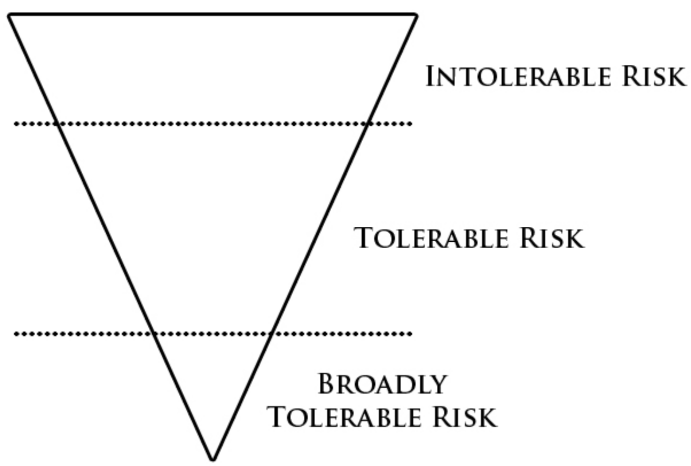
[4] International Organization for Standardization, *ISO 31000:2009: Risk Management—Principles and Practice*, ISO, Geneva, 2009, http://www.iso.org.

[5] U.K. Health and Safety Executive (HSE), *The Tolerability of Risk from Nuclear Power Stations*, 1992.

reduce such risks are usually not required. An *unacceptable risk* is a risk so high that society is unwilling to bear it and wants measures taken to reduce its likelihood or harmful consequences. A *tolerable risk* is a non-negligible risk that has not been reduced to an acceptable level but that society is willing to bear in order to secure the benefits associated with the risky activity. Within the Tolerable Risk range, incremental further risk reductions may be sought while taking into account feasibility, costs, and other criteria. Tolerable risks, occupying the middle ground between acceptable and unacceptable risks, must be reduced to levels "as low as reasonably practicable" (ALARP), meaning they are reduced to the point at which costs or other feasibility concerns prohibit further reductions. The goal of risk management is to push risks from the unacceptable, through the tolerable, and into the broadly acceptable region using specific ALARP considerations.

Figure 1. Conceptual Categories in Tolerable Risk Framework



Source: U.K.Health & Safety Executive. *The Tolerability of Risk From Nuclear Power Stations.* London: Her Majesty's Stationary Office. 1992. http://www.hse.gov.uk/nuclear/tolerability.pdf

Determining the numerical boundaries separating the regions is an important step in applying the TR framework.[6] Rather than relying on subjective judgment to determine the region

[6] U.K. Health and Safety Executive, *Reducing Risks, Protecting People,* Her Majesty's Stationery Office, Norwich, 2001.

in which a risk falls, HSE outlines risk thresholds loosely based on common risks accepted by the public, such as rock climbing, high-risk professions, and traffic accident deaths.[7] HSE determined that the highest level of risk the general public would bear in order to receive some benefit was roughly 1 in 10,000 (deaths per year per capita), and that risks with a chance of less than 1 in 1,000,000 (deaths per year per capita) were generally considered by the public to be inconsequential. Other metrics apply for different kinds of risk, such as those associated with environmental harms not related to human health. The HSE framework attempts to present risks along a continuum from the broadly acceptable to the clearly unacceptable, situate risk decisionmaking within a cost and feasibility context, and provide a framework for more clearly establishing quantitative risk thresholds.

Based on project purpose and societal preferences, regulators and other risk managers can consider various techniques and criteria to decide whether risks within the tolerable region are as low as reasonably practicable. Utility-based considerations trade risk reduction with another quantity, typically money, to determine the optimal balance between risk protection and incurred costs. ALARP considerations in this category include deterministic and probabilistic cost-benefit analyses, cost-effectiveness analyses, bounded cost constraints, maximization of multi-attribute utility, and minimization of the worst possible outcome. As an alternative to traditional cost-benefit analysis, multicriteria decision analysis tools are increasingly being applied to balance multiple nonmonetized criteria and metrics in environmental applications in general and in oil spills specifically.[8] Alternatively, rights-based considerations acknowledge that, for certain sources of risk, people are entitled to receive an absolute level of protection. Risk management considerations in this category include zero-risk standards, bounded risk constraints, compliance with specific approved processes, and stakeholder approval and compensation. Technology-based considerations recognize that risk reduction is often limited by available technology and seek to mitigate risks by using the best technologies available. Hybrid considerations combine various aspects of utility-based, rights-based, and technology-based approaches and are useful when a more nuanced strategy is required.[9]

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[7] U.K.Health & Safety Executive. *The Tolerability of Risk From Nuclear Power Stations.* London: Her Majesty's Stationary Office. 1992. http://www.hse.gov.uk/nuclear/tolerability.pdf

[8] I. Linkov, A. Tkachuk, A. Levchenko, T. Seager, J. Figueira, and T. Tervonen, “A Multi-criteria Decision Analysis Approach for Establishing Performance Metrics under Government Performance and Results Act: Example of Oil Spill Response,” in I. Linkov, R. Wenning, and G. Kiker (eds.), *Managing Critical Infrastructure Risks*, Springer, New York, 2007, 261–98.

[9] G. Morgan and M. Henrion, *Uncertainty,* Cambridge University Press, New York, 1990.

Implementing a tolerable risk framework often involves comparisons among different risk metrics, leading to great variation in the implementation of TR frameworks. Government risk management practices, particularly in the United States, have historically varied: agencies have created their own risk management practices based on social trends, the expert knowledge in the risk management community, and agency goals within the statutory context.

Implementation of Tolerable Risk Framework

Following ISO 31000 and the risk management processes of other agencies, the following steps should be taken to establish a successful risk management framework.

1. Define Risk Goals and Metrics

Defining risk management goals and metrics helps identify which areas merit consideration for reductions in risk. The scope of these metrics can include individual, project, and/or societal risks, covering topics such as the loss or degradation of life, health, personal property, national security, or the environment, etc. By defining these risk reduction parameters, later risk management is made more transparent and is focused into clearly defined areas. For offshore oil and gas development, for example, goals have included reduction in the occurrence and consequences of oil spills and reduction in major accidents, injuries, and fatalities associated with offshore operations. But specifying the goals is just one dimension of this task; the other is to develop the metrics for measuring trends and performance related to these goals. For example, what criteria define a major accident? Are injuries best tracked as a ratio of incidents to number of hours worked, by oil production activity, or by some other metric?

2. Define Risk Threshold Values

Defining threshold values provides unacceptable and broadly acceptable risk limits for each parameter, using easily understood and scientific means. In addition to specifying the thresholds themselves, this process should determine whether the identified values are static across the project portfolio or must be redefined for each project location. Clearly defined threshold values are important for identifying situations for which additional risk reductions are mandatory, potentially warranted, or unnecessary. Defining the thresholds is not always straightforward or without controversy, however. For example, thresholds for establishing unacceptable risk levels for exposure to air, water, or soil contaminants are sometimes challenged as too high or too low, but in many instances, it is not the threshold per se that is contested. Rather, significant disagreements often surface regarding the analytic tools and assumptions for assessing whether some action or exposure falls within the range of tolerable risk. In the United States, these debates were partly responsible for triggering Office of Management and Budget principles regarding risk assessment in the 1990s and again in 2007.[10]

3. Select As-Low-As-Reasonably-Practicable Considerations

For each project, the regulator or other risk manager needs to consider which methods, such as cost-benefit analysis or multicriteria decision analysis, and which criteria will be used to determine whether project risk levels are ALARP, and to choose among risk reduction measures. Selection of ALARP considerations sets the framework for the application of risk reduction methods. The regulator then needs to develop implementation guidelines.

4. Select Review Timeframes

Review timeframes are meant to ensure continued compliance with ALARP and threshold values. For example, risks considered tolerable today may become unacceptable as technology advances or as new problems arise, and firms that have reduced risks to the current ALARP levels will then be subject to new risk assessments. The regulator must determine the time within which firms must implement ALARP upgrades.

5. Apply the Framework to Facilities

When threshold values, ALARP considerations, and review timeframes are in place, the risk manager applies the TR framework to ensure compliance. Because of the scale associated with such an endeavor, it is likely that the application of a TR framework to a new facility might require several years.

6. Communicate with the Public

In parallel with implementing the TR framework, the agency should consider developing communication strategies to inform the public about its risk management strategies. Such efforts might include developing visual aids for explaining the calculated risks (e.g., the TR triangle), comparing projects with equivalent levels of risk, developing explanations of ALARP

[10] S. Katzen, "Memorandum for Regulatory Working Group," Executive Office of the President, Office of Management and Budget, January 12, 1995; and S.E. Dudley and S.L. Hayes, " Memorandum for the Heads of Executive Departments and Agencies M-07-24; Subject: Updated Principles for Risk Analysis," Executive Office of the President, Office of Management and Budget, September 19, 2007.

considerations, and sharing the results established through ALARP reductions. Simple, effective communication strategies are essential for public understanding of the actual level of protection provided.

Review of Public Agency Risk Management

Though there is no coordinated effort to adopt standardized risk management approaches across federal or international agencies, six of the eight agencies surveyed in this review have adopted a TR or modified TR framework, specifying threshold values for the unacceptable and/or broadly acceptable regions (Table 1; see Appendix A for detailed discussion).

Table 1. Conservation in a Time of Scarcity. Threshold Values and Management Criteria of Agency Risk Management Frameworks

Regulating Agency	*Threshold Values*	*Risk Management Criteria*
Bureau of Reclamation	Project failure: broadly acceptable = 10^{-4} failures per year per project Societal risk: unacceptable = 10^{-2} deaths per year per project; broadly acceptable = 10^{-3} deaths per year per project	*ALARP:* bounded cost, probabilistic cost-benefit *Non-ALARP:* bounded risk
Environmental Protection Agency	Unacceptable = 10^{-4} cancer incidents per capita per year Broadly acceptable = 10^{-6} cancer incidents per capita per year	*ALARP:* various utility-based *Semi-ALARP:* best available technology
Federal Aviation Administration	Aviation (historical values): unacceptable = 10^{-6} failures per flight per component; broadly acceptable = 10^{-9} failures per flight per component Rockets, individual risk: broadly acceptable = 10^{-6} deaths per flight per capita Rockets, societal risk: broadly acceptable = $3x10^{-5}$ deaths per flight per capita	*ALARP:* deterministic cost-benefit, probabilistic cost-benefit, cost-effectiveness
Food and Drug Administration	None	*Non-ALARP:* require compliance with specific approved processes
National Aeronautics and Space Administration	Set on an individual project basis	*ALARP:* deterministic benefit cost, probabilistic cost-benefit, bounded cost
Nuclear Regulatory Commission	Individual risk: broadly acceptable = 0.1% of general prompt death background risk Societal risk: broadly acceptable = 0.1% of general cancer death background risk	*Non-ALARP:* constrained risk
U.K. Health and Safety Executive	Unacceptable = 10^{-4} deaths per year per capita Broadly acceptable = 10^{-6} deaths per year per capita	*ALARP:* deterministic cost-benefit, probabilistic cost-benefit
Norwegian Petroleum Safety Authority	Set by each firm in coordination with regulator; typically: Major accidental risk: PLL, FAR, individual risk, F-N curves Accidental environmental risk: return periods depending on environmental damage Operational environmental risk: discharge permits, zero harmful risk	*Semi-ALARP:* quantitative risk acceptance criteria *ALARP:* Deterministic cost-benefit, Probabilistic cost-benefit

ALARP = as low as reasonably practicable.

Bureau of Reclamation. Reclamation manages facilities based on risk of project failure and risk to society. In regions with low population densities, Reclamation uses only the risk of project failure, to avoid placing an undue portion of the societal risk on a small group of people. Reclamation deviates from the traditional TR framework in that even unacceptable risks of project failure are subject to only ALARP (instead of mandatory) reductions, and acceptable risks may be considered for continued reductions if funding is available. Baseline risks at each Reclamation facility undergo a comprehensive review every six years, and facilities scoring highest are prioritized for risk reduction funding.[11]

Environmental Protection Agency. EPA uses a variety of risk acceptance considerations reflecting its diverse duties. Most ALARP considerations are utility or technology based, though rights-based considerations have also been employed (e.g., for airborne asbestos exposure). For carcinogenic substances, the boundaries between the unacceptable-tolerable and tolerable–broadly acceptable regions are set at 10^{-4} and 10^{-6} (cancer incidents per year per capita), respectively. Risks for noncancerous substances are evaluated in terms of their published daily reference dose limits, though acceptable and unacceptable risk regions are not clearly defined. EPA guidelines for human health and environmental risk assessments are considered best practices within the risk management field and are often referenced by other federal agencies.[12]

Federal Aviation Administration. FAA allows for both qualitative and quantitative risk assessments, both of which produce cost-benefit analyses ranking risk reduction alternatives. All quantitative data are transformed into a qualitative risk matrix ranking both probability and effect for decisionmaking. FAA manages aviation and rocket risks separately, though neither are held to the specific types of risk thresholds defined within the TR framework. Commercial aviation risks are assessed in relation to historical casualty rates, allowing regulators to compare new components with their predecessors; historically, risks range from 10^{-6} to 10^{-9} (failures per flight per component) for general aviation, though risks as high as 4×10^{-6} (failures per flight per component) have been shown for short-term flights.[13] Risk thresholds for commercial rocketry are more standardized. Reusable launch vehicles must maintain individual risk below a threshold

[11] U.S. Bureau of Reclamation, *Guidelines for Achieving Public Protection in Dam Safety Decisionmaking*, 2003.

[12] U.S. Environmental Protection Agency, *Risk Assessment Principles & Practices: An Examination of EPA Risk Assessment Principles and Practices*, Office of the Science Advisor, Washington, D.C.: U.S. EPA, 2004.

[13] M. Long and J. Narciso, *Probabilistic Design Methodology for Composite Aircraft Structures*, Federal Aviation Administration, 1999; A. Azevedo, *FAA Aviation Safety Tolerable Risk Principles*, Workshop on Tolerable Risk Evaluation, March 19, 2008.

of 10^{-6} (deaths per flight per capita) and societal risk below a threshold of $3x10^{-5}$ (deaths per flight per capita). Traditional rocketry launches must keep all casualties below $3x10^{-5}$ (deaths per mission per capita).[14] To become licensed, firms within both categories must demonstrate that the risk standards have been met.[15]

Food and Drug Administration. FDA currently uses ALARP considerations to manage all risks, regardless of level. Though it no longer uses strict TR thresholds, FDA was one of the first agencies to implement the TR framework and is responsible for popularizing the common 10^{-6} threshold. For the food industry, FDA manages risks mainly by requiring compliance with specific processes approved based on scientific findings, precautionary beliefs, industry concerns, and/or congressional legislation. Increasingly, bounded-risk ALARP considerations are also being applied. For the drug industry, FDA determines risks to be ALARP through cost-benefit analyses weighing the advantages and disadvantages of candidate drugs. Additional research may be requested before a candidate drug is rejected or approved.[16]

National Aeronautics and Space Administration. NASA relies heavily on risk matrices and employs both qualitative and quantitative risk assessments in an iterative adaptive management process.[17] TR thresholds are not numerically defined but are thought of as a series of iso-risk contours within the risk matrix. Risk falling within the unacceptable contour must be reduced, and risks falling within the broadly acceptable and tolerable contours are subject to ALARP risk reductions. Bounded cost constraints and deterministic and probabilistic cost-benefit analyses are often used to determine when risks reach the ALARP point.[18]

Nuclear Regulatory Commission. The current risk management structure of NRC is founded on risk objectives that closely resemble a rights-based, constrained-risk approach. NRC

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[14] J. Repcheck, "FAA's Implementation of the Commercial Space Launch Amendments Act of 2004—The Experimental Permit," Federal Aviation Administration, Office of Commercial Space Transportation, Washington, DC, 2008.

[15] U.S. Federal Aviation Administration, *Federal Aviation Administration System Safety Handbook*, May 12, 2008, http://www.faa.gov/library/manuals/aviation/risk_management/ss_handbook/, accessed July 12, 2009.

[16] U.S. Food and Drug Administration (FDA), *Guidance for Industry: Development and Use of Risk Minimization Action Plans*, 2005; U.S. FDA, *Risk Management Plan Activities in OND and ODS*, Center for Drug Evaluation and Research, 2005.

[17] H. Dezfuli, R. Youngblood, and J. Reinert, *Managing Risk within a Decision Analysis Framework*, 2nd IAASS Conference, Chicago, May 14–16, 2007.

[18] National Aeronautics and Space Administration, *Risk Management Procedural Requirements*, 2007.

specifies that nuclear risks be equivalent to or less than risks created by other forms of electricity generation and that nuclear energy pose "no significant additional risk to life and health."[19] Specific NRC risk objectives set thresholds that delineate acceptable increases in risk over background levels. NRC has established the acceptable composite increase in the risk of individual prompt death for those living within a mile of a civilian nuclear power plant as 0.1 percent of the sum of background risk (prompt deaths per year per capita), and the acceptable composite increase in societal risk of cancer death as 0.1 percent of background risk (cancer deaths per year per capita). Risk assessments within the current implementation plan are broken into three main areas—reactor safety, materials safety, and waste management—each requiring probabilistic risk assessments.[20]

Health and Safety Executive (U.K.). HSE, the developer of the TR framework, is mandated to regulate risk throughout the United Kingdom, both in the workplace and in society at large. HSE regulations use TR thresholds and deterministic or probabilistic cost-benefit analyses and rely on a holistic approach to risk. As previously mentioned, HSE has established a general unacceptable risk threshold of 10^{-4} (deaths per year per capita) and a broadly acceptable risk threshold of 10^{-6} (deaths per year per capita).[21] With tolerable risks, ALARP reductions are made based on considerations that include cost-benefit analyses, best practices, uncertainty, potential adverse consequences, technological developments to improve on the implemented system, and regulatory feasibility.[22] HSE ensures compliance with its regulations through inspections within its jurisdiction in England, Scotland, and Wales.

Petroleum Safety Authority (Norway). PSA is the agency that defines the regulatory risk framework for the Norwegian oil industry. The industry has strongly embraced the use emergency preparedness measures and risk assessments in the design and operation of offshore and onshore oil facilities.[23] Typical risk-reducing measures include physical features, like fire

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[19] U.S. Nuclear Regulatory Commission, *Safety Goals for the Operations of Nuclear Power Plants*, Federal Register, 51(1986): 30028.

[20] U.S. Nuclear Regulatory Commission, *Risk-Informed and Performance-Based Plan (RPP)*, November 29, 2007, U.S. NRC, http://www.nrc.gov/about-nrc/regulatory/risk-informed/history/2007-present.html, accessed July 12, 2009.

[21] U.K. HSE 2001.

[22] F. Bouder, D. Slavin, and R. Lofstedt, *The Tolerability of Risk: A New Framework for Risk Management*, Earthscan Publications, London, 2009.

[23] Norwegian Technological Standards Institution, *NORSOK Standard z-103: Risk and emergency preparedness analysis* (rev. 2), Norwegian Technology Centre, Oslo, 2001.

insulation, deluge systems, pressure release systems, and organizational procedures, like safety training and establishment of a safety culture. Threshold values for major accidental risk are determined by each company using individual risk criteria and societal risk acceptance criteria. For environmental risks, threshold values are specified according to a framework developed by the Norwegian Oil Industry Association. Environmental risk acceptance criteria are based on return periods and the principle that the duration of environmental damage is insignificant in relation to the expected time between such damaging occurrences. The ALARP principle is applied, and cost-benefit (risk-reduction) considerations are used to determine implementation of risk-reducing measures. Continuous, operational environmental risks are considered under a zero-harm principle and are regulated through discharge permits.

In summary, most of the agencies surveyed in this review have adopted a TR or modified TR framework specifying threshold values for the unacceptable and/or broadly acceptable risk regions. Threshold values for each agency are generally set to around 1 in 10,000 (deaths per capita per year) for the unacceptable region and 1 in 1,000,000 (deaths per capita per year) for the broadly acceptable region. The high similarity of threshold values between agencies is due to early threshold popularization by FDA and to a common threshold derivation from socially accepted risk and general background risk, as discussed by HSE.[24] Many of the surveyed agencies have divided project risk into two or more categories, specifying different thresholds for individual risk, societal risk, and/or risk of project failure.

Most of the surveyed public agencies use utility-based risk management criteria to determine when the ALARP condition has been met, usually by applying some sort of cost-benefit analysis. Some agencies avoid the ALARP approach altogether, most notably NRC, which uses a constrained-risk approach, and FDA, which requires compliance with specific approved processes. Reclamation, EPA, and PSA use combinations of ALARP, semi-ALARP, and non-ALARP considerations to tailor their risk management strategies to individual projects. Aspects of the tolerable risk framework are found throughout most agencies' risk management strategies.

[24] U.K. HSE 1992.

Risk Management for Offshore Oil and Gas

The planning and regulatory context for offshore (especially deepwater) oil and gas exploration and production involves both workplace safety hazards and the possibility of oil spills that may harm marine and coastal environments and human communities. The Minerals Management Service was formed in 1982 to assess and manage these risks, which are now the responsibility of its successor bureau, the Bureau of Ocean Energy Management, Regulation and Enforcement (which, upon completion of an announced reorganization, will become two bureaus—the Bureau of Ocean Energy Management and the Bureau of Safety and Environmental Enforcement). Risk management occurs in two main clusters of activity: (1) the planning and leasing process; and (2) the regulatory process for establishing safety and environmental regulations.

Planning and Leasing Process

Through its planning process, MMS (BOEMRE) identifies areas eligible for oil and gas leasing in five-year leasing plans and then undertakes planning for annual leasing. In both stages, the agency conducts full environmental impact statement analyses under authorities of the National Environmental Policy Act (NEPA). These analyses must include an evaluation of potential environmental, social, and economic effects. Because of the uncertain nature of whether, when, and where an oil spill will occur and how significant it will be, the agency necessarily must use risk models to evaluate the likelihood of a spill and the risks of environmental harm. A lease sale on the Outer Continental Shelf (OCS) can involve “anywhere from 100 to 500 nine-square-mile tracts which have been identified as possible production areas by interested oil companies. Also at issue are as many as 20 or 30 specific resources which have been identified … as vulnerable to oil spills on the basis of research and communication with local authorities.”[25]

In the 1970s, as offshore oil and gas activity increased, the U.S. Geological Survey (USGS) developed an Oil Spill Risk Assessment (OSRA) model to estimate probabilities of an oil spill and oil spill contact with important resources.[26] MMS notes,

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[25] R.A. Smith, J.R. Slack, T. Wyant, and K. Lanfear, “The Oil Spill Risk Analysis Model of the U.S. Geological Survey,” Geological Survey Professional Paper 1227, U.S. Government Printing Office, Washington, DC, 1982, 1.
[26] Z.-G. Ji et al., “Oil Spill Risk Analysis: Contingency Planning Statistics for Gulf of Mexico OCS Activities,” U.S. Department of the Interior, Minerals Management Service, Washington, DC, April 2004.

> [T]he occurrence of oil spills is fundamentally a matter of probability. There is no certainty regarding the amount of oil that would be produced, or the size or likelihood of a spill that would occur during the estimated life of a given lease. Nor can the winds and ocean currents that transport oil spills be known for certain. A probabilistic event such as an oil-spill occurrence or oil-spill contact to an environmentally sensitive area cannot be predicted, only an estimate of its likelihood (its probability) can be quantified.[27]

MMS (BOEMRE) has adopted the USGS model, which has three basic components: (1) estimates of the probability that a spill will occur; (2) simulated trajectories of spills to critical environmental resources; and (3) combined results of the first two elements that estimate the risks from potential oil development.[28] The model uses historical records of oil spills, ocean currents, and wind patterns. Over the years, the model has been refined, with periodic efforts to validate it by comparing its projections against actual spills. In essence, the model simulates thousands of spills at different locations of possible drilling and along pipeline and tanker routes. The model then plots the spill trajectory, calculating those trajectories over time and for different spill volumes.

In addition to its use in NEPA environmental impact statements, the OSRA model is used in environmental assessments, oil spill response plans, environmental reports completed by companies, biological opinions for Endangered Species Act consultations, and other federal agency reports.[29] Any errors or uncertainties in the model thus propagate through almost all oil spill analyses.

To estimate probability, MMS (BOEMRE) maintains data on oil spills. Estimates are normalized by volume of oil handled and modeled as a Poisson process using historical data.[30] A Poisson process assumes that the number of spills in any time interval is not dependent on the number in a preceding interval. This assumption may, however, be incorrect if technological or

[27] Zhen-Gang Ji, W.R. Johnson, C.F. Marshall, E.M. Lear (eds.), Oil Spill Risk Analysis: Gulf of Mexico Outer Continental Shelf (OCS) Lease Sales, Central Planning Area and Western Planning Area, 2007-2012, and Gulfwide OCS Program, 2007-2046. Washington, D.C.: U.S. Department of the Interior, Minerals Management Service, 2007.

[28] Ji, et al., 2004.

[29] Ibid.

[30] K.J. Lanfear and D.E. Amstutz, “A Reexamination of Occurrence Rates for Accidental Oil Spills on the U.S. Outer Continental Shelf,” Oil Spill Conference, American Petroleum Institute, Washington, DC, 1983, 355–59; see also C.M. Anderson and R.P. LaBelle, “Update of Comparative Occurrence Rates for Offshore Oil Spills,” *Spill and Science Technology Bulletin* 6 (5/6), 2000, 303–21.

regulatory changes affect spill probabilities. Moreover, each time interval must be stationary. A review of relevant data showed a decrease in spills over a certain time period and intervals of relatively stationary conditions were identified.[31] Smith et al. note that "while some of the uncertainty [in estimating oil spill risks] reflects incomplete or imperfect data, considerable uncertainty is simply inherent in the problem."[32] The paucity of data on high-consequence events makes estimations problematic. As one comparison, Norwegian oil spill projections "are determined based on statistics from spills as well as from modeled/envisioned errors and accidents thus reflecting the actual procedures and equipment used."[33]

Modeling of oil spill occurrences is challenging. Though many small (less than 100 gallons) spills occur, high-volume, high-consequence spills are extremely infrequent. Nonetheless, though a platform spill of the magnitude of the Macondo blowout had not previously occurred in the Gulf, the probability of such a spill was not zero. Moreover, oil spill data are "fat tailed": spills greater than 1,000 barrels account for just 0.05 percent of spills but for 79 percent of the total volume spilled.[34] In this sort of distribution, average spill probabilities have little use, yet these have been routinely used in risk assessments.

The Oil Spill Risk Model has been subject to various technical and analytical critiques and has undergone numerous upgrades and periodic efforts to validate projections of spill trajectories and potential effects.[35] Such efforts have been both regular and transparent. In 2003, MMS used satellite-tracked drifters to assess the efficacy of the model. The most recent model enhancements occurred in 2004.

However, for purposes of understanding risk management in the offshore oil and gas context, our focus here is on three broader institutional and decisionmaking issues: (1) what formal, regular, and transparent processes exist to periodically review, validate, and improve risk models used by the agency and industry; (2) how information generated by models is used to inform decisionmaking, including decisions about risk mitigation; and (3) what standards, if any, are used as the benchmark or tolerable risk threshold for managing and mitigating risk. That is, is

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[31] Anderson and LaBelle 2000.

[32] See Smith et al. 1982, 2.

[33] J.E. Vinnem, *Offshore Risk Assessment Principles, Modelling and Applications of QRA Studies,* 2nd ed., SpringerLink, New York, 2007.

[34] Anderson and LaBelle 2000.

[35] Smith, et al., 1982; Ji 2004; Wyant and Slack, 1978; Lanfear et al., 1979

a model that uses historical data to generate probabilities appropriate for managing offshore and coastal resources?

Use of Oil Spill Models in Decisionmaking

Resource managers face two related questions: how to incorporate information about risk probabilities into planning and other resource impact analyses, and—the central, underlying policy decision—how to determine "how safe is safe enough."

Impact analysis. Concern has persisted about how the model is used to inform decisionmaking. For example, in its comments on the 2010–2015 OCS draft five-year plan, the National Oceanic and Atmospheric Administration recommended that "future project-specific NEPA documents should fully evaluate the potential impacts of worst-case scenarios, such as a spill event during the summer salmon fisheries or winter crab fisheries."[36] The comment highlights the challenge of assessing both the likelihood that an event will occur and, if it does, the likely extent and duration of the effects on human health, human communities, and the environment. Those possible consequences should figure into assessing risks, developing mitigation measures, and investing in emergency preparedness capacity.

Such considerations did not appear to shape mitigation and related resource-management decisions about offshore oil and gas activities. For example, because the oil spill model projected the probability of a high-consequence spill as extremely low, the Fish and Wildlife Service determined that risk of harm to species listed under the Endangered Species Act associated with several deepwater oil and gas projects was so low that formal consultation under the act was not required.

In effect, the initial estimate of extremely low probability of a spill's occurring has cascading effects on decisionmaking of resource managers. For the Macondo well, the risk model generated estimates of 4,600 barrels as the most likely size of a large spill and no more than 26,000 barrels of oil spilled over the entire 40-year life of production activity on six leases, including the Macondo well site.[37] These estimates resulted in an environmental assessment determination of "no significant impact" from the project.

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[36] National Oceanic and Atmospheric Administration, "Comments on the U.S. Department of the Interior/Minerals Management Service Draft Proposed Outer Continental Shelf Oil and Gas Leasing Program for 2010-2015," U.S. Department of Commerce, Washington, DC, 2009.

[37] NOAA 2009.

One challenge of using a risk-based approach to analyzing offshore risks is precisely this cascading effect. If a risk is of very low probability (but potentially catastrophic or very high consequences), the probability of adverse impacts may be deemed so low that they are not considered in planning and resource management processes. An alternative approach is that of hazard-based analysis of risk. Such an approach evaluates events regardless of their low (or high) probability. Using this approach, a potential impact would not lose significance even if the risk is reduced through new technologies and practices. In its 2004 oil-spill risk analysis, MMS used a hazard-based assessment to attempt to better understand the effects of a spill. It is not clear, however, how this information was used in subsequent planning or Endangered Species Act consultation documents.

How safe is safe enough? How risk modeling and associated risk estimates are used in the offshore oil and gas context raises another important issue, one linked to the broad policy question of whether and how transparent policy decisions are regarding “tolerable risk” thresholds. Even if the Oil Spill Risk model is useful in estimating probabilities of a spill and projecting the likelihood that it will cause harm, a larger decisionmaking issue looms: how safe is safe enough? Risk models themselves do not establish what constitutes “acceptable” or “tolerable” risk. As noted earlier, acceptable risk can be defined in various ways, such as a risk that falls below a certain probability, a risk for which associated benefits exceed the costs of reducing the risk, or a risk that falls below some already tolerated risk level.[38] In determining safety policy, regulators must decide whether to set a quantitative risk standard and if so, how to use quantitative risk analysis.

As described above, many other agencies have established numerical thresholds for unacceptable risk. Quantifying risks and evaluating them against a numerical threshold are not straightforward tasks; they involve assumptions and uncertainties. However, such calculations, in many circumstances, can help regulators determine whether additional safety enhancements are necessary to achieve a specified risk threshold. If the data and assumptions used in these calculations are transparent, others can independently review and critique such analyses, facilitating analytic improvements and public acceptance of agency risk management choices. In general, however, MMS has not set numeric standards for unacceptable, tolerable, and acceptable risk.

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[38] P.R. Hunter and L. Fewtrell, “Acceptable Risk,” in L. Fewtrell and J. Bartram (eds.), *Water Quality: Guidelines, Standards, and Health*, IWA Publishing, London, 2001.

Standard Setting and Regulations

The standard-setting aspect of risk management applies both to the offshore planning process and to the regulatory processes for establishing safety and environmental regulations. According to former MMS officials, the agency looks at both quantitative and qualitative risk assessment but generally has favored qualitative approaches. Even where quantitative approaches have been used, the agency does not have a "bright line" safety threshold to use as a goal.

For many years, MMS required at least qualitative risk assessments for deepwater production facilities, in accordance with Recommended Practice 14j of the American Petroleum Institute (API). In addition, API Recommended Practice 14c sets forth procedures for "failure analysis" for all production facilities. Such procedures, used for production facilities, have not been used for analyzing deepwater drilling. Instead, deepwater drilling reviews have traditionally been conducted by a single engineer for the purpose of assessing compliance with prescriptive rules rather than to provide any risk assessment.[39]

The rationale for use of qualitative assessments relates, in part, to data quality. With poor data, quantitative assessments can be highly variable or even manipulated, depending on the assumptions and other criteria used. A former manager of MMS recalls instances of manipulation after safety cases came into use in Great Britain and elsewhere. For example, one risk assessment for a subsea gas project off Australia concluded, based on "failure data" and "consequence assessments," that use of subsurface safety valves was not necessary. According to a reviewer, the operator's real concern was the cost of installing and maintaining these devices. However, it was difficult for the regulator to refute the data.

A 2001 quantitative risk assessment comparing deepwater production systems devoted two of its five recommendations to data. The report's second recommendation states:

> [T]he quality of existing data sets for the Gulf of Mexico should be improved so that they are of greater value in future risk analyses. First, the type and quality of data that are currently collected should be evaluated, and any changes recommended from this evaluation should be implemented in a timely manner. Second, single agencies should be responsible for tracking and compiling similar types of data. Third, all data records should be reviewed annually by the industry and regulators to improve the clarity, quality and usefulness of the

[39] Bud Danenberger (former MMS safety official), personal communication, September 11, 2010.

> information in these records. Finally, the data should be published annually in a clear and an easily accessible format.[40]

The report's third recommendation states:

> Additional information about the populations of offshore facilities and operations in the Gulf of Mexico should be collected on an annual basis. Specifically, the following information from federal and state waters in the Gulf of Mexico would be valuable: the length of active pipelines operating per year, the number of tanker on-loading and off-loading events in ports and lightering zones per year, and the number of man-hours in production-related activities, supply vessel operations and tanker operations per year.[41]

Both industry and MMS have, on occasion, sought to quantify risks and use quantified comparative risk assessments to evaluate equipment and procedures. For example, one 2006 study prepared for MMS assesses surface versus subsurface blowout preventers on mobile offshore drilling units and provides both quantitative and qualitative comparisons.[42] A 2001 study prepared for MMS provides a quantitative risk analysis to assess and compare oil spill and fatality risks for four representative deepwater production systems in the Gulf of Mexico.[43]

Risk analysis for safety-critical components is standard practice for Norwegian production facilities. In PSA's regulatory framework, the functionality of components and systems is assessed over the lifetime of the facility, not just at the time of construction. Equipment and systems identified as highly important are more closely regulated, with specific maintenance procedures prescribed in addition to the physical safety requirements. For example, a down-hole safety valve with a high safety-integrity level must be designed to have both a lower probability of failure and shorter maintenance intervals than less critical valves near the surface. This practice mimics risk-based criteria for technical equipment.[44]

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[40] R. Gilbert, E.G. Ward, and A. Wolford, "Comparative Risk Analysis for Deepwater Production Systems: Final Project Report for the Minerals Management Service," prepared by Offshore Technology Research Center, January 2001, v.

[41] Ibid.

[42] J. Melendez, J.J. Schubert, and M. Amani, "Risk Assessment of Surface vs. Subsurface BOPs on Mobile Offshore Drilling Unites: Final Project Report," Project No. 540, prepared for Minerals Management Service, August 2006.

[43] Gilbert et al. 2001.

[44] Norwegian Oil Industry Association, *Application of IEC 61508 and IEC 61511 in the Norwegian Petroleum Industry*, 2004, http://www.itk.ntnu.no/sil/OLF-070-Rev2.pdf, accessed November 4, 2010.

Current Risk Management Framework

The questions of "how safe is safe enough" and whether and how to quantify, evaluate, or assess risk are recurrent themes among federal regulatory agencies. The Office of Management and Budget (OMB), drawing upon discussions of a multiagency Regulatory Working Group, set forth "aspirational rather than prescriptive" principles for risk analysis in January 1995.[45] Agencies were not mandated to follow the principles but instead were invited to apply them flexibly and use practical judgment. The cover memorandum accompanying the principles noted, "The science of risk assessment is rapidly changing and its use is a function of a number of factors—including legal mandates and available resources—that vary from one regulatory program to another. We therefore do not offer these principles as conclusive, complete or irrevocable."[46]

The 1995 general principles included the importance of distinguishing between risk identification and risk management policies. Other principles pertained to transparency of assumptions and analysis, peer review, consistency, distribution of risks, benefits, and costs, and policy criteria. In September 2007, the risk analysis principles were updated by OMB in a new memorandum.[47] The new memorandum retained the basic concepts of the 1995 memo but cast them as requirements to follow in risk management, consistent with agency authorities and statutes, rather than as aspirational principles.

The Department of the Interior participated in the 1995 Regulatory Working Group and commented on the 2007 updating of the risk principles. Neither the 1995 principles nor the 2007 update appears to have prompted significant internal MMS review of its risk analysis and risk management.[48] However, because MMS's risk model was developed by USGS, a scientific agency, the model, its assumptions, and its use of data largely met the requirements of many of those principles.

The more central issue in risk management by MMS (BOEMRE) centers less on the model per se and more on how risk information is used and whether a clear, quantitative safety goal would provide greater transparency in decisionmaking in both the planning and the

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[45] Katzen 1995.

[46] Ibid.

[47] Dudley and Hayes 2007.

[48] W. Cruickshank, Deputy Director, BOEMRE, email communication, September 11, 2010.

standards-setting processes. The Environmental Protection Agency, Federal Aviation Administration, Food and Drug Administration, and Nuclear Regulatory Commission all have established numerical risk thresholds or ranges of tolerable risk, as outlined above. Although numerical thresholds are not essential to risk management, they provide a transparent goal against which to benchmark practices, equipment, standards, and facilities. Risk analyses can be compromised by inadequate data and faulty assumptions. But quantitative goals nonetheless enable independent reviewers to evaluate whether a particular standard is likely to meet the specified safety threshold. Such goals also provide a clear benchmark against which industry can evaluate its risk reduction practices and techniques.

Application to Offshore Energy Development

Even if a regulating agency establishes or requires use of a quantitative tolerable risk threshold (or other type of risk threshold), implementation can vary. Risk management involves three kinds of activity[49]:

- administration, which comprises training, emergency planning, directives and supervision, inspections, communications, security, first aid, legal and regulatory requirements, and management of change;
- engineering, which includes equipment design, barriers, identification of critical equipment, warning signs and monitoring, and emergency equipment;
- operations, which includes procedures, job safety analysis, work permitting, emergency drills, pre-use checklists, maintenance, and incident management.

In general, two regulatory approaches to risk management are available to agencies. In a risk-based accountability approach, companies or the regulating agency (or both) set risk-performance standards (or a tolerable risk threshold) and take actions to reduce risks to meet that standard. In a second, more prescriptive approach, a regulatory agency prescribes technologies and procedures deemed to represent best practices. Users of either method face similar policy and analytic challenges in deciding how safe is safe enough and in generating information and evaluations to assess safety. However, there are some fundamental differences between the two

[49] Mohr—Engineering Division, *A Probabilistic Approach to Risk Assessment of Managed Pressure Drilling*, Technology Assessment and Research Study 582, Final Report, October 31, 2008.

approaches, particularly with respect to matters of accountability. Both approaches are used, alone or in combination, in offshore risk management practices.

Risk-based performance regulations. Norway uses a risk-based, industry-accountability approach to offshore energy activities. Sometimes described (somewhat misleadingly) as self-regulation, the approach places responsibility on the operator (and contractor) to identify risks and hazards; develop controls, mitigation strategies, and systems to reduce risks to defined acceptance levels; and use identified risks as the basis for prioritizing decisionmaking. The regulated company establishes the quantitative risk threshold against which it evaluates its own performance.[50] Though the Norwegian offshore safety management places significant responsibilities and accountability on the offshore operator, the regulatory agency maintains a strong oversight function.

A 2010 Norwegian report describes risk-based performance systems as an approach in which regulations are related to specific risks faced by a company or operator: "safety and contingency measures must be commensurate with the risk in each individual activity. The higher the risk, the more effort is required and the more wide-ranging measures must be implemented."[51] As described in its report delineating differences between U.S. and Norwegian approaches to offshore regulation, performance-based risk reduction regulations involve specifying "the performance or function which is to be attained or maintained by the industry. The regulatory role here involves defining the safety standards which companies must meet and checking that they have the management systems which permit such compliance."[52]

The United Kingdom uses a slightly different risk-based performance approach. It requires that each operator develop a safety case that identifies risks on an integrated, system-wide basis, including both technical and procedural (human behavior) issues, and describes how the operator will address risks and achieve specified safety levels. For both Norway and the United Kingdom, risk assessment is a legislative requirement for all new and existing installations.

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[50] Det Norske Veritas, "Summary of differences between offshore drilling regulations in Norway and U.S. Gulf of Mexico," Report for Oljeindustriends Landsforening/Norsk Oljenvernforening For Operatorselskap, DNV Re. No. 12P3WF5-9, August 27, 2010, 2.

[51] Ibid., 18.

[52] Ibid.

Some companies that operate in U.S. offshore waters use a safety case approach, though that has not been a U.S. regulatory requirement. To enhance the quality of these cases, some firms use outside reviewers to examine their risk registries or hazards identification and associated control mechanisms. Others establish equipment design criteria beyond those needed to function in all expected conditions. Still other firms verify equipment performance in their own labs rather than relying on the manufacturer's testing and certification.

Prescriptive regulations. In a more traditional risk management approach, a regulatory agency identifies equipment, technologies, and best practices deemed to contribute to safety and risk mitigation. The agency then prescribes use of these elements through regulations and undertakes inspections to affirm compliance. Noncompliance results in notices, fines, or other measures.

The prescriptive approach as applied to offshore oil and gas activities presents at least three challenges: (1) prescribed regulations may lag behind development of new and safer equipment and procedures; (2) prescriptions may not cover all the behavioral and other actions that result in safe performance; and (3) regulators shoulder the primary responsibility for inspecting facilities and affirming that they are safe.

The Norwegian and U.K. approaches require that companies specifically identify risks at offshore sites on an integrated basis and demonstrate how they are achieving specified safety standards for their operations at those sites. Both countries have some numerical, risk-based thresholds for use in these risk management processes.

In 1999, MMS cosponsored project to develop guidance on risk assessment for offshore installations.[53] The report notes,

> … the need for guidance on risk assessment was identified as an industry requirement as a result of regulations, initially promulgated in the United Kingdom and Norway, requiring quantitative risk assessments of new and existing installations as part of their safety case. At that time, no standard reference works existed, most expertise was held by individual operators and consultants and little reached the public domain.[54]

53 J.A. Spouge, "A Guide to Quantitative Risk Assessment for Offshore Installations," Marine Technology Directorate, June 1999.

54 Ibid., introduction.

The report states that "the pool of expertise in risk assessment is very small" in the offshore oil and gas arena, and "risk assessment remains to a large extent a do-it-yourself activity."[55] Though MMS cosponsored development of the risk assessment guide, in interviews, several agency regulators indicated they were unaware that it existed.

Developing guidance on risk assessment depends on high-quality data. One analyst who undertook an assessment of risk for certain offshore technologies noted,

> [T]he quality of existing data sets for the Gulf of Mexico should be improved so that they are of greater value in future risk analyses. First, the type and quality of data that are currently collected should be evaluated, and any changes recommended from this evaluation should be implemented in a timely manner. Second, single agencies should be responsible for tracking and compiling similar types of data. Third, all data records should be reviewed annually by the industry and regulators to improve the clarity, quality and usefulness of the information in these records. Finally, the data should be published annually in a clear and an easily accessible format.[56]

Examples of best practices exist. The question for MMS (BOEMRE) is how to stimulate such practices across all industry participants. Although the agency uses some risk-based performance regulations, it has not emulated Norway or the United Kingdom in requiring companies to identify risks at each offshore site and show how their technologies and practices would mitigate those risks to specific safety performance levels. Though risk-based performance regulations aim to strengthen safety cultures and accountability within firms, their effective implementation presents challenges. Specifically, such systems (1) must be comprehensive in their identification and mitigation of significant hazards, including human behavior considerations; (2) must provide clear documentation; (3) must be able to address changing or unexpected circumstances; and (4) must undergo periodic independent audits to evaluate their substance, implementation, and effectiveness.

Summary and Recommendations

Offshore oil and gas exploration and production involve both workplace safety hazards and the possibility that oil spills will occur, including large spills that may harm marine and

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[55] Ibid., 1.

[56] Gilbert et al., 2001.

coastal environments and human communities. The April 20, 2010, Macondo well blowout caused 11 fatalities and released an estimated 5 million barrels of oil. In the wake of the disaster, the reexamination of policies and practices associated with offshore energy production has included renewed attention to risk assessment and risk management and raised the following questions:

- How are risks calculated or assessed?
- What framework, if any, is used to specify how safe is safe enough (i.e., how is *tolerable risk* defined)? Are such determinations expressed in quantitative or qualitative terms?
- How is risk assessment used in the planning and leasing process to manage risk?
- How is risk assessment used in the regulatory process for establishing safety and environmental regulations to manage risk?
- What are the roles and responsibilities of the regulatory agency and firms in assessing and managing risk? Who is accountable for safety and risk management and how?

In this paper, we have given only brief attention to the first question, which pertains fundamentally to risk modeling and other technical analyses. Our focus has been on the other four questions, with particular emphasis on the second, regarding risk frameworks. We evaluated the risk frameworks of other regulatory agencies and compared them with the approach of the Minerals Management Service (now BOEMRE). In addition, we situated that analysis within a broader examination of the agency's risk management practices for offshore planning and safety regulations.

Several options for enhancing risk management practices within the agency offer opportunities to strengthen transparency, accountability, and safety performance.

Risk Assessment and Management

- *Adopt quantitative thresholds that specify unacceptable risk levels and tolerable risk levels, to enhance decisionmaking clarity and transparency.* Most of the agencies surveyed in our review have adopted a TR or modified TR framework, specifying threshold values for the unacceptable and/or broadly acceptable regions. Quantifying risks and evaluating them against a numerical threshold are not straightforward and involve assumptions and uncertainties. However, such calculations, in many circumstances, can help agencies determine whether additional safety enhancements are necessary to achieve a specified risk threshold. If data and assumptions used in these calculations are transparent, third parties can independently review and critique the analyses, facilitating analytic improvements and public acceptance of agency risk management choices.

- *Develop (1) risk assessment guidance regarding information transparency, data validation, and analytic assumptions; and (2) risk management guidance on the uses of risk assessment.* The agency should include the five elements of risk management (metrics, threshold values, as-low-as-reasonably-practicable considerations, review timeframes, and applications) set forth in ISO 31000, as well as guidance on risk communication. Disagreements often surface regarding the analytic tools and assumptions for assessing whether some action or exposure falls within the range of tolerable risk. Guidance regarding these tools and assumptions and the agency's use of risk assessments in risk management decisions will not resolve disagreements but can narrow inconsistencies in decisions and provide a better basis for third parties to evaluate the adequacy of decisions.
- *Identify and more systematically collect information for understanding and evaluating risks and safety performance.*

Regulatory Processes for Risk Management

- *Strengthen the performance-based risk management focus by adopting approaches to offshore oil and gas risk management such as those used in Norway and the United Kingdom.* These approaches make firms accountable for establishing or applying agency-set tolerable risk (safety) standards, identifying all hazards, and showing how equipment and practices will meet the established performance levels. A performance-based risk approach, however, requires shared responsibility between agencies and industry to develop and maintain these standards. One way to coordinate this shared responsibility is through an independent industry organization that develops operational and risk management standards under agency supervision, removing the burden of generating best practices from each individual firm. If some responsibility for developing standards is shifted to industry, a legal framework (and suitable resources) must be clearly defined to provide proper instruments for regulatory supervision.
- *Use a structured decision framework to assess relevant factors as a part of the process.* Tools of multicriteria decision analysis or other formal decision-analytic tools can be used.

Appendix A.

Risk Management Practices–Cross-agency Comparisons and Tolerable Risk

Igor Linkov, Matthew Bates, Drew Loney, Magnus Sparrevik, and Todd Bridges
U.S. Army Engineer Research and Development Center

Note: This appendix is a chapter in Linkov, I. and Bridges, T. (eds). Climate: Global Change and Local Adaptation *(Springer, Netherlands; 2011, in preparation), and appears unchanged here.*

ABSTRACT: The inevitable public unease in the wake of large infrastructure failure prompts questions regarding how to properly define and manage the risks of various engineered activities to socially acceptable levels. A changing climate may add additional vulnerability to infrastructure and thus should be considered in risk management strategies. Current implementations of risk management processes differ across agencies, but often rely on a concept of Tolerable Risk. The Tolerable Risk is a numerical value for the boundary in a continuum of management alternatives below which risk is tolerated to secure societal benefits, though engineering interventions may be still be necessary and proper to achieve higher degrees of protection. This chapter gives an overview of risk management and introduces the Tolerable Risk framework, reviews and summarizes risk management frameworks for several federal and foreign agencies, and recommends key features and necessary steps for a Tolerable Risk framework implementation. The ideas in this chapter draw extensively from a March 2008 interagency workshop on Tolerable Risk sponsored by USACE, Reclamation, and FERC and attended by several additional federal and foreign agencies (for more details see Workshop, 2008).

Introduction to Risk-Based Decision Making and Tolerable Risk

The Society for Risk Analysis defines risk as the "potential for realization of unwanted, adverse consequences to human life, health, property, or the environment" (SRA, 2010). Calculation of risk, especially in environmental settings, is conducted through *Risk Assessments* that place numerical values on the risk associated with a particular option or event. This requires evaluating both the probability that a particular event (for example, one foot of sea level rise) will occur and the likely impacts (for example, in terms of dollars or families displaced) should the event occur. In other words, risk is measured both in terms of the likelihood and severity of impacts of a hazardous event. The National Research Council defines risk assessment as a process that involves identifying all relevant hazards, linking each hazard to a potential adverse impact, assessing society's exposure to the hazards, and estimating the hazards' likely cumulative impact on society (National Research Council, 1983). Though risk assessments identify and quantify risk, they give no insights into whether the identified risks are socially acceptable.

Risk Management applies society's risk tolerance and preferences to risks by identifying, selecting and applying specific risk-reducing strategies. All risks are not created equal, and proper risk management recognizes that different levels of risk warrant different reactions. Some risks are high enough that action must always be taken to reduce their magnitude. Other risks are low enough that they can generally be considered negligible. Yet other risks are high enough to warrant reductions but low enough that reductions should only be undertaken when considered reasonable in the context of project costs, other risks, and social preferences. Nuanced risk-management often differentiates between individual risk (which relates to one person's increased risk from a project or event), societal risk (which aggregates individual risks to set a maximum for the total number of people who may be affected), and project-failure risk (which relates to the expected number of failures per project per year), each of which may require a different risk-management strategy.

The key components of risk management are: 1) Establishing the context and determining risk thresholds, 2) Risk identification and risk assessment, 3) Risk treatment, developing risk-reduction and mitigation strategies, 4) Monitoring and review. Communication and consultation with internal and external stakeholders should take place at each stage of the risk management process. By implementing these risk management strategies, public agencies can reduce or mitigate risks to socially acceptable levels. A general approach to risk-management implementation has been standardized under ISO standard 31000 (ISO, 2009).

Risk-management criteria

Morgan and Henrion (1990) describe four primary types of risk-management criteria and techniques: utility-based, rights-based, technology-based, and hybrid, each of which contain several variations founded on similar principles (Table 1). Utility-based techniques trade risk reduction with another quantity, typically money, to determine the optimal balance between risk protection and incurred costs. Rights-based criteria acknowledge that, for certain sources of risk, people are entitled to receive an absolute level of protection. Technology-based criteria recognize that risk reduction is often limited by the available technology and that risks should be mitigated using the best technologies available. Hybrid criteria combine various aspects of utility-based, rights-based, and technology-based criteria to evaluate risks with a more nuanced approach.

Of the utility-based techniques, *cost-benefit* analysis is the most widely used. Cost-benefit analyses seek to monetize the benefits of risk reduction and identify the point where risk protection most outbalances project costs (all relevant project inputs and effects must be monetized). Cost-benefit analyses may be deterministic, using known data, or probabilistic, incorporating uncertainty. When benefits are not easily quantifiable, a *cost-effectiveness* analysis can identify the least costly method of achieving a desired performance goal. If funding is a limiting factor, a *bounded-cost* approach seeks to achieve the greatest risk reduction with a set capital expenditure. *Multi-attribute utility* methods can identify the best tradeoffs when several non-monetized factors must be compared, even when units are incongruous. Though usually little more than a political ploy, another utility-based approach is simply to minimize the likelihood of the worst-case scenario or maximize the likelihood of the best-case scenario.

Rights-based risk management criteria focus on constraining risk to specific values. The *zero-*

risk criterion takes this to the greatest extent possible, mandating that all risks must be eliminated and that none may be introduced. *Bounded-risk* (or *constrained-risk*) criteria allow some risk to exist but do not allow risk levels to grow above a predetermined value. *Approval/compensation*-based techniques only allow risks to exist if those who bear them have given their consent or have been appropriately compensated for bearing the risk. The establishment of *approved processes* treats risks indirectly by mandating compliance with a specified set of agency-approved procedures designed to avoid risky behavior by those introducing the risk.

Technology-based criteria seek to implement the best available technology and accept whatever risk results as the lowest risk possible. This requires an additional process be set up to identify the best available technology, a process which itself may be utility, rights, or technologically based. Judgments regarding technology are often made using cost-benefit analyses or by finding the technologies that achieve the greatest risk reduction (rights based). Hybrid methods merge utility-, rights-, and technology-based criteria to produce risk reductions that are fitting for special circumstances and are unique to the implementation details of each particular project.

Table 1. Types of risk-management criteria/techniques (adapted from Morgan and Henrion, 1990)

Utility-based (ALARP) criteria	
Deterministic cost-benefit	Estimate the costs and benefits of the alternatives in economic terms and choose the alternative with the highest net benefit.
Probabilistic cost-benefit	Incorporate uncertainties to estimate the costs and benefits of the alternatives in economic terms and choose the alternative with the highest expected net benefit.
Cost effectiveness	Select a desired performance level, perhaps on noneconomic grounds, and choose the option that achieves the desired level at the lowest cost.
Bounded/constrained cost	Do the best you can within the constraints of the maximum budget society is prepared to devote to the activity.
Maximize multi-attribute utility	Rather than use monetary value as the evaluation measure, multi-attribute utility involves specifying a utility function that evaluates outcomes in terms of all important attributes (regardless of units, including uncertainties and risks). The alternative with maximum utility is selected.
Minimize chance of worst possible outcome/Maximize chance of best possible outcome	Political and behavioral considerations frequently employ the use of such criteria, which often go against society’s long-term best interest.
Rights-based criteria	
Zero risk	Independent of the benefits, costs, and magnitude of the risks, eliminate all risks, or disallow risk introduction.
Bounded/constrained risk	Constrain the level of risk so that it does not exceed a specific level or, more generally, so that it meets a set of specified criteria. This is done independent of the costs and benefits of any alternatives.
Approval/compensation	Allow risks to be imposed only on people who have voluntarily given consent or who have been properly compensated.

Approved processes	Require compliance with specific agency-approved processes that have been shown indirectly reduce risks by avoiding risky behavior.
Technology-based criteria	
Best available technology	Use the best available technology to reduce risk to the lowest level possible. As the meaning of "best available" is often economically determined, this may become a modified a utility-based technique.
Hybrid criteria	
Hybrid	Some combination of utility-, rights-, and technology-based criteria used jointly for decision-making.

The Tolerable Risk Framework

The Tolerable Risk framework provides a risk-management structure for public agencies worldwide. Tolerable Risk (TR) was first conceived by the British Health and Safety Executive (HSE) during its work on the safety of nuclear power plants (HSE, 1992). The TR framework breaks risks into acceptable, unacceptable, and tolerable categories, separated by numerical boundaries (Figure 2). By evaluating risks in relation to predetermined TR thresholds, the decision of when to implement the chosen risk-management strategies becomes transparent and unambiguous.

Under the TR framework, an *Acceptable Risk* is a risk for which the probability of occurrence is so small or for which the consequences are so slight that individuals or groups accept it willingly. Actions to further reduce such risks are usually not required. In contrast, an *Unacceptable Risk* is a risk so high that society is unwilling to bear it to receive the promised benefit. When identified, measures must be taken to reduce an unacceptable risk's likelihood or consequence of harm. Occupying the middle ground between the acceptable and the unacceptable are *Tolerable Risks*, non-negligible risks that have not been reduced to an acceptable level but which society is willing to bear in order to secure the benefits associated with the risky activity. Tolerable risks must be reduced to levels "as low as is reasonably practicable (ALARP)," meaning until costs or other feasibility concerns prohibit further reductions. Given the tradeoffs necessary in achieving the ALARP condition, TR is most often used in conjunction with the utility-based ALARP considerations from Morgan and Henrion's list of risk-management criteria (Table 1). The goal of risk management is to push risks from the unacceptable, through the tolerable, and into the broadly acceptable region.

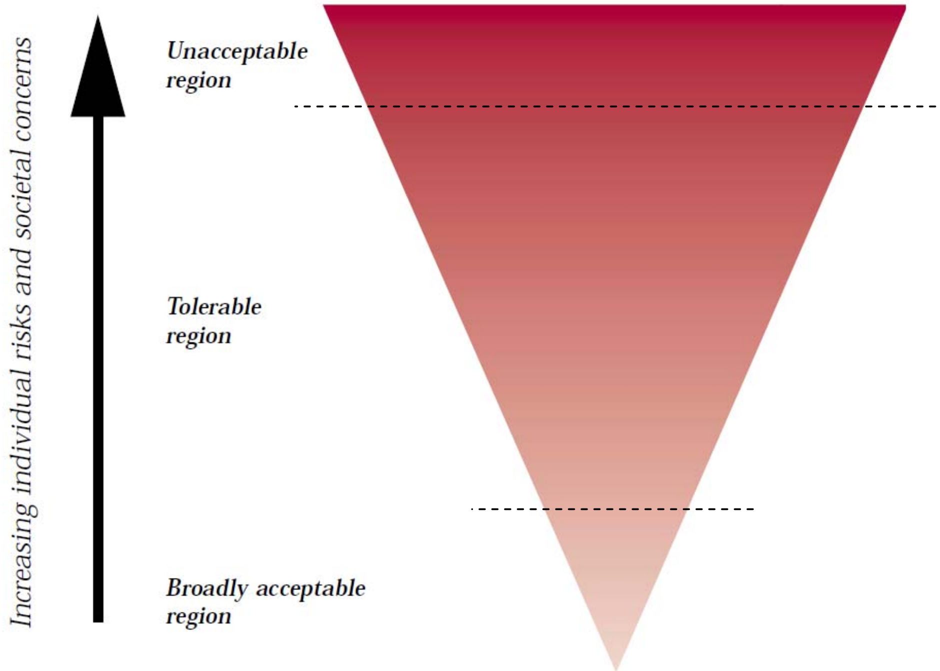

Figure 2. Conceptual categories of risk within the Tolerable Risk framework (adapted from HSE, 2001)

Development of numerical boundaries separating risk regions is an important step in applying the TR framework (HSE, 2001). Rather than relying on subjective judgment to differentiate risk regions, the HSE outlines risk thresholds loosely based on risks commonly accepted by the public, such as the risk of death from rock climbing, high risk professions, and traffic accidents (HSE, 1992). The HSE determined that the highest level of risk the general public would bear in order to receive some benefit was roughly 1 in 10,000 (deaths per year per capita), and that risks with a chance of less than 1 in 1,000,000 (deaths per year per capita) were generally considered by the public to be inconsequential (HSE, 2001 & 1992). Similar metrics can be defined for risks not related to human health, such as for those associated with environmental harm.

Application of the TR framework to risk management is relatively straightforward. After TR thresholds are in place and the governing ALARP considerations are chosen, risk assessments are conducted to place any identified issue within a TR risk region. If the identified risk falls within the broadly acceptable region, no further action is necessary, and if it falls in the unacceptable or tolerable regions, risk-reducing solutions must be developed. For tolerable risks, each solution undergoes an analysis to determine if taking further action is practicable under the organization's chosen risk-management criteria. For unacceptable risks, risk-reducing strategies must be employed until the risk enters the tolerable region. Once in the tolerable region, risk solutions continue to be implemented until the ALARP condition is satisfied. All risks are analyzed on an ongoing basis to ensure that tolerable risks remain ALARP, that broadly acceptable risks remain in the broadly acceptable region, and that further unacceptable risks are not introduced. As TR thresholds and the “reasonably-practicable” condition are not globally defined, it is left to the practitioner to determine which risk thresholds and risk-management strategies are appropriate for each individual implementation (Bowles, 2003; Melchers, 2001).

Implementing a Tolerable Risk framework often involves comparisons among risk metrics for which units rarely align (e.g. comparing risks from increased climate variability to risks from sea-level rise). This has led to great diversity in TR implementation, and federal risk management has historically never been unified under a single framework. Instead, each agency has created its own risk-management practices based on social trends, expert knowledge from the risk-management community, and agency goals within the statutory context. The United States has undergone several periods of risk-management implementation, moving from an initial concept based on zero risk to periods focused on best technological practices, cost benefit tradeoffs, and again on zero risk (Paté-Cornell, 2002). Presently, US and foreign agencies are increasingly embracing the TR framework, and ongoing conversations between federal agencies are laying the foundation for a more-standardized, interagency approach to TR implementation (USACE, Reclamation, & FERC, 2008; Munger et al., 2009).

Risk-Based Decision Making by Public Agencies

This section compares current risk-management strategies among eight federal and foreign agencies, giving special attention to areas where components of the TR framework are and are not incorporated. The basis for this comparison is a March 2008 Tolerable Risk Workshop hosted by the US Army Corps of Engineers, the US Bureau of Reclamation, and Federal Energy Regulatory Commission (Workshop, 2008). From attendee agencies, comparisons are included for the US Bureau of Reclamation, Environmental Protection Agency, Federal Aviation Administration, Food and Drug Administration, National Aeronautical and Space Administration, Nuclear Regulatory Commission, and UK Health and Safety Executive. Details for the Norwegian Petroleum Safety Authority are also included. Sources are drawn from both workshop documents and the literature. The goal of this comparison is to develop an understanding of how each agency conceptualizes and incorporates the TR framework in its risk-management activities and to summarize the risk thresholds and ALARP considerations that are commonly implemented (Table).

Bureau of Reclamation

The US Department of the Interior's Bureau of Reclamation (Reclamation) owns and operates approximately 350 reservoirs in the Western United States (Reclamation, 2010). Founded in 1902, Reclamation's mandate was to tame the West by capturing and storing water for irrigation and human consumption. Several dam failures throughout the 1970s, most visibly that of the Grand Teton Dam, spurred the passage of the Reclamation Safety of Dams Act of 1978, calling for the Department's Secretary to take risk-mitigation actions at Reclamation facilities. Additionally, in 1979, the *ad hoc* Interagency Committee on Dam Safety developed a series of *Guidelines for Dam Safety*, a document first establishing safety procedures for federally-owned dams. These legislative mandates and committee recommendations have been incorporated by Reclamation into a quantitative risk-management system incorporating TR-like thresholds (Reclamation, 2003).

Reclamation currently divides risk into separate categories for risk of project failure and societal risk. To manage the risk of project failure (e.g. for ensuring water delivery reliability and protecting public assets), a single TR threshold of 10^{-4} (failures per year per project) delineates the boundary between unacceptable and tolerable risks (no broadly acceptable threshold is specified). Reclamation breaks with the traditional TR framework in that even unacceptable risks of project-failure are not subject to mandatory reductions. Unacceptable risks are instead subject to ALARP risk reduction and are given higher funding/timeline priorities within the project portfolio. Probabilistic cost-benefit and multi-attribute utility considerations are loosely applied to determine when ALARP risk levels have been reached (Reclamation, 2003; Muller, 2008).

Societal risks (e.g. the risk of mortality from uncontrolled flooding to populations residing downstream of Reclamation projects) are defined with both unacceptable and acceptable risk regions, in a process that more closely follows the traditional TR framework. Unacceptable societal risks lie above a threshold of 10^{-2} (deaths per year per project) and require expedited action. Broadly acceptable societal risks fall below a threshold of 10^{-3} (deaths per year per project) and require no action above whatever is deemed “reasonable and prudent” by the decision maker. Between the unacceptable and broadly acceptable thresholds are tolerable risks. These are considered by Reclamation for ALARP risk reductions within the normal budget and maintenance cycles and should typically be dealt with within seven years. Broadly-acceptable risks may also be considered for ALARP reductions, pending funding. Subjective cost-benefit and multi-attribute utility considerations are also used to determine ALARP levels for societal risks (Reclamation, 2003).

In regions with low population densities, Reclamation discards the tolerable-risk thresholds and ALARP considerations for societal risk and instead relies on a bounded-risk approach that limits the population’s exposure to risks of no greater than 10^{-3} (deaths per year per project; Reclamation, 2003). This explicitly recognizes that populations in low-density areas may be exposed to a disproportionately high portion of what would otherwise be a generally acceptable societal risk and should be protected, regardless of cost.

Baseline risks at each Reclamation facility undergo a comprehensive review every six years, in which Reclamation scores dams on the basis of static, hydrologic, and seismic risks and on operational & maintenance criteria. Facilities with the riskiest scores are prioritized for funding with a bounded cost constraint that allocates resources across the entire project portfolio, to achieve the greatest overall risk reductions, nationwide (Cyganiewicz & Smart, 2000).

Environmental Protection Agency

The US Environmental Protection Agency (EPA) has long been involved with human-health and environmental risk management (EPA, 2010a). Early EPA risk management was strictly qualitative, but quantitative methods were introduced in the 1970’s, starting with a vinyl-chloride risk assessment and published guidelines for evaluating carcinogens (Kuzmack & McGaughy, 1975). After the National Research Council’s publication of *Risk Assessment in the Federal Government: Managing the Process*, the EPA quickly began formalizing guidelines for specific types of risk assessment (Natural Research Council, 1983). These guidelines are still considered best practices for human-health and environmental risk assessments among many today, and are used in risk assessments by many federal agencies (EPA, 2010a).

Due to the diversity of EPA duties, the use of risk-management thresholds and ALARP considerations varies greatly with project purpose and type. While other decision factors are often involved in shaping EPA regulation, specific risk thresholds form a basis for many EPA risk-management duties. Carcinogenic risks (e.g. from hazardous air pollutants, or at Superfund and CERCLA sites) are generally considered unacceptable if they lie above a threshold of 10^{-4} (cancer incidents per year per capita) and broadly acceptable if they lie below a threshold of 10^{-6} (cancer incidents per year per capita; EPA, 1997b, 1991, & 2004 pg 27). These thresholds were originally envisioned for a Benzene air-pollution standard, but have recently been applied more broadly. It is also notable that the EPA looks at both the magnitude and distribution of risks and develops standards to protect sensitive, rather than average, individuals. In practice, EPA risk thresholds are not constant (Travis et al., 1987) and the agency often couples utility-, technology-, and approval-based ALARP considerations with relevant economic, legal, social, technological, political, and public-interest attributes to guide its risk-management decisions (EPA, 2004).

Systemic-toxicity risks from non-carcinogenic substances are separately managed through daily oral Reference Doses (RfD) or inhalation Reference Concentrations (RfC), because the toxic effect depends on the substance accumulation rather than mutation and uncontrolled cellular growth. The RfD/RfC system uses human and animal research data to establish the daily intake amounts of a substance that will not cause harm over the course of a lifetime (EPA, 1993 & 2004). The values are scaled from a no-observed-adverse-effect level (NOAEL) and impose no judgments about risk tolerability. For composite non-carcinogenic substances, total risk is captured through a hazard index that normalizes and combines RfDs/RfCs to incorporate effects from individual chemicals (EPA, 1997a).

Depending on the situation, risks of dosage above or below the RfD/RfC may or may not be deemed acceptable, but should be managed so as to cause no harm (EPA, 1997b & 1991). The EPA emphasizes that RfD/RfC values are an extension of carcinogenic risk-management considerations and are not stand-alone criteria, yet, without clearly defined thresholds and ALARP considerations, risk management for non-carcinogenic substances requires case-by-case judgment. For yet other cases, e.g. for airborne asbestos exposure, a zero-risk approach is applied under which all exposure is considered detrimental and no risk is tolerated (EPA, 2010b).

Federal Aviation Administration

The Federal Aviation Administration (FAA) manages aviation and rocket risks separately, though neither include traditional TR thresholds. Commercial aviation risks are assessed in relation to historical casualty rates, allowing regulators to establish relative safeties by comparing new components with their predecessors. Historical commercial aviation risks range from 10^{-6} to 10^{-9} (failures per flight per component) for general aviation, though risks as high as $4\text{x}10^{-6}$ (failures per flight per component) have been shown for short-term flights (Long & Narciso, 1999; Azevedo, 2008). The probability that any one component will fail is determined by dividing the historical casualty rate by the number of individual components that must fail to achieve system failure.

Risk management for commercial rocketry is more standardized. Firm thresholds for unacceptable risk are codified in FAA regulations for both private human spaceflights via reusable launch vehicles and traditional commercial launches, though no lower threshold differentiates tolerable from broadly acceptable risks. Human spaceflights in reusable launch vehicles must maintain individual risk below an unacceptable threshold of 10^{-6} (deaths per flight per capita) and societal risk below an unacceptable threshold of $3x10^{-5}$ (expected deaths per flight per capita), where the less-stringent societal threshold permits additional takeoff and landing debris (Repcheck, 2008). The FAA requires traditional launches to keep all casualties below $3x10^{-5}$ (deaths per mission per capita) (FAA, 2000). Licensees within both categories must demonstrate that the risk standards have been met prior to receiving a license.

Though no tolerable-risk region is specified, the FAA integrates utility-based ALARP considerations (deterministic and probabilistic cost-benefit analysis and cost-effectiveness analysis) in its risk assessments for both types of projects. FAA risk assessments may be either qualitative or quantitative, though both develop a Comparative Safety Assessment by ranking alternatives for each high-consequence decision. As a type of cost-benefit analysis, these assessments must “compare each alternative considered (including no action or change, or baseline) for the purpose of ranking the alternatives...” and “assess the costs and safety risk reduction or increase (or other benefits) associated with each alternative...” (FAA, 2008). Despite the usage of ALARP risk-management methods, overall use of a TR-style framework is minimal, and neither human nor commercial spaceflight are held to stringent TR risk thresholds (FAA, 2008).

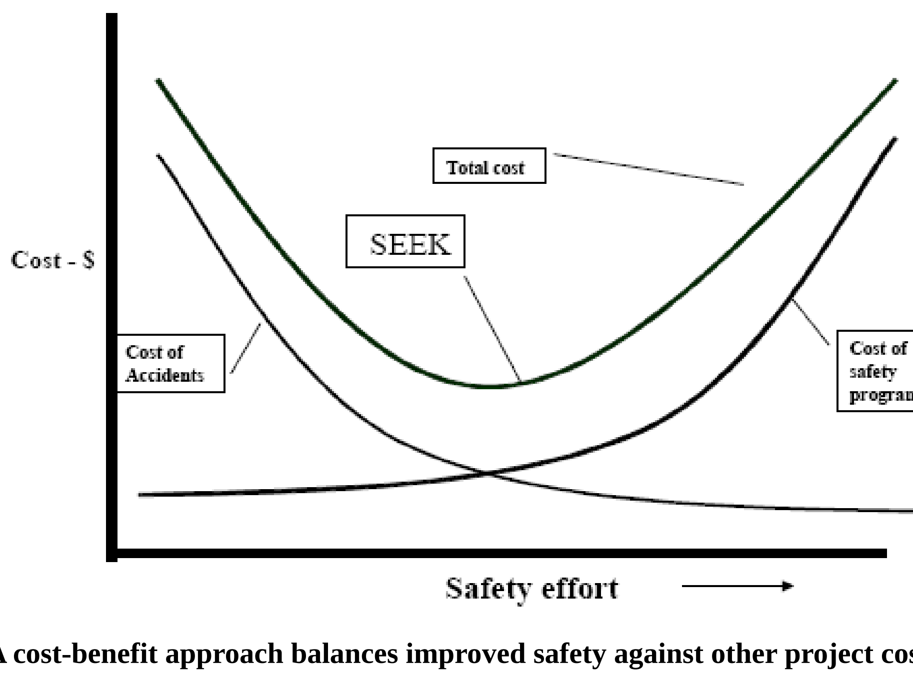

Figure 3. A cost-benefit approach balances improved safety against other project costs (FAA, 2008)

Though they do endorse quantitative methods, the FAA converts all quantitative data to qualitative data for decision-making. Risk-related decisions are typically made through a risk matrix, categorizing outcomes by both probability and effect. Any risk scoring high in the matrix (typically in the top right corner) is mitigated through additional action. Any risk below the right corner is considered acceptable, though actions may still be taken to reduce acceptable risks on a case-by-case basis (FAA, 2008).

Food and Drug Administration

The Food and Drug Administration (FDA) was one of the first agencies to implement the traditional TR framework and is largely responsible for popularizing the common 10^{-6} risk threshold. This threshold stems for a 1961 proposal by Mantel and Byan to use 10^{-8} as a *de minimus* risk level, an idea that the FDA eventually adapted and adopted with its acceptable-risk threshold of 10^{-6} for packaged meat products, as introduced in the its final rules for *Chemical Compounds in Food-Producing Animals* in 1979 (FDA, 1979; Merrill, 1988; Kelly, 1991). However, since the FDA first adopted TR thresholds, the agency has abandoned large parts of the TR framework and now relies on ALARP risk reductions for all regulated products, regardless of risk.

The FDA manages risk differently for the food and drug industries. For food products, the FDA generally manages risk by requiring compliance with specific low-risk processes approved by the agency (Daemmrich & Radin, 2007). These processes are based on scientific findings, precautionary beliefs, industry concerns, and/or congressional legislation, and can be quite detailed (FDA, 2000). For milk pasteurization, for example, the FDA requires compliance with specific pre- and post-pasteurization handling practices and dictates the temperatures and length of time of each pasteurization stage (FDA, 2009). Increasingly, food risks are also being managed through a bounded-risk approach that allows the FDA to set an unacceptable risk threshold and enables providers to implement their own strategies to meet that constraint (Daemmrich & Radin, 2007).

For drug products, the FDA determines risks to be ALARP through cost-benefit analyses that weigh the advantages and disadvantages of candidate drugs. As drug risks are widely legislated, these cost-benefit analyses often have a deterministic component, though agency-approved processes and probabilistic analyses are also employed. Drug applications are approved if the agency considers the benefits to outweigh the drawbacks and are otherwise rejected or subjected to additional study (Farley, 1995; Daemmrich & Radin, 2007). When firm TR thresholds are present, ALARP risk levels are established through risk-minimization plans submitted with the candidate application (FDA, 2005a; FDA, 2005b).

National Aeronautical and Space Administration

Through the Apollo and early shuttle programs, the National Aeronautical and Space Administration (NASA) relied on “Failure Modes and Effects analyses” in risk assessments identifying components critical to mission safety and recommending them for design improvements. With the loss of the Challenger shuttle, reprimands from the House of Representatives and the Slay committee led NASA to develop a more quantitative approach towards risk assessment (NASA, 1987). NASA’s current approach to risk management relies heavily on risk matrices and employs both qualitative and quantitative risk assessments in an iterative adaptive management process (Dezfuli, Youngblood, & Reinert, 2007; Stamatelatos, 2008).

NASA specifies individual risk management criteria for each project. TR thresholds are not numerically defined but are thought of as a series of iso-risk contours within a risk matrix. Risk falling outside of the unacceptable contour must be reduced while risks falling between the broadly acceptable and unacceptable contours are reduced until ALARP. Bounded cost constraints and deterministic/probabilistic cost-benefit analyses are often used to determine when risks are ALARP (NASA, 2008).

Table 2. Risk matrix with iso-risk contours (following NASA)

Consequence Class	Likelihood Estimate				
	Likely to Occur	Probably will Occur	May Occur	Unlikely to Occur	Improbable
Catastrophic	1	1	2	3	4
Critical	1	2	3	4	5
Moderate	2	3	4	5	6
Negligible	3	4	5	6	7

Nuclear Regulatory Commission

The Nuclear Regulatory Commission (NRC) initially managed risk by applying prescriptive requirements developed through experience, test results, and expert judgment (NRC, 2007a). With the publication of the *Reactor Safety Study* in 1975, NRC regulations began to quantify risk systematically (e.g. in WASH-1400, NUREG/75-014). The NRC's 1994 *Probabilistic Risk Assessment Implementation Plan* began to move towards a TR framework and was superseded in 2000 and 2007 with new guidance documents that each successively advocated TR to a greater degree (NRC, 2010, 2011a, & 2011b).

The current risk-management structure of the NRC is founded on a rights-based, constrained-risk approach towards delineating fixed (non-ALARP) risk boundaries. The NRC specifies that nuclear risks should be equivalent to or less than those created by other forms of electricity generation and that nuclear energy should pose "no significant additional risk to life and health" (NRC, 1986). Specifically, NRC risk objectives delineate acceptable increases in risk over background levels through quantitative health (QHO) and subsidiary risk (SRO) objectives. The QHO for personal risk establishes an acceptable composite increase of prompt death for those living within a mile of a civilian nuclear power plant as 0.1% of the sum of all background risk (prompt deaths per year per capita). Similarly, the QHO for composite societal risk of cancer death is set at 0.1% above background cancer risk (cancer deaths per year per capita). SROs are benchmarks toward QHO goals, defining acceptable risks for physical aspects of facilities. Example SROs include the risk of reactor failure and large radioactive release, set at 10^{-4} and 10^{-6} (failures per year per reactor) respectively (NRC, 1986). Risks managed through the current implementation plan are broken into three main areas—reactor safety, materials safety, and waste management—each requiring probabilistic risk assessments (NRC, 2011a).

Facility modifications must also meet risk thresholds. Alterations are measured for their effect on various facility baseline risks. For example, any potential change affecting the reactor core damage frequency (RCDF) must be evaluated. If the RCDF is initially below 5×10^{-3}, small changes in risk of less than 1×10^{-6} are approvable. If the initial RCDF is below 1×10^{-4}, then changes in risk of up to 1×10^{-5} are permissible. Similar risk-adjustment structures govern facility modifications impacting Large Early Release Frequencies and other measured quantities (Monninger, 2008).

Risk thresholds apply continuously throughout the lifespan of a reactor. Inspections measure the risk associated with various plant activities (Nuclear Energy Institute, 2007). If thresholds are found to be exceeded, the plant must take mitigating action to improve the facility's safety system and may also suffer fines (NRC, 2005).

UK Health and Safety Executive

The UK Health and Safety Executive (HSE) developed the TR framework and actively regulates risk throughout UK industry and society. The HSE grew out of the 1972 Robens Committee tasked with reforming regulation to better protect the population (Bouder, Slavin, & Lofstedt, 2009). Finding previous risk-management structures piecemeal and narrowly focused on single objectives, the Robens committee made recommendations that were incorporated into the UK Health and Safety at Work etc Act of 1974, redesigning the risk-regulatory framework of the UK and officially establishing the HSE. In 1988, in response to the Sizewell B nuclear power plant hearings, the HSE first published risk standards for nuclear power stations that incorporated the TR framework (HSE, 1992). As this initial document was revised and republished, the TR framework was expanded to include all industrial risks (HSE, 2001).

HSE regulations take a holistic approach towards risk and are implemented through TR thresholds and various ALARP criteria. As previously mentioned, the HSE has established a general unacceptable risk threshold of 10^{-4} (deaths per year per capita) and a general broadly acceptable risk threshold of 10^{-6} (deaths per year per capita) (HSE, 2001). With tolerable risks, ALARP reductions are made based on considerations including cost-benefit analyses, best practices, uncertainty, potential adverse consequences, technological developments, and regulatory feasibility (Bouder, Slavin, & Lofstedt, 2009). The HSE ensures compliance with its regulations with inspections throughout its jurisdiction in England, Scotland, and Wales.

Norwegian Oil Industry

The Norwegian oil industry has strongly embraced risk assessments and emergency preparedness measures in the design and operation of offshore and onshore oil facilities (NTS, 2001). The Petroleum Safety Authority (PSA) is the agency that regulates major accidental and environmental risks for the Norwegian oil industry, by defining both normative regulations and detailed risk-management frameworks. The PSA was created in 2004 from a split of the Norwegian Petroleum Directorate (founded in 1972), with the intention of separating the supervision of petroleum health and safety from the management of petroleum resources (NPD, 2009). The PSA has developed separate risk-management frameworks for the risk of accidental harm to humans and structures, the risk of accidental harm to the environment, and the risk of continuous environmental harm from normal operations (DNV, 2010). The PSA defines Risk-Acceptance Criteria (RAC) that are the main instruments for determining which risk reduction measures should be implemented, though the ALARP principle has gained increased focus in recent years (Aven & Vinnem, 2005; Vinnem, 2007).

One major achievement of risk management in the oil industry was the introduction of the NORSOK standards for risk analysis and emergency preparedness. The present version is from 2001 and describes a process for using quantitative risk analysis to arrive at solutions in accordance with the RAC (NTS, 2001). Typical risk reducing measures include physical measures like fire insulation, deluge systems, pressure release systems, etc., and also organizational procedures like safety training and establishing a safety culture. Based on the results of each risk analysis, multiple emergency scenarios are developed from which specific emergency preparedness measures are selected.

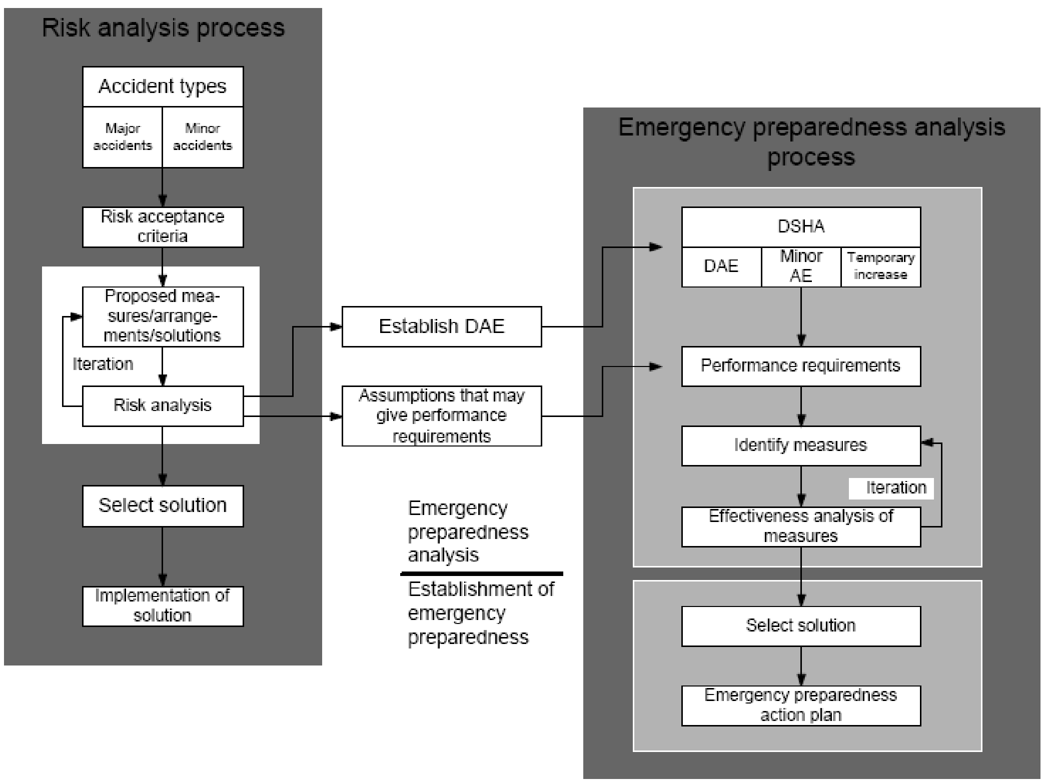

Figure 4. The Norwegian risk analysis and emergency preparedness analysis processes (NTS, 2001)

For major accidental risk (i.e. of loss of human life/health or significant structural damage), it is important to note that the NORSOK standard does not specify threshold values for the RAC. Likely due to the political infeasibility of placing a valuation on human life, the regulations give only normative recommendations on acceptance criteria and leave the specific acceptance criteria to be formulated by the individual oil companies (DNV, 2010; Vinnem, 2007). Threshold values for major accidental risk are determined by each company using individual risk criteria like the Fatal Accidental Rate, defined as the expected number of fatalities per 10^8 hours of exposure, the Potential Loss of Life, which calculates the expected number of fatalities per year, or risk matrices. Group risks are also defined by some companies using F-N Curves that show a relationship between the cumulative frequency (F) of an event and the number (N) of fatalities expected (Vinnem, 2007; Shaw 1992).

In contrast with the RAC for major accidental risk, the RAC for major environmental risk do contain specific thresholds in a framework developed by the Norwegian Oil Industry Association. These environmental RAC are based on the principle that the duration of environmental damage shall be insignificant in relation to the expected time between such damaging occurrences. Categories of environmental damage include Minor, for accidents with expected recovery between 1 month and 1 year, Moderate, for accidents with expected recovery between 1 and 3 years, and Significant, for accidents with expected recovery between 3 and 10 years (**Table 3**; Vinnem, 2007). Environmental RAC are also defined based on the size of the operation. With an inverse relationship between strictness and scope and according to the ALARP principle, the criteria are defined more strictly for any individual operation than for the whole oil field (DNV, 2007, Vinnem 2007).

Table 3. RAC limits for environmental-damage type and scope of operations (Vinnem 2007)

Environmental damage	Field specific frequency limits per year:	Installation specific frequency limits per year:	Operational specific frequency limits per operation:
Minor	$< 2 \cdot 10^{-2}$	$< 1 \cdot 10^{-2}$	$< 1 \cdot 10^{-3}$
Moderate	$< 5 \cdot 10^{-3}$	$< 2.5 \cdot 10^{-3}$	$< 2.5 \cdot 10^{-4}$
Significant	$< 2 \cdot 10^{-3}$	$< 1 \cdot 10^{-3}$	$< 1 \cdot 10^{-4}$
Serious	$< 5 \cdot 10^{-4}$	$< 2.5 \cdot 10^{-4}$	$< 2.5 \cdot 10^{-5}$

Environmental risk assessments, the results of which are compared to the environmental RAC, involve estimation of release frequencies, rates, and durations of spill and calculation of oil drift and damages, which often vary by season. The final risk estimation is often presented as the ratio between risk and acceptance criteria for the species of interest in each damage category, for relevant species and seasons (Shaw, 1992; DNV, 2007).

Lastly, the Norwegian regulations recognize that there are certain operational environmental risks inherent in oil production. Whereas accidental environmental risk is regulated based on accident return periods, risk from continuous exposure is regulated through discharge permits (e.g. for discharges of produced water, chemical use, air emissions etc.). The Norwegian Pollution Control Act of 1981 states that all pollution is illegal unless specifically allowed by law, regulations, or individual permits. This zero-harmful-discharge philosophy encourages companies to make substitutions for less-harmful chemicals and environmentally-beneficial processes, like using produced-water reinjection instead of produced-water disposal (Norwegian Government, 2003). Environmental impact is calculated with environmental impact factors (EIF) addressing the aggregated potential eco-toxicological impact from the entire operation, rather than looking only at individual contributions. The oil industry uses these EIF calculations to prioritize risk-reducing measures and to compare environmental impacts between locations – thus making it possible to prioritize risk reduction based on cost-benefit allocations at the whole-field scale (Singsaas 2008).

Summary

Though there is currently no coordinated effort to adopt standardized risk management approaches across federal or international agencies, several notable trends can be seen (Table). Many of the agencies in this review have adopted a TR or modified-TR framework specifying threshold values for the unacceptable and/or broadly acceptable risk regions. Threshold values are most often set to around 1 in 10,000 for the unacceptable region and 1 in 1,000,000 for the broadly acceptable region. The high similarity of threshold values between agencies owes to early threshold popularization by the FDA and to a common threshold derivation from socially accepted risk and general background risk, as discussed by the HSE (1992 & 2001). Risk among the surveyed agencies is often also divided into multiple categories, with different thresholds specified for individual, societal, and/or project risks.

Table 4. Summary and threshold values and of management criteria (ALARP or otherwise) within the risk-management frameworks of surveyed agencies

Regulating Agency	Threshold Values	Risk-Management Criteria
Bureau of Reclamation	Project failure: *Broadly acceptable* 10^{-4} failures per year per project Societal risk: *Unacceptable* 10^{-2} deaths per year per project *Broadly acceptable* 10^{-3} deaths per year per project	*ALARP:* Bounded cost, Probabilistic cost-benefit, *Non-ALARP:* Bounded risk (Consideration of other factors)
Environmental Protection Agency	*Unacceptable* 10^{-4} cancer incidents per capita per year *Broadly acceptable* 10^{-6} cancer incidents per capita per year	*ALARP:* Various utility-based *Semi-ALARP:* Best available technology Approved processes (Consideration of other factors)
Federal Aviation Administration	Aviation (historical values): *Unacceptable* 10^{-6} failures per flight per component *Broadly acceptable* 10^{-9} failures per flight per component Rockets: Individual risk: *Broadly acceptable* 10^{-6} deaths per flight per capita Societal risk: *Broadly acceptable* $3x10^{-5}$ deaths per flight per capita	*ALARP:* Deterministic cost-benefit, Probabilistic cost-benefit, Cost effectiveness
Food & Drug Administration	None	*Non-ALARP:* Approved processes
National Aeronautical	Set on an individual project basis	*ALARP:*

and Space Administration		Deterministic benefit cost, Probabilistic cost-benefit, Bounded cost
Nuclear Regulatory Commission	Individual risk: *Broadly acceptable* 0.1% of general prompt death background risk Societal risk: *Broadly acceptable* 0.1% of general cancer death background risk	*Non-ALARP:* Constrained risk
UK Health & Safety Executive	*Unacceptable* 10^{-4} deaths per year per capita *Broadly acceptable* 10^{-6} deaths per year per capita.	*ALARP:* Deterministic cost-benefit, Probabilistic cost-benefit
Norwegian Petroleum Safety Authority	Set by each company in coordination with the regulating authorities, typically through: *For major accidental risk:* PLL, FAR, individual risk, F-N curves *For accidental environmental risk:* Return periods depending on environmental damage *For operational environmental risk:* Discharge permits, zero harmful risk	*ALARP:* Deterministic cost-benefit, Probabilistic cost-benefit *Semi-ALARP:* Quantitative Risk Acceptance Criteria (RAC)

The majority of the surveyed agencies apply utility-based analyses to determine when ALARP conditions have been met, though some agencies avoid the ALARP approach altogether. Notable exceptions include the NRC, which uses a constrained-risk approach, and the FDA, which requires compliance with specific approved processes. Reclamation, the EPA, and the Norwegian PSA use combinations of ALARP, semi-ALARP, and non-ALARP considerations to tailor their risk-management strategies to individual projects. Of the utility-based risk-management criteria used, cost-benefit ALARP considerations are the most common.

Discussion and Recommendations

Features of a Robust Tolerable Risk Framework

Key features which must be present in a TR framework to ensure proper function include threshold values, management criteria, review timeframes, and communicability. Clearly defined risk thresholds provide managers with target values, trigger safety actions when risks rise above acceptable limits, and serve as explanatory tools that managers can refer to when questioned about project design choices. Robust threshold values must either be derived comprehensively from background risk or compared to equivalent types of risk that are commonly accepted or rejected. With either threshold definition strategy, the implemented TR framework must delineate scientifically why thresholds are set at particular values relative to the definition mechanism.

It is also important that a robust TR framework have management criteria and review processes that are as clearly defined as the threshold values. Management criteria establish priorities between the unacceptable and broadly acceptable regions and tend to be much more subjective than threshold values. Therefore, when management criteria are employed, explicit justification must accompany each criterion's application. Once a risk management strategy or tolerable risk level is established, it must be periodically reviewed to insure continuing compliance with existing regulations and the feasibility of further risk reductions. Reviews are vital for long-term risk management at infrastructure sites.

Defining TR threshold values scientifically rather than with professional judgment allows the public to have a firm understanding of the protection levels offered. When risk values fall within the tolerable region, the public must also have a clear knowledge of the reasons why further risk reductions are not feasible. If a TR framework is implemented but the public is not made aware of the identified risk thresholds and probability justifications, the framework is likely to fall short of achieving its maximum potential effect.

Steps Towards Tolerable Risk Implementation

Though the implementation of TR varies between regulating authorities, features such as focus parameters, risk thresholds, and management criteria remain largely consistent across implementations. These features, together with identified review timeframes and communication planning, can considerably reduce project risks and raise public awareness of safety improvements in infrastructure development.

The following multi-step process is envisioned to aid public agencies in implementing TR frameworks to successfully manage climate-change risks and public perceptions of these risk. Transitioning to a TR framework will likely require a process consisting of: defining the focus parameters for risk reduction, defining threshold values, selecting risk-management criteria, selecting review timeframes, applying TR to facilities, and communicating with the public.

<u>1) Definition of focus parameters for risk reduction</u>

Defining risk management goals and metrics helps to identify which areas merit consideration for reductions in risk. The scope of these metrics can include individual, project, and/or societal risks, covering topics such as the loss or degradation of life, health, personal property, national security, or the environment, etc. By defining these risk reduction parameters, later risk management is made more transparent and is focused into clearly defined areas. For offshore oil and gas development, for example, key goals have included reduction in risks of both the occurrence and impacts of oil spills and reductions in major accidents, injuries, and fatalities associated with offshore operations. But specifying the goals is just one dimension of this task; the other is to develop the metrics for measuring trends and performance relating to these goals. For example, what criteria should be used to define “major accidents?” Are injuries best tracked as a ratio of incidents to number of hours worked, by oil production activity, or by some other metric?

<u>2) Definition of threshold values</u>

Defining threshold values provides unacceptable and broadly acceptable risk limits for each focus parameter, using easily communicable and scientific means. In addition to specifying the thresholds themselves, this process should determine if the identified values are static across the project portfolio or must be redefined for each project location. Clearly defined threshold values are important for identifying in which situations additional risk reductions are mandatory, potentially warranted, or unnecessary. Defining such thresholds is not always straightforward nor without controversy. For example, thresholds for establishing “unacceptable” risk levels for exposure to air, water, or soil contaminants are sometimes contested as being either too high or too low. However, in many instances, it is not the threshold, per se, that is contested. Rather, significant disagreements often surface regarding the analytic tools and assumptions for assessing whether some action or exposure falls within the range of tolerable risk.

3) Selection of risk-management criteria

For each project, consideration needs to be given as to which methods, such as cost-benefit analysis, or which criteria will be used to determine if project risk levels are ALARP, and to choose between risk-reduction measures. Selection of ALARP considerations sets the framework for the application of risk reduction methods. Along with the selection of considerations, implementation guidelines also need to be developed.

4) Selection of review timeframes

Review timeframes are meant to ensure continued compliance with ALARP and threshold values. Among other cases, timeframes will likely need to be developed to review facilities already considered ALARP but subject to new data from periodic risk assessments, to assess the progress made towards compliance by facilities above the maximum threshold and to determine the maximum time available to implement ALARP upgrades for facilities already within the tolerable region.

5) Application of TR to facilities

When threshold values, ALARP considerations, and review timeframes are in place, the TR framework should be applied to existing infrastructure facilities to ensure compliance or to bring facilities into compliance. Because of the scale associated with such an endeavor, it is likely that the application of a TR framework to a new facility might be accomplished over several years.

6) Communication with the public

In parallel with implementing the TR framework, agencies should consider developing communication strategies to inform the public about the risk management strategies in place. Such efforts might include developing visual aids for explaining the calculated risks (e.g. explaining the TR triangle, comparing project to equivalent levels of risk), developing explanations of the ALARP considerations employed, and sharing the results established through ALARP reductions. Simple, effective communication strategies are essential for public understanding of the actual level of protection provided by infrastructure and civil works projects.

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