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Designing Safety Regulations for High-Hazard Industries

Committee for a Study of Performance-Based Safety Regulation

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Preface

Governments have long regulated the safety of industries engaged in hazardous activities. The ultimate purpose of this regulation is to ensure that the industries provide their vital goods and services with minimal harm to workers, the public, and the environment. A number of regulatory tools offering various advantages and disadvantages depending on circumstances can be used to achieve that purpose. While safety regulation cannot prevent all harmful incidents, regulators need to have confidence that the regulatory tools they choose are well suited to the particular circumstances. They must also be able to explain their choices to policy makers and the public.

For example, the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) regulates the safety of hazardous cargoes, including those moved by pipeline. The network of pipelines in the United States is extensive and heavily used. Pipelines transport most of the country's energy liquids and gases, including natural gas, to millions of homes and businesses. Because the safety of these systems is paramount, PHMSA's regulations attract considerable attention from policy makers, including scrutiny when harmful failures occur. That scrutiny is most intense when failures have catastrophic consequences.

Over the course of decades, legislation and rulemaking related to pipeline safety in the United States have produced a mix of regulatory designs in the federal pipeline safety program. Among the regulations are technical specifications for pipeline design, construction, maintenance, and operations that are highly detailed and narrowly targeted. Other regulations mandate certain capabilities and give pipeline operators discretion on how to meet them, such as in the training of their control room and inspection

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personnel. Even broader-based commands call on operators to establish comprehensive risk management programs, most notably to identify, assess, and prioritize the removal and repair of pipeline defects and other anomalies that risk failure.

The varied collection of regulatory commands in the laws governing pipeline safety can create challenges for regulatory enforcement. The regulator may monitor a firm's compliance with well-defined requirements by reviewing documents and conducting field inspections. However, conformity with standards that are more generalized can require judgment on the part of the regulator's enforcement personnel and trust in the operator's ability and willingness to comply. PHMSA regulations that require integrity management programs are referred to by the agency as "performance-based," presumably because they give operators flexibility to customize their programs to circumstances and to concentrate on enhancing the performance of their internal risk management actions, as opposed to "checklist" compliance with specifications having industrywide application.

When pipeline failures occur, especially catastrophic ones, PHMSA must explain its reliance on the various types of regulations. PHMSA must also explain its regulatory approach when it issues new rules, before congressional committees, and in response to legal challenges and recommendations by the National Transportation Safety Board (NTSB). The rationale for giving pipeline operators flexibility in the means of compliance can be particularly difficult to explain and justify because of concerns that operators might respond in perfunctory or uneven ways. Yet PHMSA's rationale for its integrity management regulations is that pipeline systems are diverse in their design, configuration, operation, and environmental settings, and therefore the agency cannot be expected to identify and regulate all of the varied and context-specific sources of risk in the industry. The development of context-specific (or case-by-case) regulations, even if that were possible, would be extraordinarily costly. For these reasons, PHMSA requires operators to assume direct responsibility for identifying and managing risks that would not otherwise be known to PHMSA.

Safety regulators in other high-hazard industries, both in the United States and abroad, also use different combinations of regulatory designs. Like PHMSA, they need to determine whether their regulations are well suited to addressing relevant safety problems. Trends in incident reports may not inform that determination if the main concern is prevention of catastrophic incidents, which are inherently rare. To help in this regard, PHMSA sponsored this study to inform its choices of regulatory tools, as well as to help other safety regulators facing similar choices. Recognizing this broader interest in the design of safety regulations in the transportation sector and other high-hazard industries such as offshore oil and gas development and chemical manufacturing, the Transportation Research Board

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and the National Academies of Sciences, Engineering, and Medicine's Gulf Research Program contributed additional funds to enable an expansion of the study scope to include case studies of industries in addition to pipelines.

To conduct the study, the National Academies formed a committee with expertise in regulation, risk analysis, and the operations and management of high-hazard industries. The committee was led by Detlof von Winterfeldt, the J.A. Tiberti Chair in Ethics and Decision Making at the University of Southern California. The contents and findings of the report represent the consensus effort of the 14 committee members, who served uncompensated in the public interest. They met five times over a 12-month period and held a subcommittee meeting in The Hague, Netherlands, to discuss regulation of the North Sea offshore oil and gas industry.

The Hague meeting and other data-gathering sessions—all open to the public—were extensive. They included briefings by the sponsor; officials from other safety agencies of the federal government, state governments, and other countries; representatives from numerous high-hazard industries and labor unions; experts in regulatory studies; and current and former safety regulators. These sessions were invaluable to the committee and provided insight into regulatory practice as well as the shared need of safety regulators for greater conceptual clarity about the regulatory tools they possess.

ACKNOWLEDGMENTS

The committee thanks the many individuals and organizations who informed its work.

The PHMSA liaison for the study was Robert W. Smith, who provided contract oversight and handled information requests from the committee. Both the immediate past and the current Associate Administrators for Pipeline Safety at PHMSA, Jeffrey Weise and Alan Mayberry, briefed the committee about PHMSA's pipeline safety program. The study was conceived and funded with Weise's leadership and support.

The committee was briefed by the following representatives of U.S. federal and state safety regulatory agencies: Brian Salerno and Susan Dwarnick, Bureau of Safety and Environmental Enforcement; William Perry and Thomas Golassi, Occupational Safety and Health Administration; Donald Arendt, Federal Aviation Administration; Timothy Brown, U.S. Coast Guard; Grady Cothen (retired), Federal Railroad Administration; and Steven Allen, Indiana Utility Regulatory Commission. In addition, the committee was briefed by Neil Eisner, American University (retired, Office of the General Counsel of the U.S. Department of Transportation); Dominic Mancini, Office of Information and Regulatory Affairs (OIRA)

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of the White House Office of Management and Budget; and former OIRA official Donald Arbuckle, now at The University of Texas.

The committee held discussions with the following representatives of safety regulatory authorities outside the United States: Peter Watson, National Energy Board of Canada; Magne Ognedal (retired) and Paul Bang, Petroleum Safety Authority of Norway; Paul Bradley, Health and Safety Executive of the United Kingdom; Hans Erik Christensen, Danish Working Environment Authority; and Roel van de Lint and Vincent Claessens, State Supervision of Mines of the Netherlands.

The committee was briefed by the following representatives of high-hazard industries: Ronald Bradley, PECO, an Exelon Company; James Crowley, Easton Utilities Commission; Robin Rorick and David Miller, American Petroleum Institute; Terrance Kutryk, Alliance Pipeline, Limited; Christopher Bloomer, Canadian Energy Pipeline Association; Peter Lodal, Eastman Chemical Company; Trish Sentance, Oil and Gas UK; Esben Mortensen, Oil and Gas Denmark; Gert-Jan Windhorst, Netherlands Oil and Gas Exploration and Production Association; Christopher Hawkes, International Association of Oil and Gas Producers; Ida Maria Winther, Maersk Drilling; and Jens Hoffmark, International Association of Drilling Contractors.

The committee invited other individuals to discuss matters relevant to the study. The Honorable Christopher Hart, NTSB, discussed NTSB's recommendations pertaining to the design of transportation safety regulations; Richard Kowalewski, The George Washington University, presented findings from A Report to the Secretary of Transportation: Pipeline Integrity Management; Jake Molloy, National Union of Rail, Maritime, and Transport Workers, discussed the experience of offshore workers with the United Kingdom's safety regulation; Michael Wright, United Steelworkers, discussed the experience of U.S. petrochemical workers with process safety programs; Ionathan Wills, Shetland Islands Council, presented his views of offshore safety regulation in the North Sea region; Peter Bjerager, Americas DNV Oil and Gas, explained the role of third-party auditors in compliance assurance; Lori Snyder Bennear, Duke University, discussed her research on the use of regulatory designs in the offshore sector; Elmer "Bud" Danenberger described offshore regulation outside the United States; and Taf Powell discussed the European Commission's Offshore Directive.

The committee is grateful to the National Academies' Gulf Research Program for providing funds for a subcommittee meeting in The Hague, Netherlands, where many of the international briefings and discussions took place. The information and insights from the workshop were crucial to the report's case study of offshore oil and gas safety regulation in Norway and the United Kingdom. Special thanks go to Taf Powell for providing

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extensive assistance with the planning and structuring of the subcommittee meeting.

This report was reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the National Academies of Sciences, Engineering, and Medicine in making each published report as sound as possible and to ensure that it meets the institutional standards for quality, objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

We thank the following individuals for their review of this report: Stephen Allen, Indiana Utility Regulatory Commission, Indianapolis; Lori Snyder Bennear, Duke University, Durham, North Carolina; James Dyer, The University of Texas at Austin; Neil Eisner, American University, Washington, D.C.; Roger Kasperson, Clark University (emeritus), Washington, D.C.; Gary Klein, Wiss, Janney, Elstner Associates, Inc., Northbrook, Illinois; William Klimack, Chevron Corporation, Houston, Texas; Karlene Roberts, University of California, Berkeley; Brian Salerno, Silver Spring, Maryland; John Samuels, Revenue Variable Engineering, LLC, Palm Beach Gardens, Florida; and Trish Sentance, Oil and Gas UK, Aberdeen, Scotland.

Although the reviewers listed above provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations of this report nor did they see the final draft before its release. The review of this report was overseen by the review coordinator, Susan Hanson, Clark University (emerita), and the review monitor, Ross Corotis, University of Colorado Boulder. They were responsible for making certain that an independent examination of this report was carried out in accordance with the standards of the National Academies and that all review comments were carefully considered. Responsibility for the final content rests entirely with the authoring committee and the National Academies.

Thomas R. Menzies, Jr., managed the study and drafted much of the report under the direction and guidance of the committee. Micah Himmel assisted with preparations, and Claudia Sauls provided extensive support to the committee in arranging the many meetings and managing documents. Karen Febey managed the report review. The committee acknowledges Norman Solomon, who edited the report.



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Summary

Safety failures in high-hazard industries can be catastrophic and lead to deaths and injuries, environmental damage, and property loss. To prevent such failures, governments in the United States and abroad regulate the safety performance of industries such as pipeline transportation, chemical manufacturing, and offshore oil and gas development. These safety regulations are often scrutinized after an incident, but their effectiveness is inherently difficult to assess when their purpose is to reduce catastrophic failures that are rare to begin with. Nevertheless, regulators of high-hazard industries must have an informed and reasoned basis for making their regulatory choices.

Regulators can design their regulations in several ways. They can regulate at a micro-level by imposing highly targeted requirements on firms to mitigate specific contributors to risks. They can regulate at a more macro-level by focusing their requirements less on individual pathways that lead to risks and more on overall catastrophic risk. For example, firms may be required to develop and manage organizational- and system-level processes that focus managers' attention on catastrophic risk. Whether they have a micro- or a macro-level emphasis, regulations can be designed in a "prescriptive" manner, by specifying means that firms must adopt or implement, or in a "performance-based" manner, by specifying ends to be achieved (or outcomes to be avoided). These alternative regulatory designs often are used in combination.

In this report, the study committee, which was asked to compare prescriptive and performance-based regulations for promoting safety in high-hazard industries, points out ambiguities in the meanings and incon2

DESIGNING SAFETY REGULATIONS FOR HIGH-HAZARD INDUSTRIES

TABLE S-1 Four Basic Regulation Design Types with Examples of Commonly Used Descriptors

	Means	Ends
Micro	Micro-means "Prescriptive"	<i>Micro-ends</i> "Performance-based"
Macro	Macro-means "Management-based"	<i>Macro-ends</i> "General duty/liability"

sistencies in the uses of these common regulatory labels. The report avoids labeling regulations as prescriptive versus performance-based and instead focuses on the most salient design features of regulations. Distinctions are made between *micro*- and *macro*-level regulations and between *means* and *ends*. On the basis of these distinctions, four main types of regulatory design are identified (see Table S-1), and the rationale for and challenges associated with each are examined under different applications.

The impetus for this report, one that suffuses the debate about how best to regulate high-hazard industries, is a particular interest in regulations that require firms to establish management systems to identify, prioritize, and mitigate their safety risks. Often mischaracterized as "performance-based," these regulations are more aptly described as having a *macromeans* design, because they require firms to address overall risk—that is, at a macro-level—by using the specified means of a management system. Notably, these regulations do not require firms to achieve specified ends, or performance outcomes, such as a demonstrable reduction in major incidents. Such an outcome would be particularly difficult to demonstrate for regulations that are intended to prevent catastrophic failures, given their complexity and rare occurrence. The regulations instead presume that consistent attention to organizational dynamics and emergent risks should reduce the probability of such failures, even if that reduction may not be provable empirically.

Requirements for management systems are often flexible in the sense that they give regulated firms the ability to customize their systems in accordance with the firms' circumstances. For example, macro-means regulations often give firms considerable latitude to develop and execute their own internal methods for risk analysis and prioritization, systems for facility and equipment monitoring and maintenance, and procedures for managing change. This flexibility may have led to the mislabeling of these regulations as performance-based, because of the resemblance to the flexibility afforded by ends-based regulations that mandate performance outcomes but give firms discretion on overall means of achieving them.

As explained in this report, the common rationale for requiring the use

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of management systems to promote safety in high-hazard industries is that safety risks, especially catastrophic risks, can arise from interactions among conditions and activities that are difficult to anticipate and may be specific to each firm or work site. Such context-specific risks will be unknown to the regulator, especially in view of the diverse and complex operations characteristic of high-hazard industries. Although the design of management regulations is more means-based than performance-based, these regulations can serve a valuable purpose by addressing risks that cannot be controlled by highly targeted micro-level regulatory interventions. How well they serve this purpose can depend on a number of factors, including the details of how the regulation is structured; the capabilities of the regulator in supporting and motivating compliance; and the capacity of the regulated firms to plan, assess, and act in ways that fulfill the purpose of the regulation.

KEY OBSERVATIONS AND ADVICE

The report is informed both by academic research and by insights from case studies of the regulatory regimes of four countries governing two high-hazard industries—the pipeline and the offshore oil and gas sectors. The case studies show how safety regulators from different countries rely on a combination of highly targeted micro-level regulations and more flexible macro-level regulations, such as those requiring management systems.

The report emphasizes that simple comparisons of the advantages and disadvantages of regulatory designs offer little more than a starting point for regulatory decision making. All regulations, including macro-level regulations that require management systems, can be structured in ways that affect these advantages and disadvantages. The use of such macro-level regulations may be advantageous in situations where the sources of risk are complex and context-specific, as is characteristic of low-frequency, high-consequence events. However, any decision to use macro-means regulations must take into account the regulator's own ability to enforce and motivate compliance (through methods such as auditing and field inspections) as well as the capacity of regulated entities to meet their obligations. If these preconditions are missing or cannot be created, the regulator should be concerned that this form of regulation will be less effective than desired.

In considering the use of macro-level regulations that provide firms with flexibility in the means of compliance, regulators must take into account not only their own ability to enforce and motivate acceptable levels of compliance but also opportunities for assisting or collaborating with the regulated industry so that all parties can transition more effectively to these regulations. For example, to promote the effectiveness of such regulations for use in high-hazard industries where regulatory impacts on catastrophic risk can be difficult to discern, regulators may work with industry to iden-

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tify, track, and analyze data on incident precursor events (e.g., near misses) and other conditions that may be indicative of catastrophic risk. Precursor or related data may not be sufficiently correlated to the risk of major incidents to aid in creating enforceable ends-based requirements. However, the data may help regulators monitor the effects of their regulatory interventions and inform operator self-assessments of their risk management programs.

The report concludes that too much emphasis is placed on simplistic and often misconstrued lists of generic advantages and disadvantages of different types of regulations. Claims about the advantages and disadvantages of regulatory types are too often anecdotal, and systematic empirical research into their applicability and effectiveness for different regulatory problems under different conditions is lacking. A safety regulator's interest in choosing among regulatory designs should be to select those best satisfying the regulator's overall policy criteria, which may include objectives such as efficiency, cost-effectiveness, or equity in addition to risk reduction. To further these objectives, the regulator will want to choose a design that is suited to the nature of the problem and the characteristics of the regulated industry, as well as the regulator's capacity to promote and enforce compliance. As the case studies in the report show, regulatory regimes often contain a mix of regulation design types, rather than a single type, to address the objectives underlying safety regulation. Regulators should therefore consider whether the best approach to the achievement of their regulatory goals may be to combine various regulatory approaches.

Finally, labels that are commonly given to regulatory types, such as "prescriptive" and "performance-based," are often used inconsistently in a confusing and misleading manner that complicates comparisons of regulatory tools and choices. Regulators, analysts, and researchers need clear concepts for regulatory designs. A systematic and commonly accepted regulatory design taxonomy, such as the one offered in this report, is needed to guide future research, analysis, and regulatory decision making.

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Introduction

This chapter identifies and provides background on issues that led to the request for this study, lays out the study charge, explains how the committee conducted its work in fulfillment of its charge, and describes the organization of the report.

CHALLENGE OF REGULATING SAFETY IN HIGH-HAZARD INDUSTRIES

Many government regulations are intended to ensure safety—for example, in the workplace; in consumer markets; and in the transportation, mining, and manufacturing sectors (see examples of federal safety programs in Table 1-1). Some regulations are aimed at preventing common harmful incidents, such as car crashes, food poisonings, oil and chemical leaks, and trips and falls on the job. Other regulations target incidents that occur much less frequently but that can lead to numerous deaths and injuries and severe environmental damage, such as airliner crashes, marine tanker spills, mine collapses, capsizings of ferries, and chemical plant explosions. Ascertaining the level of safety improvement caused by regulations intended to prevent the latter incidents can be difficult because changes in the risk of low-frequency, high-consequence events, which are rare to begin with, are seldom discernible from incident data, and other potentially relevant data on near misses may not be available (Carrigan and Coglianese 2012). Nevertheless, when a catastrophic event does occur, it is often followed by intense scrutiny of industry and government prevention efforts, including the design, content, and enforcement of safety regulations.

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TABLE 1-1 Examples of Federal Agencies Having Safety and Health Regulatory Responsibilities

Agency	Department	Safety and Health Regulatory Purview
Bureau of Safety and Environmental Enforcement	Interior	Offshore energy facilities
Consumer Product Safety Commission	Independent	Consumer products
Federal Aviation Administration	Transportation	Airports, aircraft, airlines, and air traffic operations
Federal Motor Carrier Safety Administration	Transportation	Commercial motor vehicle operations
Federal Railroad Administration	Transportation	Freight and passenger rail
Federal Transit Administration	Transportation	Public transportation
Food and Drug Administration	Health and Human Services	Food, drugs, medical devices, tobacco, and cosmetics
Food Safety and Inspection Service	Agriculture	Meat, poultry, and eggs
Mine Safety and Health Administration	Labor	Mines
National Highway Traffic Safety Administration	Transportation	Motor vehicles and motor vehicle equipment
Nuclear Regulatory Commission	Independent	Nuclear reactors, nuclear materials, and radioactive waste
Occupational Safety and Health Administration	Labor	Workplaces
Office of Air and Radiation, Office of Water, Office of Chemical Safety and Pollution Prevention, Office of Land and Emergency Management	U.S. Environmental Protection Agency	Air, water, radiation, chemical safety and pollution, and toxic and solid waste
Pipeline and Hazardous Materials Safety Administration	Transportation	Gas and hazardous liquid pipelines and hazardous cargoes
U.S. Coast Guard	Homeland Security	Maritime vessels, equipment, and operations

The April 2010 well blowout and explosion of the Deepwater Horizon drilling rig in the Gulf of Mexico is a prominent example. That high-consequence event prompted many questions about the design and implementation of a safety regulatory regime whose major purpose was to reduce the risk of such catastrophes. Until then, U.S. regulations governing offshore oil and gas development were presumed by many observers to be working well (TRB 2016, 2). Technological advances had enabled exploration and production in deeper waters and in higher-pressure, highertemperature reservoirs that were once too challenging to develop. In turn, offshore facilities, equipment, materials, and operations had become increasingly varied and complex. In a speech just weeks before the Deepwater Horizon disaster, President Barack Obama stated that technological advances had made offshore drilling significantly safer (Tumulty 2010). After the disaster, which caused the death of 11 workers and the release of millions of barrels of oil into the Gulf of Mexico, he announced the need for new steps to help "ensure that a catastrophe like this never happens again" (Tumulty 2010).

The response of the Obama administration included changes in how the industry is regulated. Investigations and inquiries that followed the Deepwater Horizon explosion had raised numerous concerns about the effectiveness of the country's offshore safety regulatory regime. Among the concerns was the high degree of specificity of the U.S. Department of the Interior's regulations, which were characterized as focusing too narrowly on individual risk factors as opposed to system-level risks that arise from interactions among technology and human operators (Deepwater Horizon Study Group 2011; National Academy of Engineering and National Research Council 2012; National Commission on the BP Deepwater Horizon Oil Spill and Offshore Drilling 2011). The design of the regulatory regime, through its reliance on a large collection of narrowly targeted commands, suggested that regulators could know most sources of risk and specify a safety intervention for each. However, the growth in diversity and complexity of the design and operations of offshore facilities had led to many facility- and operations-specific risks. The deficiencies of a highly specified regulatory approach appeared to be conceptually evident before the *Deep*water Horizon disaster, although they were not yet manifest in incident data.

¹ In the mid-1990s, the Minerals Management Service (MMS), which preceded the Bureau of Safety and Environmental Enforcement, began encouraging offshore operators to follow American Petroleum Institute Recommended Practice 75 for creating safety management programs. In 2006, the agency proposed a rule to require operators to institute a safety and environmental management systems program, described as "a comprehensive system to reduce human error and organizational failure." The rule was finalized in October 2010, about 6 months after the *Deepwater Horizon* blowout. It added to an earlier requirement, introduced

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Because of these concerns, the department created the Bureau of Safety and Environmental Enforcement (BSEE) to regulate the offshore sector and added requirements that each offshore operator establish a safety and environmental management system (SEMS) (BSEE 2010). The previous regulatory approach had been criticized for contributing to a "compliance mind-set" among offshore operators intent on meeting a "checklist" of narrowly prescribed actions (Bennear 2015; Deepwater Horizon Study Group 2011; NAE and NRC 2012). The SEMS rule was introduced to encourage operators to assume more direct responsibility for managing their sources of risk in a comprehensive manner "that looks beyond baseline compliance" (BSEE 2015, 8). For example, the rule requires that drilling operators act on their own to identify and assess all possible risks created by their operations and then to develop a plan to manage them. Such a plan might include specific steps, such as installation of safety equipment or routine monitoring of operations, as well as practices, such as documentation and record-keeping, to ensure that all the planned steps are taken. A specified process and time interval for reassessment of risks and updating of the operations plan would likely be part of an operator's SEMS.

The intent of such customized safety management systems is to prompt the executives, managers, and frontline workers of each operator to become vigilant, systematic, and deliberate in identifying and controlling all of their risks. System-level risks arising from the diverse, complex, and changing interactions among human operators, technology, and environmental and operating conditions, as discussed in Box 1-1, are among the risks targeted.

Calls for similar regulatory changes had been made after catastrophes in other industries. More than a decade before the *Deepwater Horizon* disaster, a series of major pipeline failures prompted the U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA)² to reassess its heavy reliance on regulations that prescribe specific interventions targeted to individual factors that can affect the incidence and severity of pipeline failures (Research and Special Programs Administration 1999). As BSEE would do later, PHMSA responded by adding a requirement that operators establish management systems. In this case, operators of large transmission systems were required to create programs for ensuring the integrity of pipelines whose releases could cause serious harm in locations defined as "high-consequence areas" because of their concentrations of people and natural resources (Research and Special

by MMS in 1998, for lessees of deepwater projects to submit an operations plan summarizing planned processes for identifying, evaluating, and reducing the risk of uncontrolled releases and other safety and environmental incidents.

² At the time, the U.S. Department of Transportation's Office of Pipeline Safety was administered by the Research and Special Programs Administration, whose pipeline and hazardous materials safety responsibilities were transferred to PHMSA when it was created in 2004.

Box 1-1 System-Level Risks

Interest in organizational safety planning and management programs is, in part, a response to a growing consensus that trivial, unplanned events occur all the time but occasionally can lead to disasters. Charles Perrow (1984) coined the term "normal accidents" to describe how ordinary, mundane, conventional, and routine (i.e., normal) features of complex technologies can lead to disasters. He argued that it is unrealistic to imagine that any system is immune to failure (Perrow 2007). In his now well-accepted account, accidents are a normal feature of complex technologies because, although exactly when and where failures will occur cannot be known, we can be confident that all systems are subject to some form of failure at some point in time.

"Nothing is perfect, neither designs, equipment, procedures, operators, supplies, or the environment. Because we know this, we load our complex systems with safety devices in the form of buffers, redundancies, circuit breakers, alarms, bells, and whistles. Small failures go on continuously in the system since nothing is perfect, but the safety devices and the cunning of designers, and the wit and experience of the operating personnel, cope with them. Occasionally, however, two or more failures, none of them devastating in themselves in isolation, come together in unexpected ways and defeat the safety devices. [This is] the definition of a 'normal accident' or system accident" (Perrow 1999, 356).

Technological and social systems can be analytically distinguished by variations along a continuum from linear to complex interactions among their components and by the looseness or tightness of the coupling among the component interactions. "If a system is tightly coupled," Perrow noted, what might appear to be minor component failures "can cascade faster than any safety device or operator can cope with them, or they can even be incomprehensible to those responsible for doing the coping. If the accident brings down a significant part of the system, and the system has catastrophic potential, we will have a catastrophe" (Perrow 1999, 357).

Programs Administration 2000). Today, nearly all pipeline operators must have integrity management programs.

By supplementing its long-standing "prescriptive" regulations in this manner, PHMSA sought to ensure that operators themselves would become more cognizant of and deliberate in controlling factors that can lead to pipeline failures, including those arising from system-level interactions. More recently, PHMSA has cooperated with the pipeline industry in developing guidance on the implementation of safety management systems similar to SEMS. The guidance is intended to support the development of more comprehensive systems to manage safety through integrity management as well as operating procedures, employee training, emergency preparedness,

failure investigations, and other means. However, in this case, use of the management guidance by pipeline operators remains voluntary.³

Whether BSEE's and PHMSA's embrace of a regulatory design that requires the application of such management tools has been effective in reducing the risk of incidents is difficult to ascertain. Discerning whether any of its regulations, regardless of design, are having the intended effect of reducing the risk of low-frequency, high-consequence events is a challenge for a regulator of a high-hazard industry. A lengthy period without a major incident may cause a regulator to believe its regulatory regime is having a positive effect in controlling risks that can lead to catastrophes when that may not be the case. Alternatively, the occurrence of a single catastrophe may create an understandable but potentially false perception that the regime has failed to manage risks effectively and may prompt calls for it to be overhauled or supplemented with alternative regulatory designs (Carrigan and Coglianese 2012).

Regulators of high-hazard industries must make regulatory design choices that they believe will be most effective and be able to explain the reasons for their choices to policy makers and the public, even when they cannot use incident trend data or other quantitative measures to justify those choices. To do so the regulator may need to make use of qualitative information that is suggestive of each design type's potential to reduce risks. For example, safety regulators may consider whether the sources of risk are well understood and predictable, common to most of the regulated firms, and capable of being managed with uniformly applied interventions. Under these circumstances, the regulator may favor a regulatory regime consisting of many highly focused requirements that target individual risks with specific means of control, as is characteristic of BSEE's and PHMSA's traditional regulations. Alternatively, if the nature of the problem is such that many risk factors arise from the diversity and complexity of the industry's facilities and operations, the regulator may conclude, as BSEE and PHMSA did, that a regime consisting of many specific regulatory commands will not be sufficient. In this case, the response may be to replace or supplement traditional forms of regulation with requirements for more customized management systems that compel operators to identify and manage their facility- and operations-specific risks and to build organizational cultures that address such risk in a more dynamic and holistic manner (see Box 1-2).

The nature of the problem that government intervention is intended to address is thus critical to decisions about regulatory design. However, such decisions also depend on other considerations, as BSEE's and PHMSA's experiences illustrate. An important factor is the prospects for compliance

 $^{^3}$ American Petroleum Institute Recommended Practice 1173 (http://www.api.org/~/media/files/publications/whats%20new/1173_e1%20pa.pdf).

Box 1-2 Organizational Safety Culture

The term "safety culture" was coined after the 1986 Chernobyl nuclear plant disaster. Since then it has been referenced in the media, scholarship, and organizational management both as an explanation for accidents and as a means for improving the safety of complex and tightly coupled technologies posing risks of major accidents (ACS 2012; Silbey 2009; TRB 2016).

The term has been adopted to refer to the ongoing processes that align what is important to an organization with how things actually work and what is routinely done (Weick 1987).

Three related concepts of culture are often mentioned in the literature on this topic: culture as a set of values and attitudes shared by organizational members that shape action; culture as the preferences and processes engineered into a complex system; and culture as the messages and meanings that are communicated, often unconsciously, through ongoing practices, habits, and language (i.e., what we do) (Silbey 2009).

This third concept of culture considers safety as a type of "organizational expertise" that is "situated in the system of ongoing practices" and "constituted, institutionalized, and continually redefined and renegotiated within the organizing processes through the interplay between action and reflexivity." Importantly, safety practices have "both explicit and tacit dimensions" (Gherardi and Nicolini 2000, 329). They are behavioral habits and routines and are also expressed through artifacts. They are both "material and mental and representational" (Gherardi and Nicolini 2000, 329). "Rather than a specific organization of roles and learning processes or measurable set of attitudes and beliefs," safety culture is understood as an aspirational goal to be achieved, however difficult and elusive, and "often only one of a number of competing organizational objectives" (Silbey 2009, 356). Thus, an organization may require employees to wear personal protective equipment for the safe handling of contaminants. Over time, the quality of that equipment may decline as available materials and designs improve and as knowledge of contamination increases. The purchase of new equipment may be viewed as too expensive relative to some other purchase. The weighing of costs and benefits itself may express different safety commitments, and the criterion of safety may shift as the knowledge of risk and available mitigations develops.

The effectiveness of implementing a safety culture depends on providing workers and managers with information about changing vulnerabilities and the means for addressing these vulnerabilities. It also depends on workers and managers continually revising approaches to work in efforts to remain sensitive to the possibility of failure and on their knowledge that they may be only partially aware of the possibilities for failure. A culture of safety depends on remaining dynamically, persistently engaged in self-assessments to avoid stale, narrow, or static representations of the dynamic and evolving paths to system failure. Management systems can offer tools for systematizing dynamic processes for self-assessment and responsive programming.

Safety culture, like any other type of culture, will vary across organizations. The existence of just one or even only a few models of a good safety culture is

continued

Box 1-2 Continued

unlikely, since a good safety culture expresses commitments to and is consonant with other local organizational norms and practices. If companies merge, the existence and interaction of different cultures may create a significant risk, which was part of the background of the Texas City refinery explosion (Baker Panel 2007).

with a given regulatory design. For example, if enough regulated firms lack the requisite resources and technical competencies to implement the requirements of a regulation—such as a rule that requires a small firm to develop and apply sophisticated risk assessment tools beyond its capacities—the regulator may need to search for regulatory designs that are more compatible with the industry's ability to comply. Similarly, a regulation with a design that is misaligned with the enforcement capacity of the regulator runs the risk of being ineffective if active enforcement is needed to ensure compliance—for example, if a small agency inspection staff is expected to verify that hundreds of firms are complying with numerous detailed requirements. Under these circumstances, the regulator may need to enhance its enforcement capacity or choose other regulatory designs that align better with its capacity.

BSEE and PHMSA have concluded that requirements for SEMS and integrity management programs are essential in controlling the risks in the industries they oversee. Both agencies have had to address compliance challenges arising from a regulatory design that gives operators flexibility to craft and execute their risk management programs. Each agency has done so in various ways, including initiatives to assist industry with compliance, modifications of traditional inspection programs, and changes in the structure and dictates of the regulations. Details are given later in this report. These initiatives, as both regulators have learned, can be difficult to implement. They require a commitment of resources and understanding from policy makers who may not appreciate the complexity of controlling catastrophic risks through regulation. Regulators must therefore articulate why they are committed to a particular regulatory approach, even though they may lack clear quantitative evidence of its safety benefits.

STUDY CHARGE

These examples from BSEE and PHMSA show that government agencies face important choices about how to regulate through different regulatory

designs. This study more closely examines these regulatory design choices and the factors that regulators must consider in making them, particularly when a major aim of the regulation is to prevent incidents in high-hazard industries. The study is intended to inform regulators of all high-hazard industries, including not only those involved in the production and transportation of oil and gas but also industries as diverse as the nuclear, chemical manufacturing, marine transportation, and mining sectors. Although the scale and scope of the safety threat may vary among these industries, their respective regulators face similar challenges in designing regulations that promise to reduce the occurrence of low-frequency, high-consequence events.

The study was sponsored by PHMSA's Office of Pipeline Safety, which was responsible for making the decision nearly 20 years ago to augment its long-standing set of highly detailed and targeted regulations with one mandating that pipeline operators establish integrity management programs. The decision was informed in part by experience in the United Kingdom and Norway. In those countries, regulators had supplemented their traditional regulatory regimes with requirements for oil and gas companies to establish customized safety management systems to control the diverse risks arising from the design and operation of their offshore facilities. PHMSA was persuaded that because many of the hazardous liquid and gas pipeline systems it oversees are similarly varied in their design, configuration, operations, and environmental setting, they too could benefit from a regulatory approach that emphasizes more context-specific risk management.

PHMSA's charge to the study committee is contained in the statement of task in Box 1-3. Informed by regulatory experience in the United States and abroad, the committee was expected to "identify possible opportunities for, and constraints on, making greater use of [performance-based safety regulation]" and "make recommendations about the application of this regulatory approach in high-hazard industries, such as off-shore oil and gas, pipelines, and other modes of transportation." As PHMSA officials explained to the committee, the purpose of the study was not to advise on when government regulation is needed to address a safety problem but rather to assess options for how to design a regulation once the decision to intervene has been made.

PHMSA has long referred to its integrity management regulations as "performance-based." As noted in the statement of task, this term has assumed multiple meanings. It is sometimes used in reference to regulations that require firms to achieve certain ends but without specifying the means of compliance. At other times it is used in reference to regulations that do not specify ends but require firms to apply management means while giving them flexibility in customizing those means to circumstances. PHMSA's integrity management regulation is an example of the latter design. Thus,

Box 1-3 Study Statement of Task

Many countries, including the United States, use forms of performance-based regulation to promote safety and reduce risk in high-hazard industries. The term "performance-based" is often used to refer to (a) standards that mandate outcomes and give firms flexibility in how to meet them, or (b) requirements for firms to use management systems consisting of internal plans and practices for promoting safety and reducing risk. Performance-based regulation is usually contrasted with "prescriptive" regulation—sometimes called specification, design, or technology standards—that requires firms to adopt specific means to promote safety and reduce risks. This study will compare the advantages and disadvantages of prescriptive- and performance-based forms of safety regulation and identify possible opportunities for, and constraints on, making greater use of the latter. The study will be informed by experiences of performance-based safety regulation in the United States and abroad and will make recommendations about the application of this regulatory approach in high-hazard industries, such as off-shore oil and gas, pipelines, and other modes of transportation.

the assumption can be made that the agency's decision to sponsor this study was motivated largely by an interest in obtaining a better understanding of the opportunities for and constraints on making greater use of this form of so-called "performance-based" regulation.

The study's scope is limited to examining the choices that safety regulators face in designing their regulations. Regulators face many other decisions that do not necessarily hinge on the choice of a regulatory design. Specific enforcement strategies are among the topics not examined in this report, even though the term "performance-based" is sometimes used in reference to the strategies that regulators pursue in enforcing their regulations. For example, a regulator may observe that a pipeline operator consistently meets all requirements for installing a corrosion control system or that a power plant consistently meets all limits on the emission of an air pollutant. A regulator may decide to subject firms with a record of consistent compliance to less intense enforcement activity (e.g., by reducing the reporting burden or the frequency of inspections made by regulatory personnel). This approach to enforcement is sometimes characterized as performance-based in the sense that it takes into account the performance of the regulated entity in complying with applicable regulatory commands (Coglianese and Nash 2014). However, an enforcement approach is different from, and independent of, the design of regulatory commands. As indicated by the two examples just given—a regulation prescribing means

(installation of a pipeline corrosion control system) and a regulation defining the outcome that must be achieved (keeping emissions below a certain level)—the same enforcement strategy could be applied to regulations with fundamentally different designs. Similar observations could be made about the application of "risk-based" strategies for enforcing regulations, because risk evaluations can be used to guide enforcement decisions about any type of regulatory design.

Another matter that is not addressed in this report is how safety regulators choose the objectives of their regulatory interventions, such as the desired level of risk reduction. Other National Academy of Sciences studies have addressed issues that deserve consideration by regulators when they are deciding on risk reduction approaches and objectives (Institute of Medicine 2009, 2013; National Research Council 1996). The risk reduction objective is an important choice, and the regulator may consider alternative criteria for making that choice, such as the precautionary principle, the concept of "as low as reasonably practicable" (ALARP), or efficiency and equity considerations. 4 However, regardless of the criterion used, a regulatory objective can be selected independently of regulatory design choices. For example, if the objective of a regulation is to reduce the risk of an activity by 50 percent or by 90 percent, the regulator in either case could prescribe the use of specific technologies expected to achieve the desired reduction level, or it could impose a mandatory performance standard and require that regulated entities achieve the desired reductions through any means they choose. The regulator can strive to bring about the risk reduction with either regulatory design, and there is no reason to believe that one design is inherently more effective than the other in delivering the specified risk reduction objective.

STUDY APPROACH

A committee consisting of experts in regulation, risk analysis, and the management of firms in high-hazard industries was appointed to conduct the study. To gain a better understanding of its charge, the committee commenced work by holding a series of information-gathering meetings to elicit

⁴ Precautionary principle: Minimize risk in a precautionary manner by limiting an activity whose suspected threats are not fully or well understood. ALARP: Reduce risks to the point where it is possible to demonstrate that the cost of reducing the risk further would be grossly disproportionate to the benefit gained. Efficiency: Reduce risks to the point where the marginal benefit equals the marginal cost. Equity: Reduce risks on the basis of fairness considerations, as instructed by Executive Order 12898, which directs U.S. federal agencies to identify and address the disproportionately high and adverse human health or environmental effects of their actions on minority and low-income populations to the greatest extent practicable and permitted by law.

a wide range of views from regulators and other knowledgeable sources. The meetings included briefings given by pipeline regulators at the U.S. federal and state levels and Canada's federal level, representatives from North American pipeline companies, offshore oil and gas regulators from the United States and countries in the North Sea region, and representatives from the offshore oil and gas industries in the United States and the North Sea region. Participants are acknowledged in the Preface.

The committee did not limit its information gathering to the pipeline and offshore sectors. It met with regulators and safety managers from several other sectors, including airline, railroad, and marine transportation; chemical manufacturing; and occupational health and safety. To further its understanding of regulatory implementation and evaluation processes, the committee met with experts on federal rulemaking and regulatory development and enforcement. Finally, the committee interviewed representatives from labor unions, whose members are directly affected by safety regulation, and heard from a local official of a coastal community with a keen interest in the safe performance of the offshore oil and gas industry.

The information-gathering meetings provided the committee with insight into how regulators, regulated firms, and others perceive and experience the design of safety regulations. Their perceptions and experiences varied widely—as did the terminology they used to describe regulations. The same regulations were alternatively described by different individuals as "risk-based," "goal-based," "principle-based," "management-based," and "performance-based." The term "prescriptive" was often used interchangeably to describe regulations that were also called "technical," "design-specific," or "technology-based." The terms "command-and-control" and "one-size-fits-all" were sometimes used as alternatives to the "prescriptive" label, almost always with negative connotations.

During these discussions, the inconsistent use of the term "performance-based" was especially confounding. As originally understood by most committee members, this term refers to regulations that specify a desired end or outcome. For example, a power plant may be required to limit sulfur emissions to a given level but not be told how to achieve that level. The power plant operator is thus afforded leeway to select the most suitable means of limiting emissions—by burning low-sulfur coal, installing scrubbers, or improving its energy conversion capacity, among others. This type of "performance-based" regulation is the antithesis of what most members of the committee understood to be the usual definition of a "prescriptive" regulation, under which the regulator mandates the use of a particular means of compliance. For example, the power plant operator may be required to use a particular emissions control technology such as a scrubber.

Although references to "prescriptive" regulations were often consistent with this usual definition, sometimes the term was used to refer to any type

of regulation that left regulated entities little room for flexibility. For example, regulations that are "performance-based" in the sense noted above were sometimes characterized as "prescriptive" when the required level of performance could be met by only one technology or course of action.

The committee also repeatedly heard the term "performance-based" used to describe regulations that require firms to establish management systems. As discussed above, PHMSA uses this label to refer to its requirement for the implementation of integrity management programs. BSEE also uses the term to describe its SEMS regulations (BSEE 2015, 8). The committee heard similar terminology in other high-hazard industries. A possible reason for calling such regulations "performance-based" is that they often give firms flexibility to formulate and execute the specific elements of their requisite management programs. Flexibility in the means of compliance is a hallmark of traditional performance-based regulations such as the sulfur emissions control regulation cited above (Bennear and Coglianese 2012). A fundamental difference is that regulations that require management programs are seldom accompanied by mandates that the programs achieve specified safety outcomes, such as keeping pipeline failures or offshore incidents below a defined frequency. Indeed, regulations that require management systems have been characterized in the literature as having more in common with "prescriptive" regulations, because of the fact that they *prescribe* the use of specific management actions to ensure safety (Coglianese and Lazer 2003).

The committee also surmises that the varied use of the term "performance-based" may be reflective of broader policy interest in performance. In recent decades there is perhaps no more common element of efforts to reform government policies and programs than the demand for accountability through the quantification of outputs and outcomes (Moynihan 2008). In the United States, this emphasis has taken different forms. Federal legislation such as the Government Performance and Results Act (GPRA) of 1993 and the GPRA Modernization Act of 2010 requires all public-sector recipients of federal funds to report and make use of performance data. Policy-specific reforms in areas such as welfare (e.g., Personal Responsibility and Work Opportunity Reconciliation Act of 1996) and education (e.g., No Child Left Behind Act of 2002 and Every Student Succeeds Act of 2016) encourage the use of performance measures.

Practices assumed to contribute to performance not only have been mandated by government but also have been embraced by professional groups whose members work in the public sector. The scope of interest has grown, and researchers have started to use the term "performance regimes" to describe "not just the practices of measuring and managing performance indicators but also to capture the embedded nature of these practices in almost all aspects of contemporary governance" (Moynihan et al. 2011,

141). In view of the political legitimacy ascribed to performance as a tool of governing, the likelihood of any proposed policy reform, including a new regulatory policy, being accepted is presumably higher when it is described as "performance-based."

However, a drawback of describing regulations that require management systems as "performance-based" is that the description implies that regulators are holding firms accountable for achieving specified safety outcomes, such as demonstrable reductions in the frequency of incidents. Indeed, at the outset of the study, many of the committee members were under the impression that regulations requiring safety management systems were called performance-based because they required certain safety outcomes. Others who briefed the committee held similar views, which turned out to be incorrect. Because of the inconsistent and sometimes confusing use of the term "performance-based," the committee recognized a need for greater conceptual clarity about types of regulatory designs. The committee realized that this study offered an opportunity to provide such conceptual clarity and that such clarity was crucial for conducting the study and for improving regulatory decision making. The committee, informed by the regulatory studies literature, thus developed and applied a conceptual framework for categorizing and comparing types of regulations according to their main design features. The framework, which is described in Chapter 2, is used throughout the remainder of this report.

While the conceptual framework can be applied to regulations from all fields, the committee was charged with providing advice specifically about the design of regulations to ensure safety in high-hazard industries, as informed by experiences in the United States and abroad. Accordingly, an important component of this study was the development of several detailed case studies of regulation of different high-hazard industries in the United States, Canada, and Europe. The four case studies that are provided—drawn from the regulation of the pipeline and offshore oil and gas sectors—are intended to illustrate the conceptual framework adopted by the committee and the array of implementation, compliance, and enforcement issues that accompany regulation design types applied in different high-hazard industries under different conditions. The case studies also offer insight into why some regulatory regimes have evolved as they have—for example, by relying to varying degrees on one or more regulatory design types. The case studies illuminate and enrich the committee's discussion of the key factors that safety regulators must consider in making choices about how to regulate.

In view of PHMSA's interest in "performance-based" regulations, which the committee interprets as regulations that require management programs, the report pays particular attention to the use of management-based regulations in high-hazard industries. The committee came to recognize the

special challenges that regulators of these industries face in identifying and designing regulations to control the many complex sources of risk and in determining whether their regulations are reducing the potential for major incidents. The observations and advice set forth in this report are thus offered in a constructive spirit. Their aim is to improve the ability of PHMSA and other regulators of high-hazard industries to make regulatory design choices suited to particular conditions and to explain these choices to policy makers and the public.

REPORT ORGANIZATION

The remainder of the report is organized into five chapters. Chapter 2 defines key terms used in the report and provides a conceptual framework for categorizing regulations into basic design types. The framework is based on a common nomenclature that can overcome the confusion described above when overlapping and normatively weighted terminology is used. The framework is then applied as a means of comparing designs to address different problems under different conditions. Chapter 3 illustrates this framework with examples of regulations from two different high-hazard industries—specifically the pipeline industries in the United States and Canada and the offshore oil and gas industries in the United States, the United Kingdom, and Norway. The framework could be applied in much the same way to understand the different types of regulatory designs used by other governmental entities in regulating other high-hazard industries.

On the basis of the conceptual framework and information gleaned from the literature and the case studies, Chapter 4 identifies factors for regulators to consider when they choose from among regulatory design types and structures. The discussion shows how commonly held views of the advantages and disadvantages of design types—whether characterized as "prescriptive," "performance-based," or something else—can be overly generalized and potentially misleading as a guide for making regulatory choices suited to particular problems and conditions. In response to the sponsor's interest in the use of regulations that require management programs to ensure safety in high-hazard industries, Chapter 5 more closely examines conditions that can affect the use of these regulations in this context. Chapter 6 contains a summary assessment of key observations emerging from this study and advice in support of better-informed regulatory decision making.

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Abbreviations

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BSEE Bureau of Safety and Environmental Enforcement

TRB Transportation Research Board

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2

Conceptual Framework for Regulatory Design

This chapter starts with definitions of several key terms used in this report, including a discussion of what constitutes "regulation," both broadly defined and in the narrower context of government safety regulation of high-hazard industries. Although the detailed structure of individual regulations can vary widely, this chapter offers a conceptual framework for distinguishing among four basic design types. The framework is founded on two key considerations: (a) whether a regulation commands the use of a *means* or the attainment or avoidance of some *ends* and (b) whether the command targets individual components of, or pathways to, a larger problem (*microlevel*) or directs attention to that larger problem itself (*macro-level*).

This chapter closes with a discussion of what are often viewed as the general advantages and disadvantages of regulations falling within each of the four basic design types from the conceptual framework. Claimed advantages and disadvantages are considered again later in the report, after design types have been reviewed in more detail and the circumstances in which the design types may be applied have been considered.

DEFINITIONS

Regulation can be construed narrowly in the context of the particular administrative processes of one agency or one country. It can also be construed more generically—as intended in this report—to avoid associations limited to the specific procedures of individual agencies and jurisdictions. Because the terms "regulation," "regulatory regime," "regulator," and "regulated entity" are used throughout this report, their intended mean-

ings deserve explanation. A "regulation," as construed in this report, is a binding command, not a voluntary guideline or statement of an aspiration or goal. Although regulations in their broadest sense can include the commands contained in standards developed by nongovernmental bodies, such as professional and industry trade associations that have sanctioning authority, legally binding regulations are those promulgated by governmental bodies (Sinclair 1997). Such regulations include commands found in statutes, rules issued by government agencies that administer statutes, and legal principles arising from court decisions.

By defining regulations as legally binding commands and by not focusing on the provenance of those commands, this report distinguishes an individual regulation from a final rule developed through the U.S. federal administrative rulemaking process. A final rule refers to a document promulgated by a federal agency and published in the *Federal Register*. A single published final rule can contain an entire suite of regulations (i.e., binding commands), each having a different design. The entire collection of regulatory commands that govern a particular industry or type of activity, whether in final rules, statutes, or court opinions, forms a "regulatory regime," which can comprise hundreds of regulations of different design types.

The "regulator" is the government entity that creates the command, monitors compliance, and dispenses the consequences for noncompliance; the term is used even when more than one such entity regulates a particular firm or industry. In conventional parlance, the term "regulator" is usually reserved for the administrative agencies to whom regulatory implementation and enforcement responsibilities are delegated; however, as already suggested, the regulator may also be the legislature or even the judiciary. The regulator's aim is to establish and enforce a command to bring about a socially desirable outcome that would not occur otherwise. The "regulated entity" is the individual or organization to which the command applies—that is, the party that has the legal obligation to comply and bears the consequences of noncompliance.

This report focuses on the design of regulations—that is, of legally binding commands. It does not examine the many factors that a regulator will wish to consider in devising specific strategies to facilitate and enforce compliance with its regulations. However, some examples of strategies are mentioned because a regulator's enforcement capabilities can be important in the choice of a regulatory design, as explained in this report. A regulator may use a single strategy or a combination of strategies to facilitate and enforce compliance. For example, it may require preapproval of activities

¹ The administrative rulemaking procedure of the U.S. federal government is discussed in more detail in Chapter 4.

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before they are allowed to commence (e.g., permits and licenses); actively inspect or audit regulated entities to motivate desired levels of compliance; or take a more reactive approach by responding to complaints or incident reports, in effect sanctioning violators after the fact in an effort to deter noncompliance in the future. Compliance may also be facilitated through features in the regulations themselves. Among such features are requirements for a regulated firm to provide information useful to the regulator's enforcement actions and disclosure of which may motivate the firm to pursue higher levels of compliance for fear of attracting unwanted public and marketplace attention to violations (Bennear and Olmstead 2008; Hindin and Silberman 2016).

Regulators often carry out other activities that may be considered instrumental to facilitating regulatory compliance and furthering the goals of the regime, such as educational and awareness campaigns, joint research with industry, data collection and analysis, and participation in third-party standard- and guideline-setting activities. Regulators sometimes advise on the use of such external standards or guidelines. How to design such voluntary guidance to encourage its use is of interest to regulators and the subject of research (Coglianese and Nash 2006). However, in accordance with the study charge, the subject of this report is the design of legally binding commands—government regulations—rather than voluntary programs, guidelines, and other nonbinding standards.

CONCEPTUAL FRAMEWORK

As discussed in Chapter 1, the existence of a variety of often ambiguous and sometimes misleading classifications of regulations has contributed to confusion about the choices available to regulators. The labels that others have used to describe regulation have focused on characteristics such as whether a regulation creates incentives for technological development and application, mandates data reporting, requires risk analysis, and specifies design parameters. Richards (2000) summarizes dozens of classification schemes in the literature, many of which contain different labels used to describe regulations that have fundamentally similar regulatory designs. The varied labels and taxonomies have often clouded, rather than clarified, the key dimensions of regulatory design and the choices confronting regulators when they select a design type.

Accordingly, this study required a common terminology and framework to make conceptual distinctions among regulations. The conceptual framework that is developed next in this chapter was derived from the scholarly literature on regulation and provides the basis for the nomenclature and organizing principles of the remainder of this report. The framework distinguishes between regulating specific means in a pathway of industrial activities and regulating the ends, or outcomes, of those activities. It further distinguishes between regulating components of a system (micro-level) and regulating the system as a whole (macro-level). This conceptual framework is applied throughout this report to describe and compare safety regulations used in high-hazard industries. Because regulations often carry vernacular labels, some of the more common labels are mapped to this report's typology of the four basic design types.

Means Versus Ends

A regulation can command that the regulated entity take or avoid an action, with the intention of furthering a regulatory goal or achieving an outcome related to that regulatory goal. "Means-based" regulation focuses on actions, such as the use of a technology or practice. For example, safety regulators may require firms to install a particular type of valve, retain certain documents, conduct certain observations or measurements, or inspect the condition of equipment at specified intervals. A required "means" in occupational safety regulation might be the installation of a hazard warning sign or the establishment of a worker hazard awareness training program.

Alternatively, a regulation can mandate the achievement or avoidance of certain ends. "Ends-based" regulation may require that a code-compliant building be capable of evacuating all occupants in a designated time, that a factory keep its emission of air pollutants below certain levels, or that an employer keep the workplace free of all identifiable hazards.

The commands in some regulations contain both means- and endsbased elements. For example, a regulation may require the use of protective equipment (means) that has passed approved testing standards for fire and impact resistance (ends).

Micro Versus Macro

A regulation—whether means-based or ends-based—can be distinguished along a second dimension relating to the regulation's focus or target. The regulation can be described as "micro-level" when it is targeted to a specific contributor or causal pathway to the ultimate problem that motivates regulation, or it can be described as "macro-level" when its focus is widened to the ultimate problem itself. Whether the regulation directs the attention of the regulated entity to the ultimate problem or to a causal pathway leading to that problem constitutes a crucial distinction in the types of obligations that the regulation imposes, as discussed in more detail in this report.

Micro-level regulations are more common because they are often bundled to address a problem. For example, the ultimate problem addressed by a traffic safety regulation is to reduce the harm caused by motor vehicle crashes. To achieve that purpose, the regulators will typically disaggregate the traffic safety problem into its component parts and issue regulations targeted to each part. The hundreds of Federal Motor Vehicle Safety Standards issued by the National Highway Traffic Safety Administration (NHTSA) require that automakers build cars with features providing various capabilities, such as exterior lighting, stability, braking, and occupant protection, that bear on a vehicle's crash potential and severity. These micro-level regulations are accompanied by many other government regulations, such as state requirements controlling driver qualifications and the wearing of seat belts, that affect the incidence and severity of motor vehicle crashes. In this regard, each individual traffic safety regulation is designed to target, almost in isolation, one of the many factors in the causal pathways or network leading to the ultimate problem of traffic fatalities and injuries.

In contrast to targeting intervention at a micro-level, a regulation can be designed to draw the regulated entity's attention to the ultimate problem that motivates government intervention. For example, NHTSA also has responsibility for establishing regulations to increase motor vehicle fuel economy. To achieve this purpose, NHTSA's regulations do not target the many individual attributes of a vehicle that can affect fuel economy, such as its weight, engine displacement, or aerodynamics.² Instead, the regulations require automakers to achieve a specified average fleetwide fuel economy level. In this way, NHTSA's fuel economy regulations impose obligations that directly target the ultimate goal while allowing automakers to adjust fleet mix and vehicle attributes as they see fit. Macro-level regulations like these are not directed at means or ends related to individual causal factors leading to an ultimate problem; they impose means- or ends-based obligations that focus directly on that ultimate problem itself.

Distinguishing Regulatory Designs

Whether the target of a regulation is focused at a point distant from (microlevel) or closer to (macro-level) the ultimate regulatory problem can have implications for the number of regulations that are needed, the knowledge a regulator must possess about the causes of the problem, and the ability of the regulator to monitor and verify compliance. Whether the regulatory command is means- or ends-based can also have important implications for the ability of the regulated entity to innovate and find lower-cost ways to comply as well as for the enforcement burden of the regulator. Because such implications need to be considered by regulators when they decide on

² To ensure that its regulations can be reasonably met by automobile manufacturers and suppliers and to further industry compliance, NHTSA does support research and technology activities that concern many of these specific vehicle attributes.

a regulatory design, a conceptual framework that differentiates regulations according to these basic design features can be a valuable decision-making tool.

Table 2-1 illustrates the relevance of these distinctions by mapping some example regulatory commands to the four regulatory design types that follow from the conceptual framework of this report. The terms used to describe the four design types—micro-means, micro-ends, macro-means, and macro-ends—are not currently part of the common parlance of safety or regulatory professionals. They are used in this report because they capture more precisely and accurately the underlying differences that most professionals have in mind in discussing regulatory designs.

The terms used in common parlance are often imprecise, inconsistent, or overlapping. Some are normatively loaded as well. What this report calls "micro-means" regulation, for example, is often referred to as "prescriptive" regulation, which often carries a negative connotation. What this report calls "micro-ends" regulation is often referred to as "performance-based" regulation, which, as noted in Chapter 1, can carry a more positive connotation.

Furthermore, some regulatory professionals use "performance-based regulation" to refer to what this report calls "macro-means" regulations—that is, to requirements that firms adopt certain management programs and

TABLE 2-1 Four Basic Types of Regulations with Examples

	Means	Ends
Micro	Micro-Means Install a hazard warning sign having a certain color scheme Install a particular type of valve Inspect the condition of equipment at a defined time interval Construct a pipeline by using a specified grade of steel	Micro-Ends Ensure that an electrical component of a product passes a test for shock resistance Limit sulfur dioxide emissions to certain levels Demonstrate the capability to evacuate all occupants from a building in a designated time
Macro	 Macro-Means Engage in threat and risk analysis Establish and execute a safety management program Reevaluate and revise safety management plan at regular intervals 	 Macro-Ends Keep the workplace free from recognized hazards Design and maintain a facility to prevent releases of hazardous substances Avoid a transportation accident

SOURCE: Adapted from Coglianese 2010.

risk analysis activities. Yet such macro-means regulations are "prescriptive" in that they require firms to take certain actions (i.e., in ordinary language, they *prescribe* actions). Those actions are intended to cause a firm's managers to identify strategies for achieving the end state reflected in the regulator's ultimate outcome of concern (Bardach and Kagan 1982; Coglianese and Lazer 2003; Huising and Silbey 2011).

Macro-means regulations do not require firms to adopt specific risk reduction technologies or practices or even to achieve specific limits on risk levels or other measures of safety performance. Thus, this type of regulation gives firms flexibility in choosing their micro-level behavioral routines and technologies. However, macro-means regulations do not allow the substitution of some other type of action; they literally tell firms how to manage themselves. The regulations mandate that firms' managers study their operations comprehensively and develop strategies suited to mitigating the risks they identify (Coglianese 2010). Often, this type of regulation imposes on firms the obligation to "plan-do-act-check" with respect to addressing a problem (Coglianese 2010). The regulations usually define the basic elements of a compliant management system. For example, firms may be expected to conduct an internal risk analysis; identify and evaluate risk control options; implement preferred controls; prepare a written plan for communicating safety-related work rules and ensuring they are understood and observed; and establish procedures supporting manager and worker training, documentation, and compliance monitoring (Silbey and Agrawal 2011). In addition, the regulations may require periodic program audits and feedback mechanisms to support efforts to improve the firm's management (Chinander et al. 1998; Coglianese and Lazer 2003; Kunreuther et al. 2002).

The legal commands in the cell in Table 2-1 labeled "macro-ends" deserve mention because they do not bring to mind regulations in the classic sense. That is because they have not been operationalized into any specific proactive and narrowly defined obligations designed to prevent the occurrence of the ultimate problem. However, the imposition of liability or penalties if such a problem does occur brings about a type of regulatory obligation. A good example of a macro-ends command is a general duty provision in a statute or regulation, such as the Occupational Safety and Health Act's requirement that employers ensure that their workplaces "are free from recognized hazards that are causing or likely to cause death or serious physical harm to . . . employees." Other examples are the liability provisions contained in the Oil Pollution Act and the Clean Water Act,

³ Occupational Safety and Health Act Section 5(a)(1).

which impose financial consequences on offshore oil and gas operators for oil spills.⁴

By imposing liability or penalties when problems arise, macro-ends commands can create incentives that operate behaviorally in a manner similar to traditional, ex ante regulation (Kolstad et al. 1990). For example, a commonly observed safety practice is the placement by building maintenance personnel of small warning signs notifying passersby of wet floors, a practice that is intended to prevent someone from slipping. When macroends commands result in such behaviors, they can, in practice, yield results similar to what other types of means-based regulation might produce.

NOMENCLATURE MAPPED TO COMMON REGULATORY LABELS

As noted earlier, Richards' (2000) review of the scholarly literature identified a wide range of labels used to describe different types of regulations. The ambiguity and diversity of existing labels led the committee to refrain from trying to identify and map existing labels definitively to the four cells in Table 2-1. However, for readers with an interest in knowing where some common labels used to describe regulatory designs might fit into the organizing scheme of this report, a loosely matched list is provided in Table 2-2. In the sections of this report that follow, these more common labels are sometimes provided in parentheses next to the four regulatory design terms simply to remind the reader of the types of regulations being discussed.

How some frequently mentioned types of regulation fit into the four cells of Tables 2-1 and 2-2 may not be immediately obvious. For example, "market-based" regulations—such as permit trading regimes, cap-and-trade systems, and emissions taxes (Schmalensee and Stavins 2017; Tietenberg 2006)—are actually just a type of micro-ends regulation. Micro-ends regulations often require each regulated entity to achieve the same outputs, but with market-based regulation, outputs can vary across regulated entities. A market-based emissions tax imposes an obligation to pay a tax on outputs measured on a per unit (marginal) basis. This is a micro-ends regulation under which the "penalties" for producing emissions are meted out marginally and called a tax instead of a penalty. Under a cap-and-trade or emissions trading scheme, just as with an emissions tax, the performance of regulated facilities can vary. With emissions trading, the particular micro-ends obligation that each firm must meet will simply depend on the quantity of tradable permits it holds.

So-called "information disclosure regulation" is another example of a type of regulation that might at first appear to be difficult to place in one of the four cells in Tables 2-1 and 2-2. The reason lies in the different purposes

⁴ Clean Air Act Section 112(r)(1).

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TABLE 2-2 Map of Common Regulation Descriptors to Conceptual Framework

	Means	Ends
Micro	Micro-Means Prescriptive regulation Design standards Technology-based regulation Specification standards	Micro-Ends • Performance-based regulation • Output-based regulation • Market-based regulation
Macro	 Macro-Means Management-based regulation Performance-based regulation System regulation Goal-based regulation Safety case regulation Enforced self-regulation 	 Macro-Ends Tort and ex post liability General duty provisions Outcome-based regulation

SOURCE: Adapted from Coglianese 2010.

behind the information generation and reporting that are required (Fung et al. 2007; Hamilton 2005; Kleindorfer and Orts 1998; Sunstein 1999). The cell in Table 2-1 into which information disclosure requirements fit will depend on their purpose. When information disclosure is intended as a means to a desired end state, such as an informed consumer, it can be characterized as micro-means. If the purpose of information disclosure is to increase the regulated entity's awareness of its contribution to the ultimate problem—and thus to prompt it to address that problem⁵—the requirement can be characterized as macro-means.

ADVANTAGES AND DISADVANTAGES COMMONLY ASSOCIATED WITH REGULATION DESIGN TYPES

These examples of the different terms used to describe regulatory designs indicate how much variation can exist across individual regulations even though they can be grouped generally into four main design types. Regulations can vary still further within each design type, not just across the four main types. In other words, not all micro-means regulations are the same; not all macro-means regulations are the same; and so forth. Differences in how regulations falling within the same category in Table 2-1 are structured and in the exact legal duties they impose can affect what a regulation

⁵ Thaler and Sunstein (2009, 191) have considered certain environmental information disclosure requirements to constitute what they call a "social nudge," because disclosure of pollution can serve as a means of informing community members, who in turn put pressure on firms' managers to improve performance.

achieves and what costs or other adverse effects it produces. In Chapter 4, a more detailed discussion of the various ways that regulations of the four basic design types can be structured is provided.

Implications follow from distinguishing the four main types of regulatory designs. Each of the four types is associated with what are generally considered to be different advantages and disadvantages, which can be useful as a starting point in deciding which regulatory design would best be used in a particular case. A clear understanding of the differences between the four main design types is essential in selecting and justifying the design type most suitable for solving a given problem.

Micro-means regulations (which, as noted, are often called "prescriptive") provide clear instructions about actions that must be taken by the regulated party, which can be easily monitored to verify compliance. However, these regulations are further removed from the ultimate health, safety, and environmental concerns that motivate government intervention. They offer little flexibility (short of waiver or revocation) for the regulated industry in responding to the regulation, even if better means are or may become available.

Micro-ends regulations (which are often called "performance-based") have the advantage of being closer to the ultimate health, safety, or environmental concern of the regulator. For example, setting standards with regard to oil concentration in emissions from offshore oil platforms is closer to the end (prevent damage to the offshore environment) than is requiring a specific water—oil separation technology. Micro-ends regulations also allow more flexibility by the regulated industry in meeting the regulation. However, such regulations can carry disadvantages; in some contexts a firm's attainment of the required ends can be difficult to monitor. For example, an ends-based mandate to reduce emissions can require investments in monitoring, testing, and modeling technologies that are costly or that may be insufficiently reliable for verifying compliance.

Macro-means regulations (which are often called "management-based") have the advantage of providing flexibility for the regulated entity with regard to operational actions to undertake, technologies to use, or plans to be formulated by management. They can be easier for the regulator to develop than a collection of highly targeted, micro-means regulations. They can be used when outcomes are difficult to measure directly. Such regulations may also infuse a greater sense of responsibility and accountability (i.e., safety culture) into the regulated firms. Among their disadvantages may be the limitations of regulatory agencies in monitoring and enforcing them if the agencies lack the expertise to review firm-specific management plans and the execution of those plans. Comparable limitations may exist among firms, especially smaller ones, which may need to hire personnel with new skills (or train existing personnel) to conduct risk analyses, design

and implement complex management systems, and monitor management plans and their execution.

Macro-ends regulations (such as tort liability and "general duty" provisions) have the advantage of focusing directly on the ultimate ends. However, such ex post liability and penalties may not always be viewed as adequate for spurring efforts to achieve those ends. For example, in the safety context, firms may underestimate their liability because they believe that incidents will not occur, because bankruptcy and insurance protections limit their liability as a practical matter, or because the benefits of misconduct may exceed the ultimate penalties (Bennear 2012; Manski 2004; Manski and Molinari 2010). Furthermore, in cases where the harm created by noncompliance can be catastrophic, ex post liability and penalty determinations can be complicated and unacceptable as the exclusive means of regulatory control.

These claimed general advantages and disadvantages are discussed in more detail in Chapter 4, where they are also considered in the context of structural differences in regulations as well as differences in the nature of regulatory problems, variation in regulators' capabilities, and differences in firms' characteristics. The asserted generic advantages and disadvantages were raised here to show that much can be at stake when a regulator, confronting a specific safety challenge in a high-hazard industry, must choose between different regulatory designs. Chapter 3 considers case studies showing how, in multiple countries, the four main regulation design types are used in different ways, and in combination with one another, to regulate high-hazard industries.

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3

Applications of the Conceptual Framework: Case Studies from the Pipeline and Offshore Oil and Gas Sectors

To illustrate the regulatory design concepts from Chapter 2 with examples from high-hazard industries, this chapter contains four case studies. The first two review the pipeline regulatory regimes in the United States and Canada. The second two, from the offshore oil and gas sector, contrast the offshore regulatory regime in the United States with the regimes of the United Kingdom and Norway in combination.

The four case studies are structured similarly. Before the individual U.S. and Canadian regimes for pipelines are examined, background is provided on the general structure, features, and operations of the pipeline industry in North America and the public safety interest that motivates its regulation. A similar structure is followed for the offshore sector. A general survey of the offshore oil and gas industry is provided, and then the U.S., UK, and Norwegian regulatory regimes are reviewed.

In each case, consideration is given to the following:

- Number, size, and geographic scope of the regulated firms; the complexity of their operations; and characteristics of their workforces where appropriate;
- Government agencies responsible for administering the regulations, including their budgetary resources and staffing levels and competencies;

- Types of regulations that make up the regimes on the basis of the conceptual framework discussed in Chapter 2;¹
- Challenges regulators and regulated firms face in implementing, enforcing, and complying with the regulations; and
- Challenges associated with assessing the effectiveness of the regulations in preventing catastrophic incidents.

In addition to providing real-world examples of the various types of regulatory design, the case studies help illuminate the next chapter's discussion of the factors regulators and policy makers must consider in making regulatory design choices. Among them are the characteristics of the industry and activities being regulated, the resources and competencies of the regulatory agency, and the broader policy and legal environment. The case studies are offered for these illustrative purposes, with no preconceptions about, or intention to assess, the safety performance of the two industries or relative effectiveness of the five regulatory regimes.

The case studies were developed by reviewing specific regulations and industry and government documents. Chapters 4 and 5 draw on the broader scholarly literature to explain regulatory design choices by using examples from the case studies. Additional insights for the case studies were obtained from meetings with representatives from regulatory agencies and industry, including pipeline operators, drilling contractors, and oil and gas producers. The case studies of the offshore sector, whose operations are more labor-intensive than those of pipelines, were further informed by briefings from labor union representatives. Offshore workers in the United Kingdom and Norway have formal roles in the development, review, and implementation of safety regulations. The committee met with union officials from these countries to elicit worker views on the regulatory approaches. The committee would have valued the opportunity to have surveyed or met firsthand with workers, unionized and nonunionized, from a wide range of offshore professions; however, such means of access were impractical given the committee's resources.

Offshore workers in the United States are not unionized. Thus, information on worker views of safety regulation could not be obtained directly. Nevertheless, the committee met with an official from a U.S. union representing workers in petrochemical industries. He conveyed his understanding of how safety management programs work in these industries and how workers view them. The committee also invited briefings from

¹ The case studies focus on micro-level and macro-means regulations and provide little information on the use of macro-ends regulations. However, all of the countries examined have such regulations, mainly in the form of liability regimes. For more information on these liability regimes, see Bennear (2015) and BIO by Deloitte and Stevens and Bolton (2014).

environmental interest groups from the North Sea region. Although these efforts were unsuccessful, a local official from a North Sea coastal community offered his views on the functioning and performance of the region's offshore regulations. These individuals and the many others who informed the case studies are acknowledged in the Preface.

PIPELINE SAFETY REGULATION IN THE UNITED STATES AND CANADA

The pipeline industries in the United States and Canada share many characteristics, and regulation in both countries is intended to promote safety. These topics are discussed next. That discussion is followed by an examination of the regulated firms, the regulatory agencies, and the regulatory regimes of each of the two countries. Many pipelines cross the U.S.—Canadian border, and the two countries have many similar regulatory requirements. Nevertheless, the regulatory regimes differ in some important respects, as explained in the case studies.

General Characteristics of the North American Pipeline Industry

A vast network of pipelines transports most of the natural gas and hazardous liquids, including crude oil and refined petroleum, shipped within the United States and Canada. As shown in Figure 3-1, the network consists of several system types that vary in size, physical properties, and use characteristics. Field and gathering pipelines are at the front end of the transportation process. They carry raw gas and crude oil short distances from production fields to processing and storage facilities. Their diameter and pressure profiles can vary considerably. Most gathering systems consist of smaller-diameter pipes (<6 inches) that operate under low to moderate pressure [<400 pounds per square inch (psi)]. However, some gathering lines can be much larger, especially when they are used to transport natural gas from fields to processing plants.

Further downstream, transmission pipelines transport the processed gas and crude oil longer distances. Their high-pressure (400 to 1,400 psi), large-diameter (≥6 inches) lines can span several thousand miles. They connect to other transmission systems and storage hubs or terminate at refineries, chemical plants, and utilities. Transmission pipelines also carry gasoline, diesel, and other refined petroleum products from refineries to distribution centers.²

Most natural gas is transferred from transmission pipelines to local distribution systems for delivery to homes and businesses. Distribution

² Some systems transport propane gas rather than natural gas.

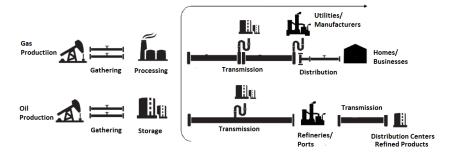


FIGURE 3-1 Types of hazardous liquid and gas pipeline systems.

NOTES: Flow lines, which carry wastewater or "produced" water to injection wells after separation of the water from the oil and gas, are not shown. Flow lines are subject to varying degrees of regulation but are not discussed further in this report. SOURCE: National Energy Board.

pipelines typically consist of a series of high-capacity steel mainlines that feed a grid of smaller-diameter (≤6 inches), low-pressure (≤100 psi) metal and plastic service lines connected to metered customers.

Gathering, transmission, and distribution pipeline systems differ in many respects, both within and across system types. Gathering lines are usually owned by the gas and oil producers, whereas transmission pipelines are usually owned by energy transportation companies that are paid to move the shipments of others. The operators of the largest transmission networks employ hundreds of engineers and technicians for system control, operations, maintenance, and surveillance. Their systems are configured with pump or compressor stations positioned every 20 to 80 miles and SCADA³ systems for remotely controlling flow and monitoring lines for leaks. A single transmission company may operate a network of lines and storage centers. However, some transmission lines are not part of networks. For example, a company may operate a single line that connects an oil storage depot to a refinery less than 100 miles away.

The variation in size and scope of natural gas distribution systems is even greater than that of transmission systems. On one end of the distribution spectrum are large utilities that serve millions of customers in multiple communities. Their systems consist of hundreds of thousands of miles of pipeline, which are monitored and controlled by SCADA systems. They employ hundreds of engineers and technicians. On the other end are numerous gas distribution systems owned by individual municipalities and

³ Supervisory control and data acquisition.

cooperatives. Many serve fewer than 10,000 customers, perhaps only a few hundred. The small municipal distribution systems seldom have SCADA systems and have few technicians and engineers on staff. The diversity within the gas distribution industry creates distinctive regulatory design and enforcement challenges.

Transmission and distribution systems both can vary widely in design, configuration, materials, and construction methods. These characteristics reflect the state of practice and the level of technology of the period in which they were installed, along with other factors. For example, some older transmission pipelines cannot accommodate in-line cleaning and inspection devices known as "pigs" because their pipe geometries are incompatible. Some older gas distribution systems, which can date to the early 1900s, still contain iron pipe. The various pipe materials and fabrication methods, welding techniques, and external coatings used over the course of decades have thus led to systems requiring different condition monitoring, maintenance, and repair practices.

In addition, pipeline systems are located in a wide range of environments that expose them to different soil chemistries; moisture levels; temperature extremes; and risks from natural hazards such as floods, earthquakes, and landslides. They span urban, suburban, and rural settings and have exposure to environmentally sensitive areas as well as to concentrations of people and activities such as farming and excavation that risk third-party damage. A single pipeline can span many natural and human settings; this is even more so for a large network of pipelines.

Pipelines also differ in the products they transport, especially in the case of hazardous liquid pipelines. For example, crude oil can differ in chemistry and in levels of density, viscosity, water, and sediment. These characteristics can affect operating, maintenance, and integrity management practices, such as pressure settings, cleaning frequencies, and the injection of chemicals for corrosion and flow control. The intensity of pipeline use can also influence these procedures. A pipeline that is underutilized or idle for periods because of low or no flow may need to be monitored more closely for internal corrosion caused by oxygen ingress, water, and deposits of sediment during those periods. Gathering lines that carry raw gas and crude oil from well sites can have high levels of water and other contaminants such as salt, carbon dioxide, and sediment. The levels depend on the production source and whether extracted product is treated near the field.

The variability in pipeline physical properties, use patterns, operating conditions, and environmental exposures means that operators must take into account many context- and system-specific factors when they choose pipeline design and construction methods and operating, maintenance, and repair procedures. Some of these choices will be highly tailored or unique, while others will be more uniform and standardized. Because there are

hundreds of thousands of miles of pipeline, multiple operators often face many of the same conditions and circumstances. Standards for practice and technology application have thus been developed for universal or common use. For example, call-before-you-dig systems can control many of the risk factors associated with third-party damage, regardless of whether the pipeline is in an urban or rural setting; cathodic protection can control many of the risk factors associated with external corrosion, regardless of whether the pipeline is coated or uncoated; and vigilance in keeping water and sediment levels below certain thresholds can help prevent internal corrosion, regardless of whether the system has older or newer steel pipes.

Public Safety Interest of Regulation

Pipelines can fail to contain their product for many reasons. Among them are violent ruptures, cracks, and small breaches caused by time-dependent mechanisms (such as corrosion and stress cracking) and by singular events (such as an excavation strike or a flood). Society has an interest in preventing such failures to protect lives and property; minimize harm to wildlife and wildlife habitats; and avoid contamination of air, water, and soil.

The United States averaged 280 pipeline failures resulting in fatalities, injuries, fire, explosion, loss of property, or environmental damage above a reporting threshold per year from 2006 to 2015. Most reported failures involved slow leaks, as opposed to sudden ruptures. From 2006 to 2015, the United States averaged 33 pipelines failures per year that resulted in deaths or injuries requiring hospitalization. Some resulted from ruptures.⁴

Ruptures can have catastrophic consequences. The 2011 rupture of a corroded gas distribution main in Allentown, Pennsylvania, killed 5 people, damaged 50 buildings, and caused the evacuation of 500 people. The 2010 rupture of a natural gas transmission line in San Bruno, California, caused an explosion that killed 8 people and damaged more than 100 homes. Releases from gathering and transmission lines that do not result in fires and explosions can also be harmful to the environment, especially when lines pass through or near environmentally sensitive areas. For example, the release of more than 800,000 gallons of crude oil from a ruptured transmission pipeline in Marshall, Michigan, into a tributary of the Kalamazoo River resulted in the country's most expensive onshore oil spill cleanup.

⁴ See Figure 1, https://fas.org/sgp/crs/misc/R44201.pdf.

⁵ See https://www.phmsa.dot.gov/PHMSA/Key_Audiences/Pipeline_Safety_Community/Safety_Awareness_and_Outreach/Pipeline_Incidents/UGI_Utilities_Pipeline_Leak_in_Allentown,_PA,Pipeline.

⁶ See https://www.ntsb.gov/investigations/AccidentReports/Reports/PAR1101.pdf.

⁷ See https://www.ntsb.gov/investigations/AccidentReports/Reports/PAR1201.pdf.

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TABLE 3-1 Length of Hazardous Liquid and Natural Gas Gathering, Transmission, and Distribution Pipelines in the United States, 2014

	Length (miles)
Gas and oil gathering	240,000
Hazardous liquid (oil and refined products) transmission	199,642
Gas transmission	301,816
Gas distribution	2,168,835
Total	2,910,293

SOURCES: Gathering Pipelines: Frequently Asked Questions (https://www.phmsa.dot.gov/portal/site/PHMSA/menuitem.6f23687cf7b00b0f22e4c6962d9c8789/?vgnextoid=4351fd1a 874c6310VgnVCM1000001ecb7898RCRD&vgnextchannel=f7280665b91ac010VgnVCM 1000008049a8c0RCRD&vgnextfmt=print#QA_0); Pipeline Safety: Department of Transportation Needs to Complete Regulatory, Data, and Guidance Efforts (http://www.gao.gov/assets/680/672809.pdf).

Case 1: U.S. Pipeline Safety Regulation

The United States has about 200,000 miles of hazardous liquid transmission pipelines, 300,000 miles of gas transmission pipelines, 240,000 miles of oil and gas gathering pipelines, and 2.2 million miles of gas distribution pipelines (see Table 3-1). The federal government establishes minimum safety regulations that apply to all pipelines, but states are allowed to regulate intrastate pipelines as long as their programs are certified by the federal government. States cannot establish regulations for intrastate systems that are weaker than or incompatible with the federal requirements, but they can adopt more stringent requirements.

Most states have opted to regulate their intrastate gas transmission and distribution systems by imposing requirements that are compatible with and sometimes more stringent than those imposed at the federal level.⁸ Only about one-third of states have sought certification to regulate intrastate hazardous liquid transmission pipelines, and therefore responsibility for regulating these systems and enforcing compliance rests largely with the federal government.⁹ More than 90 percent of the country's 240,000

⁸ Except for Alaska and Hawaii, all states, as well as Washington, D.C., and Puerto Rico, participate in the program (http://www.napsr.org/About-NAPSR).

⁹ See http://pstrust.org/wp-content/uploads/2015/09/2015-PST-Briefing-Paper-14-Jurisdictional-Issues.pdf.

miles of oil and gas gathering pipeline are exempt from federal regulation, although some systems are regulated by states. 10

The Regulated Industry

Pipeline companies that must comply with government safety regulations are large in number and operate systems that vary widely in scope. About 600 companies own hazardous liquid pipelines.¹¹ The dozen largest operate lines throughout the country; some of them operate lines in Canada as well. However, about 80 percent of hazardous liquid pipeline operators own less than 200 miles of pipeline.

About 1,800 companies operate gas pipelines. About two dozen of them own more than 1,000 miles of transmission pipeline and account for 80 percent of all gas transmission pipeline mileage. However, most gas pipeline operators are local utilities. The United States has about 1,500 gas distribution systems, most of which are operated by utilities. About 120 of these systems serve more than 1 million customers, and about 600 serve fewer than 1,000. Most have between 1,000 and 10,000 customers. About two-thirds of all gas distribution systems are municipally owned, including most of the smaller systems. For example, of the 94 gas distribution systems in Indiana, only three have more than 30,000 customers. The small operators seldom have SCADA systems, control rooms, or even compressors, and these operators average fewer than two dozen employees, most of whom are technicians and administrative personnel.

The Regulators

Pipelines are regulated at the federal and states levels in the United States. The U.S. Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) administers the federal regulations. State regulations are usually administered by public utility commissions. The federal government sets the minimum safety standards for all pipelines but depends on states with approved programs for oversight and enforcement

 $^{^{10}}$ See https://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Pipeline/Technical%20 Advisory%20Committees/Tab%207b%20-%20Briefing%20-%20TPSSC%20Gas%20 Gathering%20Lines%20-%20Dewitt.pdf.

¹¹ See http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/110404%20 Action%20Plan%20Executive%20Version%20_2.pdf.

¹² See https://www.eia.gov/pub/oil_gas/natural_gas/analysis_publications/ngpipeline/MajorInterstatesTable.html.

 $^{^{13}}$ See 2014 PHMSA Distribution Annual Report Data (http://www.phmsa.dot.gov/pipeline/library/data-stats/distribution-transmission-and-gathering-lng-and-liquid-annual-data).

¹⁴ See http://onlinepubs.trb.org/onlinepubs/pbr/Allen071216.pdf.

of intrastate pipeline systems in particular. Without this state role, PHMSA would be responsible for ensuring that all systems, including the thousands of natural gas utilities, comply with the applicable federal regulations.

PHMSA's Office of Pipeline Safety (OPS) administers the federal pipeline safety program. In this capacity, it establishes the regulatory agenda, administers an enforcement program, provides technical assistance to state pipeline safety programs, sponsors safety-related research, investigates incidents, and collects and analyzes reports on releases. OPS is funded by user fees assessed on each regulated transmission pipeline operator on a per mile basis. For fiscal year 2016, OPS's total budget was approximately \$150 million, an increase of about 40 percent since 2010. 16

In 2016, OPS had a staff of about 270, approximately half of whom were inspectors.¹⁷ According to the Congressional Research Service, annual PHMSA budget requests have indicated an OPS staffing shortfall averaging about 25 employees per year from 2000 to 2016, with most of the gap occurring among inspector positions.¹⁸ PHMSA has reported that its ability to recruit inspectors with the array of engineering competencies it needs to enforce all of its regulations has been hampered because of competition with the higher-paying private industry.¹⁹

PHMSA estimates that about 80 percent of all pipeline inspections are conducted by state personnel.²⁰ A reason for this large state enforcement role is that some states not only inspect intrastate gas distribution and transmission pipelines for compliance with federal and state regulations but have also been delegated authority by PHMSA to inspect interstate transmission pipelines. Approximately 400 state personnel are authorized to inspect interstate systems. PHMSA reimburses states for up to 80 percent of their total pipeline safety program expenditures.²¹ The scope of a state regulator's activity is illustrated again by Indiana, whose public utility commission inspects the facilities of 94 gas distribution systems, 15 intrastate gas transmission systems, and more than three dozen master meter operators.²²

¹⁵ See https://www.phmsa.dot.gov/org/office-of-pipeline-safety.

¹⁶ See https://fas.org/sgp/crs/misc/R44201.pdf.

¹⁷ See https://fas.org/sgp/crs/misc/R44201.pdf.

¹⁸ See https://fas.org/sgp/crs/misc/R44201.pdf.

¹⁹ See https://fas.org/sgp/crs/misc/R44201.pdf.

²⁰ States inspect about 69 percent of regulated gas gathering lines, 35 percent of gas transmission lines, and 99 percent of gas distribution lines. They also inspect most liquefied natural gas plants and tanks (https://www.phmsa.dot.gov/pipeline/state-programs).

²¹ See https://www.phmsa.dot.gov/pipeline/state-programs.

²² Master meter operators are responsible for one meter and its downstream distribution piping for users such as mobile homes and apartment complexes.

Regulation Design Types

When federal pipeline safety regulations were first established in the 1970s, they were derived primarily from industry consensus standards in effect at the time.²³ Consensus standards are developed by nongovernmental bodies using agreed-on procedures. Industry organizations, such as the American Petroleum Institute (API) and the American Gas Association, are important sources of pipeline standards in the United States. Professional societies such as the American Society of Mechanical Engineers and the National Association of Corrosion Engineers also play an important role in developing consensus standards that apply to pipelines. Since passage of the National Technology Transfer and Advancement Act of 1995, federal policy has favored the use of consensus standards.²⁴ More than 60 consensus standards have been "incorporated by reference" in federal pipeline safety regulations, which means that these otherwise nongovernmental standards have been adopted by regulators, placed in binding federal rules, and now must be followed in the same manner as any other governmentissued regulation.²⁵

Box 3-1 shows the breadth of the subject matter addressed by hundreds of regulations that make up the federal safety regime for hazardous liquid pipelines. The regime for gas pipeline systems covers many of the same topics. State regulations are too numerous and varied to describe here. However, state regulations can apply stricter standards than or address matters not covered under federal regulations.

A review of the complete U.S. pipeline safety regulatory regime, as formed by federal and state regulations collectively, is not practical or necessary for the purposes of this study. The federal regime alone contains numerous examples of the regulation design types discussed in Chapter 2. It includes many regulations that are highly targeted, with a micro-level orientation. These regulations have aspects that are means-based (e.g., requirements that a pipe be made from a specific grade or thickness of steel) and aspects that are ends-based (e.g., requirements that a pipe pass a pressure test). In addition, the federal regime contains several regulations that are more generalized. They are better described as having a macro-level

²³ See https://primis.phmsa.dot.gov/comm/inspection.htm.

²⁴ Office of Management and Budget Circular A-119 provides guidance to agencies on the use of consensus standards.

²⁵ Concern about the public's ability to access and review these standards has at times been an issue when references are made in federal regulations to industry consensus standards that are proprietary. See specifically PHMSA's implementation of Section 24 of the Pipeline Safety, Regulatory Certainty and Job Creation Act of 2011. Section 24 states that the Secretary "may not issue guidance or a regulation . . . that incorporates by reference any documents or portions thereof unless the documents or portions thereof are made available to the public, free of charge, on an Internet website."

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Box 3-1

Major Provisions of U.S. Hazardous Liquid Pipeline Safety Regulations

Title 49 CFR Part 195—Transportation of Hazardous Liquids by Pipeline

Subpart C-Design

§195.100 to §195.134

Includes pipe and component design requirements governing design temperature; internal design pressure; external pressure and loads; valves and fittings; closures and connections; and station pipe and breakout tanks.

Subpart D—Construction

§195.200 to §195.266

Includes construction-related requirements governing material inspection; transportation of pipe; location of pipe; installation and coverage of pipe; welding procedures and welder qualifications; weld testing and inspection; valve location; pumping stations; and crossings of railroads and highways.

Subpart E-Pressure Testing

§195.300 to §195.310

Includes requirements governing pressure testing of pipe, components, tie-ins, and breakout tanks. Also contains requirements for risk-based alternatives to pressure testing of older pipelines.

Subpart F-Operations and Maintenance

§195.400 to §195.452

Includes requirements for an operations, maintenance, and emergency response manual; maximum operating pressure; inspections of breakout tanks and rights-of-way; valve maintenance; pipe repairs; line markers and signs; public awareness and damage prevention programs; leak detection and control room management; and integrity management in high-consequence areas.

Subpart H-Corrosion Control

§195.551 to §195.589

Includes regulations on coatings for external corrosion control; coating inspection; cathodic protection and test leads; inspection of exposed pipe; protections from internal corrosion; protections against atmospheric corrosion; and assessment of corroded pipe. orientation because they require operators to establish management plans and programs aimed at reducing overall risk. A number of examples of these varied regulatory design types follow, starting with the more numerous micro-level regulations.

Micro-Level (Prescriptive and Performance-Based) Regulations As noted, many of the federal pipeline regulations require operators to follow referenced consensus standards. For example, hazardous liquid pipeline regulations state that new steel pipe must comply with the mandatory provisions of API Specification 5L (Specification for Line Pipe),²⁶ that valves must meet the minimum requirements of API Specification 6D (Specification for Pipeline Valves),²⁷ and that welding must be performed by a qualified welder in accordance with API Standard 1104 (Welding of Pipelines and Related Facilities).²⁸ These standards are sometimes means-based in that they require the use of specific designs, materials, or equipment, but many have elements that are ends-based because they establish testing and evaluation criteria.

Some regulations do not reference consensus standards but instead directly specify a means to be used or a procedure to be followed. For example, copper pipe used in gas distribution mains must have a minimum wall thickness of 0.065 inch,²⁹ gas service lines must have a shutoff valve in a readily accessible location outside the served building,³⁰ and operators must inspect their mainline valves at least twice per year.³¹

Other PHMSA regulations with a micro-level orientation can be characterized as having an ends-based design because they provide the operator with latitude for selecting compliant pipe designs, materials, and installation procedures as long as pipelines and their installation procedures pass certain tests or have certain qualities. An example is a regulation that establishes a formula for calculating a gas pipeline's safe maximum operating pressure when choices can be made among design parameters, materials, and fabrication (e.g., welding method) options.³² The pipeline designer is thus given flexibility to combine design, material, and fabrication choices to satisfy other goals, such as accommodating a certain operating environment or meeting a desired throughput capacity. Another example is the PHMSA rule governing pipeline coating systems to prevent external corrosion, which states that a coating must have sufficient adhesion to the metal

²⁶ §195.106(b)(1)(i); §195.106(e).

²⁷ §195.116(d).

²⁸ §195.222; §195.228(b).

²⁹ §192.125(a).

^{30 §192.365(}b).

^{31 §195.420(}b).

³² §192.105.

surface to prevent under film migration of moisture, be sufficiently ductile to resist cracking, have enough strength to resist damage due to handling and soil stress, and support any supplemental cathodic protection.³³ Any coating system may be used as long as it meets these requirements. Other examples are requirements that compressor stations have emergency shutdown systems "capable of blocking gas" out of the station,³⁴ that pipe be installed with "adequate protection" to withstand anticipated external pressures and loads,³⁵ and that pipe materials be "chemically compatible" with any commodity they transport.³⁶ By specifying required qualities rather than mandating particular technologies, these regulations offer operators a degree of flexibility.

Macro-Level (Management-Based and Liability) Regulations A number of federal pipeline regulations can be characterized as means-based but at a macro-level because they require operators to establish certain plans, procedures, and management programs. In general, these regulations do not require a specific safety outcome to be achieved by the mandated program. An example is the requirement that all pipeline operators develop a written public awareness program that follows the guidance in API Recommended Practice 1162 (Public Awareness Programs for Pipeline Operators); however, the regulation does not establish a means of measuring the success of the program in raising public awareness.³⁷ Another is the requirement that each operator with a SCADA system establish written procedures that, among other things, define the roles and responsibilities of a controller during normal and emergency conditions and create a recording system for controller shift changes.³⁸ In this case, the regulation gives operators discretion to develop program content, but in other cases the regulations can be highly prescriptive of program content. An example of the latter is the requirement that all operators have a call-before-you-dig notification system as part of the public awareness program.³⁹

Perhaps the most prominent macro-means commands in PHMSA's regulatory regime are those requiring operators to develop and follow a written integrity management (IM) program.⁴⁰ These regulations require a program containing risk-based plans and procedures for choosing specific methods to be used for assessing the condition of pipelines, for selecting

³³ §192.461.

^{34 §192.1697(}a).

³⁵ §192.103.

³⁶ §195.4.

³⁷ §192.616; §195.440.

³⁸ §192.631.

³⁹ \$192.616; \$195.440.

⁴⁰ §192 Subparts O and P; §195.450 and §195.452.

preventive and mitigative measures, and for measuring the program's effectiveness in managing risks. Operators are given flexibility to choose the methods and processes to be used in complying with the required program elements. The flexibility is intended to recognize the variability among pipeline system designs, configurations, and operating environments.

IM regulations were first applied in 2000 for large hazardous liquid transmission pipelines that could affect environmentally sensitive areas. They were extended to gas transmission pipelines in 2003. In 2006, Congress required PHMSA to extend IM program regulations to all gas distribution systems. 41 However, as discussed above, the distribution sector differs in many fundamental ways, such as in the presence of many small pipeline operators, from the transmission sector. The inspection of distribution systems is also handled almost entirely by states, and state inspectors are now responsible for ensuring compliance with distribution system IM requirements. To accommodate these differences, PHMSA's regulations for distribution systems simplify many of the IM requirements that apply to operators of transmission systems. For example, the regulations for distribution systems require each operator to prepare and implement a written IM program containing several key elements (e.g., identify threats, assess and prioritize risks, identify and implement appropriate measures to mitigate risks, measure performance, and evaluate effectiveness). The elements are presented in a general manner to facilitate compliance by a diverse set of operators. Even more streamlined IM requirements apply to master meter operators and owners of propane pipe systems. Nevertheless, for reasons explained below, the extension of IM regulations to distribution systems has led to a number of implementation and enforcement challenges.

The federal pipeline safety laws and regulations themselves do not contain a macro-ends general duty provision imposing an overarching requirement that pipeline systems be operated and maintained safely. Some state regulations may contain such provisions. At the federal level, an ex post liability and penalty regime was created by the Oil Pollution Act of 1990 (OPA 1990), which amended the Clean Water Act of 1972. Although it does not address personal injury, the amended act makes the responsible party liable for other damages. In addition, pipeline operators

⁴¹ Pipeline Inspection, Protection, Enforcement and Safety Act of 2006.

⁴² An example of a general duty requirement is Section 5(a)(1) of the Occupational Safety and Health Act of 1970, which requires that employers provide a workplace that is "free from recognizable hazards that are causing or likely to cause death or serious harm to employees."

⁴³ The penalty regime was established by the Clean Water Act of 1972, which, as amended by OPA 1990, assesses maximum penalties for a harmful discharge of oil from an offshore installation of \$25,000 per day or \$1,000 per barrel, except where the discharge is the result of gross negligence or willful misconduct, in which case the penalty shall be no less than \$100,000 and no higher \$3,000 per barrel of oil.

can be subject to tort laws that impose a liability, strict or fault-based, on anyone whose conduct causes harm to others and the environment. The possibility of a tort action, such as civil suits brought by victims of the Allentown gas line explosion and by the State of Michigan for environmental and economic damages caused by oil released into the Kalamazoo River, can create ex ante incentives for operators to take precautionary measures.

Implementation, Compliance, and Enforcement Challenges

Micro-level regulations, including most references to industry consensus standards, can create a number of implementation challenges for regulators and compliance challenges for industry. In briefings to the committee, PHMSA officials acknowledged the difficulty of keeping references to consensus standards current because of their sheer number (consensus standards sometimes incorporate other consensus standards), the need for PHMSA staff to participate on more than two dozen consensus standards committees, and the need to initiate rulemaking proceedings to include references to updated standards.⁴⁴ The demands of this rulemaking process are discussed in Chapter 4.

PHMSA and industry representatives agreed that micro-means standards can be appropriate when a common risk source is well known, is predictable, and can be targeted with a trusted control measure. However, they expressed concern that if the standards are too rigid, they can limit the ability of operators to use alternative but equally or more effective means suited to their individual circumstances. Larger operators in particular questioned whether a collection of micro-means regulations could adequately address the risks that arise from their complex and diverse systems. PHMSA officials expressed similar views. The agency's rationale for introducing the IM regulations was to place more direct responsibility for safety assurance on pipeline operators, who know the details and presumably many of the sources of risk of their systems. In its original justification for the IM rule applied to hazardous liquid pipelines, PHMSA reasoned that "our analyses indicate that many accidents are caused by complex factors involving mechanical and control system failures, previous outside force damage, system design errors and operator error. These accidents indicate the need for operators to address the potential interrelationship among failure causes and to implement coordinated risk control actions to supplement the protection of the regulations."45

Some pipeline operators have exhibited difficulty in complying with the required analytical, procedural, and planning requirements of the

⁴⁴ See http://onlinepubs.trb.org/onlinepubs/pbr/Mayberry071216.pdf.

⁴⁵ See https://primis.phmsa.dot.gov/iim/docsr/IMPLgLiq_PublishedFinalRule.pdf.

IM regulations. In 2006—a few years after the first IM regulations were introduced—the U.S. Government Accountability Office interviewed operators concerning their experience in complying with the requirements. Most claimed to be generally satisfied with their ability to comply, but some raised concerns about the regulations' many documentation requirements. ⁴⁶ In briefings to the committee, PHMSA officials expressed concern about the lack of operator progress in complying with some program requirements, particularly requirements for risk modeling and assessment. The officials reported that many simplistic risk management methods were still being used by operators and that many operators had not developed the ability to improve programs by evaluating their effectiveness in managing risks. ⁴⁷

Deficiencies in the IM programs of operators have also been found in three National Transportation Safety Board (NTSB) investigations of severe pipeline incidents since 2010, including the gas pipeline explosion in San Bruno. NTSB concluded that the development and execution of IM programs requires operators to have the expertise to integrate multiple technical disciplines, including engineering, materials science, geographic information systems, data management, statistics, and risk management. 48 NTSB concluded that sufficient expertise was often lacking among operators and recommended that PHMSA increase its guidance to industry on how to develop and implement key elements of IM programs. PHMSA officials noted that they have been working with industry to fill some of these gaps—for example, by forming a risk modeling working group consisting of government and industry experts. PHMSA also cooperated with the pipeline industry in the development of API Recommended Practice 1173 (Pipeline Safety Management Systems), which provides guidance on the development of a pipeline safety management system. PHMSA officials expressed a view to the committee that to overcome a "culture of minimum" compliance," operators must have an effective safety management system.⁴⁹ The application of API Recommended Practice 1173 remains voluntary.

Along with these efforts to offer more compliance guidance to industry, PHMSA has been adding more details to its requirements for IM programs—a development that some industry representatives described as increasingly "prescriptive." For example, revised regulations now explain to operators how they should validate their risk models and prioritize their repairs of defects discovered through IM programs.⁵⁰

PHMSA officials noted a number of challenges in enforcing compliance

⁴⁶ See http://www.gao.gov/assets/260/251383.pdf.

⁴⁷ See http://onlinepubs.trb.org/onlinepubs/pbr/Mayberry071216.pdf.

⁴⁸ See https://www.ntsb.gov/safety/safety-studies/Documents/SS1501.pdf.

⁴⁹ See http://onlinepubs.trb.org/onlinepubs/pbr/Mayberry071216.pdf.

⁵⁰ Hazardous Liquid NPRM (Nov. 2015), 80 FR 61610, and Gas NPRM (March 2016), 81 FR 20722.

with IM program requirements. They pointed out that some inspector staffing positions remain unfilled and that inspectors at the federal and state levels have complained about the difficulty of assessing compliance with "subjective" regulatory requirements. NTSB has previously urged PHMSA to strengthen aspects of inspector training and to develop minimum professional qualifications for all personnel involved in implementing and enforcing IM programs. PHMSA officials explained that they have sought to fill all of the vacancies in the federal inspection workforce and to make the inspection process more data-driven, risk-informed, and investigative.

State regulators also reported that some aspects of the enforcement of IM regulations can be especially challenging for their inspection personnel.⁵¹ They described operator compliance with management-based commands, such as IM regulations, as being difficult to assess when state inspectors do not have the requisite auditing skills and training to evaluate the content and quality of IM program plans and their execution. The simplified IM requirements coupled with the need for audit-based enforcement by dozens of state agencies—encompassing a wide range of inspector resources and capabilities—led PHMSA to issue an 11-page inspection form for state inspector guidance.⁵² This form is designed to be a checklist verifying documentation and is considerably shorter and less thorough than the 132-page inspection manual⁵³ that PHMSA's personnel, along with some state personnel, use to review the IM programs of larger interstate transmission systems.

State regulators also reported that local gas distribution systems differ in their ability to develop and follow IM programs, an indication of variability in the complexity, size, and staffing of these systems. This problem was confirmed by a representative from a small municipal system.⁵⁴ The representative also pointed out that PHMSA has been working to help operators of small systems comply, most notably by supporting the development of software that guides smaller systems in the creation of an IM plan. The software program, known as SHRIMP (Simple, Handy, Risk-Based Integrity Management Plan), creates IM plans that can be customized to small gas pipeline systems. In addition, PHMSA has teamed with state

⁵¹ See http://onlinepubs.trb.org/onlinepubs/pbr/Allen071216.pdf.

⁵² See https://primis.phmsa.dot.gov/dimp/docs/Form_22_PHMSA_DIMP_InspectionForm_192.1005_Operators.pdf.

⁵³ PHMSA Gas Integrity Management Inspection Manual: Inspection Protocols with Results Forms, August 2013 (https://primis.phmsa.dot.gov/gasimp/documents.htm).

⁵⁴ See http://onlinepubs.trb.org/onlinepubs/pbr/Crowley071216.pdf.

regulators in the development of inspection methods and guidance for the evaluation of these plans.⁵⁵

Evaluation Challenges

Major pipeline failures have at times led to calls for regulatory evaluation and change. As noted in Chapter 1, several catastrophic failures during the 1990s prompted PHMSA to promulgate its first IM regulations in 2000. The occurrence of catastrophic failures in recent years has tended to have the opposite effect of prompting calls for regulators to target regulations to specific risks. PHMSA has responded with proposals to add detail and specificity to its IM regulations, as noted above.

After the 2010 San Bruno explosion, the Office of the Secretary of Transportation commissioned its own evaluation of the effectiveness of the IM regulations in assuring pipeline safety. The report, which was released in April 2016, concluded that there has been no clear evidence of the positive safety outcomes expected when the IM rules were first introduced, particularly for gas transmission pipelines. The report attributed safety gains to the effect of other regulations, especially requirements for operators to establish damage prevention programs. Although many of the statistical analyses in this commissioned evaluation of PHMSA's IM regulations are caveated and qualified, their credibility is not examined here because an assessment of the safety performance of individual regulations was not the purpose of the case studies.

Liability concerns have reportedly inhibited operators from sharing safety-related data among themselves and with regulators, which has hampered the ability of PHMSA to evaluate its regulatory requirements and aid operators in improving their IM programs. This issue has been recognized by Congress, which in 2016 required the creation of a Voluntary Information Sharing System Working Group.⁵⁷ The purposes of this group, which consists of state regulators, operators, safety advocates, and labor representatives, are to advise the agency on ways to encourage operators to share inspection results and other data that can be used to improve the industry's risk analysis practices and to assess the effectiveness of federal regulations.

⁵⁵ In a manner similar to personal income tax preparation software, SHRIMP asks users a series of questions about the design, construction, inspection, and maintenance of their piping system. On the basis of the answers, SHRIMP ranks items by relative risks (e.g., exposed pipe with metal loss), proposes actions for addressing them (e.g., upgrading cathodic protection), and suggests performance measures (e.g., tracking the number of low cathodic protection readings).

⁵⁶ See https://www.transportation.gov/sites/dot.gov/files/docs/IM-PE_Report.pdf.

⁵⁷ See http://www.phmsa.dot.gov/pipeline/regs/technical-advisory-comm/voluntary-information-sharing-system-working-group.

TABLE 3-2 Length of Hazardous Liquid and Gas Transmission and Distribution Pipelines in Canada, 2014

	Length (miles)
Oil and gas gathering and feeder	165,000
Oil, gas, and products transmission	65,000
Gas distribution	270,000
Total	495,000

SOURCE: Pipelines Across Canada (https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/energy/files/pdf/14-0277-%20PS_pipelines_across_canada_e.pdf).

During the group's first meeting in December 2016, participants discussed ways to encourage the exchange of pipeline inspection information and the development of advanced pipeline inspection technologies and enhanced risk analysis.⁵⁸

Case 2: Canadian Pipeline Safety Regulation

The Canadian network of hazardous liquid and gas pipelines spans about 500,000 miles, including transmission, gathering, and distribution pipelines (see Table 3-2). Approximately 270,000 miles are gas distribution lines and 65,000 miles are large-diameter transmission lines, several of which cross the U.S. border. The remaining 165,000 miles are in field gathering and transmission pipeline feeder systems.⁵⁹

Regulatory jurisdiction over Canadian pipelines is divided among the federal and provincial governments. The federal government regulates about 45,000 miles of pipelines crossing provincial or international borders. They typically consist of larger-diameter transmission pipelines that carry oil and natural gas long distances. Provincial governments regulate pipelines operating exclusively within their borders. These usually consist of upstream oil and gas gathering and feeder pipelines and include gas distribution pipelines. Because of its many production fields, storage terminals, upgraders, and refineries, Alberta alone regulates about 240,000 miles of

⁵⁸ See https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=12.

⁵⁹ Feeder systems transport oil and gas from field storage sites to transmission terminals or gas processing plants. Their mileage is usually included in gathering system mileage in the United States but may also be included in transmission mileage depending on pipe size and system length.

 $^{^{60}}$ See https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/energy/files/pdf/14-0277-%20PS_pipelines_across_canada_e.pdf.

⁶¹ See https://www.neb-one.gc.ca/bts/nws/rgltrsnpshts/2016/01rgltrsnpsht-eng.pdf.

pipeline.⁶² A total of about 450,000 miles of pipelines are provincially regulated.

The Regulated Industry

The Canadian pipeline industry resembles that of the United States. Approximately 100 companies are subject to Canada's federal regulations because they operate one or more lines that cross a provincial border.⁶³ For regulatory purposes, the companies are categorized as Group 1 and Group 2. Group 1 companies receive a greater degree of regulatory oversight than Group 2 companies.⁶⁴ The former include companies that operate extensive systems and serve many shippers. The latter generally operate smaller, less complex pipeline systems with few or no third-party shippers.

Thirteen of the federally regulated pipeline companies are classified as Group 1. A number of them operate transmission systems in the United States. Pipeline companies falling under provincial jurisdiction generally operate gathering, feeder, or distribution pipelines. They can be independent entities, affiliates of federally regulated companies, or provincial or municipally owned companies. As in the United States, many distribution pipeline systems are operated by local utilities.

The Regulators

The National Energy Board (NEB) is the Canadian federal regulator with responsibility for pipelines crossing provincial or international borders. It is an independent agency governed by seven permanent board members with 460 full-time staff.⁶⁵ In addition to pipelines, NEB regulates international power lines, energy exports and imports, and oil and gas exploration and production in certain northern and offshore areas. Its pipeline regulatory responsibility covers the complete life cycle of a pipeline from its siting, design, and construction through its operation, maintenance, and decommissioning. Funds for NEB's regulatory regime are appropriated by the federal government; however, industry levies based on company traffic activity recover about 90 percent.⁶⁶

For intraprovincial pipelines, regulatory oversight is the responsibility

⁶² See https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/energy/files/pdf/14-0277-%20PS_pipelines_across_canada_e.pdf.

⁶³ See https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/www/pdf/publications/emmc/14-0177 Pipeline%20Safety e.pdf.

⁶⁴ See https://www.neb-one.gc.ca/bts/whwr/cmpnsrgltdbnb-eng.html.

⁶⁵ See https://www.neb-one.gc.ca/bts/nws/fs/nbqckfcts-eng.pdf.

⁶⁶ See https://www.neb-one.gc.ca/bts/cstrcvr/prsnttn/ssntlcstrcvr/ssntlcstrcvr-eng.html; https://www.neb-one.gc.ca/bts/pblctn/dtrrprtndnbfnnclsttmnt/dtrgnrlrprt2015-2016-eng.html.

of the province and is exercised through a number of mechanisms. Some provinces have created administrative agencies with pipeline regulation and enforcement responsibilities; others have established public review boards or utility commissions with legislated authority.⁶⁷

Both NEB and provincial regulators rely to a significant degree on the Canadian Standards Association (CSA) for the development of standards for pipeline design, construction, operations, and maintenance. CSA is an independent not-for-profit standards development organization. Its overarching standard (CSA Z662) for oil and gas pipeline systems is developed and maintained under the direction of a joint committee composed of federal and provincial regulatory authorities, pipeline operators, oil and gas producers, suppliers, fabricators, contractors, and general interest participants. Because of this involvement by government authorities, CSA standards have traditionally been referenced by Canadian federal and provincial regulators.

Types of Regulation

Although federal and provincial pipeline regulatory regimes are distinct, they share a common foundation through the adoption in whole or in part of the pipeline standards developed by CSA. Most of these standards are technical (micro-level), with some specifying required means and others specifying required ends. In recent years, both federal and provincial regulators have introduced more macro-means, management-based regulations. NEB introduced its first safety management system requirement in 1999 in response to studies of catastrophic incidents and the recognition that a series of highly targeted and detailed regulations could lead to some facility-specific risks not being adequately addressed.⁷⁰ The agency's regulations for management programs have expanded over time. They now include requirements that operators establish safety, security, damage prevention, environmental protection, and IM programs.⁷¹

Because so many management programs have been called for, NEB has taken the step of requiring that operators have an overarching management

⁶⁷ See https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/www/pdf/publications/emmc/14-0177_Pipeline%20Safety_e.pdf.

⁶⁸ See https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/www/pdf/publications/emmc/14-0177_Pipeline%20Safety_e.pdf.

⁶⁹ See http://d1lbt4ns9xine0.cloudfront.net/csa_core/ccurl-zip/218/296/SDP_2-1_Part_1_%20 Participants-and-organizational-structure-2014.pdf.

⁷⁰ See http://news.gc.ca/web/article-en.do?mthd=tp&crtr.page=1&nid=1060979&crtr.tp1D=1.

⁷¹ See http://laws-lois.justice.gc.ca/PDF/SOR-99-294.pdf.

system integrating the many required management programs.⁷² Operators are provided with guidance on the implementation of this system as well as on the implementation of individual management programs. These guidelines can be specific in comparison with the generality of NEB regulations. For example, the regulation requiring an IM program states that a company "shall develop, implement and maintain an integrity management program that anticipates, prevents, manages and mitigates conditions that could adversely affect safety or environment during the design, construction, operation, maintenance or abandonment of a pipeline."⁷³ NEB's Guidance Notes cover management system requirements, condition monitoring, mitigation, and record-keeping expectations in substantial detail.⁷⁴

CSA standards now also require pipeline operators to establish a number of macro-means, management-based programs. By referencing these standards, provincial regulators have joined NEB in requiring operators to establish programs for IM, damage prevention, emergency management, and the like. CSA issues guidelines to assist smaller, provincially regulated operators in complying with these program requirements.⁷⁵ Although the standards are usually generalized, the guidelines on implementation can be detailed.⁷⁶ Many provinces require operators not only to follow the CSA standard but also to comply with CSA's more detailed implementation guidance.

Implementation, Compliance, and Enforcement Challenges

In briefings to the study committee, representatives of NEB and Canadian transmission pipeline operators shared their perspectives on the challenges associated with regulatory implementation, compliance, and enforcement. As did U.S. pipeline regulators and operators, they observed that the more technical, micro-level requirements in the CSA standards are more readily understood by company staff and agency inspectors, which facilitates compliance with and enforcement of the requirements. They reported that the macro-means, management-based regulations leave openings for interpretation that create challenges in achieving an understanding among the regulators and companies concerning expectations and deliverables.

Despite these challenges, the NEB official emphasized the importance of management systems for driving safety improvements by inducing opera-

⁷² See http://laws-lois.justice.gc.ca/PDF/SOR-99-294.pdf.

⁷³ See https://www.neb-one.gc.ca/bts/ctrg/gnnb/nshrppln/gdncntnshrpplnrgltn-eng.html#s40.

⁷⁴ See https://www.neb-one.gc.ca/bts/ctrg/gnnb/nshrppln/gdncntnshrpplnrgltn-eng.html.

⁷⁵ See https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/www/pdf/publications/emmc/14-0177_Pipeline%20Safety_e.pdf.

⁷⁶ See https://www.nrcan.gc.ca/sites/www.nrcan.gc.ca/files/www/pdf/publications/emmc/14-0177 Pipeline%20Safety e.pdf.

tors to assess and control their risks on a continuing basis. The transmission pipeline industry representatives also said that a strict focus on complying with micro-level standards was too limiting and cited the industry's "Integrity First" initiative as an example of an effort to exceed many of these detailed regulatory requirements.

Both regulators and operators mentioned the need for appropriate knowledge and skill sets among agency and company personnel in establishing and enforcing management-based regulations. The NEB official described a transitional requirement for instruction, training, and technical support for enforcement personnel to allow them to conduct management audits, as opposed to the customary inspection of equipment and practices using checklists. The official also noted the challenge of obtaining adequate resources for determining compliance with these macro-means regulations. It was reported that, on the basis of existing administrative resources, nearly a year is needed to audit a company's management programs, and each audit requires significant support from agency technical personnel. Similarly, regulated companies had to obtain resources and special expertise to develop their management programs, including the capacity to determine key performance indicators and criteria for program audits. Both NEB and industry representatives emphasized the need for collaboration among regulators and industry to facilitate compliance with these macro-means regulations.

The committee did not have an opportunity to meet with provincial regulators or with operators of intraprovincial pipelines, such as Canadian gas distribution systems. As a result, the challenges they face in implementing, enforcing, and complying with pipeline safety regulations were not documented.

Evaluation Challenges

The NEB official who briefed the committee noted that administering regulations with multiple approaches, such as micro-level technical standards and macro-level management requirements, can become complicated. In addition, the occurrence of major incidents tends to lead to public and political demands for more detailed requirements and prescription in the governing regulations. To assess the performance of its macro-means regulations, NEB has developed a set of pipeline performance measures through a consultation process with industry and the public and by drawing from information on program goals and performance measures reported annually by operators. The committee was told that a few reporting cycles may be needed to identify trend information helpful for evaluating the effectiveness of the agency's management program requirements.

Observations on Pipeline Safety Regulation in the United States and Canada The federal, state, and provincial governments of the United States and Canada administer pipeline safety regulatory regimes that have much in common. Both countries depend to a substantial degree on their jurisdictional partners—states in the United States and provinces in Canada—to develop and enforce regulations that apply to their vast pipeline networks.

Regulators in both countries oversee pipeline industries with substantial diversity. The pipeline systems vary widely in size and scope, age, technology vintage, design configurations, operating complexity, and environmental setting. The companies that own and operate the systems also differ significantly in size and sophistication; they range from multinational firms to local utilities. Nevertheless, the pipeline systems of the two countries have many features and conditions in common simply because they carry many of the same commodities and operate in many of the same environments.

Regulatory regimes in both the United States and Canada use a combination of highly targeted micro-level standards and more generalized macro-means requirements for management programs. Both countries' regimes reference consensus standards for technical aspects of pipeline construction, operations, and maintenance. Where pipelines share certain features and conditions, these technical standards can have widespread applicability in addressing known risks with trusted means of control. Nevertheless, regulators in both countries indicate that pipeline systems and their operations are sufficiently varied and complex that the identification and reduction of all risk factors through the use of micro-level standards is impractical. They have established a number of macro-means regulations as a way to compel operators to account for the specific risks associated with their individual systems and operations.⁷⁷

Both the U.S. and the Canadian regulators acknowledged that adoption of macro-means regulations has created enforcement and industry compliance challenges. Agency inspectors who had grown accustomed to enforcing detailed, technical standards have had to be retrained to oversee compliance with the less precise and less predictable requirements for management programs. Regulators from Canada's provinces were not interviewed in this study, but state regulators in particular, who conduct three-quarters of U.S. pipeline inspections, have encountered difficulties in aligning inspector skill sets and competencies with the need to assess operators' IM programs. The prevalence of small pipeline operators, particularly in the gas distribution

⁷⁷ PHMSA's main management-based regulation is its IM requirements. As noted in Chapter 1, footnote 3, the agency has also supported the development of an industry consensus guideline (API Recommended Practice 1173) on pipeline safety management systems, but unlike Canada it has not made the use of such management systems mandatory.

sector, has also led to challenges for industry compliance with macro-means requirements. Operators of smaller systems contend that they do not have the resources and technical capacity to understand, much less meet, some IM requirements. Federal and state regulators have had to work closely with these smaller operators in developing suitable means of compliance.

Although macro-means regulations in the United States and Canada are often described as giving operators flexibility to choose implementation means, they are accompanied by substantial requirements and guidance on compliance. The U.S. regulations governing IM programs have become more detailed and prescriptive of program elements and content over time. That trend has been prompted in part by evidence, following major incidents, of some operator programs having serious deficiencies or not being properly carried out. Federal regulators have thus taken steps to assist operators in strengthening key elements of their IM programs, such as by promoting the use of more sophisticated risk modeling tools and encouraging the sharing of best-practice information among operators. Canadian regulators have also supplemented their regulations with extensive guidance on how to comply with the many types of management programs that are required in federal and provincial regulation.

Efforts to evaluate the effectiveness of a safety regulatory regime in reducing the occurrence of major pipeline failures are complicated by their rarity. Both U.S. and Canadian pipeline regulators are attempting to gather empirical data to evaluate their macro-means requirements such as IM. However, both have acknowledged that when major incidents do occur, the rationale for these regulations may be difficult to explain to legislators and the public, who may demand more detailed or extensive regulatory prescription as a result.

OFFSHORE SAFETY REGULATION IN THE UNITED STATES AND THE NORTH SEA REGION

The offshore oil and gas industries of the United States and North Sea countries share many characteristics and are both regulated to prevent routine harms and rarer catastrophic events. The generic aspects of the industry's structure, features, and operations are described next. The ensuing case studies indicate that the United States, the United Kingdom, and Norway have established regulatory regimes that share certain attributes of regulatory design and implementation but also exhibit notable differences.

Generic Structure, Features, and Operations of the Offshore Oil and Gas Sector

Most offshore oil and gas development, whether in the United States, the North Sea, or other regions of the world, involves a typical series of industry activities: field evaluation and exploratory drilling; design, construction, and installation of the production system; drilling of additional production wells; hydrocarbon extraction and processing operations; and the eventual decommissioning and plugging of wells. The specific methods and technologies used for each activity can differ among regions and among fields. This variability stems from many factors, which are often related to the location, size, and physical properties of the field and to the technologies available at the time of its development. Characteristics such as reservoir attributes, water depth, distance from shore, and marine and weather conditions combine with projected yield, profitability calculations, and hydrocarbon storage and transportation requirements to influence specific technology choices.

Despite this heterogeneity, certain elements are common to each offshore oil and gas activity. For example, exploratory drilling may be undertaken from several kinds of floating or bottom-supported rigs, with rig choice depending on site-specific factors such as water depth. However, the basic steps involved in drilling and completing a well are generic to most offshore fields. The drilling phase usually begins with the hammering of a tube, called a conductor, into the seafloor. A drill bit connected to drill pipe is then lowered into the conductor. As the borehole is excavated, drilling fluids, called "mud," are pumped at high pressure down the drill pipe. The hydrostatic pressure from the mud keeps formation fluids from entering the borehole. At specific intervals, drilling is suspended while the borehole is lined with more tubes, called casings, and cement is pumped to seal the space between the outside of the casing and formation rock. Several casing strings may be added, one inside the other, until the reservoir is reached. After the first casing string is cemented, a large valve called a blowout preventer is installed at the casing head. Pressure in the mud column is monitored, and heavier fluids are pumped into the borehole during drilling to keep out formation fluids that could cause a blowout that risks explosions, fires, and discharges into the sea. When this drilling work is complete and the wells are properly lined, sealed, and temporarily plugged,⁷⁹ the mobile

⁷⁸ These activities occur after required government permits have been obtained and there are sufficient indications of the presence of oil and gas to warrant the expense of exploratory drilling.

⁷⁹ A set of valves called a "Christmas tree" may be installed to control well pressure and flow in preparation for the production phase.

drilling unit moves to other sites while the production system is designed and installed.

Production activities likewise involve many site-specific methods and technologies but also have many generic features. A production platform, or a man-made island with production equipment, is usually located above or near the well.80 A number of processes take place on the platform or on ancillary facilities, sometimes including the separation and processing of the oil and natural gas, treatment and disposal of extracted water and gases, and storage of the extracted product before it is exported by underwater pipeline or shuttle tanker. The specific design and configuration of the production installation depend on considerations such as water depth, marine and weather conditions, expected recovery volumes, distance from shore, and the need for oil and gas storage. Nevertheless, most production platforms have common features, such as gas compression, power generation, and piping systems. Most larger platforms have rooms and catering facilities for crews, as well as maintenance shops, warehouses, and laboratories. Larger platforms have facilities to accommodate vessels such as anchor-handling tugs, diving support boats, and pipe-laying ships, along with helipads for the air transport of crews and supplies. Nearly all have systems for monitoring and controlling critical equipment such as heat exchangers, pumps, generators, and compressors, as well as sensor, alarm, and automatic shutdown systems. To protect workers, the facilities have firefighting and lifesaving equipment.

All offshore projects face the challenge of ensuring the safety of operations that take place in a physically constrained space; often in harsh environmental conditions; and with a constant risk from volatile hydrocarbon mixes being extracted, processed, and stored under high pressure. Advances in drilling, production, and safety technologies during the past half century have helped the industry meet this challenge. These advances have allowed the development of fields that are more remote, in deeper waters, and in harsher environments such as the Arctic. As the depth of wells and production volumes have increased, installations have tended to become larger, more complex, and more costly. The increasing cost and complexity of drilling and production have in turn led to more specialization among companies supplying the needed services and technologies and thereby added to organizational complexity and the need to coordinate decisions, diverse workforces, and communications.

The entity having responsibility for managing and ensuring project safety is the leaseholder. Most governments award fixed-period leases for

⁸⁰ Subsea production systems are also used. They are located on the seafloor and connected to a platform that may be several miles away. A single production platform can serve as the host for several subsea systems.

the exploration and development of mineral resources under their waters. A single lease can have many owners with various percentages of working interests. One holder is usually designated as the operating company. Operating companies are generally responsible for all of the activities on their leases but seldom carry out all activities by themselves. The operator usually contracts with a company to supply and operate the drilling rig. In turn, the drilling contractor usually hires specialized companies to provide supplies and services such as cementing, maintenance and repair of mechanical equipment, diving, and helicopter transport. Although operating companies typically own their production platforms, they too hire contractors to handle many of the key production processes and services.

Unlike pipelines, which require relatively few workers for their control, maintenance, and operation, the offshore workforce is large and has a diverse set of skill requirements in specialties ranging from crane and helicopter operations to diving, welding, and well engineering. At any given time an offshore facility can have more than 100 workers, including mechanics, electricians, derrickmen, medics, cleaners, painters, and cooks as well as workers in supervisory positions such as an installation manager, a captain, and a chief engineer. Many of these workers are likely to be employed by different companies.

Public Safety Interest of Regulation

Offshore oil and gas development, especially drilling, is labor intensive, involves hazardous materials, and takes place in environmentally sensitive areas. Offshore projects thus pose risks of explosions, fires, and toxic emissions that can kill and injure workers, contaminate ocean and coastal environments, harm wildlife and communities and businesses that depend on these natural resources, and damage oil and gas development and production facilities. Storms, structural failures, capsizing, and other mechanisms can cause serious incidents. The location of facilities miles offshore can create challenges for the evacuation and rescue of workers and for the control and containment of spills. Deepwater (generally considered to be >1,000 feet water depth) projects that require drilling through layers of unknown pressure zones create special risks.

Ensuring the safety of projects has long been a public concern in countries that permit offshore oil and gas development. The April 2010 loss of well control by the *Deepwater Horizon* drilling rig, which caused the death of 11 workers and the release of an estimated 5 million barrels (more than 200 million gallons) of oil, led to major changes in the U.S. regulatory regime as well as to reassessments of regimes worldwide. Earlier disasters, including the 1988 explosion of the *Piper Alpha* platform in the UK sector of the North Sea (killing 167) and the 1980 capsizing of the *Alexander L*.

Kielland rig in the Norwegian sector (killing 123), had prompted similar reevaluations and changes in offshore regulatory regimes abroad (Bennear 2015).

Although disasters rightly attract the attention of policy makers and the public, offshore facilities are subject to a wide range of safety and environmental risks. Far more common than well blowouts and explosions are helicopter crashes, diving accidents, vessel collisions, crane lifting accidents, and equipment and operational failures that cause human casualties, property loss, and hydrocarbon releases. In the absence of consistent reporting of offshore incidents globally, assessment of the safety performance of the industry and its methods of regulation can be difficult. On an annual basis from 2009 to 2016, the United States averaged nearly 4 fatalities, 241 injuries, and 6 spills of 50 or more barrels of oil from offshore incidents, including the *Deepwater Horizon* disaster. Comparable incident reporting data are difficult to obtain for the multijurisdictional North Sea fields. The UK sector averaged about 0.7 deaths and 40 severe injuries per year from 2007 to 2015. However, these incident data do not include helicopter crashes, which are included in the U.S. data.

Similarities and differences with regard to the offshore sectors of the United States and the North Sea region and to the design and enforcement of their safety regulatory regimes are discussed after presentation of the case studies below.

Case 3: U.S. Offshore Oil and Gas Safety and Environmental Regulation

The Department of the Interior (USDOI) is responsible for administering federal laws governing mineral exploration and development of the U.S. outer continental shelf (OCS), which is the region generally more than 3 miles from the coast. The main governing statute is the Outer Continental Shelf Lands Act of 1953. In 2010, USDOI assigned responsibility for administration of the law to two newly created agencies, the Bureau of Ocean Energy Management, which awards leases, and the Bureau of Safety and Environmental Enforcement (BSEE), which issues and enforces regulations intended to ensure safe and environmentally responsible exploration and production. These agencies were created from the Minerals Management Service (MMS), whose long-standing administration of both leases and

⁸¹ Bureau of Safety and Environmental Enforcement database as of September 30, 2016.

⁸² See http://www.hse.gov.uk/offshore/statistics/hsr2015.pdf.

safety regulations was perceived after the *Deepwater Horizon* disaster to create a conflict of interest.⁸³

BSEE's regulatory regime is the focus of this case study. However, the U.S. Coast Guard (USCG) is responsible for regulating the safety of vessels, which include mobile drilling rigs and floating platforms. USCG's regulations, for example, cover the seaworthiness and evacuation and fire protection capacity of these units. The two agencies have agreements on the division and coordination of inspection duties and other matters. This division and coordination, which are not examined here, can complicate efforts to make changes in offshore regulations and regulatory approaches.⁸⁴

The Regulated Industry

About 2,100 platforms (including man-made islands) operate on the U.S. OCS along with numerous platforms in state waters near the coastline.⁸⁵ The installations vary in configuration from single-structure facilities to multiple-structure facilities connected by walkways. Most are in the Gulf of Mexico, which accounted for more than 95 percent of the 565 million barrels of oil and 1.4 trillion cubic feet of natural gas produced from the OCS in 2015.⁸⁶

Most platforms (2,000 of the 2,100) operate in shallow waters of less than 1,000 feet. They are likely to be older and more lightly manned than the deepwater platforms. A few shallow-water platforms are more than 50 years old, and most are at least 20 years old. Deepwater platforms are usually less than 20 years old. Many shallow-water platforms, which are often located less than 25 miles from shore, are manned only part of the day and thus not equipped with living quarters. Deepwater facilities are frequently more than 50 miles from shore. Thus, they are more likely to have personnel on board 24 hours per day and to provide living quarters.

Despite the much larger number of shallow-water platforms, the 50 or so deepwater installations account for most of country's offshore oil and gas production. Their deeper wells are more productive but more complicated to drill. Accordingly, their designs and operations tend to be more

⁸³ USDOI press release "Salazar, Bromwich Announce Next Steps in Overhaul of Offshore Energy Oversight and Management," January 19, 2011. (https://www.doi.gov/news/press releases/Salazar-Bromwich-Announce-Next-Steps-In-Overhaul-of-Offshore-Energy-Oversight-and-Management).

⁸⁴ Federal agencies other than BSEE and USCG having regulatory authority over aspects of offshore oil and gas operations include the Occupational Safety and Health Administration, the U.S. Environmental Protection Agency, the National Oceanic and Atmospheric Administration, and PHMSA (for offshore pipelines).

⁸⁵ See https://www.data.bsee.gov/homepg/data_center/leasing/WaterDepth/WaterDepth.asp.

⁸⁶ See https://www.data.bsee.gov/homepg/data_center/production/ocsprod.asp.

complex, and the companies that own and operate them tend to be large, usually multinational oil and gas production companies. A 2011 study found that of the 132 firms operating production platforms in the Gulf of Mexico in 2010, 117 operated only in shallow waters, some specializing in low-yield, low-capital operations.⁸⁷ Of the 15 firms that operated deepwater platforms, 10 had a market capitalization of more than \$10 billion, and 6 had a capitalization of more than \$100 billion. These 10 firms accounted for about 30 percent of all active platforms in the Gulf of Mexico.

According to BSEE's 2016 Annual Report, about 60 mobile drilling rigs were operating in the Gulf of Mexico during 2016.⁸⁸ Most of the contractors operating these rigs compete for business globally and own rigs of various design types. The high cost of owning and operating increasingly sophisticated rigs and the technological demands of designing, drilling, and completing wells in deep water have been factors in a trend toward industry consolidation. Industry statistics show that 10 companies accounted for about 75 percent of the rigs drilling wells in the Gulf of Mexico during 2015.⁸⁹

The Regulator

When it was created in 2011, BSEE inherited responsibility for the offshore safety program from MMS, which had earlier inherited the program from the U.S. Geological Survey. BSEE establishes the regulatory agenda, administers an enforcement and inspection program, investigates incidents, and oversees industry spill preparedness. ⁹⁰ To fulfill these functions, BSEE is funded in part by rent from OCS leases and fees charged for inspections and reviews of plans and permits. In fiscal year 2016, BSEE's total budget was approximately \$190 million, about one-third of which was funded by service fees. ⁹¹

BSEE has about 850 employees, including approximately 120 inspectors and 130 engineers who review permit applications, facility plans, and company safety programs. Three-fourths of the inspection personnel are stationed in the Gulf of Mexico. 92 In 2016, BSEE inspectors carried

⁸⁷ See http://www.rff.org/files/sharepoint/Documents/oilspillcomission/RFF-DP-10-61.pdf.

⁸⁸ See https://www.bsee.gov/sites/bsee.gov/files/bsee_2016_annual_report_v6b.pdf.

 $^{^{89}}$ See http://www.offshore-mag.com/content/dam/offshore/print-articles/volume-76/02/survey.pdf.

⁹⁰ See https://www.bsee.gov/who-we-are/our-organization/national-programs.

⁹¹ See https://www.bsee.gov/sites/bsee.gov/files/budget-justifications//bsee-fy-2017-budget.

⁹² See https://www.bsee.gov/sites/bsee.gov/files/fact-sheet/fact-sheet/5-yr-dwh-fact-sheet-final.pdf.

out more than 20,000 inspections of more than 2,000 facilities.⁹³ Annual inspections are required for all production platforms. Mobile drilling rigs are inspected on a monthly basis when they are active. Inspectors use helicopters stationed at BSEE district offices to travel to offshore facilities.

After the *Deepwater Horizon* disaster, BSEE's budget was doubled and the agency was authorized to hire more inspectors.⁹⁴ In its fiscal year 2017 budget request BSEE reported that because of a significant pay gap between the federal government and private industry, the agency has had difficulty in recruiting and retaining qualified engineers and inspectors.⁹⁵

Types of Regulation

BSEE regulations pertain to all phases of offshore oil and gas development. Hus, major parts of the regulatory regime address drilling operations (e.g., casing, cementing, and drilling fluid requirements, as well as special Arctic requirements), well completion (e.g., pressure management), well operations and equipment (e.g., rig and blowout preventer requirements), production safety systems (e.g., emergency shutdown and firefighting systems), platforms and structures (e.g., design and construction), and safety and environmental management systems (SEMS).

This regulatory regime has taken shape over the decades following passage of the Outer Continental Shelf Lands Act of 1953. Many existing regulations had their origins in consensus standards and recommended practices developed by API, engineering societies, and other private standards development organizations. For example, when a blowout preventer system is installed, it must meet the requirements of API Standard 53 (Blowout Prevention Equipment Systems for Drilling Wells);⁹⁷ all cranes must be operated in accordance with API Recommended Practice 2D (Operation and Maintenance of Offshore Cranes);⁹⁸ and production platforms must conform to API Recommended Practice 2A (Planning, Designing, and Constructing Fixed Offshore Platforms).⁹⁹

In recent years, BSEE has added regulations that have a more macrolevel perspective, most notably the requirement for operators to establish a SEMS program. Some of these macro-level regulations also reference consensus standards, including API Recommended Practice 75 for the de-

⁹³ See https://www.bsee.gov/sites/bsee.gov/files/bsee_2016_annual_report_v6b.pdf.

⁹⁴ Budget of the United States Government, Fiscal Year 2012, p. 101.

⁹⁵ See https://www.bsee.gov/sites/bsee.gov/files/budget-justifications//bsee-fy-2017-budget.pdf (p. 27).

⁹⁶ 30 CFR Part 250—Oil and Gas and Sulphur Operations in the Outer Continental Shelf.

⁹⁷ §250.730.

⁹⁸ §250.108.

^{99 \$250.901.}

velopment and implementation of SEMS programs. ¹⁰⁰ In total, BSEE's regulations contain references to more than 100 consensus standards.

Micro-Level (Prescriptive and Traditional Performance-Based) Regulations Most BSEE regulations can be characterized as micro-level, either means- or ends-based. Highly targeted means-based regulations are common. For example, a detailed table in the agency's regulations prescribes cementing and setting requirements for well casings and liners. The regulation further specifies that a pressure test must be conducted below the surface casing and all intermediate casings. The regulation further specifies that a pressure test must be conducted below the surface casing and all intermediate casings.

Many of the agency's means-based regulations seek to standardize certain facility features and equipage. For example, rules specify the kinds of safety devices, ventilation systems, and gas monitors that must be installed in fluid-handling areas. To protect workers from hydrogen sulfide exposure, the regulations are highly specific; among other things, they delineate where warning signs should be placed and how they should be designed—by using "a high-visibility yellow color with black lettering." This specificity is intended to provide uniformity of warning devices across installations to ensure a high level of visibility and familiarity among workers.

Other micro-level regulations are ends-based. A number of "general requirements" are presumably intended to address situations in which applicable standards cannot be developed for all circumstances. An example is the requirement that all platforms and related structures be designed to ensure their structural integrity, with consideration given to "the specific environmental conditions at the platform location." ¹⁰⁵

Ends-based regulations often state that a given practice or component must possess a certain capability. Welding, for example, must be done "in a manner that ensures resistance to sulfide stress cracking." ¹⁰⁶ In its 2016 Well Control rule, BSEE states that an operator's casing and cementing program must provide "adequate centralization" to ensure proper cementation around the casing. ¹⁰⁷ The regulation implies that operators can use conventional bow-type centralizers as recommended in referenced industry consensus standards but does not specify or limit how centralization should be achieved. Thus, the use of other options brought about by advances

 $^{^{100}}$ §250.1902(c).

¹⁰¹ §250.462(e).

¹⁰² §250.427.

¹⁰³ §250.459.

¹⁰⁴ §250.490.

¹⁰⁵ §250.900.

¹⁰⁶ §250.490.

¹⁰⁷ 81 Federal Register 25888, 25918 (April 29, 2016).

in technology and practice to ensure the outcome of centralization is not precluded.

An interesting example of a micro-level regulation can be found in the statutory mandate that the Secretary of the Interior "shall require on all new drilling and production operations and, wherever practicable, on existing operations, the use of the best available and safest technologies which the Secretary determines to be economically feasible." 108 On its surface, this provision appears to be ends-based because it stipulates a required attribute of offshore technologies—that is, they must be the "safest available." However, the condition that the Secretary shall decide which technologies qualify under this standard indicates that the overall provision authorizes a means-based restriction on operators. Operators are bound to use technologies that have been deemed suitable by BSEE. In turn, BSEE is directed by the statute to use safety performance and economic feasibility as the criteria for making its determinations about the means that operators must use. To aid in its decision making, BSEE has established a process for identifying qualifying technologies (National Academy of Engineering and National Research Council 2013). To date, BSEE's new process has not been implemented beyond identifying a small number of technologies that are candidates for further review. 109

Macro-Level (Management and Liability) Regulations The fact that most offshore safety regulations are micro-level led to criticism after the 2010 *Deepwater Horizon* explosion. The National Commission on the BP *Deepwater Horizon* Oil Spill and Offshore Drilling characterized the regulatory regime as "consisting of hundreds of pages of technical requirements that could not adequately address the risks generated by the offshore industry's new technologies and exploration and production activities." A National Academy of Sciences study questioned whether the technical regulations were capable of keeping up with the rapid advances that had enabled a large increase in deepwater drilling in the Gulf of Mexico (National Academy of Engineering and National Research Council 2012).

Most of BSEE's regulations were issued long before the *Deepwater Horizon* explosion, but several rulemakings since 2010 are described by the agency as being less "prescriptive" and more "performance-based" (BSEE 2015). The most prominent example is the rule requiring operators to implement and maintain a SEMS program.¹¹¹ BSEE's SEMS regulation

¹⁰⁸ The mandate is contained in amendments to the Outer Continental Shelf Lands Act.

 $^{^{109}}$ See https://www.bsee.gov/what-we-do/offshore-regulatory-programs/emerging-technologies/BAST.

 $^{^{110}}$ See https://www.gpo.gov/fdsys/pkg/GPO-OILCOMMISSION/pdf/GPO-OILCOMMISSION. pdf.

^{111 30} CFR Part 250, Subpart S.

DESIGNING SAFETY REGULATIONS FOR HIGH-HAZARD INDUSTRIES

is more accurately described as means-based rather than performancebased, because it requires operators to set program goals and undertake other management-related actions. It does not mandate specific safety or risk-reduction outcomes. Instead, it sets forth a list of elements of a compliant program. For example, to be compliant, a program must include a formal hazards analysis of facilities and activities, written management-ofchange procedures, written operating procedures that provide instructions for conducting safe activities, a program for training personnel to perform their duties safely, and procedures for investigating incidents. The rule reguires operators to have their programs audited for compliance with these elements by an accredited third-party agent. Under agreement with BSEE, API's Center for Offshore Safety is responsible for the development of good practice documents for SEMS programs and for accrediting and ensuring that third-party auditors meet the program's goals and objectives. 112

By requiring management systems, the SEMS regulation has created implementation challenges for BSEE, especially with regard to enforcement. It has also presented compliance challenges for an offshore industry long accustomed to a regulatory regime consisting mostly of micro-level, technical requirements.

Finally, when they are viewed in isolation, some of the regulations in BSEE's offshore program have a macro-ends design. An example is the requirement that drilling operations be conducted in a safe manner to protect against harm or damage to life, property, and natural resources. However, these regulations are often followed by numerous means-based requirements that provide little or no discretion to the regulated entity. Perhaps the most significant form of macro-ends regulation, not formally part of BSEE's program, is the strict liability and penalty regime created by OPA 1990 and referenced earlier with regard to pipelines.

Implementation, Compliance, and Enforcement Challenges

While BSEE has relied increasingly on regulations that require management programs to fill gaps in its regulatory content and coverage, the regulatory regime within which offshore oil and gas development takes place remains one that is oriented toward micro-level, technical regulations. Keeping these regulations current and compatible with advances in practice and technology is a continuing challenge, especially as more advanced drilling and production systems allow for the development of deepwater fields. Because the regulations incorporate many consensus standards by reference, BSEE staff must have subject matter experts who can participate on API standards committees addressing offshore matters.

¹¹² See http://www.centerforoffshoresafety.org.

BSEE's investigation and enforcement group is larger than the one that existed in MMS. Its enforcement efforts usually begin with a review of permit applications. For example, a drilling application will be reviewed to ensure that cementing and drilling fluid programs are designed to conform to applicable requirements. Most enforcement resources go to the inspection of existing facilities to check compliance with the agency's many detailed regulations. Inspections usually consist of a facility visit, announced or unannounced, in which the inspection team follows a set of guidelines from the *National Office Potential Incident of Noncompliance (PINC) List*. One or more inspectors approach the platform by helicopter and view the surroundings for signs of leaked oil and vent gas. On landing, the inspector conducts a walk around to check on the general condition of the platform, test safety devices with the operator, and review paperwork in accordance with PINC list guidelines.

As reported earlier, there are thousands of installations in the Gulf of Mexico alone. Because BSEE inspectors must visit so many facilities annually, the inspections usually last only a few hours. Inspectors issue a citation on detecting a violation, either a warning to take corrective action in a given amount of time or a notice requiring action before an activity can resume. In 2016, more than 2,100 facilities (rigs, platforms, pipelines, or onshore meters) were inspected by BSEE. The inspections led to nearly 2,400 notices of noncompliance, about one-third of which were warning notices. 115 BSEE officials who briefed the committee reported that the agency has been piloting a risk-based inspection program. 116 Under the program, poorly performing facilities (e.g., many reportable incidents or notices of noncompliance) or those with distinguishing risk characteristics (e.g., size of facility, production of hydrogen sulfide) would be identified and subjected to more frequent and intensive inspections, which would improve deployment of resources. 117 Progress with program implementation was not reported. Additional enforcement efficiencies are anticipated from technological developments. For example, advances in the remote monitoring of blowout prevention systems and other safety- and environmental-

¹¹³ A deepwater production project can take a decade or more to come online. Accordingly, BSEE evaluates information provided by operators in project applications many years in advance of the commencement of production activities.

 $^{^{114}}$ See http://www.rff.org/files/sharepoint/WorkImages/Download/RFF-DP-13-36-REV2. pdf.

¹¹⁵ See https://www.data.bsee.gov/homepg/data_center/company/incs/incs.asp.

 $^{^{116}}$ See https://www.bsee.gov/newsroom/latest-news/statements-and-releases/press-releases/bureau-of-safety-and-environmental.

¹¹⁷ See http://onlinepubs.trb.org/onlinepubs/pbr/Dwarnick101716.pdf.

critical equipment are expected to reduce the need for BSEE inspectors to visit facilities when critical systems are being tested. 118

BSEE officials explained to the committee that assessing operator compliance with the many required elements of a SEMS program is more challenging than assessing compliance with micro-level, technical regulations. Enforcing the latter regulations requires familiarity with BSEE's many detailed standards; enforcing the former requires an assessment of an operator's compliance with more subjective requirements such as whether appropriate methods are in place to identify and control all significant hazards. Such assessments require enforcement officers to have a strong understanding of offshore operations and their associated risks, a competency that has not been required of the many inspectors conducting PINC checklist reviews.

BSEE officials identified several issues related to operator compliance with SEMS requirements. The agency found that its original requirement for self-auditing of SEMS programs was insufficient for ensuring compliance. Operators reportedly exhibited more interest in program documentation than in application, as evidenced by a tendency to adopt standardized SEMS programs as opposed to "fit for purpose" ones. ¹¹⁹ To address this problem, BSEE replaced the provision for self-audits with a requirement for third-party audits. ¹²⁰ The agency has been working with the offshore industry through API's Center for Offshore Safety (COS) to improve the ability of third-party auditors to detect weaknesses in SEMS programs and to help operators eliminate them. Because it lacks the capability to accredit third-party auditors, BSEE delegated accreditation responsibility to COS.

In a related initiative, BSEE has emphasized the elevation by operators of safety assurance to a core organizational value, as expressed in the agency's 2013 safety culture policy statement. The complexity of offshore operations, including reliance on many contractors, is viewed as a complicating factor in the development of a consistent organizational commitment to safe practices. SEMS programs are intended to be a cornerstone in the effort to strengthen the offshore industry's safety culture.

The committee was interested in learning how the offshore workforce views BSEE's regulatory approach, including the agency's reliance on microlevel regulation and its promotion of the macro-means approach of SEMS.

 $^{^{118}}$ As more production is handled by subsea systems, the use of remote sensing technologies will be essential. See TRB 2016.

¹¹⁹ See http://onlinepubs.trb.org/onlinepubs/pbr/Dwarnick101716.pdf.

¹²⁰ §250.1920.

¹²¹ See https://www.bsee.gov/site-page/safety-culture-policy.

¹²² See http://www.trb.org/Main/Blurbs/174395.aspx.

¹²³ See https://www.bsee.gov/sites/bsee.gov/files/congressional-testimony/regulations-and-guidance/bsee-salerno-testimony-final.pdf.

The size and fragmentation of the U.S. offshore workforce and the lack of labor union representatives to consult about the views of at least some workers proved problematic for eliciting worker perspectives. A labor union official from the petrochemical sector reported that an advantage of detailed, micro-level regulations is that they can be transparent and understandable to workers. On the basis of his experience with refinery process management programs, he questioned whether the efforts of offshore operators to establish SEMS programs have had the level of participation from workers needed to ensure that the programs are effective.

Evaluation Challenges

MMS first proposed requiring all operators to establish SEMS programs to address safety issues that the agency believed were not being addressed by the regulatory regime's many detailed regulatory requirements. 124 On the basis of incident investigations and evaluations of inspection records, MMS concluded that the latter regulations were not effective in ensuring good communications among operators and contractors, the systematic analysis of job hazards, the development of safe work procedural guidelines, or the rigorous maintenance of facilities and equipment. The first SEMS regulation to address these regulatory shortcomings, also known as the workplace safety rule, was eventually promulgated by BSEE, but not until 6 months after the April 2010 *Deepwater Horizon* explosion.

The many years required for promulgation of the SEMS rule illustrates the challenge offshore regulators face in ascertaining the effectiveness of their regulations in bringing about change. Because catastrophic incidents are rare, regulatory effectiveness can be difficult to assess quantitatively (Bennear 2015). MMS concluded that its traditional regulatory regime was inadequate by analyzing incident panel investigation reports, incident reports, and incidents of noncompliance inspections; however, connections between such evidence and major incident risk proved difficult to establish. That such risks are lowered by requiring operators to undertake job hazards analyses, establish procedures to improve communications among operators and contractors, establish work procedural guidelines, and introduce other required elements of a SEMS program can be even more difficult to support empirically.

To aid with such evaluations and inform the development of SEMS programs, BSEE has emphasized the collection and analysis of data from incident records, near-miss reporting, and real-time monitoring. For example, it has enlisted the U.S. Department of Transportation's Bureau of Transportation Statistics to develop and manage a voluntary and confiden-

¹²⁴ See https://www.gpo.gov/fdsvs/pkg/FR-2006-05-22/pdf/E6-7790.pdf.

tial near-miss reporting system, called Safe OCS.¹²⁵ The intention is for information obtained from the Safe OCS database to be shared with BSEE, industry, and the public to help identify incipient safety issues.¹²⁶

The offshore safety regulatory regimes in the United Kingdom and Norway are reviewed in the next section. After that review, several observations concerning the design of the various offshore regulatory regimes are offered.

Case 4: North Sea Offshore Oil and Gas Safety Regulation

More than 90 percent of the oil and 60 percent of the natural gas produced in Western Europe is from offshore fields. ¹²⁷ Nearly all of the production is in the North Sea and adjacent waters of the Barents and Norwegian Seas and west of the Shetlands (see Figure 3-2).

Denmark and the Netherlands, as well as the United Kingdom and Norway, have territorial waters in the North Sea. This case study contains information on the offshore safety regulatory regimes of the United Kingdom and Norway, which account for most of the region's oil and gas production. 128

The Regulated Industry

Offshore operations in Norway produce about 600 million barrels of oil and 115 billion cubic meters of natural gas per year. This output is comparable with that from the Gulf of Mexico. The second-largest North Sea producer, the United Kingdom, extracts about 350 million barrels of oil and 40 billion cubic meters of natural gas per year. Total North Sea oil and gas output is higher than the output from the Gulf of Mexico but far below the North Sea's peak production periods during the 1990s and early 2000s.

The number of offshore units in the North Sea is difficult to estimate because of different treatments of platform complexes, unmanned facilities, and inactive units in national statistics. Nevertheless, data suggest that the

¹²⁵ See https://near-miss.bts.gov.

¹²⁶ See https://www.bsee.gov/sites/bsee.gov/files/congressional-testimony/regulations-and-guidance/bsee-salerno-testimony-final.pdf.

¹²⁷ See http://ec.europa.eu/eurostat/statistics-explained/index.php/File:Energy_production,_2004_and_2014_(million_tonnes_of_oil_equivalent)_YB16.png.

¹²⁸ Most references in this chapter to North Sea production levels, fields, and installations include activity and installations in adjacent waters such as the Barents, Norwegian, and Irish Seas as well as the Atlantic Ocean west of the Shetlands.

 $^{^{129}}$ See https://www.eia.gov/beta/international/analysis_includes/countries_long/Norway/norway.pdf.

¹³⁰ See https://www.eia.gov/beta/international/analysis.cfm?iso=GBR.

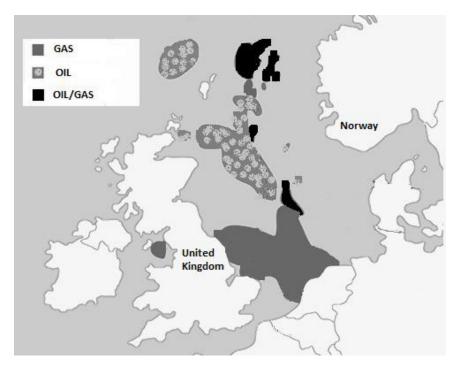


FIGURE 3-2 Oil and gas fields in the North Sea and nearby waters.

NOTE: Norway has additional fields in the Norwegian and Barents Seas that are not shown.

SOURCE: http://www.crystolenergy.com/assessing-future-north-sea-oil-gas.

United Kingdom has about 260 manned and unmanned operational installations and that Norway has about 100.¹³¹ Thus, in total the region has fewer than half the number of units in the Gulf of Mexico, where there are more low-yield installations.¹³² Most North Sea production platforms operate in water not deeper than 300 feet. They include massive structures (which may be freestanding or anchored in place) capable of accommodating hundreds of workers, with some of the largest located in the central and northern waters. Platforms in the southern waters produce mostly gas and are generally smaller, with some used for holding oil and gas for trans-

 $^{^{131}} See \ https://www.ogauthority.co.uk/data-centre/data-downloads-and-publications/infrastructure; http://www.npd.no/en/Publications/Reports/Unmanned-wellhead-platforms/Location-of-platforms.$

¹³² See http://www.npd.no/en/Publications/Reports/Unmanned-wellhead-platforms/Location-of-platforms.

shipment. Although many of the North Sea's largest fields are located at shallow depths, newer discoveries have been made farther from shore in deeper waters. 133

Harsh weather and marine conditions in the North Sea can complicate drilling and support activities such as helicopter transport. Project complexities and capital requirements have also increased as more fields have been developed in deeper, high-pressure zones. Because of the investment and technology demands of North Sea production, global oil and gas companies account for most of the region's development activity. Some of the region's major producers have large government ownership stakes, such as Norway's Statoil and Denmark's DONG. As in the United States, most drilling activity is contracted to international companies. About 60 percent of the region's drilling rigs are owned by 10 large companies. Because of declining oil and gas prices worldwide, the number of active drilling rigs in the region has reportedly declined by more than half during the past decade. 135

The offshore workforce in the United Kingdom and Norway fluctuates in response to production activity, which depends on world oil and gas prices. According to industry estimates, during 2016 about 34,000 people were directly employed by UK oil and gas producers and businesses providing support services. ¹³⁶ The Norwegian government estimates that about 50,000 people were directly employed in its oil and gas industry during 2016. ¹³⁷

The Regulators

In Norway, offshore safety oversight is the responsibility of the Petroleum Safety Authority (PSA). PSA oversees the activity of about 60 mobile drilling units and 80 production platforms.¹³⁸ The agency has a 170-member staff with expertise in areas such as drilling and well technology, process safety management, structural integrity, emergency preparedness, and occupational health and safety.¹³⁹ In the United Kingdom, responsibility for

¹³³ Most notable is the 2010 discovery of the Johan Sverdrup oil field located about 90 miles off the shore of Norway. The field is estimated to contain more than 2 billion barrels of oil.

 $^{^{134}}$ See http://www.offshore-mag.com/content/dam/offshore/print-articles/volume-76/02/survey.pdf.

¹³⁵ See http://www.worldoil.com/news/2016/10/7/north-sea-drilling-activity-plunges-to-all-time-low.

¹³⁶ See researchbriefings.files.parliament.uk/documents/CBP-7268/CBP-7268.pdf. The Health and Safety Executive estimates a population of 32,077 offshore full-time equivalent workers in 2015 (http://www.hse.gov.uk/offshore/statistics/hsr2015.pdf).

¹³⁷ See http://www.norskpetroleum.no/en/economy/employment/#direct-employment.

¹³⁸ See http://www.ptil.no/map-of-our-area-of-responsibility/category994.html.

¹³⁹ See http://www.psa.no/employees-at-the-psa/category988.html.

offshore safety regulation lies with the Health and Safety Executive (HSE), which oversees about 20 mobile units and 300 production facilities. ¹⁴⁰ Its offshore division employs about 125 people. Like those of PSA, HSE managers and inspectors have a range of professional expertise, including well engineering, electrical control, diving operations, emergency preparedness, and human and organizational factors.

Types of Regulations

The offshore safety regulatory regimes of the North Sea region have their origins in reforms introduced in response to major incidents, when investigations led authorities to question the effectiveness of their traditional regulations. After the 1988 *Piper Alpha* disaster, the Cullen Report recommended that the United Kingdom's micro-level regulatory regime be replaced by a "goal-setting" regime patterned after the approach used in Norway (Cullen 1990). Parliament responded by assigning HSE responsibility for administering regulations that would require offshore operators to develop a "safety case" for each installation. Norway had earlier established its goal-setting regime in the aftermath of the 1980 *Alexander L. Kielland* disaster, and in the intervening years other North Sea countries, including Denmark and the Netherlands, had introduced similar regimes. 141

Although they are called goal-setting regimes and are sometimes characterized as "performance-based," the UK and Norwegian offshore regulations have a macro-means design. They require the operator, or "duty holder," to establish a number of safety assurance processes and programs intended to reduce catastrophic risk; however, the regulations do not mandate outcomes, such as a demonstrable reduction in incidents or some other end state believed to be indicative of risk reduction. Instead, the regulations require that operators undertake rigorous risk analysis and management planning and act in accordance with the plans. An operator is considered to be in compliance if the quality and execution of the required risk analysis and management plans are substantiated. The occurrence of an incident or series of incidents would not violate the regulation per se but could lead the regulator to investigate whether the operator violated the regulation's means-based requirement for a rigorous risk management program. Liability for the incident under a macro-ends regulation, such as a general duty provision, could also apply, if the jurisdiction has such a separate obligation.

The use of these macro-level regulations does not imply that the United

¹⁴⁰ See http://www.hse.gov.uk/offshore/statistics/hsr2015.pdf.

¹⁴¹ In addition to regulating installations, UK and Norwegian regulators assess each operator's competency and safety performance before granting offshore leases and permits.

Kingdom or Norway abandoned micro-level regulations. Both regimes have retained many highly targeted safety regulations such as requirements specifying the minimum number of evacuation paths on a platform or the maximum duration of a work shift. Furthermore, as discussed next, operators are advised and in some cases directed to use consensus standards that are mostly micro-level in their design.

Micro-Level (Prescriptive and Performance-Based) Regulations The UK regulatory regime consists of three sets of regulations in addition to the safety case regulations¹⁴²: (a) Prevention of Fire and Explosion, and Emergency Response (PFEER);¹⁴³ (b) Management and Administration;¹⁴⁴ and (c) Well Design and Construction. 145 These regulations and their accompanying guidance contain many micro-level requirements. For example, a PFEER regulation states simply that an operator must have physical plant on the installation for the provision of safe evacuation. ¹⁴⁶ However, guidelines on methods of compliance are more prescriptive. HSE's Approved Code of Practice states that "[allternative means of evacuation should be provided to take account of scenarios where the normal means of getting people to and from the installation could not operate. . . . In most cases, alternative means would be means of evacuation by sea provided by TEMPSC [totally enclosed motor-propelled survival craft]. In these circumstances, there should be sufficient TEMPSC places for 150% of the people on board, unless an alternative standard is justified."147 An operator following the HSE guidance on the means of compliance (use of totally enclosed motorpropelled survival craft that can accommodate 150 percent of people on board) is considered to be in observance of the PFEER regulation.

The UK's Well Design and Construction regulations offer another example of how micro-level standards are used. The regulations simply state that operators must ensure that suitable well control equipment is provided to protect against blowouts. However, HSE offers more detailed compliance guidance in *A Guide to the Well Aspects of the Offshore Installations and Wells Regulations*. Documents outline the "particulars to be included" in a well control system. Among them are a listing of the equip-

¹⁴² Offshore Installations (Offshore Safety Directive) (Safety Case, etc.) Regulations.

¹⁴³ Offshore Installations (Prevention of Fire and Explosion, and Emergency Response) Regulations.

¹⁴⁴ Offshore Installations and Pipeline Works (Management and Administration) Regulations.

¹⁴⁵ Offshore Installations and Wells (Design and Construction, etc.) Regulations.

¹⁴⁶ PFEER Regulation 15.

¹⁴⁷ See http://www.hse.gov.uk/pUbns/priced/l65.pdf (p. 39).

¹⁴⁸ See http://www.legislation.gov.uk/uksi/1996/913/regulation/17/made.

¹⁴⁹ See http://www.hse.gov.uk/pubns/priced/184.pdf.

ment, drilling fluids, and cement to be used.¹⁵⁰ Conformance with applicable consensus standards, such as API Standard 53 on Blowout Prevention Equipment Systems for Drilling Wells, is an example of a listed "particular" that would facilitate HSE acceptance of a safety case.

Norway's offshore safety regulations, which are established by legislation, also contain some requirements that are highly detailed and targeted. PSA officials gave the following example of a regulation: "Facilities equipped or connected to a processing plant shall have a gas release system. The system shall prevent escalation of situations of hazard or accident by rapid escalation of the pressure in equipment, and it shall be designed so that release of gas does not entail major harm to personnel and equipment." The regulation was characterized by PSA officials as presenting a goal that operators must meet but with their choice of means. However, the officials pointed out that PSA guidelines—called "non-legal supplements"—provide operators with more details on how to comply with this regulation [i.e., by following consensus standards NORSOK S-001 and ISO 13702 (Control and Mitigation of Fires and Explosions on Offshore Production Installations—Requirements and Guidelines)]. 153

Macro-Level (Management-Based and Liability) Regulations In the belief that offshore operators should assume full responsibility for safety assurance, UK and Norwegian regulators demand that firms follow systematic risk management procedures, the essential elements of which are defined in regulation. Duty holders must establish and follow a set of management plans and practices that the regulator confirms will allow them to identify, assess, and manage their operations- and facility-specific risks. As discussed next, operators are required to demonstrate compliance with these requirements for risk management programs in a document called a "safety case" in the United Kingdom and an application for an acknowledgment of compliance (AOC) certificate in Norway.

UK's Safety Case The safety case document is the cornerstone of the United Kingdom's offshore regulatory regime.¹⁵⁴ It is intended to be a comprehensive document explaining how the duty holder intends to comply with all regulations and applicable statutes. The purpose is to give "confidence"

¹⁵⁰ See http://www.hse.gov.uk/pubns/priced/l154.pdf.

¹⁵¹ See http://www.psa.no/framework-hse/category403.html.

¹⁵² Section 35 Gas Release Systems (http://www.psa.no/facilities/category400.html#_Toc438215597).

¹⁵³ See http://www.psa.no/facilities/category405.html%20-%20p35.

¹⁵⁴ Offshore Installations (Offshore Safety Directive) (Safety Case, etc.) Regulations. The European Offshore Safety Directive was a driver for an update of the Safety Case Regulation in 2015. It was intended to standardize regulatory approaches across the European Union.

to operators, owners, workers, and the competent authority that the duty holder has the ability and means to manage and control major accident hazards effectively." ¹⁵⁵ In a safety case tailored for each offshore installation, the duty holder must demonstrate to the satisfaction of HSE that sound and systematic methods have been used to identify, evaluate, and select suitable measures to control all risks that can lead to major incidents. What qualifies as an acceptable degree of risk management is not defined in the safety case regulations; the duty holder is expected to make such determinations consistent with all applicable regulations and statutory provisions. In accordance with standard language in UK safety law and regulation generally, not only the offshore domain, risks should be reduced to "as low as reasonably practicable" (ALARP).

According to the UK regulations, each safety case must contain certain elements. For example, the document should explain the duty holder's SEMS program, the minimum contents of which are delineated in regulation. A compliant SEMS program description should include an overview of the command and control structure of the company, how the management and control of major hazards will be implemented through the organization, and the scheme for verifying that safety- and environmental-critical elements have been identified and controls established. The safety case document must contain a summary of worker involvement in the preparation of the safety case and explain the arrangements that have been made to enable ongoing dialogue and cooperation among managers and worker representatives. The law requires duty holders to consult worker safety representatives in the preparation of a safety case.

The regulations do not require a specific format for the safety case document. However, HSE recommends a self-contained document that presents the main arguments clearly and includes the supporting details, or "particulars," to lend conviction to the arguments made. The recommended structure is similar to the one shown in Figure 3-3. An executive summary and introduction to the main features of the safety case are followed by factual information about the installation and its environment and activities, the company's SEMS program, the hazards and risk assessment demonstrations, and an explanation of how the installation complies with specific PFEER regulations.

The safety case regulations state that the regulator, HSE, should work with operators to ensure that safety case submissions are acceptable. To do so, HSE has developed the aforementioned schedules of particulars that should be included in a safety case to strengthen it. The agency also provides a suite of guidance documents, including guidelines on the applica-

¹⁵⁵ See http://www.hse.gov.uk/pUbns/priced/l154.pdf (p. 6).

¹⁵⁶ See http://www.hse.gov.uk/pUbns/priced/l154.pdf.



FIGURE 3-3 Safety case document format. SOURCE: C. Hawkes, International Association of Oil and Gas Producers.

tion of the ALARP principle. ¹⁵⁷ HSE-approved safety cases are not publicly available (and therefore could not be reviewed by the study committee), but government and industry representatives who briefed the committee estimated that most documents are several hundred pages long, largely because of technical appendices that provide justifications and elaborations with regard to risk identification, assessment, and management methods used. ¹⁵⁸ The representatives also reported that certain sections in a safety case document will be uniform across an operator's safety cases. A reason for this uniformity is that some safety case elements, such as the description of a company's SEMS program, will be the same for all installations. Many of the referenced risk assessment methods and risk control measures will also be uniform because they are based on protocols in consensus standards.

Each installation must have an accepted safety case that is revised as necessary to remain current throughout its life. The duty holder must conduct a thorough review of its safety case every 5 years or when significant events occur, such as changes in ownership. Proposed changes must be submitted to HSE.

Although HSE does not require that offshore workers participate in all key decisions in a safety case, they must be consulted during the revision, review, or preparation of safety cases. The regulation's workforce guidance states that duty holders are not obliged to accept any proposals made during this consultation, but they must consider them properly.¹⁵⁹

¹⁵⁷ See http://www.hse.gov.uk/offshore/is2-2006.pdf.

¹⁵⁸ The study committee was able to obtain a safety case document for a decommissioned drilling rig that had been prepared for another North Sea country. That document contained many of the same elements required by HSE for safety cases.

¹⁵⁹ Offshore Installations (Offshore Safety Directive) (Safety Case, etc.) Regulations 2015, Guidance on Regulations, p. 10 (http://www.hse.gov.uk/pUbns/priced/1154.pdf).

Norway's AOC Certificate In Norway, the offshore operator is responsible for ensuring that its activities and those of subordinate parties are in compliance with government safety regulations. A key feature of the regime is a requirement that operators demonstrate compliance by applying for an AOC certificate before commencing an activity such as exploration drilling, production drilling, a change in facility ownership, or modification of a facility. Box 3-2 shows the items to be included in an AOC application. The items are similar to those required in a UK safety case. For example, in addition to providing details describing the facility, the application must document the company's SEMS, all analyses carried out to assess hazards and identify major incident risks, all control measures used, and the analyses that guided emergency preparations. The application must affirm that offshore workers have participated in all key decisions. PSA has established guidelines on the format and content of the application that are similar to the guidelines developed by HSE for safety cases. ¹⁶¹

PSA's level of scrutiny in reviewing the AOC application depends on factors such as the agency's experience with the operator and its contractors, previous knowledge of the facility, and the presence of any special conditions (e.g., an environmentally sensitive location). PSA reviews the application's compliance with all relevant regulations. As discussed above, most of the regulations are presented as goals or principles; however, they are usually accompanied by PSA interpretations and guidelines. The PSA guidelines, for example, state that NORSOK Z-013 and ISO 31000 (Risk Management Principles and Guidelines) should be used to meet the requirements for risk and emergency preparedness analyses and that Norwegian Oil and Gas Guideline 070 should be used as a basis for establishing performance requirements for safety barriers. 163

PSA refers to its approval of an AOC as "consent." A grant of consent indicates that the agency has confidence that the operator can execute the planned activity within regulatory parameters and in accordance with the promises provided in the application.¹⁶⁴

Implementation, Compliance, and Enforcement Challenges

According to the UK and Norwegian regulators, industry representatives, and a labor union official who briefed the committee, implementation of the North Sea region's goal-based regulatory regimes is made possible by trust-

¹⁶⁰ See http://www.psa.no/consents/category890.html.

¹⁶¹ See http://www.psa.no/getfile.php/136181/Regelverket/SUT-veiledningen_e.pdf.

¹⁶² See http://www.psa.no/dealing-with-consent-applications/category950.html.

¹⁶³ See http://www.ptil.no/framework-hse/category403.html# Toc438218436.

¹⁶⁴ See http://www.psa.no/about-consents/category949.html.

Box 3-2 Contents for an Application for AOC Certificate

All applications for consent shall contain

- (a) Information on which activities the applicant wants to carry out;
- (b) A description of the activities covered by the application, and the progress plan for these activities;
- (c) An overview of governing documents for the activities covered by the application;
- (d) A description of the management systems for the activities covered by the application;
- (e) An overview of exemptions granted according to the health, safety, and environmental legislation and an assessment of these in view of the activities consent is applied for;
- (f) Information on whether agreements have been entered into with contractors, and possibly which enterprise is considered the principal undertaking in connection with these agreements;
- (g) A description of the analyses and assessments that have been carried out in regards to health, safety, and the environment for the activities and offshore or onshore facilities covered by the application, and the results and measures that will be implemented as a result of these assessments;
- (h) A description of the results from internal and external follow-up;
- (i) General drawings of the offshore or onshore facility;
- (i) A statement regarding the application from the employees' elected representatives;
- (k) A summary of the results from the environmental risk and emergency preparedness analyses, as a description of how the planned emergency preparedness against acute pollution will be safeguarded in the areas where the results are also of significance to health, safety, and working environment; and
- (1) An overview of which other permits for activities have been applied for.

SOURCE: P. Bang, Norway Petroleum Safety Authority.

ing and collaborative relations among all three parties. In both countries, offshore operators are required to consult worker safety representatives concerning the preparation, review, and revision of their safety cases and AOC applications. In turn, HSE and PSA officials assist industry by developing guidelines for preparing safety cases and AOC applications and by collaborating in the development of tools for risk-related decision making.

Certain relationships that were cited by UK and Norwegian officials resemble those found in some U.S. sectors, where representatives from industry and nongovernmental organizations serve on agency-sponsored regulatory advisory committees. However, important differences in the nature of the collaborative relationships surfaced in the committee's dis-

cussions with government, industry, and labor representatives from the North Sea region. For example, the UK safety case regulations require HSE officials to do more than review document submissions for strict regulatory compliance. The agency is directed by law to work with operators to improve their safety cases as necessary. HSE officials may challenge specific decisions in a safety case document, but typically they do this by asking for more details and justifications. The committee was told that the two parties—regulator and operator—typically engage in a dialogue in which they identify opportunities to build a stronger safety case.

Once a safety case is approved or an AOC certificate is granted, the operator must implement the arrangements promised in the document. Failure to do so is considered a breach of regulation. Regulators may have confidential meetings with duty holders to discuss implementation. Operators are expected to monitor compliance though internal or third-party verifications. HSE's inspectors may visit the installation to seek evidence of compliance. Typically, the operator is notified in advance of these inspections. They may last 2 or 3 days and are conducted by teams of specialists following a series of inspection guides (e.g., on well control, maintenance, and evacuation and rescue). HSE officials stated that an important purpose of the inspections is to identify opportunities for the duty holder to strengthen compliance where it is deficient or weak. If the inspection team finds a problem that does not pose a safety threat requiring immediate intervention, the team will work with the duty holder as it tries to solve the problem.

Inspected installations are rated by HSE as being fully compliant, broadly compliant, or poor or very poor in compliance. Duty holders with poor performance ratings are inspected more frequently and in greater depth than duty holders with stronger compliance ratings. In 2015, HSE conducted 135 planned inspections on 104 offshore installations involving 47 duty holders. The inspections, as well as 92 investigations, found more than 750 noncompliance issues, but enforcement notices were issued in only 35 instances because other mechanisms were used to resolve the issues.

In describing its enforcement program, PSA officials were reluctant to use the term "inspection." They referred to their reviews of operator documents and periodic announced visits to installations as "supervisions" or "follow-ups" intended to obtain "insights" into an operator's implementation. PSA officials explained how the agency stations multidisciplinary teams at the onshore facilities of operators, who are required to set up

¹⁶⁵ See http://www.hse.gov.uk/offshore/inspection.htm.

¹⁶⁶ See http://www.hse.gov.uk/offshore/statistics/topic-performance-scores-2015.pdf.

¹⁶⁷ See http://www.hse.gov.uk/offshore/statistics/hsr2015.pdf.

onshore control rooms that replicate those of the offshore installations. The PSA teams integrate with operator personnel and meet with them on a regular basis. The integrated teams help validate the execution of the activities and processes that were promised by the operator as part of the AOC, and PSA team members contribute their engineering skills and process knowledge to inform safe practice.

The UK and Norwegian regulators emphasized that these review and collaboration functions require a highly skilled technical staff. To review about 100 safety cases per year, ¹⁶⁸ HSE's offshore division has a team of specialists covering a range of expertise, from well engineering and mechanical systems to diving and emergency planning. HSE bills the operator for time spent reviewing safety cases, inspecting facilities, and engaging in other consultations. ¹⁶⁹ A former PSA official familiar with the agency's transition from micro-level to macro-means regulations reported that the agency also had to retrain personnel and hire many technical experts to fulfill the new review and collaboration functions.

As noted above, worker involvement in the development of safety cases and AOCs is required, and operators must have ongoing mechanisms to consult workers on safety matters. The labor union officials who briefed the committee reported that these "tripartite" relations among industry, operators, and workers have been important in overcoming initial skepticism among workers about the new regimes. The officials explained that the introduction of macro-means regulations was initially met with concern by workers accustomed to clearly defined requirements in rules. They worried that operators would set risk management priorities and devise management plans that workers would not be able to evaluate. To build worker trust, PSA has created an ongoing safety forum where government, industry, and labor representatives discuss and follow up safety, emergency preparedness, and working condition issues.¹⁷⁰

The collaboration and trusting relationships that underpin the North Sea tripartite regimes are not immune to scrutiny. An industry representative from a North Sea country with a regime modeled after those of the United Kingdom and Norway reported political pressure to make relations between industry and regulators more formal and arms-length. Such steps were seen by some as necessary to increase public trust. An invited speaker from a coastal community on the North Sea expressed concern that offshore operators may be given too much responsibility to prioritize risks and make risk control decisions under the ALARP concept. The speaker maintained

¹⁶⁸ See http://www.hse.gov.uk/offshore/statistics/hsr2015.pdf.

¹⁶⁹ Duty holders are given itemized bills of the number of hours expended by HSE personnel engaged in safety regulatory review and compliance activities.

¹⁷⁰ See http://www.ptil.no/safety-forum/category917.html.

that more public engagement and government oversight of these decisions are warranted. However, the entirety of the committee's discussions with the region's government, industry, and labor representatives did not reveal a strong undercurrent of opposition to the region's collaborative approach.

Evaluation Challenges

Both PSA and HSE investigate reports of safety incidents, require reporting of workplace injuries and hydrocarbon releases, and conduct research and analyses that use data from these reports and follow-up investigations. These data are used to analyze safety trends and identify areas where improvements in regulation, collaboration, and enforcement activities may be needed. Because major offshore incidents are rare, empirical assessment of the effectiveness of the program requirements in preventing major incidents can be difficult. PSA's safety data program, referred to as RNNP, ¹⁷² uses a formula for weighting certain types of reported incidents (e.g., well control, fires and explosions, gas leaks) to create a composite indicator of major incident risk. ¹⁷³ By assessing trends in the indicator over time, PSA estimates that the risk of a major incident in the Norwegian oil and gas sector has been reduced by about 50 percent during the past decade. ¹⁷⁴

The UK and Norwegian government, industry, and labor representatives who briefed the committee shared the view that the risk of major incidents has been reduced by the shift to a macro-means approach implemented in a collaborative environment, although they acknowledged the difficulty of measuring this effect quantitatively. Their reasoning emphasized that operators needed to be given the latitude to customize risk reduction efforts to the operator's individual circumstances. These representatives maintained that by putting the responsibility for risk mitigation more squarely on the operator, the use of macro-means regulation has fostered a safety mind-set that was lacking when operators were only expected to comply with detailed sets of individual rules.

¹⁷¹ See http://www.hse.gov.uk/offshore/statistics.htm; http://www.ptil.no/rnnp-and-major-accident-risk/category977.html.

 $^{^{172}}$ RNNP abbreviates "Risikonivå i Norsk Petroleumsvirksomhet," which means "risk level in Norwegian petroleum activities."

¹⁷³ See http://www.psa.no/about-rnnp/category911.html.

¹⁷⁴ See http://www.ptil.no/rnnp-and-major-accident-risk/category977.html.

Observations on Offshore Safety Regulation in the United States and the North Sea

Both the U.S. and the North Sea offshore oil and gas industries experienced major incidents that prompted changes in government safety oversight and regulation. In general, these changes have led to more macro-means requirements being placed on offshore operators to establish and follow procedures and programs for identifying, assessing, and managing the risks of their activities. Governments in the North Sea, led by those of the United Kingdom and Norway, moved earliest and farthest in this direction by requiring systematic identification of risks by operators and justification of proposed means of managing them. The United States has only recently added regulations requiring that operators establish safety management programs and engage in deliberate and documented risk identification and assessment. In all of these countries, the changes in program requirements were imposed on the basis that traditional, micro-level regulations targeting individual risks have not been sufficient in accounting for and controlling all important risks.

Neither the United States nor the North Sea countries have abandoned micro-level regulation. The offshore regulatory regimes depend heavily on such regulations. In all of the countries studied, the required actions are specified directly in regulations or in guidelines that reference consensus standards. The U.S. regime contains hundreds of detailed regulations prescribing actions that must be taken to control specific risks. Such detailed regulatory directives are less common in the UK and Norwegian regimes, where micro-level regulations are more generalized and can be described as ends-based. Nevertheless, agency guidelines on how to comply with a regulation refer extensively to more means-based consensus standards, which accord automatic compliance if they are followed. In addition, as a practical matter, operators often make the case that they have identified and controlled risks by promising to follow micro-level consensus standards.

The most significant difference between the United States and the North Sea countries concerns the approaches used to encourage and enforce compliance with regulations. The U.S. approach is heavily dependent on inspectors making short, sometimes unannounced, visits to installations. They look for conformity to specific regulatory requirements and issue notices when instances of nonconformity are found. The United States has more than 2,000 offshore installations that, by law, must be inspected at least annually. In 2016, these inspections, which were conducted by a staff of about 120 inspectors, produced 2,400 notices of noncompliance. In overseeing the safety of several hundred offshore facilities each, UK and Norwegian regulators have strong enforcement powers and can use them when necessary; however, they also view themselves as problem solvers. They

conduct planned but in-depth inspections of facilities or, as in Norway, assign teams to integrate with operator personnel for ongoing verification of and assistance in compliance with regulations and operator promises. When an incident of noncompliance is discovered, regulators work with the operator to find a solution, which reduces notices that result in sanctions. UK regulators in 2015 conducted 135 facility inspections, all announced, and issued 35 notices.

The UK and Norwegian approach to compliance is demonstrably more collaborative than the U.S. approach. Collaboration among regulators, operators, and labor representatives is viewed as critical to the successful implementation of regulations requiring operators to establish and follow macro-means management programs for identifying and controlling major incident risks. Operators collaborate with labor to develop and implement programs and with regulators to strengthen and adhere to them. Rather than review each operator's proposed management plan strictly with regard to compliance with regulatory provisions, HSE and PSA review the proposed plans and then meet with operators to offer ideas on how to improve them. Such extensive collaboration requires regulators to have staff with a level of technical competency and industry knowledge that far exceeds what is traditionally needed to enforce compliance with detailed, micro-level regulations.

Significantly, North Sea legislators have granted regulators the resources and procedural freedoms to make these supportive changes. When economic conditions lead to significant pay differentials between industry and government, hiring and retaining qualified personnel to implement the regulatory programs can be challenging for North Sea regulators, as it is for BSEE in the United States. To help pay for HSE's skilled personnel, operators are required to compensate the agency for the time spent reviewing safety cases and their implementation. Furthermore, officials in these countries were willing to emphasize collaboration even at the expense of public transparency in some aspects of the regulatory process. For example, while operator consultations with offshore workers add a degree of transparency to the process, safety cases are not openly available, and their development offers little opportunity for the general public to consider the duty holder's application of HSE guidance on determining an acceptable level of safety and environmental risk.

The more recent introduction of regulations requiring management programs is testing the ability of the U.S. regulator, BSEE, to develop the requisite staffing competencies and to add a collaborative dimension to what remains largely an arms-length relationship with the regulated industry. BSEE's structuring and implementation of its safety management regulations have occurred under legal and institutional conditions different from those of the North Sea countries. In comparison with these countries, the

regulatory process in the United States has been described as more adversarial than collaborative (Kagan and Axelrad 2000). It provides a number of opportunities for contestation of regulatory design decisions, including the public notice-and-comment provisions of the Administrative Procedure Act, White House regulatory reviews, and the division of responsibilities among government branches (Aubuckle 2009). A high degree of collaboration is not a common feature of the U.S. approach to developing and implementing regulations and would be impractical for BSEE to adopt in the same extensive manner as in the North Sea countries. BSEE has thus structured and implemented its macro-means regulations in a different—albeit less collaborative—way that reflects the conditions under which it operates.

As illustrated by these differences in the macro-means regulations of BSEE and the North Sea offshore regulators, regulations of the same basic design may be structured and applied in various ways that accommodate a particular set of conditions. In the next chapter, further consideration is given to the choices that regulators face in deciding on the basic design of their regulations as well as the regulation's structural details in response to underlying circumstances. Such variability in circumstances and in how regulations of the same basic design can be structured differently in response to circumstances complicates comparisons of the advantages and disadvantages of different regulatory designs.

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4

Considerations for Choosing a Regulatory Design

To illustrate the options available to regulators for addressing safety in high-hazard industries, the case studies in Chapter 3 showed the various regulatory designs used to promote safety in oil and gas pipeline transportation and offshore oil and gas development in the United States, Canada, the United Kingdom, and Norway. In both industries, the purpose of the regulation is to reduce the occurrence of harmful incidents, including catastrophes. In each country, safety regulators use a mix of the four basic types of regulations—micro-means, micro-ends, macro-means, and macro-ends—as described in Chapter 2. Table 4-1 gives common labels for regulations conforming to each of these four design types, which are available to the regulators of any industrial sector.

The case studies suggest that safety regulators do not find any single design type applicable to all circumstances. Specific circumstances can matter so much that reliance on generalities about a given design type's advantages and disadvantages can be misleading. This chapter explains why such generalities can be more confusing than helpful. By drawing on available research and examples from the case studies, the chapter shows how contextual factors such as the nature of the regulatory problem, industry characteristics, and local conditions (e.g., the regulator's capacity) can change the distribution of advantages and disadvantages of each type of regulation. Those advantages and disadvantages are also affected by the details of the regulation's design; that is, choices about how to structure a regulation have implications for implementation and compliance. The discussion in this chapter is intended to help regulators of any high-hazard industry choose among available regulatory designs and then explain their

	Means	Ends
Micro	Micro-means "Prescriptive"	<i>Micro-ends</i> "Performance-based"
Macro	Macro-means "Management-based"	Macro-ends "General duty/liability"

choices to policy makers and the public. The discussion here also informs Chapter 5, where the report elaborates on the challenges associated with macro-means safety regulation. In an overall assessment (see Chapter 6), the report responds specifically to the study request to compare the advantages and disadvantages of the various regulatory designs used in high-hazard industries.

REGULATION AS PROBLEM SOLVING

Regulators must decide which combination of the four regulation design types promises to achieve the ultimate goal of the regulatory regime as well as any other policy goals and criteria. For clarity of presentation and analysis, the chapter examines separately the regulator's choices about (a) which of the four design types to use and (b) how to structure rules within each design type. In practice, of course, choices about a regulatory design type and more specific structural details need to be made in concert.

On the basis of the assumption that a regulator has made at least a preliminary determination that a regulation is needed, this section considers the role of the following three factors in choosing the design of a regulation:

- The nature of the problem to be solved,
- The characteristics of the regulated industry, and
- The regulator's resources and capacities.

Figure 4-1 gives examples of potentially relevant elements of each of these three factors: problem, industry, and regulator. The relationships among these factors, as well as their interaction with a regulatory design type, affect regulatory outcomes. The relationships can be expressed, for illustrative purposes, in the following simplified function statement:

Outcome: f [regulatory design, (problem, industry, regulator)]

Nature of Problem

Severe consequences?
High or low frequency of occurrence?
Well or poorly understood causes and risks?
Trusted interventions?

Industry Characteristics

Private incentives aligned with regulatory goals? A few large firms? Many small firms? Mix of sizes? Degree of variability in activities and operations? Technological diversity and rate of change?

Regulator Capabilities

Legal authority?
Sensitivity to public and political expectations?
Administrative and procedural constraints?
Budgetary resources?
Human capital and hiring flexibility?
Time availability?

FIGURE 4-1 Factors affecting the selection of regulation design.

Although elements of the three factors may often be largely external to the regulation itself, they may not be fixed. Some, such as the regulator's legal authority and its budgetary resources for enforcement and supportive activities, can be changed by policy makers. Other elements may change for reasons such as market or technological developments that affect the size, scope, complexity, and technological and managerial sophistication of the regulated industry. The possibility of change in these elements implies that a regulator may wish to make changes over time in the mix of regulatory designs that are used.

In the following sections, the role of each of the three factors is discussed in more detail, with examples from the case studies. Although the discussion in this chapter proceeds by first taking up each factor in turn and then considering each regulatory design separately, the regulator will benefit from incorporating consideration of all factors and designs into its decision making. Furthermore, as the case studies show in high-hazard industries, regulators often use a combination of different regulatory designs. For example, they may augment their micro-level regulations with

macro-means regulations intended to address varied and context-specific risks. The three factors discussed in this chapter may seldom justify the use of just one overall regulatory design for regulating an entire sector. Instead, they may indicate the use of different designs for targeting distinct facets of safety within an industry.

Nature of the Problem

The problems that regulations are intended to remedy vary in their likelihood, their complexity, their severity, and the degree to which their causes are understood. In choosing a regulatory design, the safety regulator will be mindful of the ultimate problem to be solved—the prevention of harmful outcomes such as fatalities, injuries, and environmental damage. To find remedies, the regulator almost always disaggregates the problem into its parts. For example, the regulator may focus on individual contributors to risk and then design regulations targeted to each. How the problem is disaggregated is relevant to the choice of regulatory designs because some design types may work better in addressing one risk contributor while others may work better for other contributors. The result may be a regulatory regime consisting of multiple regulatory design types.

Reliance on a mix of regulatory designs was observed in the case studies of Chapter 3. For example, pipeline regulators administer regimes that are intended to prevent the catastrophic harm caused by occasional major pipeline ruptures as well as the harm caused by the more common problem of leaks. One contributor to both failures is external corrosion of steel pipe. To address this relatively well-understood mechanism, both the U.S. Pipeline and Hazardous Materials Safety Administration (PHMSA) and the Canadian National Energy Board (NEB) require pipeline operators to install cathodic protection, an established means of preventing external corrosion of pipe steel under a wide range of conditions. The nature of this contributor to the pipeline safety problem—a phenomenon that is well understood and that can be mitigated with a material intervention applied uniformly across all regulated entities—lends itself to a micro-means regulation that some would call "prescriptive."

Other contributors to problems may not have such singular remedies. Their causes may be assessed in ways allowing for regulations that obligate firms to achieve a specific quantitatively measured end or performance level rather than to use specific interventions. For example, a pipeline may fail from a crack or split at its seam when it is overpressurized. The likelihood of such damage can be influenced by steel type, wall thickness, fabrication

¹ Cathodic protection generally involves the application of a low-voltage electric current to the pipeline.

methods, and other design and technology choices. Instead of making each of these choices for the pipeline operator, PHMSA regulations establish a formula for calculating a pipeline's safe maximum operating pressure. A pipeline designer can adjust the choice of pipeline parameters, materials, and fabrication options to keep operating pressure within specified limits. Other interests in addition to ensuring safety, such as adding throughput capacity or accommodating local conditions, may also be achieved. In this case, a source of the safety problem—a risk contributor that can be measured and addressed through various means—lends itself to a "performance-based," or micro-ends, regulation.

Some causes of pipeline failure cannot be addressed with micro-level regulations alone. Pipelines are damaged by excavation strikes and other activities such as the plowing of agricultural fields. Damage caused by third parties is a major risk concern because the presence of people can make the outcomes catastrophic (PHMSA 2014). "Call-before-you-dig" systems are a proven way to reduce the incidence of excavation damage, and therefore PHMSA requires their use by all pipeline operators. However, the potential for third-party strikes varies according to context-specific factors. Among them are whether the pipeline passes near residential, agricultural, or industrial locations with different degrees of exposure to human activities that can damage buried pipes and to concentrations of people who could be harmed by ruptures. Therefore, the agency requires operators to develop a customized damage prevention program with the understanding that the elements of the program—such as whether protective pipe casings will be installed, rights-of-way patrols will be deployed, or public awareness campaigns will be intensified—will reflect context-specific risk factors. In this way, PHMSA combines a micro-means regulation (requirements for call-before-you-dig notification systems) with a macro-means regulation (requirements for written damage prevention management programs) to address a multifaceted problem ill-suited to a single regulatory design.

Some safety problems are more difficult to disaggregate into contributing factors. They involve interactive sets of factors that can vary over time and across regulated entities. For example, regulators of offshore oil and gas facilities face a particular challenge in designing regulations to prevent catastrophic incidents whose risks arise from the interaction of many facility- and operations-specific factors. An important part of these regulators' responsibility is to reduce foreseeable harms associated with offshore occupations, such as injuries to workers during drilling jobs, helicopter transport, and maintenance activities. However, success in reducing foreseeable workplace harms may have little discernible impact on risk factors that can lead to catastrophic events such as facility explosions, fires, and capsizings. As oil and gas producers have expanded their activities into deeper waters requiring more complex facilities and operations, the risk factors

have been changing. They have sometimes become more difficult for regulators to identify or measure so that one or more micro-level regulations can be applied. In recognition of this circumstance, the United Kingdom's offshore regulator, the Health and Safety Executive (HSE), chose its "safety case" regime, which seeks a more holistic approach to regulation. Similarly, the Bureau of Safety and Environmental Enforcement (BSEE), which regulates the U.S. offshore sector, requires offshore operators to institute safety and environmental management systems (SEMS) that incorporate a variety of risk planning, analysis, communication, and reporting processes.

Both SEMS and safety case regulations overlie a collection of highly targeted, micro-level regulations intended to address specific risks that are common among offshore installations, are fairly well understood, and can be reliably mitigated with specific interventions. The macro-means requirements of SEMS and safety case regulations demand that the operator manage any additional risk factors that are not targeted directly by micro-level regulations. In this sense, the SEMS and safety case regulations are intended to fill gaps in traditional micro-level regulations to improve the regulator's ability to reduce the severity and frequency of foreseeable incidents.

In calling for the establishment of programs that identify risks and implement risk management systems, the macro-means SEMS and safety case regulations are also intended to address the context-specific risks interacting with one another to produce catastrophes. As discussed in Chapter 1, the systemic problems that can arise from such interactions—called normal, inescapable, and thus inevitable problems by Perrow (1984)—cannot be fully addressed simply by imposing micro-level requirements for the use of specific facility designs or for the performance of specific equipment. Like macro-ends regulations that penalize firms or impose liabilities on them should a harmful incident occur, macro-means regulatory designs are concerned not only with the risks relating to how facilities are designed and equipped but also with how the facilities are operated on a daily basis.

These examples from the pipeline and offshore industries show how the nature of the problem can affect the choice of the regulatory design types that make up a regulatory regime. The challenge in making these choices can be described as identifying a good fit between the problem that needs to be solved and the characteristics of a regulatory design.

Industry Characteristics

The degree of government intervention into and regulation of a safety problem depends in part on the industry's incentives and ability to address the problem as well as the public's demand that the problem be mitigated. Individual industries and firms have incentives to ensure safety. For example, a commercial airline presumably has an interest in safety because—among other reasons—its customer demand would disappear if its planes were prone to crashes. Government intervention by regulation is often demanded in cases where an industry is not believed to have internalized a perceived threat fully or to have selected an optimal level of safety precaution from a societal standpoint. Some industries or firms may lack sufficient incentive to address a safety problem. Some may lack the ability to recognize and respond to a problem, perhaps because the harms are slow to manifest themselves and long term in nature. Therefore, at the most basic level, an understanding of the industry is important in deciding on a need for government regulation (Coglianese 2010).

An understanding of the industry is also important for choosing the design of a regulation. In particular, the degree of heterogeneity of the firms and technologies in the industry can be an important factor in choosing a design (Coglianese 2010). An industry consisting of firms whose size, resources, operations, and technology are similar presents a regulatory challenge different from that presented by an industry whose firms differ widely in these characteristics. In the former case, micro-means regulations may be a promising design type, because the prescribed technologies, materials, and practices may have widespread applicability. However, circumstances can vary. The uniformity of micro-means requirements may be problematic in cases where uniform actions would be ill-suited to some firms and would preclude the use of alternative means that may be more cost-effective (Gunningham and Johnstone 1999; Hahn 1989). Under these conditions, ends-based regulation allowing the regulated firm to choose among options for achieving the desired ends may be more promising (Gunningham 1996). Many industry consensus standards that are referenced in government regulations, as exemplified in Chapter 3, can be characterized as having an ends-based quality because they do not mandate the use of a particular practice or technology (e.g., the grade of steel in a pipe) but instead define the qualities or outcomes to be achieved (e.g., pipe strength properties). These standards are often developed by industry actors cognizant of the need to accommodate a range of users and applications.

The case studies in Chapter 3 show that the offshore oil and gas and pipeline industries use a wide range of technologies and practices. BSEE regulates more than 2,000 offshore facilities in the Gulf of Mexico alone. Some operate in shallow waters and others in deeper waters, where facility designs and operations are much more complex. The complexity of offshore facility designs and operations has grown as production has expanded to deeper waters and harsher environments. In the North Sea, HSE and the Petroleum Safety Authority (PSA) regulate considerably fewer offshore facilities, but many of them are massive structures serviced by hundreds of workers. Many platforms have multiple contractors and complex management configurations, which make coordination and accountability difficult,

if not opaque. PHMSA and NEB regulate pipeline systems ranging in scope from transcontinental networks owned by multinational corporations to local distribution systems run by small gas utilities. The systems share many basic features and have many similar risk concerns, but they differ in many fundamental aspects such as physical design and configuration, technology vintage, use patterns, operating environments, capitalization, history, and staffing capabilities.

Knowledge of all the context-specific risks contributing to a safety problem in such complex industries can be challenging for a government regulator (Coglianese and Lazer 2003; Huising and Silbey 2011; Silbey and Ewick 2003). Cognizant of the challenge, BSEE, NEB, HSE, PHMSA, and PSA have all issued macro-means regulations requiring operators to establish customized management plans and systems to identify and control all their significant sources of risk. Each of the five agencies recognized the importance of accounting for the diversity and complexity of the activities and businesses it regulates when it chose this regulatory design.

As some of these regulators have found, a diverse industry can also complicate the use of such macro-means regulations. Both the offshore and the pipeline industries consist of operators with a range of management capabilities because of variability in the size and resources of firms. The offshore industry, particularly in the United Kingdom and Norway, consists mostly of large multinational drilling and production companies who generally prefer macro-means regulations that give them flexibility to control their facility-specific risks. Such companies are more likely than smaller operators to have resources for assessing risks and designing locally appropriate systems. Larger pipeline operators exhibit a similar preference for such regulations. However, when PHMSA extended its macro-means requirements for integrity management programs to gas distribution systems, hundreds of smaller gas utilities were affected. Many of these pipeline operators complained about the impracticality of developing and implementing management system requirements with small engineering departments and limited staffing resources. They preferred the more direct and comprehensible requirements of "prescriptive" micro-means regulations that create more predictability about the actions required for compliance.

The case studies illustrate how another industry characteristic—the degree of technological diversity across firms and rate of change in the state of technology over time—can affect the choice of a regulatory design. Where technologies are diverse or fast-changing, safety regulators who rely extensively on micro-means regulations run the risk of the requirements being inapplicable, becoming outdated, or creating an obstacle to the introduction of beneficial new technologies (Silbey and Ewick 2003). As noted, offshore oil and gas production technology has become more complex as development has moved to deeper waters. BSEE continues to rely

on many highly targeted micro-means regulations but has also introduced some micro-ends regulations in recognition of a dynamic technological landscape. For example, in its 2016 well control regulation,² BSEE states that an operator's casing and cementing program must provide adequate centralization to ensure proper cementation around the casing.³ By allowing operators to use conventional bow-type centralizers as recommended in referenced industry consensus standards but not requiring them to use such a device, the regulation recognizes that advances in technology and practice are leading to other options to ensure the desired outcome of centralization.

The macro-means regulations of offshore and pipeline regulators can also be applicable when technologies or processes vary across firms or change over time. By requiring uniform management actions such as planning and systems analysis, this form of regulation leaves the details of facility design or operational technologies to each firm.

Regulator Capabilities

No matter how well a regulation is designed, its potential to have impact will depend on the regulated industry's level of compliance (Coglianese and Lazer 2003). Examples of the regulator's role in motivating and compelling compliance are provided in the case studies in Chapter 3. They show how regulators can use persuasion or technical support to promote compliance. For example, regulators provide guidance on best practices, conduct research to develop compliant technologies and practices, and participate in the development of industry consensus standards to operationalize regulations. The case studies also show how regulators use enforcement mechanisms such as inspections, audits, and fines. Because the support and enforcement capacity of a regulator bear on the prospects for compliance and because the capabilities required vary with regulatory design, they are important considerations in the choice of a regulatory design.

PHMSA's program for ensuring compliance with its pipeline safety regulations illustrates how regulatory design types and regulator capabilities relate, both with one another and with industry characteristics. The agency's enforcement program was established to ensure that pipeline operators comply with a specific type of regulatory design, micro-level regulations. In what is often called a "checklist" process, inspectors visit facilities to ensure that specified procedures, technologies, equipment, and systems are in place and being used. For example, they may verify that a specific valve type is installed and functioning as required. To aid in the inspection

² 81 Federal Register 25888, 25918 (April 29, 2016).

³ Centralization entails keeping the casing or liner in the center of the wellbore to help ensure efficient placement of a cement sheath around the casing string.

of thousands of pipeline systems that can span tens of thousands of miles, PHMSA enlists state pipeline safety agencies to help enforce its regulations. Personnel from state agencies inspect nearly all gas distribution systems, most other intrastate transmission systems, and some interstate transmission systems as well.

A challenge for PHMSA has been to ensure that federal and state personnel have the capabilities needed to enforce its newer macro-means regulations that require integrity management programs. Determining what constitutes an adequate integrity management program demands a different skill set on the part of the regulatory inspector, because both the auditing of management processes and physical inspections of facilities are required. When PHMSA issued its first integrity management regulations nearly 20 years ago, it recognized that its enforcement program would need to adapt. The agency continues to experience problems in hiring and retaining enforcement personnel with the necessary expertise, in part because of disparities between government and private-sector pay scales. PHMSA's heavy reliance on state inspectors presents an additional challenge. Like some federal inspectors, many state inspectors are accustomed to checklist procedures rather than program audits. When integrity management programs were mandated for gas distribution systems, states became responsible for enforcing compliance. Thus, PHMSA must not only make changes to its own inspection workforce but also ensure that dozens of state programs have the requisite enforcement capabilities and resources.⁴

PHMSA's experience illustrates how a regulator choosing among regulatory designs may want to consider each design's compatibility with the regulatory designs and capabilities of other regulators of the subject industry. Industries must often comply with regulations issued by multiple authorities. North American transmission pipeline operators are subject to federal and state regulations in the United States, as well as regulations in Canada. Offshore mobile drilling units are governed by both BSEE and U.S. Coast Guard (USCG) regulations when operating in U.S. waters and by the requirements of other countries when operating elsewhere. In such cases, the regulator may want to choose regulatory designs that align with those of other regulatory regimes, both to facilitate industry compliance and to leverage the enforcement capabilities of multiple regulators.⁵

⁴ Canada's NEB has also experienced challenges in obtaining adequate resources for instruction and training of enforcement personnel to accommodate macro-means regulations. NEB reported that with existing staff resources, nearly 1 year can be required for the agency to complete an audit of an operator's management systems.

⁵ As noted in Chapter 3, BSEE and USCG have closely aligned jurisdictional and regulatory responsibilities related to offshore energy development on the U.S. outer continental shelf. The two agencies collaborate to reduce the redundancy and ensure the consistency and clarity of their regulations. They also coordinate inspection and other enforcement activity.

BSEE's experience in enforcing its macro-means SEMS regulations offers another example of the relationship between regulatory design and regulator capabilities. BSEE is faced with overseeing compliance by hundreds of offshore operators and their contractors and has many of the same personnel issues as PHMSA. Like those of PHMSA, BSEE's inspectors had traditionally enforced micro-level regulations by visiting offshore facilities and inspecting for compliance through use of a checklist procedure. The agency uses approximately 125 inspectors to enforce compliance on more than 2,000 facilities. Because micro-level regulations can be enforced relatively quickly by using standardized protocols, BSEE has been able to function with a smaller enforcement workforce having fewer technical experts. The addition of SEMS requirements has caused the agency to begin reevaluating its enforcement personnel needs and strategies. BSEE has sought to compensate for its difficulties in hiring and training auditors for SEMS compliance by requiring offshore operators to hire independent program auditors. Nevertheless, the agency must develop a capability to evaluate the auditors and their accreditors.

The regulatory activities of HSE and PSA in the North Sea also illustrate how a change in regulatory design can have implications for the regulator's personnel and other capabilities. As discussed in Chapter 3, these regulators employ relatively large workforces to oversee compliance at fewer than 500 offshore facilities. The detailed reviews of required management plans in safety cases and acknowledgment of compliance (AOC) applications are labor-intensive activities calling for a range of skills and industry competencies among regulatory personnel. HSE and PSA have therefore had to obtain the budgetary commitments to employ personnel having such expertise, including knowledge of risk analysis and experience in the offshore oil and gas industry. However, HSE's and PSA's adoption of macro-means regulatory approaches required more than transformations of their workforces over the past two decades. Both agencies have changed the way they oversee the offshore industry in the North Sea region, which has had implications for a range of required capabilities.

To support their macro-means regulations, HSE and PSA have chosen to develop a capability to collaborate with the offshore industry and workforce. HSE is required by law to work with offshore operators to improve their safety cases, and it functions in part as a "problem solver." When HSE personnel visit offshore facilities to verify conformity with safety case plans, they do not conduct checklist inspections but instead spend days meeting with workers and managers and observing their practices and performance. Before inconsistencies with safety case plans are cited and sanctions imposed, HSE personnel meet with operators to discuss options for resolving them, unless there is an immediate risk of serious harm that warrants a notice to stop the activity immediately. PSA's collaborative ef-

forts to facilitate compliance are perhaps illustrated best by its deployment of multidisciplinary teams to each operator's onshore control room. These teams not only validate that operators are following the plans and processes promised in their AOCs but also contribute engineering and industry process expertise to inform operators about safe practice. Both HSE and PSA contend that the capability to engage in this high degree of collaboration and consultation is essential to the implementation of their macro-means regulations because it provides valuable insight into the context-specific risks that can arise at individual facilities and across operators.

On a smaller scale than HSE and PSA, PHMSA has demonstrated an increasing willingness and capability to collaborate with U.S. pipeline operators to facilitate compliance with its macro-means integrity management regulations. When PHMSA first introduced the requirement for integrity management programs, it expected pipeline operators to develop expertise in risk modeling and analysis that would soon permeate the industry. Because the development of this industry expertise has been slower than expected, PHMSA has had to compensate by developing its own risk modeling expertise and collaborating with industry in work groups to further the state of practice. In addition, by working with small pipeline operators, the agency has developed a computer program known as SHRIMP (Simple, Handy, Risk-Based Integrity Management Plan) to help this segment of the industry comply with its integrity management regulations.

These examples indicate that the selection of a regulatory design type and its use in combination with other design types can have significant implications for the regulator's enforcement program and for its other supportive activities. The examples illustrate the importance of a regulator having or being able to develop the capacity to implement and enforce a selected design. A regulator that lacks or cannot develop a required capacity, such as a staff with sophisticated risk analysis and auditing competencies, may find that the attributes of a regulation type that make it attractive can create a considerable burden and practical obstacle to regulatory effectiveness.

ISSUES IN REGULATORY DESIGN, IMPLEMENTATION, AND EVALUATION

In deciding how to design a regulation, the regulator must do more than merely identify a promising general type of regulatory design. Regulations of the same design type can differ markedly in their structural details, which will have implications for how well they will achieve the regulator's goals. Faced with many constraints, the regulator may not be able to structure a regulation of the preferred design type that produces the desired response. Under these circumstances, other design types may need to be considered.

This section explains how and why the structural details within each

design type matter. For example, although micro-ends regulations may offer regulated firms greater flexibility than do micro-means regulations, not all micro-ends regulations will be the same in terms of the degree of flexibility they offer.

Coglianese and Nash (2017) discuss the history of the federal tailpipe emission standards, which are micro-ends regulations intended to provide flexibility to vehicle makers in reducing emissions by adjusting engine operating conditions, changing fuel requirements, installing after-treatment devices, and taking other measures. However, when the U.S. Environmental Protection Agency (EPA) reduced its permissible nitrous oxide limits by nearly 90 percent in 2007, most engine manufacturers were forced to adopt catalytic converters for after-treatment, the only available means to meet the new standard at the time. Thus, the flexibility imparted in this case was minimal because of a structural feature—the degree of stringency in the performance limit established by the regulation. A micro-ends requirement structured so that it can be met with only one available technology is, for practical purposes, just as constraining, in the short term, as if the regulator had imposed a micro-means obligation to use that technology (Coglianese 2016).6 Much the same can be said of the other regulatory design types. For example, a micro-means regulation that simply requires the use of "monitoring technology" will have effects different from that of one requiring the use of a specific type of sensing equipment.

The structural details of a regulation can affect not only compliance flexibility but also the regulation's performance with regard to a variety of policy objectives, such as the prospects for implementation (including compliance and enforcement) and ease of evaluation of impacts. A regulator is likely to have multiple objectives in selecting a regulation, so offering a "recipe" for choosing an appropriate structure for each design type is impractical. On the basis of experience from actual regulations, however, there are some common questions—as discussed in the following sections—that a regulator should consider in deciding how to structure a given type of regulation to meet policy objectives.

Micro-Means (Prescriptive) Regulations

As shown in the top left-hand cell of Table 4-1 and noted in Chapter 2, micro-means regulations are often described as prescriptive and sometimes called design, specification, technology-based, or command-and-control

⁶ Such a restrictive ends-based requirement may still promise flexibility in the longer term if it eventually can be met by using new technologies. A micro-means regulation, in contrast, can accommodate future technological change only through waivers from or amendment of the regulation.

regulations (Coglianese 2010). A common characteristic of these regulations is that they obligate regulated firms to take or refrain from taking particular actions (e.g., following a certain procedure, using a given material, or installing a type of equipment). In general, the decision to use a micro-means regulation implies that the regulator has a good understanding of the specific hazard, means of mitigation, the capacities of the applicable technologies, and the operations of the regulated firms. Only with such an understanding can the regulator prescribe specific actions and have confidence that the actions will be suitable and effective.

Even when circumstances suggest that a micro-means regulation may be desirable—such as the existence of a trusted control measure used by a homogeneous industry—the regulator has many choices to make in developing and applying such a regulation in a particular case. Some of the choices are illustrated by the following questions:

- What kind of means should the regulator require (e.g., use of a technology, design, practice, or procedure)?
- Should the regulator give firms more than one means from which to choose (e.g., "the manufacturer shall install either automatic seat belts *or* air bags")?
- Should all firms be required to use the same means? Or should different means be required for different categories of firms, depending on, for example, the size of a regulated facility or its operating conditions?
- Should waivers or exemptions be permitted? If so, on what basis should they be granted?
- Should the means requirement be combined with an equivalency provision allowing the regulated entity to substitute another means that yields an equivalent outcome? If so, who should bear the burden of proving the equivalency (or lack thereof): the regulated firm or the government?
- Are required means themselves subject to required performance tests [e.g., "the facility shall install pressure relief valves (means) that activate at *X* pounds of pressure (ends)"]?
- What paperwork or monitoring protocols, if any, should be imposed on regulated firms to document their use of the required means?

The answers to these questions can have implications for the structure and performance of a micro-means regulation. Assessment of the desirability of using micro-means regulation will depend on answers to questions such as these. For example, consider the question, "Should all firms be required to use the same means?" If allowing different types of firms

to use different means would indeed be desirable, the very applicability of a micro-means design may be questionable. On the other hand, if a given practice or technology is widely available, known to be effective, and can feasibly be used by most firms, the regulator may conclude that requiring the uniform use of that means is appropriate, even if some exceptions or different categories might need to be provided. After all, a micro-means design can also provide advantages, such as greater clarity with regard to the actions expected of the regulated firm and thus greater assurance that the actions will be undertaken (Coglianese 2010). In the case studies, many observers claimed that smaller operators of gas pipeline systems tended to favor such specific means-based regulatory commands because they provide greater certainty and simplify decision making, which can be important for firms with limited resources and technical staff.

However, the clarity and directness of a "one-size-fits-all" means-based regulation can lead to rigidity. Such regulations prevent firms from applying more innovative solutions, which was a concern raised by larger pipeline operators in the case studies. In deciding whether to use this form of regulation, the regulator will need to consider whether it will be able to recognize when changes in the state of practice and technology demand changes in regulatory requirements and then to make these changes. If the process for changing regulatory requirements is cumbersome and costly for example, lengthy rulemaking proceedings are required—the regulator may be concerned that any micro-means requirements it imposes today will become outdated and hinder the introduction of more effective remedies. This concern may be abated if the regulation can be designed to ensure that requirements are kept current—for example, by basing them on regularly updated consensus standards developed by nongovernmental standardssetting organizations. Such an option will prove less helpful in the United States, because ordinarily, regulations must still be amended to require later versions of consensus standards. In all countries studied in Chapter 3, pipeline and offshore safety regulators reference industry consensus standards, although the mechanisms for ensuring that the most recent standards are referenced vary.

The regulator may consider other modifications to compensate for an overly inclusive micro-means regulation. One option would be to add an equivalency provision allowing firms to substitute other means for the required one as long as the alternative met certain performance requirements. This decision will need to be considered carefully. It may require that the regulator institute a process for assessing equivalency, which may be costly and complicated to implement if the industry is large and waiver requests are abundant. Adding such a provision can also affect enforcement. One of the implementation advantages of a one-size-fits-all means-based regulation is that inspectors may be more readily trained and able to work more

quickly when they are tasked with observing whether uniformly required means are being followed. Uniformity of means can be helpful for a regulator such as BSEE, whose inspectors make more than 20,000 inspections per year. They often visit multiple offshore facilities in 1 day and follow a checklist of standardized items to observe. Federal and state pipeline inspectors follow similar checklist procedures for enforcing the many micromeans regulations that apply to thousands of operators and hundreds of thousands of miles of pipeline. The use of different oversight techniques may be required when compliant means are more varied.

Micro-Ends (Performance-Based) Regulations

As shown in the top right-hand cell of Table 4-1 and discussed in Chapter 2, micro-ends regulations are often referred to as performance-based, goal-based, process-based, and risk-based. Other terms, such as outcome-based, are also used. Regulations of this type require the regulated firm to attain or avoid a specific set of outcomes as an intermediate step in addressing the ultimate problem that motivates the regulation (Gunningham 1996; Viscusi 1983). The flexibility afforded by micro-ends regulations has made them attractive to policy makers. Indeed, an executive order on regulation adopted during the Clinton administration and is still in force directs federal agencies to specify performance objectives when new regulations are developed wherever feasible.

The Chapter 3 case studies describe micro-ends regulations that are targeted to specific aspects of the ultimate safety problem of preventing harmful failures in pipelines and offshore facilities. Examples include BSEE's requirement that welding be done in a manner that ensures resistance to sulfide stress cracking, HSE's requirement that lifeboats have sufficient places for 150 percent of the workers on the facility, and PHMSA's requirement that pipeline coating systems have sufficient strength to resist soil stresses. These regulations prescribe outcomes to be achieved—resistance to stress cracking, evacuation capacity for workers, and strength to resist soil stresses—rather than mandating the particular means for achieving these outcomes.

A regulator interested in pursuing a micro-ends regulatory design faces many choices about how to structure such rules. They are illustrated by the following questions:

- Can clearly defined performance indicators be identified that will capture the relevant end outcomes?
- How specifically should performance be defined (e.g., "avoid unsafe pressures" versus "avoid pressures above *X* psi")?

- Who is collecting the performance data? How can the integrity of the data be verified?
- On the causal chain leading to the ultimate problem, how close to that ultimate outcome should performance be set (e.g., on an early step or nearer to a penultimate one)?
- Who should bear the burden of proving that performance has or has not been satisfied—the regulator or the regulated facility?
- Should performance be measured in actual practice, or should compliance be based on predicted outcomes and assessed via simulation?
- On what criteria should levels of performance be determined (e.g., feasibility, de minimis risk, current technical achievability)?
- Should performance requirements be applied to individual units (e.g., each smokestack) or to an aggregate collection of units (e.g., the entire facility)?
- How should the required performance levels vary with the characteristics of the regulated unit or facility (such as age or size)? Or should all regulated units or facilities be required to achieve the same level of performance?
- Should a facility be able to bank or trade, within the facility or with other regulated entities, any desirable performance achieved in excess of minimally required ends?
- What kind of recordkeeping or reporting requirements should be imposed on facilities to document their performance?
- Should regulators prepare micro-means guidance to accompany micro-ends regulation?

Answers to questions such as these can have significant implications for the regulation's outcome as well as for the burdens imposed on the regulator and the industry. For example, the regulator must decide how to define "performance." A basic design challenge for a micro-ends approach is finding performance indicators that capture the outcomes sought. For complex functions, a measure or set of measures that capture poorly defined risks may be difficult to find. Vague performance measures can lead to difficulty for the regulator in ensuring compliance in a uniform fashion (May 2011).⁷ For example, in environmental regulations, chemical releases are easily measurable but not as accurate as indicators of risk, which are harder to measure (Bennear 2006).

A performance requirement presumably must not be so ambitious or

 $^{^7}$ New Zealand adopted flexible performance-based regulatory standards for buildings, but enforcement failed because the standards were so vague that performance became difficult for regulators to ensure (May 2003).

strict that it offers no feasible means of compliance. If it is defined very narrowly, the requirement can limit the flexibility of firms to innovate and respond in more cost-effective ways. If the only feasible way to meet a tightly defined performance requirement is to use a particular technology, the micro-ends regulation will lead to outcomes identical to those of a micro-means regulation that prescribes the use of that technology (Ashford et al. 1985).

In designing micro-ends regulations, a regulator must understand the causal pathways to the larger problem, because the regulations need to focus on an intermediate problem or step on the causal chain leading to the ultimate problem (May 2003). For example, if the goal of a regulator is to reduce fire risks at industrial facilities, establishing a micro-ends regulation to limit the level of equipment noise will unlikely do much to address the ultimate problem. The relevant causal pathways or network may be relatively clear for ascertaining how certain intermediate outcomes such as levels of pollutants can adversely affect human health, which is the ultimate regulatory concern. In other cases, such as problems arising in complex industrial systems, these relationships may not be well understood (Coglianese 2016). In the examples of regulations governing lifeboat occupancy capacity and pipeline stress resistance capability, micro-ends regulations target concerns on the causal pathway that are far removed from the ultimate safety problem. However, micro-ends regulations can be written to mandate outcomes that are closer to that ultimate problem. An example is the EPA regulation that limits mercury emissions from power plants to a given number of pounds per unit of energy output. A plant can meet the EPA limit by using various combinations of control technologies and operational processes (EPA 2012). In this case the ultimate problem is the prevention of cancer and neurological illnesses attributed to levels of mercury in the environment. Because a major portion of the mercury in the environment derives from power plants, the structure of EPA's regulation of this emissions source leads to a response that is closely connected to the ultimate problem.

Structuring a regulation that mandates desired outcomes with a direct bearing on the ultimate problem and that are measurable or can be accurately modeled, as is the case with the emission of mercury, can be challenging for a regulator. In the EPA example, the problem of mercury contamination is well understood. In addition, a plant's compliance with a quantitative performance requirement can be assessed with technologies for monitoring mercury combustion flue gases and by-products from power plant stacks. When sources of an ultimate problem are numerous and diffuse, identification of measurable ends with a strong connection to the problem may be difficult for the regulator. The regulator might be able to identify some intermediate, measurable outcomes that contribute to the

problem, but not all of them—especially when the problem concerns industrial catastrophes that can arise from one of any number of combinations of intermediate outcomes (Reason 1997).

Knowledge by the regulator of whether the outcomes required have a causal connection to the ultimate problem is important in choosing a performance requirement (Coglianese 2010; Stavins 1998). As discussed in Chapter 3, BSEE has enlisted the U.S. Department of Transportation's Bureau of Transportation Statistics to develop and manage a near-miss reporting system.⁸ Analysis of such data (e.g., by using anomaly detection and predictive maintenance algorithms) could provide BSEE with a better understanding of the most likely causes of offshore catastrophes. Measurable outcomes (e.g., behaviors or types of events) connected closely enough to catastrophic risk that they can serve as proxies for catastrophes may be identifiable. With this information, BSEE may be able to design micro-ends regulations that rely on such proxies for the ultimate problem as the basis for the outcomes embedded in the regulatory obligation.

In choosing how to structure a micro-ends regulation, the regulator will need to consider the measurability of the relevant outcomes for the purpose of ascertaining compliance. Methods of determining performance can vary. They include direct observation of actual outputs or outcomes on a continuous or periodic basis, testing under conditions similar to actual conditions, and computer simulations based on models of the relationship between inputs and outputs (Coglianese 2016). Offshore facilities are dispersed and in remote locations. Thus, monitoring of outcomes (e.g., the incidence and volume of releases) may prove challenging, especially in comparison with conducting spot checks to ensure that well-defined micro-means regulations are being followed.

Decisions about measurability could fall prey to the "streetlight effect," a type of observational bias that occurs when people search for something and look only where doing so is easiest. This bias is illustrated by the parable of the drunk looking for his lost keys under a lamppost, simply because that is where the light is. A regulator may inadvertently impose regulatory obligations to meet intermediate objectives of a larger problem that are more easily measured but less significant in terms of their causal relevance to the ultimate problem.

The relevance and measurability of outcomes are only some of the issues that a regulator will need to consider in designing a micro-ends regulation. Another issue is the need to ensure that the required tests for performance are well calibrated and reflect the full trade-offs of values and interests at stake. A micro-ends regulation that mandates the design

⁸ The program is called the Safe Outer Continental Shelf Confidential Reporting System, or SAFEOCS (https://www.safeocs.gov).

of child-resistant packaging for pharmaceuticals and hazardous household products may succeed in inducing manufacturers to produce packages that children cannot open; however, these packages may prove exceedingly difficult for adults to open as well (Coglianese 2016). Another possibility is that the flexibility afforded by micro-ends regulation will bring about perverse responses, as in the case of the "teaching-to-the-test" phenomenon. Some firms may satisfy the performance test in ways that do not address the ultimate problem that motivated the regulation (Coglianese and Nash 2017; May 2003). This occurrence is a form of goal displacement made possible if performance measures do not fully capture outcomes.

Manipulation of performance metrics by the regulated entity is another form of performance perversity. Massaging or simply making up data has been found in regulation and multiple policy areas where those being assessed also collect the data for which they are being held accountable (Moynihan 2017). One technique for dealing with this problem is to monitor a variety of metrics beyond those included in regulatory standards that might reveal perverse behavior.

Macro-Means (Management-Based) Regulations

As shown in the bottom left-hand cell of Table 4-1 and noted in Chapter 2, macro-means regulations are often referred to as management-based. These regulations seek to harness the special information advantage that a regulated firm possesses about the details of its operations and facilities. They are premised on two beliefs. The first is that firms themselves, with their many interactive human and technological processes, are in a better position than the regulator to know what actions should be taken to achieve the regulatory outcome. The second is that if firms are given the flexibility to act, they will have greater opportunity to find more cost-effective outcomes and a higher likelihood of compliance (Ayres and Braithwaite 1992; Coglianese 2010; Coglianese and Nash 2001; Kleindorfer 1999).

As discussed in Chapter 2, this type of regulation is referred to by many names, including process regulation, performance-based regulation, systems-based regulation, safety case regulation, and enforced self-regulation (Coglianese 2010). It has been applied in a variety of domains around the world, including food safety, mine safety, rail safety, chemical accident avoidance, and pollution prevention (Bennear 2007; Coglianese and Lazer 2003; Hutter 2001). It is often used in contexts exhibiting high levels of heterogeneity in industry practices and for problems associated with systemic interactions. In such circumstances the regulator can have difficulty in identifying both widely applicable micro-means requirements and outcomes that are sufficiently discrete, relevant to the problem, and measurable.

The case studies in Chapter 3 illustrate how macro-means regulations

can differ in use and design details. The safety case and AOC regulations are viewed as central to HSE's and PSA's regulatory regimes, whereas BSEE's SEMS regulation is viewed as an accompaniment to a larger suite of micro-level regulations. In regulating pipelines in Canada, NEB administers a large number of macro-means regulations in combination with micro-level regulations. PHMSA uses macro-means regulation in a more targeted manner to focus on integrity management. The following are examples of the choices regulators face in the design of macro-means regulations:

- How detailed should the management requirements be? For example, should they simply call for facilities to engage in a "comprehensive risk plan," or should they specify what such plans should contain (e.g., start-up procedures, emergency operations, inspection protocols, etc.)?
- Should regulated entities be required to submit their management plans to the regulator before commencing operations (as in the HSE safety case)? Or must they merely develop the plans and keep them and any other documentation on file for whenever a regulator inspects (as is the case with PHMSA's integrity management regulations)?
- How will regulators address poorly developed plans?
- What kind of recordkeeping and documentation, and how much, should be required?
- How will the regulator ensure that the plan is being followed?
- Should regulated entities be required to obtain a third-party audit of their management plan and system?
- Should a specific frequency of audits be mandated so that management can know whether the plan is being followed, or should management merely be mandated to develop a procedure for ensuring that the plan is being followed?
- To what extent should performance measures be used as a supplemental regulatory obligation (via ends-based regulations), or should they merely be used as feedback loops for improvements in the management system?

Many of these questions have been addressed by the regulators studied in Chapter 3. For example, the question about the level of detail of management requirements is being considered by PHMSA as it revises its integrity management regulations in response to concerns about the safety performance of some operators. When PHMSA first introduced these regulations, the emphasis was on allowing operators to customize required elements of their management programs. The intent was to encourage programs that would be more applicable to individual circumstances and to prompt in-

novation in areas such as pipeline risk analysis and management. PHMSA has been adding more prescription to the regulations in recent years to address concerns about the ambiguity of the requirements and to give operators more guidance on how to improve their risk management processes. Meanwhile, HSE and PSA have taken the contrary approach. They have limited the amount of prescription in their macro-means regulations out of concern that too much direction could curb the ambition, capacity, and commitment of operators to take more responsibility for safety. This approach rests on what might be called a corporatist philosophy that regards health and safety as a shared responsibility of the firm, the workforce, and government (Hutter 2001). The varying approaches regulators have taken to defining the requirements of macro-means regulation illustrate how a regulator's choice of regulatory structure can be affected by a desire to balance various objectives. The structure of a macro-means regulation can affect not only the objective of ensuring that firms are compliant but also the objective of motivating firms to assume direct responsibility for solving the underlying problem (Hutter 2001).

One of the structural questions about macro-means regulation concerns whether the regulated firm should be required to submit its management plans for approval or keep them on file for inspection. The case studies illustrate how variations in this aspect of regulatory design can have implications for agency staffing. Both the UK safety case and the Norwegian AOC regulations require offshore operators, or "duty holders," to demonstrate to their respective regulators (HSE and PSA) that their safety plans are based on rigorous analysis before they can begin the planned activity. In contrast, PHMSA's integrity management regulations do not require advance approval, but inspectors may review the program's content and execution once the program is in place. As noted earlier in this chapter, preapproval of plans by HSE and PSA can entail a process of intense scrutiny by the regulators' technical experts, as well as collaboration with the applicants to strengthen their proposals. To undertake timely and thorough review and collaboration, HSE and PSA maintain a large staff with technical and industry expertise, including proficiency in risk analysis. Because PHMSA's retrospective reviews of plans do not require the same timely response as a preapproval, the staffing and competency demands on agency personnel are more modest, perhaps in alignment with the agency's constrained hiring capabilities. BSEE, which faces similar constraints on the hiring of technical personnel, has designed its SEMS regulation to require third-party audits and certifications of operator programs within 2 years of initial implementation and once every 3 years thereafter. This strategy is intended to help mitigate enforcement problems associated with limited government resources (Coglianese 2010).

Lack of clarity in aspects of the management plan may lead to parts

of the plan being neglected (Haines 2009). Smaller firms, in particular, may struggle with interpretation. One study of the use of risk management plans for hazardous chemicals found that some smaller firms engaged in gaming behaviors to present a false perception of compliance (Chinander et al. 1998). One tactic was to store hazardous chemicals off-site so that the firm technically fell below the threshold for regulation. Risk was increased because some chemicals were being stored in unsafe conditions.

Macro-means regulation appears to be associated with a reduction of risks in some settings in which it has been applied. However, research suggests that the behavioral impact of such regulation may be difficult to sustain over a longer period of time as required management planning becomes, for at least some firms, a paperwork exercise (Bennear 2007; Coglianese and Nash 2004; Silbey and Agrawal 2011). One concern with regard to macro-means regulations is what some in the offshore industry call "pencil-whipping"—extensive documentation of the management system that may have little relation to practice. Management-based regulation may help induce managers to start thinking about previously ignored problems, but once the easier problems have been resolved, ongoing diligence in risk management activities may become more challenging to ensure.

Macro-means regulations usually require a governmental oversight presence to ensure that firms conduct the necessary planning and implement their plans (Coglianese 2010). To ensure that approved plans are being followed, HSE and PSA observe the actions and procedures of offshore operators by visiting facilities for extended periods or by integrating agency personnel into operations centers. Officials at the two agencies indicate that this approach requires the employment of personnel with extensive knowledge of industry procedures. Audit-like reviews of planning documents and records, which is characteristic of PHMSA's inspections of operator integrity management programs, do not verify the execution of plans in the same direct manner that, say, inspection of installed safety devices can verify compliance. Regulators who impose macro-means regulation may need to enhance their enforcement capabilities or find effective ways to rely more on government inspectors or third-party auditors.

Regulators face a challenge in structuring a management-based regulation that can be evaluated for impact. Such an evaluation may be expected by policy makers to justify a form of regulation that, on the one hand, may be perceived as impinging too deeply on a firm's internal affairs or, on the other, as ceding too much control to firms in the identification, prioritization, and management of risks. Despite the potentially greater need for justifying macro-means regulations with demonstrable results, their impact in reducing harms associated with infrequent events arising from a diverse, context-specific set of causes can be difficult to discern. That would be the

case for any form of regulation under these circumstances, but evaluation of the impacts of macro-means regulations poses additional challenges.

First, the benefits of this type of regulation can be difficult to isolate. They derive not from anything directly measurable but from whatever additional improvements are made in management systems. As Dawson et al. (1988) conclude, the creation of health and safety structures and procedures within a company is an "imperfect measure" that does not in itself indicate an improvement in health and safety. Because most firms will have had some management systems in place before the regulation, the relevant benefits will be the marginal risk reductions resulting from any changes in management practices. Most offshore drilling contractors are international firms subject to macro-means regulations of multiple countries. For example, whether BSEE's SEMS requirement has led to any consequential changes in the management programs used by a multinational firm based in the United Kingdom, where similar programs have been required for years, can be difficult to ascertain.

Second, estimation of the costs of macro-means regulations can be difficult because of the flexibility afforded by this type of regulation. The costs to firms can take two forms: (a) administrative costs related to the planning, analysis, and documentation required and (b) capital and operating costs related to the actions that firms implement as a result of this planning and analysis. Identification and quantification of these costs in advance by the regulator can be complicated, because each firm may respond differently to the management requirements, precisely as the flexibility of this regulatory design allows.

Macro-Ends (General Duty/Liability) Regulations

As shown in the bottom right-hand cell of Table 4-1 and discussed in Chapter 2, macro-ends regulations impose a general duty on firms to achieve safe outcomes; a liability and penalties may result if they do not. The general duty may be stated outright in a regulation, such as the Occupational Safety and Health Administration's general duty provision calling for the removal of all recognizable workplace hazards. The obligation to achieve safe outcomes may also arise in an ex post manner from more general liability law (e.g., tort law) or as a result of specific statutory liability, such as under the Clean Water Act's provisions providing penalties for polluting spills.

Unlike the other three regulation design types, the legal obligation contained in a macro-ends regulation imposes no explicit prospective requirements, either means or ends, related to any of the nodes or links on the causal pathway leading to the harm. The consequences for the firm follow from the occurrence of the harmful event. Although this form of regulation applies its consequences after the fact, it can create ex ante incentives for

preventive behavior (Kolstad et al. 1990). In this sense, a macro-ends regulation may be viewed as the ultimate form of "performance" regulation. It can cause some firms to identify and control their risks in a systematic and thorough manner.

The absence of explicit requirements can raise concern that some firms' managers may neglect their responsibility. They may accept a calculated risk of some future losses from lawsuits and other penalties, especially if such losses might be ameliorated by insurance or bankruptcy (moral hazard), or if the risk of losses may be discounted because of short-sightedness or the "NIMTOFF" (not in my term of office) tendency (Kunreuther and Meyer 2017). There may also be legal limits on liability for catastrophes, as is the case for nuclear accidents and oil spills. Even without legal caps on liability, the losses arising from events may be so large that some liable firms in industries consisting of a range of firm sizes may be unable to compensate in full parties claiming damage. These conditions can create an incentive for regulators to augment the macro-ends form of regulation with other types of ends- and means-based regulation to prevent catastrophic incidents from occurring in the first place.

Tort and statutory liability constitute macro-ends regulation in the U.S. pipeline and offshore industries. Norway, the United Kingdom, and Canada also have highly developed liability systems for claims from pipeline and offshore oil and gas incidents (Bennear 2015; BIO by Deloitte and Stevens and Bolton 2014). Issues that policy makers and regulators may want to consider in using this form of regulation include the following:

- In designing a macro-ends regulation, the main tasks will be to define one or more triggering events and corresponding penalties, liability, or other consequences. Should the triggering event for liability be defined generally (e.g., failing to operate safely or in compliance with regulations) or in terms of specific occurrences (e.g., explosions, injuries)? The latter may help to define (but not necessarily be exclusive of) the former.
- Should authorities impose strict liability that requires no showing of fault? Or should liability be based on a showing of negligence?
- Should joint and several liability be allowed and, if so, how far should chains of liability run?
- What defenses, if any, should be available to firms to excuse them from or to limit their liability?
- Should liability be based on a showing of actual damages or be determined on a fixed basis (akin to liquidated damages)?
- How readily can damages be quantified?
- What role, if any, should insurance play in providing coverage for any liability?

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- Should punitive damages be allowed?
- Should liability be capped?
- Should criminal liability be available?
- For regulated entities that are corporations, should liability be limited to the organization, or should individual officers or directors be subject to civil or criminal liability?

Implementing liability is comparatively easy. It does not depend on a routine regimen of inspection and monitoring. A catastrophe that triggers liability will presumably be visible and difficult for a regulated entity to hide. To the extent that liability depends on a showing of fault, the government will need to have the capacity to build the case for responsibility and the expertise to quantify and monetize the level of harm created. Dispute resolution and claims processing functions may also be needed.

One difficulty in evaluating the impact of liability on safety outcomes is the possibility that, even though the consequences of a macro-ends regulation do not apply until after an accident occurs, such regulation can create ex ante incentives that may be hard to observe (Kolstad et al. 1990). A further difficulty lies in finding a counterfactual benchmark to show what happens in cases where such a regime does not exist and then comparing that benchmark with what occurs under the liability regime. Cross-jurisdictional comparisons may provide some insight as to the possible ex ante effects of liability, but other differences between jurisdictions could confound inferences about the impact of liability.

OTHER FACTORS AFFECTING REGULATORY CHOICE

As has been shown, safety regulation entails much more than making a generic choice about which of the four main types of regulatory designs to use for each component of the regulatory program. Within each design, regulators face many important choices concerning how to structure, implement, and evaluate the regulations. Decisions concerning these subsidiary choices will be based on the nature of the problem, the characteristics of the industry, and the capacity of the regulator. In some cases, these subsidiary considerations will help determine which main design to deploy. In principle, certain design types may have great appeal, such as those often associated with flexibility, namely micro-ends (performance) regulation or macro-means (management) regulation. However, in some circumstances, consideration of the subsidiary choices discussed above may dampen that appeal and make other regulatory designs more attractive.

Regulatory design choices can also be affected by other factors such as requirements of the U.S. federal rulemaking process, including directives governing public engagement and regulatory impact analysis, statutory

mandates, and the prospects for judicial review. Some of these factors are noted below.

Public Engagement

As outlined in Box 4-1, U.S. federal regulatory agencies develop rules through a process called "notice and comment" rulemaking. Under this procedure, an agency publishes a proposed rule in the *Federal Register*, invites the public to submit input on that proposal, and takes any comments into consideration in developing its final rule. Beyond this minimal role for public involvement in rulemaking, agencies can involve the public in regulatory decision making in a range of ways. Among them are public hearings, dialogue sessions, and advisory committee meetings. Public input can provide agencies with information helpful in structuring, implementing, and evaluating any of the four types of regulations. For example, regulators in the course of developing a means-based regulation may benefit from hearing industry's comments about existing best practices. They may benefit from hearing community members' concerns when mandatory ends are selected or the sufficiency of a firm's management system is assessed.

Box 4-1 Overview of U.S. Federal Regulatory Process

In issuing regulations, U.S. federal agencies are required to follow a public rule-making process. The Administrative Procedure Act (APA) generally requires agencies to provide notice of a proposed rule, solicit public comments on the proposal, and explain how comments were considered before issuing the final rule. An agency's decision to propose a new rule or modify an existing one may be influenced by statutory requirements; studies and recommendations from agency staff; concerns arising from accidents or problems affecting society; recommendations from congressional committees or federal advisory committees; presidential directives or requests from other agencies; lawsuits; and petitions by citizens, businesses, governments, and interest groups.

In following the APA process, an agency in the early stages of rulemaking may publish an "advance notice of proposed rulemaking" in the *Federal Register*, even before it issues a notice of proposed rulemaking, to solicit early feedback and information from the public.^a In developing a proposed rule, most agencies—

^a Some agencies develop proposed rules through a negotiated rulemaking. Under this process, the agency invites representatives of affected interests to meetings, where they attempt to reach a consensus on the terms of the proposed rule. If the participants reach an agreement, the agency may endorse their ideas and use them as the basis for the proposed rule.

Box 4-1 Continued

with the exception of independent agencies such as the Nuclear Regulatory Commission—are required by executive order to analyze the benefits and costs of proposed rules likely to have an annual national economic impact of more than \$100 million and to have their analysis reviewed by the Office of Information and Regulatory Affairs (OIRA). Federal regulators must also make allowances for the requirements of other statutes such as the Regulatory Flexibility Act, which effectively requires regulators to take into account how their requirements will affect businesses of different types; the National Environmental Policy Act, which requires environmental impact assessments; and the National Technology Transfer and Advancement Act, which requires that the voluntary technical standards of consensus bodies be used whenever practicable.

When an agency issues a "notice of proposed rulemaking" in the *Federal Register*, it formally announces its proposed rule and provides the public with an opportunity to comment. During the comment period, the agency may hold public hearings to improve understanding of the proposed rule's coverage and requirements and to provide additional opportunities for interested parties to make statements and submit data. When it drafts the final rule, the agency must explain its reasoning and demonstrate that it has taken the comments, scientific data, expert opinions, and other feedback obtained during the rulemaking process into account. For economically significant rules issued by executive (nonindependent) agencies, the draft final rule must be forwarded again to OIRA for a review that can request additional analysis and lead to further changes to the rule before publication in the *Federal Register* as a final rule. Once a final rule is published in the *Federal Register* and takes effect, it can be added to the Code of Federal Regulations.

After publication of the final rule, the agency's attention turns to the practical demands of ensuring compliance. Consideration will likely have been given to compliance during a rule's development. For example, a regulation that prescribes specific actions by the regulated entity, such as an occupational safety rule requiring shop workers to wear protective eyewear, is certain to create compliance and enforcement demands on the regulator different from those of a rule calling for the manufacturer to institute safety management procedures aimed at the more generalized goal of providing a workplace free of hazards.

^b Agencies place each rulemaking and supporting document (e.g., proposed and final rule, economic or environmental analyses and information collection materials) and all public comments received, sometimes including any ex parte communications and late-filed comments, in a public docket.

As the case studies indicate, offshore safety regulators in the United Kingdom and Norway strongly believe that their macro-means regulations (i.e., safety case and AOC management-based regulations) demand considerable collaboration and trust among regulators, industry, and labor. If such tripartite collaboration is in fact essential—and pursued without opportunity for direct public participation—this finding warns of a potential issue for the application of a similar regulatory design in the United States. Federal regulators operate under norms that limit communication with just a subset of interested parties. Other transparency rules and procedural constraints can affect the ability of regulatory officials to engage in dialogue with the regulated industry and other interests, including labor, consumer, and environmental representatives.

Regulatory Impact Analysis

For many significant rules, governmental procedure in the United States requires the conduct of certain types of analyses before a regulatory decision. Among the analyses are regulatory impact analysis, cost-benefit analysis, analysis of impacts on small businesses or local governments, and paperwork burden analysis. The requirements for fulfilling each of these analyses may depend on the choice of a regulatory design and on its specific structure. A review of the effects of all of these required processes is not given here, but some implications can be illustrated by reference to the key process requirements of White House regulatory review. Executive Order (EO) 12866 requires that all significant regulatory proposals, including those with an annual effect on the economy of \$100 million or more, contain estimates of the costs and benefits of regulatory alternatives. The estimates must be submitted for review by OIRA, which is in the Office of Management and Budget (OMB).9 OIRA Circular A-4 gives agencies guidance concerning how to comply with the regulatory review requirements in EO 12866.¹⁰

EO 12866 encourages agencies to design their regulations "in the most cost-effective manner to achieve the regulatory objective" and to "identify and assess alternative forms of regulation." In particular, the order says agencies "shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt." Circular A-4 further encourages agencies to consider ends-based standards: "Because they allow firms to have the flexibility to choose the most cost-effective methods for achieving the regulatory goal,

⁹ See https://www.reginfo.gov/public/jsp/Utilities/EO_Redirect.jsp.

¹⁰ See https://www.federalregister.gov/documents/2003/10/09/03-25606/circular-a-4-regulatory-analysis.

and create an incentive for innovative solutions, performance standards are generally preferred to design standards."

On the basis of such statements, agencies may find that, all things being equal, OIRA will look more favorably on proposed and final rules taking the form of micro-ends standards, or even those imposing macro-means management requirements. Both of these forms of regulation are likely to be proposed for situations in which the regulated industry is highly heterogeneous. Since firms are expected to act differently to comply with the regulation, the costs and benefits may be difficult to assess with a high level of precision. These variable responses will need to be considered by the regulator and OIRA along with the many other issues presented in this chapter.

Statutory Mandates and Judicial Review

Since the passage of the National Technology Transfer and Advancement Act of 1995, federal policy has encouraged the use of consensus standards as opposed to standards unique to the government. OMB guidance (Circular A-119) to agencies participating in standard-setting activities specifies that such standards should be developed on the basis of performance criteria when appropriate. In addition, some statutes direct agencies to use particular types of regulation. For example, the Motor Vehicle Safety Act of 1966's provision calling for federal automobile safety standards to be written in "objective terms" has long been understood to require that the National Highway Traffic Safety Administration only write micro-ends standards. Agencies must adhere to such statutory requirements, even if conditions suggest that another regulatory design would be more appropriate.

After a U.S. federal agency issues a final rule, anyone affected by that rule may file a petition in court asking for a review of the rule's legality. The court's assessment is made against the underlying statute, all applicable administrative procedures, and, under the "arbitrary and capricious" test, various indicators of reasonableness and reasoned decision making. Under the arbitrary and capricious test, agencies are expected to consider alternatives and choose among them on the basis of available evidence or expert judgment.

Finally, litigation periodically arises with respect to each of the four types of regulatory designs. The information available to the committee does not allow it to conclude whether one of the four main regulatory types fares better in terms of staving off litigation or withstanding judicial scrutiny. At least until further research can be completed, estimating the

¹¹ See https://www.federalregister.gov/documents/2016/01/27/2016-01606/revision-of-omb-circular-no-a-119-federal-participation-in-the-development-and-use-of-voluntary.

risk that an agency regulation will be sent back by the courts will presumably continue to necessitate a context-specific inquiry into statutory constraints and the evidence and options before the agency when it issued its regulation.

ASSESSMENT

The study's statement of task calls for a review of the advantages and disadvantages of regulations that are frequently referred to as "prescriptive" and "performance-based" and asks for advice on when safety regulators of high-hazard industries should choose the latter. On the basis of the conceptual framework in Chapter 2 and the case studies in Chapter 3, this chapter has examined several factors that can make a regulatory design and its structural variants more or less advantageous in addressing specific safety problems under a range of implementation conditions. The discussion indicates that the degree of advantage and disadvantage exhibited by any regulation design type can depend on the details of its design and the context of its use—that is, the nature of the problem being addressed, the characteristics of the industry being regulated, and the capabilities of the regulator responsible for implementing and enforcing the regulation. Blanket statements about each regulation design type's pros and cons may offer an apparently attractive set of heuristics to start the decision-making process. However, such statements are apt to be misleading if they are used as a basis for selecting a regulation design type because of the importance of structural details and the context of implementation.

As summarized in Chapter 2, the various regulatory designs are associated with certain advantages and disadvantages. The following sets forth some of the claimed advantages by design type:

Micro-means (prescriptive) regulations (a) may be easier to follow by regulated firms and to communicate to workers given that the regulations tell firms exactly what to do and (b) may be easier to enforce, for much the same reason.

Micro-ends (performance-based) regulations (a) may allow more flexibility by different firms in how to meet the regulation with different means and (b) may allow greater opportunities for firms to innovate over time in ways that meet the regulation.

Macro-means (management-based) regulations (a) may allow for flexibility and opportunities for innovation by firms within the regulated industry; (b) may be used when outcomes are difficult to measure directly;

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and (*c*) may help infuse a sense of responsibility, accountability, or safety culture into the regulated industry.

Macro-ends (general duty/liability) regulations (a) may provide flexibility and opportunities for innovation by firms within the regulated industry and (b) may reinforce other types of regulatory designs as a backstop.

Regulatory design types are also often associated with certain disadvantages. The following sets forth some of the potential disadvantages by design type:

Micro-means (prescriptive) regulations (a) may result in less effective or less cost-effective methods of addressing risk at some firms because one size does not always fit all and (b) may not afford regulated entities room to change if they are not updated, even with the availability of more cost-effective risk management strategies or innovations in underlying technologies or processes.

Micro-ends (performance-based) regulations (a) may be difficult for the regulator to monitor or establish compliance with and (b) may foster a "teaching-to-the-test" effect or encourage gaming of the performance standard.

Under *macro-means* (*management-based*) regulations, (a) both the regulated firm and the regulator may need to develop new skills to implement or oversee the regulation effectively and (b) the regulator may have difficulty in monitoring and establishing compliance and in maintaining motivation for continuous improvement.

Macro-ends (general duty/liability) regulations (a) may not adequately prevent harms because regulatory consequences are only imposed after an event occurs and (b) may not provide adequate direction to firms that lack knowledge of what to do or lack the incentives to find out.

The diversity of claimed advantages and disadvantages indicates the challenge a regulator faces in choosing among regulatory designs. The purported advantages and disadvantages listed above are numerous, and each design type can be said to have its advantages and disadvantages. In addition, the purported advantages and disadvantages of each design are relative to the other designs. The regulator's task is to determine how well different designs or combinations of designs will work under the constraints and conditions encountered in practice *in comparison with other regulatory designs or combinations*. All conditions being equal, a micro-means regula-

tion may be expected to provide less flexibility than a micro-ends regulation while being easier to monitor and enforce. But conditions are not always equal, and comparisons can only be made in the context of the conditions under which a regulation will be applied and in reference to the particular problem it is intended to address.

A regulation's advantages and disadvantages will also depend on how it is structured. A regulation that is micro-ends in character will not necessarily provide firms with flexibility. If in a particular context a required end can only be achieved in one way at the present time, an ends-based regulation will be no different from a means-based regulation in terms of the flexibility offered.

Ultimately, generalizations about advantages and disadvantages may provide useful guidance for a regulator who is just starting to think about regulatory options. However, generalized claims about the advantages and disadvantages of different regulatory designs cannot adequately substitute for careful analysis of how a regulation will apply in a particular setting. Such analysis, as opposed to general claims, is needed to ensure effective decisions by regulators.

In Chapter 5, the application of macro-means safety regulation to high-hazard industries is discussed on the basis of insights from this chapter. In that context, regulators must choose among regulatory designs to develop a regulatory approach that will reduce the risk of low-frequency, high-consequence events.

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Abbreviations

EPA U.S. Environmental Protection Agency
PHMSA Pipeline and Hazardous Materials Safety Administration

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5

Designing Macro-Means Safety Regulation in High-Hazard Industries

When regulators have decided to develop a regulation, they must assess the advantages and disadvantages of various regulatory designs for their policy purposes. The study committee was asked to help inform and advise regulators as they make such assessments. In particular, the committee was asked for its advice with respect to the use of regulations that call for management systems to supplement the use of traditional "prescriptive" regulations to promote safety in high-hazard industries such as the pipeline and offshore oil and gas sectors. This chapter begins with a brief review of the preceding chapters of this report and a recap of why the committee has adopted the label "macro-means" for regulations that require firms to establish and maintain safety management systems. The chapter then proceeds to examine challenges that U.S., Canadian, and North Sea pipeline and offshore safety regulators have faced in using this type of regulation to address the prevention of low-frequency, high-consequence events. Their experiences suggest important reasons for and practical considerations in the use of such regulations by any safety regulator. The chapter concludes with observations and advice applicable to regulators of all high-hazard industries.

RECAP OF REASONING AND FINDINGS OF REPORT

Chapter 2 provided a conceptual framework for characterizing and comparing regulation design types, including those calling for the use of management systems. The terms "prescriptive" and "performance-based," which are used in the study charge, were shown to be ambiguous and often misleading. In particular, the term "performance-based" is misapplied when it

is used to describe regulations that require firms to establish management systems. Such regulations are not performance-based in the traditional sense of obligating firms to meet or avoid specified outcomes through means of their choice. On the contrary, by requiring the use of management systems, these regulations specify the means to be used rather than the outcomes to be achieved.

In this report, regulations that require management systems are called "means-based," because the prescribed systems are the means by which a firm is expected to ensure safety. The label "macro-means" is used because the management systems such regulations require aim directly at the ultimate problem of catastrophic risk. They are intended to direct a firm's managers to plan, analyze, and manage in a more comprehensive manner with the ultimate goal of safety in mind. The analysis and planning required by most macro-means regulations are intended to increase the industry's awareness of risk factors and sources, including failure of technology, human error, and the interactions between technology and human behavior. In addition, macro-means regulations call on firms to develop plans, practices, or procedures to address both technological and human risk factors and then to keep track of compliance with those procedures, report on progress, and periodically reevaluate and improve internal risk management efforts.

In considering the use of macro-means regulation in high-hazard industries, the committee examined the pipeline and offshore oil and gas industries in the United States, Canada, Norway, and the United Kingdom. The case studies in Chapter 3 showed how regulators in all four countries have adopted a combination of regulatory designs to address the range of safety risks arising in each industry. Some of these risks are well known and can be addressed with highly targeted and trusted interventions; others arise from the complexities of individual facilities, operations, and practices. To address the latter risks, pipeline and offshore safety regulators across the four jurisdictions use macro-means regulations to require firms to create management plans and establish customized internal programs for managing the specific risks created by those firms' facilities and operations.

Chapter 4 explained how regulators can decide when to use macromeans or other regulation design types and how they can structure any given regulation falling within a design type in various ways. General observations about the advantages and disadvantages of regulation design types can be misleading because they can overlook differences in the conditions under which any individual regulation will be applied and can fail to account for the various ways of structuring a specific regulation within any of the four main design types. Nevertheless, as observed in the case studies, high-hazard industries do share some conditions that appear to have led different safety regulators to adopt regulations with general similarities in their designs. Across the two high-hazard industries and all jurisdictions studied,

regulators use both micro-means and micro-ends design types. However, because the sources of catastrophic risk associated with high-hazard industries are varied and context-specific, regulators supplement micro-level regulations with macro-means regulations that require the establishment of safety management programs customized to each firm's facilities, operating procedures, management capacities, and environmental setting.¹

The case studies show differences as well as commonalities in how macro-means regulations are structured. For example, to a greater degree than in the United States, regulators in Europe require firms to subject their facilities' management plans to an extensive review by the regulator before the commencement of operations and periodically thereafter. This process is known as a "safety case." As discussed in Chapter 4, safety case regulation is one way of structuring macro-means regulation. The burden of demonstrating the adequacy of a firm's management analysis and planning to the regulator is placed on the firm, as opposed to the regulator having to demonstrate the inadequacy of a firm's required analysis and planning. Structural differences like this affect not only how a regulation performs in practice but also what advantages and disadvantages it will exhibit. As Chapter 4 indicated, relevant conditions include the nature of the specific problem or threat to safety that needs to be addressed, specific industry characteristics and capacities, and the resources and capabilities of the regulator and its organization and personnel. Because of these context-specific variations, general propositions about the pros and cons of any regulatory design must be qualified to take account of the relevant structural features of a regulation falling within that design type and the conditions under which it will be applied.

In the sections that follow, consideration is given to the reasons U.S., Canadian, and North Sea pipeline and offshore safety regulators have set forth for adopting macro-means regulations and to the challenges they have faced in implementing and enforcing these regulations.

RATIONALE FOR USING MACRO-MEANS REGULATION IN HIGH-HAZARD INDUSTRIES

Safety regulators of all high-hazard industries are expected to reduce the occurrence of low-frequency, high-consequence events, whose risks can arise from the interaction of many context-specific factors. The complexity inherent in high-hazard activities, combined with the low frequency of catastrophic incidents, limits a regulator's ability to use highly targeted,

¹ As has been observed previously by Bennear (2015), the combining of regulatory design types by regulators of high-hazard industries has evolved over time, which suggests convergence toward this pattern but not necessarily inevitability.

micro-level regulatory designs because of the impracticality of ensuring that each possible causal pathway to catastrophe has been taken into account. Many sources of risk that are common among firms in high-hazard industries are susceptible to regulation; the use of macro-means regulation can be viewed as a way of addressing the residual risk created by factors that are unknown to the regulator and that can arise from interactions. Macro-means regulation can thus serve as a backstop strategy for addressing the residual risk not covered by micro-level regulation as well as the risk created by the interaction of facets of an industrial operation. As this section explains, the same complexity and relative rarity of catastrophic events that may help justify the use of macro-means regulation can present challenges in their implementation.

As Chapter 3 showed, regulators of high-hazard industries have augmented micro-level rules with macro-means regulations. Requiring management activities, though, does not assure the regulator or regulated industry that these activities actually reduce the risk of catastrophic events. Requirements for risk analysis and the development of management programs do not necessarily even demand that such programs, once established, lead to a demonstrable end state of improved safety. With respect to high-hazard industries, of course, the absence of such a binding performance metric is understandable because catastrophic incidents are rare to begin with, and any requirement for a program to achieve a demonstrated reduction in the frequency of these incidents would be impractical.

In assessing the impact of any regulatory intervention, regulators must seek an understanding of the causal relationship between the intervention and reductions in risk. For regulation aimed at low-frequency, high-consequence events, such causal relationships may be harder to identify, but trends and patterns in the occurrence of more frequent, lower-consequence incidents may provide insight into changes in catastrophic risk. In addition, the regulator may monitor conditions and events believed to be indicative of catastrophic risk, such as reports of conditions known to be associated with failures, operator errors, and so-called "precursor" and "near-miss" events. The aim is to capture relevant data that will allow quantitative methods of risk analysis to inform decisions about future regulatory interventions or modifications in existing interventions, such as changes in required risk management plans and programs. Examples of such quantitative methods are provided in Box 5-1.

The importance of collecting and analyzing data to develop a better understanding of the regulatory problem—reducing the risk of low-frequency, high-consequence events—is recognized in the pipeline and offshore oil and gas sectors. The Bureau of Safety and Environmental Enforcement (BSEE), which oversees offshore safety in the United States, has enlisted the U.S. Department of Transportation's Bureau of Transportation Statistics

Box 5-1 Risk Analysis for Low-Frequency, High-Consequence Events

Quantitative risk assessment methods for low-frequency, high-consequence events have been developed and discussed over the past three decades in both the general risk analysis literature (Kunreuther 1994; Waller and Covello 1984) and the petroleum engineering risk analysis literature (Threadgold 2011). Traditional technical methods for using data, modeling assumptions, and understanding of complex system architectures to estimate the risks of rare but high-consequence failures and the effects of preventive measures include probabilistic risk assessment (Modarres 2006; Oldenburg and Budnitz 2016), Bayesian belief networks (Luxhøj and Coit 2006), and Monte Carlo simulation techniques (Mignan et al. 2014). Within probabilistic risk assessment, Bayesian methods for analyzing accident precursor events and near misses and hierarchical analysis in modeling uncertainties about local conditions and failure rates have been well established as useful approaches for risk assessment when adequate data are available (El-Gheriani et al. 2017; Yi and Bier 1998).

More recently, deep learning methods and related machine learning techniques for predictive maintenance using sensor data have been developed (Liao and Ahn 2016; SAP 2017). They promise to enable system owners and operators to make better use of available sensor log data in detecting and applying predictively useful patterns to quantify failure risks and recommend preventive risk management interventions. Commercial deployment and empirical evaluation of the performance of these methods in the oil and gas industry are under way. Such big-data, machine learning methods may help meet the technical challenges of predicting and evaluating how preventive actions affect the probability distributions for times-to-failure and hazard functions for occurrence rates of rare, high-impact events.

to develop and manage a voluntary and confidential near-miss reporting system.² BSEE's plan is for information provided by this database to be shared with industry and the public to help identify safety issues in their incipiency, guide regulatory decisions, and aid operators in developing and implementing their safety management programs. Other data collection examples can be found in the surveys of offshore workers that Norway's Petroleum Safety Authority (PSA) conducts and in its efforts to analyze reports of certain types of precursor incidents (e.g., losses of well control, fires and explosions, and gas leaks) to identify areas that need more regulator and operator attention.

Despite such efforts (including the use of methods described in Box 5-1), confirming the risk-reducing effects of regulatory actions remains problem-

² See https://near-miss.bts.gov.

atic because of variability and uncertainty in the sources of risk—the very reasons why management programs can be a relatively attractive regulatory option. On the basis of a formula weighting the safety data it collects, Norway's PSA has created (as discussed in Chapter 3) a composite indicator of major accident risk. The indicator suggests that the likelihood of a major accident in the country's oil and gas sector has been reduced by about 50 percent over the past decade. The low frequency of major accidents has precluded verification of the accuracy of PSA's estimate. Even if the estimate of risk reduction offered by this index is accepted, how much (if any) of that reduction can be causally attributed to PSA's macro-means regulation is unclear.

PSA's risk reduction calculation was one of only a few estimates that the committee could find purporting to support a claim about the risk-reducing effects of a regulatory regime that requires safety management plans and programs. In a related context, Coglianese and Lazer (2003) report insurance industry data showing a 40 percent decline in damage claims during roughly the 10-year period following the adoption of macro-means regulations by the Occupational Safety and Health Administration to address incidents at major chemical facilities. Coglianese and Lazer also report data indicating at least some initial decline in cases of foodborne illnesses after the adoption of federal macro-means food safety regulation and in reported toxic pollution after the introduction of state-level macro-means environmental regulation. However, as the authors acknowledge, caution is required with regard to inferring any causal connection between the macro-means regulations and improvements in these measures.

Bennear (2007) offers the only study of which the committee is aware that can support a causal connection between macro-means regulation and an improvement in regulatory outcomes. Bennear analyzed more than 30,000 regulated manufacturing facilities in the United States. She compared levels of toxic chemical emissions from facilities located in states with macro-means pollution prevention regulations with emissions from facilities in states without these regulations. After controlling for other factors, she estimated that facilities in states with macro-means regulations reduced their emissions by about 30 percent compared with facilities in states without these regulations.

Such evidence suggests that, under some circumstances, macro-means regulations can achieve regulatory objectives. Despite such evidence and the theoretical reasons why macro-means regulation appears to be well suited to addressing the complex sources of risk that give rise to low-frequency, high-consequence events, the extent to which such regulation will yield safety improvements in any particular high-hazard setting remains uncertain. As noted in Chapter 4, not all macro-means regulations are structured uniformly, nor are they applied under uniform or static conditions. PSA's

macro-means regime, like others that require management programs, has a particular structure and is implemented under conditions that may not exist elsewhere. Indeed, the case studies indicate considerable variability in regulatory structures and conditions. Thus, acceptance of PSA's calculations that its macro-means regulations have reduced the risk of catastrophes does not mean that a comparable level of risk reduction can be expected from the application of such a regulatory design in other contexts. According to Bennear's 2007 study of macro-means pollution regulations in the United States, facilities in states that had adopted these regulations were no longer showing any statistically significant improvements after 6 years, which suggests either that conditions can change or that the effectiveness of macro-means regulations can decline over time.

A question that some observers have raised concerning management regulation is whether all the attention paid to system-level thinking will undercut or slow progress in achieving risk reduction through other means, such as more creative thinking or more effective communication (Ely and Meyerson 2010). For example, if the most important causes of catastrophes are neither linear nor hierarchical but more chaotic, the regulator may want to consider the possibility that requirements for linear and hierarchical management activities will prove ineffectual or even counterproductive.

This report does not examine the safety effectiveness of macro-means regulation generally or provide answers to questions about its efficacy in addressing different causes of catastrophic risk. These are legitimate candidates for further research, especially as experience with macro-means regulation grows. The focus of the report has been on providing regulators with an understanding of the factors they will need to consider as they decide whether to use macro-means regulation with its many structural variants. Designing and implementing a macro-means regulation to address the problem of catastrophic risk can be challenging, or even futile, if conditions such as industry characteristics and regulator enforcement capabilities are not supportive. Some of the challenges are discussed in greater detail below on the basis of examples from the case studies in Chapter 3.

USE OF MACRO-MEANS REGULATION IN HIGH-HAZARD INDUSTRIES WITH VARIED CHARACTERISTICS

Chapter 3 set forth case studies of two high-hazard industries: pipeline transportation and offshore oil and gas development. Other high-hazard industries, which the committee did not study in similar detail, are also subject to safety regulation. Among them are chemical manufacturing, air transportation, and nuclear power. Regulators face many of the same considerations in designing safety regulations for other high-hazard industries as those that have been raised throughout this report, as briefly noted in

Box 5-2. One of the considerations in selecting and structuring macromeans regulation in any industry will be the characteristics of the firms within that industry.

As discussed in Chapter 4, the level of diversity or heterogeneity among the firms within an industry can affect the applicability of any regulatory design type. Heterogeneity can be characterized along a number of dimensions. Chapter 4 emphasized how heterogeneity in facility design and operation can sometimes provide a justification for a macro-means approach, especially when difficulties in monitoring and enforcing outputs make ends-based regulation unworkable. Macro-means regulation does not depend on uniform facility design and operation, and its flexibility often makes it a promising option when firms exhibit a high level of diversity in technological design and organizational operations.

Firms in a regulated industry may differ not only in their facilities, technologies, and operations but also in their size and in their managerial and analytic sophistication. For example, firms in the pipeline industries of the United States and Canada range from multinational corporations operating transcontinental oil and gas transmission pipelines to public utilities operating local gas distribution networks. All of these systems, even small utilities (because of their proximity to concentrations of people), have the potential for catastrophic events. However, the different capacities of smaller and larger pipeline operators often lead to different views about the practicality and utility of macro-means regulations.

Small operators are more resistant to the adoption of regulations requiring safety management programs. They sometimes complain about the lack of specificity in macro-means regulations, which they claim leads to uncertainty and unpredictability about the actions they are expected to take. They also claim that they do not possess and cannot readily acquire the specialized technical and management competencies in some areas, such as risk analysis, needed to develop and implement the required management activities. Smaller operators reportedly tend to prefer micro-means regulations that give them clear direction. They view the terms "prescriptive" and "one-size-fits-all" as somewhat positive rather than altogether negative descriptors of regulation. Operators of larger and more varied pipeline systems usually have more of the capabilities needed to conduct the risk analysis and internal planning called for by macro-means regulations. They tend to favor these regulations because of the flexibility offered in the technological and operational means of reducing risks. Even for these operators, if a macro-means regulation contains too many prescriptive demands about program elements and their execution, the flexibility benefits may be diminished and the regulation's perceived advantages may be reduced.

The offshore case studies also show how the degree of operational and technological complexity can affect the applicability and appeal of

Box 5-2 Safety Regulation in the Nuclear and Chemical Sectors

The nuclear and chemical sectors, which were not included as case studies in this report but were addressed in presentations to the committee, are high-hazard industries that raise societal concern about catastrophic accidents. Their regulation can be examined on the basis of the conceptual framework developed in this study.

The U.S. Nuclear Regulatory Commission (NRC) is responsible for promoting the safety and security of commercial nuclear power plants, other commercial nuclear facilities, and commercially used nuclear materials. The commission relies extensively on micro-means as well as macro-means regulations as part of its Reactor Oversight Process (ROP), which applies to the country's 100 nuclear power plants.^a The ROP uses input from NRC inspectors, at least two of whom are permanently posted at each plant, as well as "performance indicator" data from the operators of the reactors. As part of the ROP, the safety culture of the licensee is evaluated. Licensees are expected to require a "questioning attitude" in their employees, who are expected to be able to question management decisions. Information from inspections is used to establish whether a more thorough risk assessment and additional inspections are necessary. Accordingly, NRC's regulatory work depends on the quality of its inspectors and technical staff. In addition, there are about 20,000 nuclear materials licensees in the United States. Because of the high number of entities and the significantly smaller risks they pose, NRC has agreements that delegate regulatory authority to state safety agencies, whose regulation tends to be more micro-level in its orientation.

The chemical sector has a significant degree of heterogeneity, which can affect the applicability of regulation design types. In the European Union, for example, the same regulatory framework^b that is applied to large petrochemical companies and oil refineries is applied to more varied manufacturing companies that use chemicals for cleaning, fuel, and manufacturing processes. Large multinational corporations often have significant in-house expertise in engineering, risk analysis, and planning, whereas smaller companies may be dependent on consultants and third parties for these functions. These differences are relevant to the ability of firms to comply with regulations as well as to perceptions about the practicality and utility of a particular regulatory design. For these reasons, the European chemical sector is regulated through a mix of regulatory designs, including macro-means regulations requiring management systems and safety cases and a collection of micro-means and micro-ends regulations targeting specific risks.

^a See https://www.nrc.gov/reactors/operating/oversight/rop-description.html.

^b Control of major accident hazards involving dangerous substances ("Seveso III Directive") (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012L0018).

regulations requiring management programs in the high-hazard domain. Norway's offshore regulators were among the first to adopt regulations requiring management programs in response to the installation of massive and complex production facilities to accommodate the harsh weather and marine conditions of the North Sea. The Norwegian regulators realized that these facilities presented risks that could not be targeted solely by adding more detailed micro-level regulations. They responded by making fundamental changes in their country's regulatory regime to emphasize safety management planning by offshore operators. As discussed in Chapter 3, the disproportionate representation of large, multinational firms in Norway's offshore oil industry was relevant to this decision.

Oil and gas exploration and production activity in U.S. waters is more varied. It is carried out in many smaller, simpler facilities in shallow waters and a small but growing number of more complex, technologically sophisticated facilities in the deeper areas of the Gulf of Mexico. The country's offshore safety regulatory regime reflects this diversity in that it consists of a mix of micro- and macro-level regulations, with more of the former. The continued presence of many long-standing micro-means regulations may be viewed as undercutting the flexibility afforded by the more recent addition of macro-means regulations that require management systems. However, micro-level regulations may be more appropriate for the hundreds of operators that have not experienced dramatic changes in technology and operational complexity and whose facilities and operations are more uniform and better understood by regulators.

These situational differences illustrate how a macro-means regulation can be affected by the characteristics of the industry being regulated. Heterogeneity in the technologies, facility designs, and operational and behavioral practices within an industry may justify the use of macro-means regulation. Heterogeneity in firm size and managerial capacities can make this form of regulation more challenging or even questionable.

USE OF MACRO-MEANS REGULATION IN HIGH-HAZARD INDUSTRIES BY REGULATORS WITH VARIED CAPABILITIES

Five safety regulators were studied in this report. The U.S. Pipeline and Hazardous Materials Safety Administration (PHMSA) and Canada's National Energy Board (NEB) were reviewed in the pipeline case studies. BSEE, Norway's PSA, and the United Kingdom's Health and Safety Executive (HSE) were reviewed in the case studies of the offshore oil and gas industry. The regulations administered by these five regulators provide a rich set of examples of regulation design types and insight into how each regulator's capabilities can affect the suitability of regulatory design choices.

All five regulators use macro-means regulations requiring operators

to establish management programs, but the regulations are structured in different ways. BSEE's and PHMSA's macro-means regulations have prominent roles in their regulatory regimes, but they are clearly supplemental to a larger collection of micro-means and micro-ends regulations that target individual sources of risk. In contrast, HSE's and PSA's regulations requiring management plans and programs are central features of their regimes, despite these requirements being accompanied by macro-ends (liability) regimes and by many micro-means and micro-ends requirements found in regulations, guidance documents, and referenced industry consensus standards. In regulating interprovincial pipelines, Canada's NEB relies on macro-means regulation more than PHMSA does, but it too enforces many micro-level regulations.

Macro-means regulation was made central to HSE's and PSA's offshore safety regimes more than two decades ago. In doing so, officials made calculated decisions to overhaul their regulatory programs in ways that they believed would support and complement the new regulatory approach. Both agencies changed their compliance and enforcement strategies to emphasize greater collaboration with regulated operators. In turn, operators were given the responsibility, in consultation with workers, to develop their own risk management plans and programs and make a convincing argument—or "safety case"—that the plans would be executed and would prove effective.

Rather than reviewing each operator's proposed management plan strictly with regard to compliance with regulatory provisions, HSE and PSA review the proposed plans and then meet with operators to offer ideas on how to improve them. In this respect, the regulators view themselves as joint problem solvers with industry, and that view extends to the role government officials play in enforcement.³ UK and Norwegian regulators deploy teams of skilled personnel to operators' facilities, and team leaders meet with facility managers to verify that the actions promised in plans are being taken. Before they issue citations for observed instances of noncompliance with the approved management plans, the regulators try to work with operators to resolve any deficiencies.

HSE and PSA illustrate how their organizations' capabilities can be integral to the functioning of regulations requiring management programs. Both regulators had determined that, to implement a macro-means regulatory approach, they would need to make major changes in personnel. "Checklist" inspectors would be phased out in favor of engineers and other subject matter experts with the skills to oversee macro-means regulation. This meant that the regulator needed staff capable of reviewing proposed

³ This collaborative approach is considered in various forms in the scholarly literature. For examples, see Coglianese and Kagan 2007; Huising and Silbey 2011; Thomas and Hawkins 1984.

management plans, consulting with operators on needed improvements, and identifying and proposing solutions to gaps in execution. Significantly, each country's elected officials granted the regulators the freedom and resources to make these supportive changes, including the ability to adopt a regulatory approach that emphasizes collaboration among regulators and regulated entities. In this regard, policy makers have accepted the notion of collaboration among directly affected parties in the setting of risk management priorities and deemphasized public openness and participation in that process. The existence of routines for consultation with offshore workers through unions and other labor representatives adds some openness and transparency to the collaborative process. However, the safety case documents produced under the macro-means regulations in the North Sea are not publicly available, and there is little opportunity for direct engagement with members of the general public.

The structuring and implementation of management regulations in the U.S. offshore and pipeline sectors have occurred under legal and institutional conditions different from those of the North Sea countries. For example, U.S. safety regulators must follow well-defined administrative procedures for issuing regulations. They must share certain regulatory responsibilities with state governments and even sometimes with private organizations when statutes contain citizen-suit provisions—all of which can affect a federal regulator's flexibility in enforcement methods. The conditions in Norway and the United Kingdom that supported policy makers and regulators in adopting a highly collaborative approach with industry and labor do not exist in the United States (Kagan and Axelrad 2000). North Sea regulators have a much smaller number of regulated entities to oversee than do regulators in the United States, and the former inhabit more tightly bound social networks that appear to reinforce compliance within a more collaborative regulatory environment. U.S. regulators have structured and implemented their approach to macro-means regulation differently, in a manner reflecting the conditions under which they operate. The U.S. regulatory approach does not generally involve a high degree of collaboration, and implementation by U.S. regulators of macro-means regulation in the same manner as the North Sea countries would be impractical. For example, the much greater number of regulated facilities would require greater resources and time if a safety case approach to regulation were applied in the United States.

Whether the U.S. or North Sea regulatory approaches are more effective in promoting offshore safety was not considered in this report. An assessment of the effectiveness of any jurisdiction's regulatory approach was not part of the study charge. Furthermore, the infrequent occurrence of catastrophic events would make any assessment based on such events impractical for the committee within the parameters of its charge.

Consideration of the applicability of macro-means regulation based on conditions existing in the regulatory setting may be a more tractable approach. In this regard, PHMSA's implementation of its integrity management (IM) requirements and BSEE's implementation of its safety and environmental management systems requirements could indicate several challenges associated with each regulator's capabilities and constraints. Some are common among U.S. regulatory agencies; others are specific to these regulators.

For example, one regulator-specific constraint affecting implementation of a macro-means regulation is PHMSA's current need to rely on state personnel to enforce compliance with its gas distribution integrity management program (DIMP) regulations. DIMP regulations require operators to develop, write, and implement an IM program that, among other things, evaluates and prioritizes risks, identifies and implements measures to address risks, and monitors and evaluates results. Because of the operatorspecific nature of this planning and its execution, physical inspections of equipment and facilities must be supplemented with audit-like reviews of operator records. PHMSA has issued an 11-page inspection form concerning DIMP audits for the guidance of state agencies, 4 which are likely to encompass a wide range of inspection resources and capabilities simply because of their large number. The approximately 50 questions on the form focus on whether certain required program elements are present in the operator's written plan rather than on more holistic assessments of the quality of the program and its execution. Inspectors are asked to give mostly yes/no answers to questions such as the following: "Do the written procedures contain the method used to determine the relative importance of each threat and estimate and rank the risks posed?" "Has the operator demonstrated an understanding of its system?" "Were commercially available product(s)/templates used in the development of the operator's written integrity management plan?"

If PHMSA had the staff to perform all DIMP inspections, or if it could reasonably expect all state enforcement partners to perform in a manner comparable with that of the most qualified states, the protocols might be more demanding. For example, to guide PHMSA's personnel in reviewing the IM programs of interstate gas transmission systems, the agency has developed a 132-page inspection manual. Clearly, that manual offers considerably more detailed guidance than does the 11-page checklist form for DIMP inspections. A likely reason for the shorter form is that the DIMP requirements themselves are less complicated than the IM requirements ap-

⁴ See https://primis.phmsa.dot.gov/dimp/docs/Form_22_PHMSA_DIMP_InspectionForm_192.1005_Operators.pdf.

⁵ PHMSA Gas Integrity Management Inspection Manual: Inspection Protocols with Results Forms, August 2013 (https://primis.phmsa.dot.gov/gasimp/documents.htm).

plicable to transmission systems. However, the two protocols also differ in quality. The 132-page manual does not merely call for yes/no answers about whether certain program elements are contained in the operator's plan. PHMSA's IM auditors are expected to make more sophisticated assessments of the content of the program by reviewing records and conducting interviews. For example, audit teams are asked to verify that the operator's threat identification has considered interactive threats, that risk assessments were revised as necessary as new information was obtained or conditions changed on the pipeline segments, and that the operator has checked the data for accuracy. Audit teams are instructed to review operator records to the point where they can achieve an "adequate understanding regarding the degree of an operator's commitment to compliance with applicable requirements and/or the degree to which the operator's program has been effective with respect to achieving compliance."

It is unclear whether the more thorough audit protocol for pipeline transmission systems is better suited to the enforcement of PHMSA's macromeans IM regulations than the simpler DIMP checklist used by state inspectors. PHMSA likely believes that the former is superior in at least some respects; otherwise, it would have required a simpler protocol for its own auditors. The simpler protocol was apparently introduced in part because PHMSA recognized that not all of its state partners could be expected to conduct such detailed audits, given the diversity of their technical competencies and resources.

This aspect of PHMSA's experience in implementing IM regulations provides another example of the importance of considering underlying conditions in assessments of the applicability of different types of safety regulations. It illustrates further the ambiguous and potentially misleading nature of terms such as "prescriptive" and "performance-based." If a regulator lacks the resources—in terms of budget, personnel levels, or staff skills—to oversee macro-means regulation, that regulatory design cannot be expected to deliver as many safety advantages as what might be needed.

OTHER MACRO-MEANS ISSUES DESERVING ATTENTION

Macro-means regulation can be an attractive regulatory design for high-hazard industries with complex and diverse sources of catastrophic risk. However, as the previous sections suggest, regulators cannot assume that it will be a good fit under all circumstances. In some cases, achieving the best fit will mean modifying the structure of the macro-means regulation to suit the circumstances. In others, it will mean modifying some of those circumstances—especially with respect to enhancing the resources and ca-

⁶ PHMSA Gas Integrity Management Inspection Manual: Inspection Protocols with Results Forms, August 2013, p. 3.

pabilities of the regulator. The regulator will want to consider many issues in structuring a macro-means regulation consistent with the regulator's own implementation capabilities. Several points that were discussed in Chapter 4 bear highlighting:

- The regulator will want to develop the capability to assess the quality of a firm's management plans in terms of criteria such as comprehensiveness, degree of efficacy, adequacy of internal monitoring and controls, and commitment to implementation and improvement over time.
- The regulator will want to assure a strong connection between what a firm's management plan calls for and what actually happens at a complex facility. The regulator must keep in mind the possibility that the threat of harsh punishment of a firm's failure to comply with internal plans or to meet internally adopted goals may lead firms to establish less ambitious goals or to plan less rigorously.
- The regulator will want to be able to assess a firm's seriousness in sustaining high-quality management to ensure that its management requirements do not become routinized and that its planning does not turn into empty paperwork exercises. There is evidence that safety vigilance tends to taper off irrespective of regulatory design. Because the implementation of management systems cannot be directly observed in the same manner as micro-means standards, efforts to prevent such slippage over time may be particularly important for this form of regulation.
- The regulator will want to be attentive to the possibility of some firms taking advantage of the operational flexibility afforded by macro-means regulation. They may seek to hide or they may conveniently overlook hazardous practices or conditions. They may create internal plans with diffused and vague requirements that are largely facades masking resistance to high-quality safety practices.
- The regulator will want to be aware of how other types of regulations governing the same problem and the same firms might affect the success of macro-means regulation and seek to make those other regulations complementary rather than obstructive. For example, a firm's planning efforts under a macro-means regulation might result in promising ideas for addressing safety risks, but existing micro-level regulations demanding actions incompatible with these ideas may diminish the value of macro-means regulation. In addition, the interaction between macro-ends regulation and macro-means regulation should be considered. The background threat of liability in the event of a catastrophe may motivate a firm to plan more carefully, but the possibility of a firm's internal plans

being used against it in a subsequent action for liability could have the opposite effect of causing the firm to plan less ambitiously.

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6

Summary Assessment

The study committee was asked to offer observations and advice about the design of a safety regulatory approach for high-hazard industries, such as offshore oil and gas and pipelines. This report emphasizes that simple comparisons of the advantages and disadvantages of regulatory designs offer little more than a starting point for regulatory decision making. All regulations, including macro-level regulations that require management systems, can be structured in different ways that affect their advantages and disadvantages. A safety regulator's primary aim in choosing among regulatory designs should be to select designs that best suit the nature of the safety problem to be addressed. The regulator should take into account its own capabilities and resources for ensuring compliance and the capacity of regulated entities to meet their obligations. If such preconditions are missing or cannot be created, the regulator should be concerned that the type of regulation being considered will be inapplicable to the circumstances and potentially ineffective.

Labels given to regulatory types, such as "prescriptive" and "performance-based," are used inconsistently. They are often applied in a confusing and misleading manner that complicates comparisons of regulatory tools. Regulatory regimes that require management plans and programs are sometimes referred to as performance-based but are more aptly described as means-based regulation. They call for actions and behaviors aimed at improving the ultimate outcome of concern to the regulator; however, they do not require the achievement of specific performance outcomes. Still, like regulations that impose binding outcomes, requirements for management systems are often flexible in the sense that they allow

regulated firms to customize their systems according to circumstances. For example, macro-means regulations often give firms considerable latitude in developing and executing internal methods for risk analysis and prioritization, systems for facility and equipment monitoring and maintenance, and procedures for managing change. The resemblance of the flexibility of this type of regulation to the flexibility afforded by ends-based regulations that mandate performance outcomes but give firms discretion on means of achieving them may have led to the mislabeling of macro-means regulations as "performance-based."

The use of macro-means regulations may be desirable when the sources of risk arise from facets of individual operations and facilities and their interactions. Such sources of risk may be complex and unknown to the regulator. In practice, macro-means safety regulations that require management systems tend to be used in combination with micro-level regulations that target specific sources of or pathways to overall risk. In considering the use of macro-level regulations that provide firms with flexibility in the means of compliance, regulators must take into account not only their own ability to enforce and motivate acceptable levels of compliance through means like auditing and field inspections but also opportunities for assisting or collaborating with the regulated industry so that all parties can transition more effectively to these regulations. For example, to promote the effectiveness of such regulations for use in high-hazard industries where regulatory impacts on catastrophic risk can be difficult to discern, regulators may work with industry to identify, track, and analyze data on incident precursor events (e.g., near misses) and other conditions that may be indicative of catastrophic risk. Precursor or related data may not be sufficiently correlated to the risk of major incidents for the purpose of creating enforceable ends-based requirements. However, the data may help regulators monitor the effects of their regulatory interventions and inform operator self-assessments of their risk management programs.

This report concludes that too much emphasis is placed on simplistic and often misconstrued lists of regulatory advantages and disadvantages. Claims about the advantages and disadvantages of regulatory types are too often anecdotal. Systematic empirical research into the applicability and effectiveness of regulatory types for different problems and under different conditions is lacking. Nevertheless, a safety regulator's interest in choosing among regulatory designs should be to select those best satisfying the regulator's overall policy criteria, which may include objectives such as efficiency, cost-effectiveness, or equity, in addition to risk reduction. To further these objectives, the regulator will want to choose a design that is suited to the nature of the problem and characteristics of the regulated industry, as well as to the regulator's own capacity to promote and enforce compliance. As the case studies in the report show, safety regulatory regimes often

contain a mix of regulatory design types, rather than a single type. Regulators should therefore consider whether the best approach to achievement of their regulatory goals may be to combine various regulatory designs in addressing the overarching problem of safety in high-hazard industries in different ways.

Regulators, analysts, and researchers need clear concepts for regulatory designs. A systematic and commonly accepted regulatory design taxonomy, such as the one offered in this report, will be valuable in guiding future research, analysis, and regulatory decision making.

Study Committee Biographical Information

Detlof von Winterfeldt, Chair, is the J.A. Tiberti Chair in Ethics and Decision Making and Professor of Industrial and Systems Engineering at the Viterbi School of Engineering and Professor of Public Policy and Management at the Price School of Public Policy at the University of Southern California (USC). He took a leave of absence from USC to serve as the Director of the International Institute for Applied Systems Analysis (IIASA) in Laxenburg, Austria. Concurrently with his term at IIASA, he was a Centennial Professor of Management Science at the London School of Economics and Political Science. His research interests are the foundation and practice of decision and risk analysis as applied to technology development, environmental risks, natural hazards, and terrorism. He has served on numerous National Academies of Sciences, Engineering, and Medicine committees, including the Committee on Decision Making Under Uncertainty, the Committee on Transportation of Radioactive Waste, and the Board on Mathematical Sciences and Their Applications. He is a Fellow of the Institute for Operations Research and the Management Sciences (INFORMS) and of the Society for Risk Analysis. In 2000 he received the Ramsey Medal for distinguished contributions to decision analysis from the Decision Analysis Society of INFORMS. In 2009 he received the Gold Medal from the International Society for Multicriteria Decision Making for advancing the field, and in 2012 he received the distinguished achievement award of the Society for Risk Analysis. He earned his bachelor's and master's degrees in psychology from the University of Hamburg and a PhD in mathematical psychology from the University of Michigan.

Kenneth E. Arnold (NAE), is the Senior Technical Advisor for WorleyParsons and President of K. Arnold Consulting, Inc. He has more than 45 years of experience in projects, facilities, and construction related to upstream oil and gas development. He spent 16 years at Shell in engineering research management before forming Paragon Engineering Services, a project management and offshore engineering company, in 1980. Paragon was sold to AMEC in 2005. Mr. Arnold is the author, co-author, or editor of several textbooks and numerous technical articles on the design and project management of production facilities. He taught production facility design at the University of Houston and has been active in the Society of Petroleum Engineers (SPE) and other technical societies. He was named Houston's 2003 Engineer of the Year by the Texas Society of Professional Engineers and is the recipient of the SPE Public Service Award and the DeGolyer Distinguished Service Medal. He was elected to the National Academy of Engineering in 2005, cited for work in process safety management for offshore oil and gas production facilities. He served on two Marine Board committees, including the 1990 Committee on Alternatives for Offshore Inspection, and was a member of the Marine Board for 6 years. He chaired the Transportation Research Board (TRB) Committee on the Effectiveness of Safety and Environmental Management Systems for Outer Continental Shelf Oil and Gas Operations and is a member of the Gulf Research Program Research Advisory Committee. He earned a bachelor's degree in civil engineering from Cornell University and a master's degree in civil engineering from Tulane University.

Cary Coglianese is the Edward B. Shils Professor of Law and Professor of Political Science at the University of Pennsylvania, where he serves as the director of the Penn Program on Regulation and has served as the law school's Deputy Dean for Academic Affairs. He specializes in the study of regulation and regulatory processes, with an emphasis on the empirical evaluation of alternative regulatory strategies and the role of public participation, negotiation, and business-government relations in policy making. His books include Achieving Regulatory Excellence; Does Regulation Kill Jobs?; Regulatory Breakdown: The Crisis of Confidence in U.S. Regulation; Import Safety: Regulatory Governance in the Global Economy; and Regulation and Regulatory Processes. Before joining the faculty of the University of Pennsylvania, he was on the faculty of Harvard University's John F. Kennedy School of Government for 13 years, where he was, among other things, a co-author of the report Performance-Based Regulation: Prospects and Limitations in Health, Safety and Environmental Protection. He also has taught as a visiting law professor at Stanford and Vanderbilt, founded the Law and Society Association's international collaborative research network on regulatory governance, and served as a founding editor of the journal Regulation and Governance.

He is a public member of the Administrative Conference of the United States and chair of its rulemaking committee. He is a co-chair of the American Bar Association (ABA) administrative law section committee on e-government and a past co-chair of its committee on rulemaking. He has led a National Science Foundation initiative on e-rulemaking, served on ABA's task force on improving regulations.gov, and chaired a task force on transparency and public participation in the regulatory process. He earned an AB degree from the College of Idaho and an MPP, a JD, and a PhD in political science from the University of Michigan.

Louis Anthony Cox, Jr. (NAE), is President of Cox Associates, an applied research company specializing in quantitative health risk assessment, causal modeling, probabilistic and statistical risk analysis, data mining, and operations research. Since 1986, Cox Associates mathematicians and scientists have developed and applied computer simulation and biomathematical models, statistical and epidemiological risk analyses, causal data mining techniques, and operations research and artificial intelligence risk models to improve health, business, and engineering risk analysis and decision making. He is on the faculties of the Center for Computational Mathematics and the Center for Computational Biology at the University of Colorado Denver and is Clinical Professor of Biostatistics and Informatics at the University of Colorado Health Sciences Center, where he has focused on uncertainty analysis and causation in epidemiological studies. Dr. Cox was elected to the National Academy of Engineering in 2012, cited for his application of operations research and risk analysis to significant national problems. He has served on numerous National Academies committees. He is a member of the Board on Mathematical Sciences and Their Applications and of the Industrial, Manufacturing, and Operational Systems Engineering Peer Committee. He was a member of the Committee on Options for Implementing the Best Available and Safest Technologies for Offshore Oil and Gas Operations. He earned a bachelor's degree from Harvard University and a master's degree in operations research and a PhD in risk analysis from the Massachusetts Institute of Technology (MIT).

Robin L. Dillon-Merrill is a Professor and the area head for the Operations and Information Management Group in the McDonough School of Business at Georgetown University. Her research focuses on explaining how and why people make certain decisions under conditions of uncertainty and risk. Her work examines the critical decisions that people have made after near-miss events in situations with severe outcomes, including hurricane evacuation, terrorism, cybersecurity, and National Aeronautics and Space Administration (NASA) mission management. She has received research funding from the National Science Foundation, NASA,

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Lois N. Epstein is the Arctic Program Director for the Wilderness Society. She is responsible for programs to protect Arctic ecosystems by ensuring that oil and gas operations are safe and environmentally sound and located in nonsensitive areas. She advocates for oil and gas regulations that are effective in ensuring safety and protecting the environment by testifying before Congress and other governmental bodies, engaging in onshore and offshore regulatory development and planning processes, and serving as a technical advisor to Native and non-Native members of the public. Before joining the Wilderness Society, she was a private consultant on environmental policy issues and a senior engineer for several nonprofit organizations. She was President of LNE Engineering and Policy, a consultancy, and a Senior Engineer for Cook Inletkeeper and the Environmental Defense Fund. In these positions, she was responsible for analyzing and publicizing the performance of the oil and gas industry, discussing the industry's performance with government and industry decision makers, and seeking remedies for gaps in state and federal regulations. She is President of the Board of Directors of the Pipeline Safety Trust. She has served on a number of federal advisory committees, including the U.S. Department of Transportation's Technical Hazardous Liquid Pipeline Safety Standards Committee, the U.S. Environmental Protection Agency's Effluent Guidelines Task Force, and the Bureau of Safety and Environmental Enforcement's (BSEE's) Offshore Energy Safety Advisory Committee. She earned a master's degree in civil engineering from Stanford University, a bachelor's degree in English from Amherst College, and a bachelor's degree in mechanical engineering from MIT. She is a licensed engineer in Alaska.

Orville D. Harris is President of O.B. Harris, LLC, an independent consultancy specializing in the regulation, engineering, and planning of petroleum liquids pipelines. From 1995 to 2009, he was Vice President of Longhorn Partners Pipeline, LP, which operates a 700-mile pipeline carrying gasoline and diesel fuel from Gulf Coast refineries to El Paso, Texas. In that position, he was responsible for engineering, design, construction, and operation of the system. From 1991 to 1995, he was President of ARCO Transportation

Alaska. That company owns four pipeline systems in the state, including the Alyeska Pipeline Service Company, which transports 25 percent of the crude oil from the North Slope of Alaska to the Port of Valdez. From 1977 to 1990, he held several supervisory and managerial positions at ARCO Pipeline Company, including District Manager for Houston and Midland, Texas, Manager of the Northern Area, and Manager of Products Business. At ARCO Transportation, he directed the efforts of a team of corrosion engineers making \$400 million of repairs to the Alveska system. He is a past member of the Board of Directors of the Association of Oil Pipe Lines and of the Pipeline and Hazardous Materials Safety Administration's Technical Hazardous Liquids Pipeline Safety Standards Committee. He served on the TRB Committee for a Study of Pipeline Transportation of Diluted Bitumen and on the Division on Earth and Life Studies Committee on the Effects of Diluted Bitumen on the Environment. He holds a bachelor's degree in civil engineering from The University of Texas and an MBA from Texas Southern University.

L. Robin Keller is a Professor of Operations and Decision Technologies in the Paul Merage School of Business at the University of California, Irvine. Among the positions she has held since joining the school's faculty in 1982 are Doctoral Program Director, Associate Dean, and Area Coordinator for Operations and Decision Technologies. Her research centers on decision analysis. It spans multiple attribute decision making; fairness; perceived risk; probability biases; problem structuring; temporal discounting; and planning protection against terrorism, environmental, health, and safety risks. She served as a program director for the Decision, Risk, and Management Science Program of the U.S. National Science Foundation from 1989 to 1991. She is a past president of INFORMS and of its Decision Analysis Society. She was awarded the society's 2015 Ramsey Medal for distinguished contributions to decision analysis and was named an institute Fellow in 2004. She has served as Vice President-Finance and Council Member of the Institute of Management Sciences. She has published more than 60 journal articles, technical reports, and book chapters and was Editor-in-Chief of Decision Analysis. She has served on several National Academies committees, including the U.S. Committee for the International Institute for Applied Systems Analysis and the Committee on Ranking FDA Product Categories Based on Health Consequences. She earned a BA in mathematics, an MBA, and a PhD in management science from the University of California, Los Angeles.

Allison M. Macfarlane is a Professor of Science and Technology Policy at The George Washington University and Director of the Center for International Science and Technology Policy at the Elliott School of International

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Arthur D. Meyer retired in 2013 from Enbridge, where he was the Chief Operating Officer, Liquids Pipelines. He and his team had responsibility for the operation of 17,000 miles of pipeline delivering more than 2 million barrels per day of oil, refined products, and other petroleum liquids to customers across North America. Enbridge operates the world's longest crude oil and liquids transportation system. It has a significant presence in natural gas transmission and storage, midstream processing, gas distribu-

tion, and renewable energy, and it is involved in power transmission. He has 35 years of experience in the pipeline industry. Prior executive appointments at Enbridge included Senior Vice President, Pipeline Integrity and Engineering; Senior Vice President, Major Projects; President, Enbridge Pipelines (Athabasca), Inc.; President, Enbridge Wind Power, Inc.; Vice President, Technology; Vice President, Liquids Marketing; Vice President, Engineering; and General Manager, Producers Pipelines, Inc. Before joining Enbridge, he held leadership and engineering roles at Trans Mountain Pipe Line Company, Ltd., Alberta Products Pipe Line, Ltd., and the pipeline division of Gulf Canada, Ltd. He has been active in industry associations. He served as Chair of the U.S.-based Pipeline Research Council International, President of the Alberta Chamber of Resources, and Chair of the Petroleum and Natural Gas Steering Committee of the Canadian Standards Association. He has served on boards or committees of the Canadian Energy Pipeline Association, the Association of Oil Pipe Lines, the Steering Committee on U.S. Energy Pipelines and Research, and the International Pipeline Conference Foundation. He has been appointed to several government advisory roles and served with nonprofit organizations in support of health, education, and the arts. He holds a BSc in mechanical engineering and an MBA, both from the University of Alberta.

Donald P. Movnihan is a Professor of Public Affairs at the La Follette School of Public Affairs, University of Wisconsin, Madison. His research examines the application of organization theory to public management issues such as performance, budgeting, homeland security, election administration, and employee behavior. In particular, he studies the selection and implementation of public management reforms. His book, The Dynamics of Performance Management: Constructing Information and Reform (Georgetown University Press, 2008), was named best book by the Academy of Management's Public and Nonprofit Division and received the Herbert Simon Award from the American Political Science Association, which honors the book with the most significant influence in public administration scholarship in the last 3 to 5 years. In 2014, he received the Kershaw Award, which is provided every 2 years by Mathematica and the Association of Public Policy and Management to one scholar under the age of 40 for outstanding contributions to the study of public policy and management. He was awarded the 2011 National Academy of Public Administration/Wilder School Award for scholarship in social equity. He is President of the Public Management Research Association and a Fellow of the National Academy of Public Administration. He earned a bachelor's degree in public administration from the University of Limerick and a master's degree and a PhD in public administration from the Maxwell School of Citizenship and Public Affairs at Syracuse University.

Susan S. Silbey is the Leon and Anne Goldberg Professor of Humanities, Professor of Sociology and Anthropology, and Professor of Behavioral and Policy Sciences, Sloan School of Management, at MIT. Her research centers on governance and regulatory and audit processes in complex organizations. Her most recent research focuses on the creation of management systems for containing risks, including ethical lapses as well as environment, health, and safety hazards. She has authored or co-authored several books. Among them are The Common Place of Law: Stories from Everyday Life (with Patricia Ewick) (1998), In Litigation: Do the "Haves" Still Come Out Ahead? (with Herbert Kritzer) (2003), and Law and Science (II): Regulation of Property, Practices, and Products (2008). She is on the editorial board of Regulation and Governance, Engaging Science, Technology and Society, Qualitative Sociology, and Annals of the American Association of Political and Social Science, where she was Issue Editor of Organizational Challenges to Regulatory Enforcement and Compliance: A New Common Sense About Regulation. She is a recipient of numerous prizes and awards, including a John Simon Guggenheim Foundation Fellowship and the Harry Kalven, Jr., Prize for advancing the sociology of law. She is Past President of the Law and Society Association and a fellow of the American Academy of Political and Social Science. She earned a BA from Brooklyn College of the City University of New York and an MA and a PhD from The University of Chicago.

James A. Watson IV is President and Chief Operating Officer of the Americas Division of the American Bureau of Shipping. Before he began this appointment in 2013, he was Director of BSEE. In that position, he was responsible for promoting safety, protecting the environment, and conserving resources through the regulatory oversight and enforcement of offshore operations on the U.S. Outer Continental Shelf. Before he joined BSEE, he rose to the rank of Admiral in the U.S. Coast Guard (USCG). He served as USCG's Director of Prevention Policy for Marine Safety, Security and Stewardship, where his responsibilities included commercial vessel safety and security, ports and cargo safety and security, and maritime investigations. He was designated as the Federal On-Scene Coordinator for the governmentwide response to the Macondo oil spill in the Gulf of Mexico in June 2010. He has served on the TRB Committee on Offshore Oil and Gas Safety Culture Framing Study. Admiral Watson holds a bachelor's degree in marine engineering from the U.S. Coast Guard Academy, a master's degree from the University of Michigan in mechanical engineering and naval architecture, and a master's degree in strategic studies from the Industrial College of the Armed Forces.