

APPENDIX

REGULATORY PROGRAMS AND ORGANIZATIONS ANALYZED JANUARY-APRIL 2012

TABLE OF CONTENTS

<u>I. METHODOLOGY</u>	2
<u>II. VOLUNTARY PROGRAMS</u>	3
1. Energy Star.....	3
2. National Environmental Performance Track.....	4
3. Voluntary Protection Program.....	4
4. ISO 14001.....	5
5. ExxonMobil’s Operations Integrity Management System (OIMS).....	6
6. International Association of Drilling Contractors (IADC) Health, Safety and Environment Case Guidelines.....	7
7. International Regulators’ Forum (IRF).....	7
8. Consolidated Supervised Entities Program (CSE).....	8
9. Toxic Coal Ash – Utilities Solid Waste Activities Group (USWAG).....	8
10. Leadership in Energy and Environmental Design (LEED).....	9
11. Responsible Care.....	9
12. Institute of Nuclear Power Operations (INPO).....	10
13. Center for Offshore Safety (COS).....	10
<u>III. MANDATORY PROGRAMS</u>	11
1. Sarbanes-Oxley.....	11
2. Federal Aviation Authority (FAA) Designee Program.....	12
3. Safety and Environment Management System (SEMS).....	13

4. Food and Drug Administration (FDA) Medical Device Approval Process.....	14
5. UK Safety Case.....	15
6. US Coast Guard Mariner Licensing and Certification.....	16
7. Massachusetts Licensed Site Professionals.....	17
8. National Contingency Plan and Remedy Optimization.....	18
9. OSHA Machine Guarding and Safety Standards.....	18
10. OSHA Fire Safety Standards.....	19
11. OSHA Air Toxics Standards.....	20
12. Clean Air Act Risk Management Plans.....	20
13. Underground Injection Control.....	21
14. SUBSAFE.....	22
15. Surface Mining Regulation under SMCRA.....	22
<u>IV. STANDARDS ORGANIZATIONS.....</u>	23
1. American Society for Testing and Materials (ASTM).....	23
2. Institute of Electrical and Electronics Engineers (IEEE).....	24
3. Underwriters Laboratories (UL).....	24
4. American Congress of Government Industrial Hygienists (ACGIH).....	25
5. National Fire Protection Association (NFPA).....	25
6. American Petroleum Institute (API).....	26
7. American National Standards Institute (ANSI).....	27
8. ANSI-ASQ National Accreditation Board (ANAB).....	27
9. International Organization of Supreme Audit Institutions (INTOSAI).....	28

I. METHODOLOGY

In order to identify potential recommendations for the regulation of offshore drilling, we studied a host of regulatory programs in the areas of health, safety, and the environment. We examined both voluntary and mandatory programs. As used in this document, “mandatory programs” are those programs in which firms are required to participate by government regulation. “Voluntary programs” are programs for which the government does not require firms to participate, regardless of whether firms may need to join the program for other reasons. Thus, INPO is considered voluntary in this document, even though the nuclear industry mandates participation in the organization. In addition to health and safety programs, we also considered several programs in the financial sector that feature particularly innovative methods of verification and enforcement. Finally, we examined a variety of private Standards Development Organizations (SDOs). SDOs are important to our research because the standards that they create are often adopted into mandatory regulations, including regulations pertaining to the offshore oil and gas industry.

After a broad survey of programs created by federal agencies, industry, and third-party groups, we chose to focus on approximately 40 programs and organizations that we determined to be particularly relevant to the offshore drilling industry. We attempted to select programs for further analysis that included substantial input from industry and involved a subject matter potentially analogous to offshore drilling.

We examined the effectiveness of each of these programs. To determine the effectiveness of a particular program, we considered a variety of factors including: (1) empirical impacts on safety, health, or other subject matter, (2) effects on compliance with other regulatory mandates, (3) the existence of clear, measurable goals, (4) verification of compliance, (5) strength of enforcement for non-compliers, (6) accountability of parties capable of making changes, (7) balance between flexibility and the maintenance of minimum standards, and (8) transparency of the program. In order to assess the presence or absence of these factors in each program, we looked to sources such as GAO reports, EPA Inspector General investigations, CRS materials, news articles, and performance data published by programs themselves.

After extensively researching the relative effectiveness of different regulatory programs, we attempted to identify the design factors that led to the success or failure of each program. In particular, we looked at whether industry involvement in the programs enhanced or hindered their effectiveness. We considered the pros and cons of industry involvement in each program, as well as whether the programs could function at all without an industry role. We then tried to determine whether the most effective programs had design characteristics that could be utilized in the regulation of offshore drilling. The

following appendix summarizes our findings with respect to each regulatory program that we analyzed, and the white paper describes our general findings and our recommendations for offshore drilling regulation.

II. VOLUNTARY PROGRAMS

1. ENERGY STAR	
Administered by:	EPA and DOE
Program Description:	Energy star is a voluntary labeling program that recognizes energy efficient products. A variety of electronics and other products may be awarded the Energy Star label if they meet certain efficiency standards, usually 10-25 percent below the industry average for a particular category of product. The performance of each product was initially assessed primarily through self-reporting. In response to criticism, EPA and DOE have recently required third-party verification of efficiency data by an EPA-accredited testing laboratory for all products.
Verification of compliance:	The program initially relied largely on the self-reporting of efficiency data. In response to verification issues with this process, EPA and DOE have begun requiring third-party certification of all products by a third-party certifier that is accredited by the EPA.
Enforcement:	Denial of Energy Star Label for products that do not meet program requirements.
Effectiveness:	Mixed Success. The program has achieved broad participation, and has the potential to generate substantial energy savings. It has been plagued, however, by verification issues. In 2009, a GAO investigation found that EPA and DOE approved a number of ridiculous, fictional products. The agencies' response of requiring third-party certification seems promising, but the effectiveness of this reform has not yet been thoroughly studied.
Sources:	<ul style="list-style-type: none"> • http://www.energystar.gov/ia/partners/publications/pubdocs/2010%20CPPD%204pgr.pdf?7ea2-485 • http://www.cee1.org/eval/00-new-eval-es.php3 • http://www.gao.gov/new.items/d10470.pdf • http://www.nytimes.com/2010/03/26/science/earth/26star.html • http://www.epa.gov/oig/reports/2011/20101028-11-P-0010.pdf • http://www.recovery.gov/Accountability/inspectors/Documents/IG-0827-508.pdf • http://www.gao.gov/assets/270/267314.pdf • http://www.gao.gov/assets/590/585547.pdf

2. NATIONAL ENVIRONMENTAL PERFORMANCE TRACK	
Administered by:	EPA
Program Description:	Performance Track was designed with the goal of rewarding environmental leaders and encouraging them to go beyond what was required by regulations. Individual facilities were admitted to the program if they (among other requirements) created an Environmental Management System (EMS), demonstrated past achievement, and set goals for future improvement. In return, facilities received perks including fewer inspections under relevant environmental statutes and the use of the “Performance Track” logo. The program was cancelled in 2009.
Verification of compliance:	The main enforcement mechanism consisted of annual reports submitted by the parties. The EPA reviewed these reports for data accuracy but did not independently inspect any facilities. The EPA could conduct an initial site visit of facilities, but this requirement was not mandatory and the EPA visited only about 30 percent of facilities.
Enforcement:	Removal from the Performance Track program.
Effectiveness:	Failure. An investigation by the EPA Inspector General revealed that only 2 out of 30 facilities sampled met their commitments under the program. Moreover, there was essentially no method for tracking the effectiveness of EMSs or the performance of the program overall. Some sources suggest that the EPA placed too much emphasis on recruiting new members to the detriment of creating coherent project goals and receiving substantive commitments from members.
Sources:	<ul style="list-style-type: none"> • http://www.epa.gov/performance-track/ • http://www.rand.org/content/dam/rand/pubs/technical_reports/2010/RAND_TR732.pdf • http://www.huffingtonpost.com/2009/03/17/epa-halting-ineffective-g_n_175628.html • http://articles.philly.com/2008-12-09/news/25243398_1_performance-track-environmental-performance-epa • http://www.epa.gov/oig/reports/2007/20070329-2007-P-00013.

3. VOLUNTARY PROTECTION PROGRAM	
Administered by:	OSHA
Program Description:	The Voluntary Protection Program (and related programs such as OSHA's Safety and Health Achievement Recognition Program (SHARP)) reward firms that are exemplary in occupational health and safety. To be eligible, firms must have a suitable Safety and Health Management System (SHMS) in place, have accident rates below the average industry rate in at least one of the last three years, and commit to continuous safety improvement and reporting.
Verification of compliance:	Each facility is subject to an initial inspection by OSHA inspectors to ensure that an effective SHMS is in place, and each facility must continually report accident and injury rates. Each facility is then reevaluated every 3-5 years. Facilities with significant injuries or deaths are potentially subject to additional inspections and a re-evaluation of their status in the program.
Enforcement:	If the injury reports at a VPP facility are above the industry average over 3 years, then the site will be placed on conditional status or placed in a rate-reduction plan. If there is a serious injury or a death at a facility, the OSHA regional office must evaluate the site to determine if its SHMS needs to be revised or if the firm needs to be removed from the program.
Effectiveness:	Mixed success. The program has clear goals and verification measures, and some statistical evidence suggests that the VPP has reduced injury rates in participating firms. Critics, however, have suggested that the injury rates reported by members are unreliable. Moreover, the national OSHA does not have data on the results of inspections by regional offices, so it is not clear what happens when participating facilities are inspected after serious injuries or deaths.
Sources:	<ul style="list-style-type: none"> • http://www.osha.gov/dcsp/vpp/ • http://www.gao.gov/new.items/d04378.pdf • http://www.nytimes.com/2007/04/25/washington/25osha.html?_r=1&hp&oref=slogin • http://www.osha.gov/dcsp/vpp/all_about_vpp.html • http://www.iwatchnews.org/2011/07/07/5130/model-workplaces-not-always-so-safe • http://www.help.senate.gov/newsroom/press/release/?id=1f1932db-064c-42b2-8148-be16b81951b2 • http://www.gao.gov/new.items/d09395.pdf

4. ISO 14001	
Administered by:	International Standards Organization
Program Description:	Voluntary Environmental Management System launched in 1993, primarily designed for business. Companies must assess their environmental impact, create an environmental policy and plan, set goals, monitor progress and aim for continuous improvement. Each individual company sets its own goals, there are no standards or minimum requirements set by ISO 14001 or the ISO 14000 family.
Verification of Compliance:	Companies can self-certify. However many choose to become certified by an independent body. These are national bodies which are accredited by the International Accreditation Forum (IAF). Usually the company has a choice about which certification body they approach. The company pays for certification.
Enforcement:	None.
Effectiveness:	ISO 14001 is one of the most widely adopted voluntary standards and management systems in the world. Since it doesn't actually set environmental standards, adoption could be seen as the measure of success. However there is little evidence that adoption of ISO 14001 improves environmental outcomes. It may be that the companies who adopt it are the ones who already have better environmental practices, or given the lack of enforcement mechanisms it may be that companies are simply able to complete the paperwork with negligible impact on their practices. Compared to other environmental management systems, ISO 14001 has very weak monitoring and public disclosure requirements. The role of the certification bodies may not be as strong as expected. Because they are paid by the company concerned and there is strong competition, they may be under pressure to give a positive certification even when this is not warranted.
Sources:	<ul style="list-style-type: none"> • http://www.iso.org/iso/iso_14000_essentials • http://www.iso.org/iso/iso_14000_essentials • http://remas.iema.net/content/results.htm • Prakesh and Potoski, <i>Racking to the Bottom? Trade, Environmental Governance and ISO 14001</i>, 50(2) Am J of Pol Science (2006) 350 • Potoski and Prakash, <i>Covenants with Weak Swords: ISO 14001 and Facilities' Environmental Performance</i>, 24(4) J of Policy Analysis and Management (2005) 745 • Idé, <i>The Effectiveness of International Environmental Regimes: The Case of the ISO 14000 Regime</i> Thesis for MPP/MPA degree, Concordia University, 2002 http://spectrum.library.concordia.ca/1890/1/MQ72868.pdf

5. EXXONMOBIL'S OPERATIONS INTEGRITY MANAGEMENT SYSTEM (OIMS)	
Administered by:	ExxonMobil and its subsidiaries, including Esso, Exxon, Mobil, Aera Energy and Hunt Petroleum
Program Description:	ExxonMobil's internal safety and environmental management system, developed after the Exxon Valdez oil spill in 1989. The Framework has 11 elements: management ownership; nine operational elements including risk assessment, management of change and training; evaluation and improvement. In its structure it seems fairly similar to SEMS.
Verification of Compliance:	Central ExxonMobil teams carry out inspections and audits of subsidiaries.
Enforcement:	Unclear – we have not been able to locate many resources relating to this program.
Effectiveness:	Unclear from available sources. Esso's use of the system was criticized by the Australian Commission investigating a massive gas explosion in their Longford plant in 1998. A central ExxonMobil audit had been conducted shortly before the explosion which failed to identify systematic and widespread safety risks. However we have not been able to locate any comprehensive review of OIMS.
Sources:	<ul style="list-style-type: none"> • http://www.exxonmobil.com/Corporate/Files/OIMS_Framework_Brochure.pdf • Hopkins, A., <i>Lessons from Longford: The Esso Gas Plant Explosion</i>, CCH Australia Limited (2001)

6. INTERNATIONAL ASSOCIATION OF DRILLING CONTRACTORS (IADC) HEALTH, SAFETY AND ENVIRONMENT CASE GUIDELINES	
Administered by:	Respective national regulators. Created by the IADC which represents the worldwide oil and gas industry. Members include many of the major oil and gas producers as well as 1000s of contractors and consultants.
Program Description:	Model Health, Safety and Environment case (management system) guidelines for both onshore and offshore drilling units. The model is accepted by regulators in 10 countries including the UK, Norway and Cuba, and is required by regulators in another 10 countries including Canada and Brazil. The model provides a very thorough outline of the different elements of a safety management system. It contains five substantive parts: management duties, safety information, risk management, emergency response and performance monitoring. It provides step-by-step approaches to risk assessment and comprehensive discussion of factors to take into account during auditing.

Verification of Compliance:	Via national regulatory procedures.
Enforcement:	Via national regulatory procedures.
Effectiveness:	Unclear – we have not been able to find any research evaluating the IADC model. There may be some research in the countries in which it is required as the mandatory system, however we have not had time to explore this. As it is used in different jurisdictions its effectiveness is likely to vary according to the ways in which it is implemented and verified.
Sources:	<ul style="list-style-type: none"> • IADC HSE Case overview: http://www.iadc.org/hsecase/index.html • IADC membership: http://www.iadc.org/membership/directory.htm.

7. INTERNATIONAL REGULATORS’ FORUM (IRF)

Administered by:	IRF
Program Description:	IRF is an international organization of eleven national regulators of the offshore oil and gas industry. The IRF includes BSEE, and analogous government regulators from the UK, Norway, Australia, Denmark, Mexico, New Zealand, Canada, Brazil, and the Netherlands. IRF has an annual meeting at which it reviews previous activities, shares technical data, and plans for future health and safety improvements. IRF also encourages open communication between meetings and maintains a website to disseminate technical information and performance results. For example, IRF publishes publicly the performance data of each country, including amount of hydrocarbons released, fatalities, and serious injuries.
Verification of Compliance:	N/A
Enforcement:	N/A
Effectiveness:	It is difficult or impossible to accurately assess the impact that IRF is having on the performance of government regulators in individual countries. Nonetheless, it seems that IRF is very useful in coordinating the efforts of regulators, facilitating the sharing of information, and bringing transparency to offshore drilling regulation.
Sources:	<ul style="list-style-type: none"> • http://www.irfoffshoresafety.com/about/ • http://www.irfoffshoresafety.com/conferences/2011Summit/IRF%202011%20Summit%20-%20Summary%20of%20theConclusions.pdf • http://www.irfoffshoresafety.com/country/performance/

8. CONSOLIDATED SUPERVISED ENTITIES PROGRAM (CSE)	
Administered by:	SEC
Program Description:	SEC created program to cover investment bank holding companies over which the SEC did not previously have authority. Such entities could elect to be supervised by the SEC. In return, these entities were allowed to set their capital ratios based on mathematical models and scenario testing done by the entities themselves. Capital ratios determine how much capital a bank must have available, i.e., not invested elsewhere.
Verification of Compliance:	Essentially none. The SEC deferred entirely to the entities' risk assessments and determinations on capital ratios.
Enforcement:	No enforcement mechanism beyond general securities law.
Effectiveness:	Failure. Bear Sterns was in full compliance with CSE prior to its collapse. The SEC terminated the program in 2008 because the program was "fundamentally flawed." In the SEC's view, the program failed because (a) it was entirely voluntary and entities could opt in and out and (b) the lack of specific statutory authority for the SEC to regulate investment bank holding companies on a non-voluntary basis.
Sources:	<ul style="list-style-type: none"> • https://www.federalregister.gov/articles/2004/06/21/04-13413/supervised-investment-bank-holding-companies#h-11 • http://www.sec.gov/news/press/2008/2008-230.htm • http://www.sec-oig.gov/Reports/AuditsInspections/2008/446-a.pdf

9. TOXIC COAL ASH – UTILITIES SOLID WASTE ACTIVITIES GROUP (USWAG)	
Administered by:	EPA
Program Description:	EPA adopted an action plan produced by Utilities Solid Waste Activities Group (USWAG), an industry trade group, to regulate for handling and disposal of toxic coal ash. Participation in the plan by public and private utilities is entirely voluntary. Further, most of the standards in the plans contain opt-out provisions if a utility can make a minimal showing that such standard is inapplicable.
Verification of Compliance:	Essentially none. While a participating plant operator is required to monitor its own plant, there is no requirement for third-party/government monitoring or audit of operator's monitoring system.

Enforcement:	Essentially none. Even where contamination is discovered from an operator's monitoring, the only consequence is that the operator must, within 90 days, consult with relevant agency and begin to develop a risk-based management plan to address contamination.
Effectiveness:	Failure. Participation is entirely voluntary. There is basically no oversight by the government or by an independent third-party. The TVA Kingston Fossil Plant coal fly ash slurry spill provides further evidence of the program's failure.
Sources:	<ul style="list-style-type: none"> • http://www.uswag.org/pdf/2006/CCPfinal.pdf • http://earthjustice.org/sites/default/files/library/references/noda_appendix_-d.pdf

10. LEADERSHIP IN ENERGY AND ENVIRONMENTAL DESIGN (LEED)	
Administered by:	Created and administered by the non-profit U.S. Green Building Council
Program Description:	LEED certification uses independent third-party verification that buildings satisfy sustainability and efficiency criteria. There are four levels of LEED certification: certified, silver, gold, and platinum. The LEED standards are developed through a consensus-based approach by a LEED committee.
Verification of Compliance:	All data must be verified by an independent third-party.
Enforcement:	LEED certification is only granted after third-party has verified that the building qualifies for the relevant level of certification. However, there is no ongoing certification after the original certification is granted.
Effectiveness:	Mixed success. The program has led to improvements in construction methods and processes. However, it is possible to manipulate the process by making superficial changes to a building that will be removed after certification is granted.
Sources:	<ul style="list-style-type: none"> • http://www.usgbc.org/DisplayPage.aspx?CategoryID=19 • http://www.gbci.org/main-nav/building-certification/certification-guide.aspx • http://www.fas.org/sgp/crs/misc/R40147.pdf

11. RESPONSIBLE CARE	
Administered by:	American Chemistry Council (ACC)
Program Description:	Responsible Care is a voluntary initiative of the global chemical industry focused on improving performance, communication and accountability in the manufacturing of chemicals. It is run by International Council of Chemical Associations (ICCA) and administered in the US by ACC. Participating members are required to implement a management system based on the Responsible Care Management System. This management system must be certified by an independent, third-party auditor every three years. Companies are also required to collect and disclose to ACC data regarding safety, energy, pollution, and accountability.
Verification of Compliance:	Each participating company must have its management system certified at the headquarter level and facility level by an independent, accredited auditor. This requirement was added in 2004. Prior to this, no verification was conducted.
Enforcement:	Participation in Responsible Care is mandatory for membership in ACC. Noncompliant companies are not suspended from ACC.
Effectiveness:	Failure but with recent improvements. Prior to 2004, Responsible Care did not require third-party audits. Participating companies were able to adopt Responsible Care without making substantive changes to their manufacturing processes. A 2000 study from the Academy of Management Journal found that participating firms actually performed worse than nonparticipating firms in lowering total emissions. The 2004 changes are for the better, but it is yet to be seen whether safety and environmental improvements will follow.
Sources:	<ul style="list-style-type: none"> • http://responsiblecare.americanchemistry.com/Performance-Results • http://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Management-System-and-Certification • http://responsiblecare.americanchemistry.com/Responsible-Care-Program-Elements/Management-System-and-Certification/RCMS-Technical-Specifications.pdf • Jody Freeman, <i>Private Parties, Public Functions and the New Administrative Law</i>, 52 Admin. L. Rev. 813 (2000) • http://mba.tuck.dartmouth.edu/pages/faculty/andrew.king/docs/selfreg.pdf • http://n.ethz.ch/~yblumer/download/RC/Responsible%20Care/Diverses/Kritischer_bericht.pdf

12. INSTITUTE OF NUCLEAR POWER OPERATIONS (INPO)

Administered by:	INPO
Program Description:	Following the crisis at Three Mile Island, the nuclear utility industry established INPO to create the highest levels of safety and reliability at nuclear power plants. While the NRC has primary regulatory authority over the nuclear industry, INPO works parallel to NRC in monitoring facilities. Each facility is inspected by INPO every two years. Inspectors focus on a holistic assessment of the entire operations of a plant rather than particular pre-determined criteria. Based on these inspections, a facility is assigned a score from one to five. These scores are presented at annual conference where the top performing facilities are honored with an award. Further, a facility's inspection score significantly impacts insurance premiums meaning that poor performers pay much more for insurance.
Verification of Compliance:	Inspections are conducted by teams of around 20 people made up of 1/3 full-time inspectors, 1/3 industry members on loan to INPO for 1-2 years, and 1/3 industry members on loan from other facilities for only that particular inspection.
Enforcement:	Suspension or expulsion from INPO membership.
Effectiveness:	Success. The nuclear industry has experienced measureable improvements in decreasing radiation doses, increasing plant efficiency, and facilitating information sharing in the nuclear industry since the creation of INPO.
Sources:	<ul style="list-style-type: none"> • http://www-ns.iaea.org/downloads/ni/safety_convention/us4thnatlreport.pdf • http://www.inpo.info/AboutUs.htm • http://www.nrc.gov/reactors/operator-licensing/op-licensing-files/msum051707.pdf • http://gao.justia.com/nuclear-regulatory-commission/1991/5/nuclear-regulation-rced-91-122/RCED-91-122-full-report.pdf

13. CENTER FOR OFFSHORE SAFETY (COS)	
Administered by:	API
Program Description:	Created in response to the BP Oil Spill, COS is an industry safety organization modeled off of other organizations including INPO and Responsible Care. The main goals of the program are facilitating the adoption of RP 75, and conducting third-party audits to ensure an adequate management system in compliance with RP 75. All companies who are a member of API must participate in the COS program, and any offshore drilling company can join voluntarily. The internal structure of the organization is not yet entirely laid out, but the board will be composed entirely of industry officials (with requirements for certain numbers of representatives of contractors, suppliers, drillers, etc.)
Verification of Compliance:	COS will conduct audits of companies to ensure compliance with RP 75. It is unclear exactly who will conduct these audits, and who would be considered an “independent” third-party auditor.
Enforcement:	The repercussions of failing an audit are equally unclear. It seems like an organization could lose membership in API if it failed an audit, but such a punishment is not explicitly required.
Effectiveness:	It is too early to tell if COS is effective. To the extent that it tries to emulate INPO, it could be effective. Several critics have raised concerns about COS’s position within API, and the extent that auditors are truly independent may be critical. Establishing credible threats for noncompliance (as done successfully by INPO and not done effectively by Responsible Care) will also be important.
Sources:	<ul style="list-style-type: none"> • http://www.centerforoffshoresafety.org/ • http://new.api.org/Newsroom/safety-enhancements.cfm?renderforprint=1 • http://www.chron.com/business/energy/article/Oil-and-gas-industry-creates-offshore-safety-1690079.php • http://green.blogs.nytimes.com/2011/03/17/oil-industry-to-form-safety-group/#more-95883 • Michael Baram, Preventing Accidents in Offshore Oil and Gas Operations: The U.S. Approach and Some Contrasting Features of the Norwegian Approach, Boston Univ. School of Law Working Paper No. 09-43 (2010) • http://onlinepubs.trb.org/onlinepubs/sr/srSEMSInterimReport.pdf

III. MANDATORY PROGRAMS

1. SARBANES-OXLEY	
Administered by:	SEC
Program Description:	Managers of publicly traded companies are required to create a system of internal controls designed to ensure accuracy and prevent fraud in the accumulation and disclosure of financial data. Management must include in the company’s annual report an assessment of the internal controls. Additionally, a company’s CEO and CFO are required to personally certify in the company’s annual report that they are responsible for establishing and maintaining internal controls and that they have evaluated the effectiveness of the internal controls. A CEO or CFO is subject to civil and criminal liabilities for knowingly providing a false certification.
Verification of Compliance:	A registered public accounting firm must report on and attest to management’s assessment of the internal controls. This attestation must be made in accordance with standards issued or adopted by the Public Company Accounting Oversight Board (“PCAOB”).
Enforcement:	Civil and criminal liability for CEO/CFO for knowingly false certification
Effectiveness:	Success. The number of corrective filings by companies increased significantly after enactment suggesting greater commitment to accuracy. A study by the Institute of Internal Auditors Research Foundation, found that SOX has succeeded in creating active participation by the board, the audit committee, and management in internal control systems.
Sources:	<ul style="list-style-type: none"> • http://www.glasslewis.com/downloads/Restatements2005Summary.pdf • http://www.glasslewis.com/downloads/Restatements2005Summary.pdf • http://www.theiia.org/bookstore/product/sarbanesoxley-section-404-work-looking-at-the-benefits-1408.cfm • http://www.glasslewis.com/downloads/Restatements2005Summary.pdf • http://fei.mediaroom.com/index.php?s=43&item=204

2. FEDERAL AVIATION AUTHORITY (FAA) DESIGNEE PROGRAM	
Administered by:	FAA
Program Description:	Individuals and organizations carry out certifications and examinations on behalf of the FAA, for a range of functions including pilot examinations, engineering, manufacturing and airworthiness. Designees carry out up to 90% of the FAA's certification functions, however they are not involved in standard setting. Individuals are appointed as designees for 3 years following a panel interview and evaluation process. Individuals are paid by the company who is seeking the certification and not by the FAA. Organizations are appointed as designees for 5 years and then select their own individual unit members to carry out the FAA functions.
Verification of Compliance:	The FAA conducts inspections and audits of its various designees. The frequency varies across the different programs, for example the pilot examiners are inspected at least annually.
Enforcement:	The FAA has powers to immediately suspend or revoke an individual or organization designation on very wide grounds, including poor performance, conflict of interests, lack of integrity and non-timeliness of reports.
Effectiveness:	This is a well-established program, with the FAA using private parties to carry out functions since the 1920s. It significantly expands the FAA's resources, adds technical expertise and makes the certification process far quicker than it would otherwise be. However several GAO and DoT reviews have raised concerns about the quality and consistency of FAA oversight. There is inadequate data collection and insufficient numbers of designee evaluations. Poor performance is not identified or addressed and FAA staff do not have the training or guidance necessary to carry out their oversight role. The FAA claims that it is improving its designee management and data systems.
Sources:	<ul style="list-style-type: none"> • http://www.faa.gov/about/history/deldes_background/ • http://www.faa.gov/documentLibrary/media/Order/FAA%20Order%208100.8D.pdf • http://www.gao.gov/new.items/d0540.pdf • http://www.oig.dot.gov/sites/dot/files/FAA%20ODA%206-29-11.pdf • http://www.gao.gov/assets/320/311045.pdf • http://www.gao.gov/new.items/d12117.pdf • http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgOrders.nsf/0/4adc44e71e8e04a38625793d004d5d61/\$FILE/8100.8%20Rev%20D%20Major%20Changes.pdf

3. SAFETY AND ENVIRONMENT MANAGEMENT SYSTEM (SEMS)	
Administered by:	Bureau of Safety and Environmental Enforcement (BSEE), Department of Interior
Program Description:	Mandatory (since October 2010) management system for all offshore facilities including mobile units (MODUs). The federal rule incorporates by reference API's previously voluntary management system (RP 75) with some additional requirements and clarifications. The system has 13 elements, many of which are common to other management systems, including management ownership, hazards analysis, management of change, operating procedures, critical equipment integrity, training, emergency response, audits and record-keeping. Management systems are intended to ensure the company, rather than the regulator, is entirely responsible for conducting a thorough and site-specific risk assessment and for putting in place all necessary measures to mitigate or reduce the risks.
Verification of Compliance:	Audits of the SEMS plan and its implementation (by eg assessing processes or equipment integrity, although details are unclear at this stage) by designated employees or independent third parties nominated by the company (although note that BSEE is proposing to restrict this to third parties only). BSEE may also observe or participate in these audits as well as having power to conduct its own audits or direct the company to carry out an audit. The audit powers and duties are in addition to annual announced and periodic unannounced inspections to check compliance with all of the Offshore regulations.
Enforcement:	Primarily through notices of non-compliance and civil penalties (fines). BSEE also has the power to disqualify operators from the Outer Continental Shelf or seek criminal penalties for certain knowing and willful violations under Section 24(c) of the Outer Continental Shelf Lands Act (OCSLA or the Act) (43 U.S.C. 1350(c)). In calendar year 2011, BSEE obtained civil penalties in 30 cases with a total of \$1.9m in fines.

<p>Effectiveness:</p>	<p>The SEMS rule only fully came into force in 2011 so as yet there are no evaluations of its effectiveness. The introduction of a mandatory goal-based risk management system is seen as a step forward by many and was one of the recommendations of the Oil Spill Commission. However the fact that SEMS is almost entirely an incorporation of the API's existing standard raises concerns over its potential effectiveness. RP 75 is far less stringent than offshore safety management systems used in other countries and the International Association of Drilling Contractors' (IADC) model Health, Safety and Environment case guidelines. In its voluntary incarnation, RP 75 was used by over 50% of offshore operators in 2009, including by all the high activity operators (which presumably includes BP at the time of the Deepwater Horizon disaster). Our report makes various recommendations for strengthening SEMS with a particular focus on improving data collection, strengthening audits and formalizing the role of frontline workers. [see pages XXX]. There are also problems with the effectiveness of the enforcement mechanisms, especially the low level of fines relative to the profits made by the offshore industry.</p>
<p>Sources:</p>	<ul style="list-style-type: none"> • 30 CFR 250 Subpart S • BOEMRE Final Rule October 15, 2010, <i>Oil and Gas and Sulphur Operations in the Outer Continental Shelf – Safety and Environment Management Systems</i> 75 FR 63610 • BOEMRE Proposed Rule September 14, 2011, <i>Oil and Gas and Sulphur Operations in the Outer Continental Shelf – Revisions to Safety and Environment Management Systems</i>, 76 FR 56683 • http://www.bsee.gov/Inspection-and-Enforcement/Inspection-Programs/Inspection-Programs.aspx • http://www.bsee.gov/Inspection-and-Enforcement/Civil-Penalties-and-Appeals/Civil-Penalties-and-Appeals.aspx • Oil Spill Commission Final Report, esp chs??? • Oil Spill Commission Working Paper No. 22, <i>A Competent and Nimble Regulator: A New Approach to Risk Assessment and Management</i> http://www.oilspillcommission.gov/sites/default/files/documents/A%20Competent%20and%20Nimble%20Regulator%20A%20New%20Approach%20to%20Risk%20Assessment%20and%20Management.pdf • http://publications.api.org/Exploration-Production.aspx

4. FOOD AND DRUG ADMINISTRATION (FDA) MEDICAL DEVICE APPROVAL PROCESS	
Administered by:	FDA
Program Description:	Section 253 FDA Modernization Act of 1997 required the FDA to establish a third party certification program for medical devices. Currently third parties can review approval applications for over 670 devices (although in practice this number may be lower due to the respective expertise of the third parties). Third parties may only review devices within the s510(k) approval process: devices which are classified as low or moderate risk and which are not novel in their technology or application. Third parties are also involved as experts for the Medical Devices Advisory Committee which review applications for novel technologies.
Verification of Compliance:	The FDA assesses, trains and audits the third parties. The final decision on approval still rests with the FDA; the third party can only make recommendations. FDA rules attempt to eliminate conflicts of interest although third parties are paid by the device manufacturers. The rules also prohibit forum-shopping by device manufacturers ie they may not approach a second certifier if the first review is unfavorable.
Enforcement:	FDA can disqualify third parties.
Effectiveness:	Third party certification appears to play a minor role in the process. Currently there are just 10 registered third parties. A 2009 GAO review of the FDA approval process found that only around 9% of eligible reviews were conducted by third parties and the FDA expected this number to decrease as its internal processes became more efficient. The GAO has concerns about certain aspects of the FDA oversight of the medical device market, however these do not directly relate to the use of third parties. The GAO does not seem to think that directives to increase the use of third parties will be particularly helpful in remedying these weaknesses. News reports from 2010 suggest that the FDA was reviewing the use of third parties and had significant concerns about the quality of these reviews.

Sources:	<ul style="list-style-type: none"> • 21 CFR Part 807, Subpart E • GAO, Medical Devices, FDA's Premarket Review and Postmarket Safety Efforts (April 13, 2011) http://www.gao.gov/assets/130/126013.pdf • GAO, <i>Food And Drug Administration: Opportunities Exist to Better Address Management Challenges</i>, February 2010, p1 http://www.gao.gov/assets/310/300950.pdf • http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm • http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm GAO, <i>Medical Devices: FDA Should Take Steps to Ensure That High-Risk Devices Are Approved Through the Most Stringent Premarket Review Process</i>, January 2009 http://www.gao.gov/new.items/d09190.pdf • http://online.wsj.com/article/SB10001424052748703447104575117892340074732.html
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5. UK SAFETY CASE	
Administered by:	Health and Safety Executive (HSE), a non-departmental public body; although accountable to the Executive and Parliament it has an independent Board of Directors and management appointments are non-political.
Program Description:	Introduced after the 1988 Piper Alpha disaster, offshore operators are required to submit a safety case which assesses all possible risks, demonstrates that these have been reduced to a level as low as reasonably practicable (ALARP) and that all relevant regulations have been complied with. Operations may not begin until the HSE is satisfied with the safety case. All regulations are performance based. Operators are required to use good practice as a minimum; these good practice standards are developed and adopted by industry with regulator involvement as it sees fit. Note that the safety case regime is solely focused on safety; there is a separate environmental assessment and inspection regime (predominantly set by European regulations) administered by the Department of Energy and Climate Change.

<p>Verification of Compliance:</p>	<p>High levels of inspections (announced and unannounced) by HSE inspectors, who are highly qualified and receive ongoing training. Certain safety critical elements must be independently verified by third party auditors, paid by the operator. Operators are required to report safety data including hydrocarbon releases, with criminal penalties for non-compliance. There are workforce safety representatives, elected by workers on the rig, who have statutory powers of inspection and the right to request an HSE inspection.</p>
<p>Enforcement:</p>	<p>Through criminal and civil penalties. HSE has direct powers of criminal prosecution.</p>
<p>Effectiveness:</p>	<p>An independent review of the UK regime following Deepwater Horizon generally considered the regime to be effective in promoting safety and encouraging industry safety innovation and noted that the emergency response frameworks and independent certification requirements were particular strengths. It identified certain areas for improvement including stronger checks on whether the safety cases are fully implemented and better sharing of lessons learned from near misses. Other evaluations have not been quite as positive. Although there was a sharp improvement in the safety data following the initial introduction of the regime in 1992, this has tailed off in recent years. A systematic review by HSE of the condition of all North Sea rigs in 2009 found that significant numbers of operators were deliberately failing to maintain non-safety critical infrastructure to the point that it posed risks on the ageing rigs. New voluntary performance indicators were developed by the industry body and it is now responsible for overseeing data collection and reporting to HSE.</p>
<p>Sources:</p>	<ul style="list-style-type: none"> • Offshore Installations (Safety Case) Regulations 2005 • http://www.hse.gov.uk/offshore/index.htm • http://www.hse.gov.uk/offshore/safetycases.htm • http://www.decc.gov.uk/assets/decc/11/meeting-energy-demand/oil-gas/3875-offshore-oil-gas-uk-ind-rev.pdf • Steinzor, <i>Lessons from the North Sea: should “safety cases” come to America?</i> 38(2) Boston College Env Aff L Rev (2011) 387

6. US COAST GUARD MARINER LICENSING AND CERTIFICATION

Administered by:	Coast Guard
Program Description:	<p>The CG relies upon third parties to train and license mariners. To become a qualified instructor or a designated examiner a person must provide documentary evidence to the CG that they have adequate experience, are qualified and hold an equal license/endorsement. Documentary evidence can either be in the form of performance evaluations of on-the-job conduct or a certificate from a train-the-trainer course, which is either based on the IMO model course or another CG approved course. Designated Examiners are approved individually and issued a letter of qualification for 5 years. Qualified Instructors are not approved individually, but are approved as part of a course or approved training program.</p>
Verification of Compliance:	<p>The Coast Guard, through its regional offices, audits Qualified Instructors and Designated Examiners. The types of audits include: announced periodic audits, unannounced audits in response to complaints, informal visits – either announced or unannounced, mariner’s surveys or separate tests, site inspections, and covert audits. The schedule of audits varies based upon the degree of authority being exercised by the third party. For example, a school that offers exams in lieu of CG exams will be subject to announced audits annually and informal visits quarterly; whereas a school offering a course for less than 30 days sea time will only be audited at the discretion of the USCG.</p>
Enforcement:	Suspension or withdrawal of approval.
Effectiveness:	<p>Unclear. The Office of Inspector General issued a critical report in 1997 indicating that the program was not well managed and under-audited. The Coast Guard has implemented several revisions to the program since then, but none that seem to fundamentally change the auditing process or the CG’s oversight of third parties.</p>
Sources:	<ul style="list-style-type: none"> • http://www.uscg.mil/nmc/marpers/pag/oversight.pdf • http://www.uscg.mil/hq/cg5/nvic/pdf/1997/n6-97.pdf • http://www.oig.dot.gov/sites/dot/files/pdfdocs/r9cg7013.pdf

7. MASSACHUSETTS LICENSED SITE PROFESSIONALS	
Administered by:	Massachusetts Department of Environmental Protection (DEP)
Program Description:	Clean up of hazardous waste sites under the Massachusetts Contingency Plan is carried out by licensed site professionals (LSPs) that are licensed by a Board. The Board's regulations set forth licensing requirements and standards for professional conduct. LSPs are hired by individual property owners to determine whether a cleanup is necessary, and to craft and carry out a cleanup plan.
Verification of Compliance:	The Board can initiate enforcement actions sua sponte or in response to complaints. The Board has the authority to conduct investigations and commence adjudicatory proceedings. DEP is also required to audit a statistically significant number of sites annually.
Enforcement:	Public censure, suspension or revocation of license, and for knowing material misrepresentations, civil penalties – not to exceed \$1,000 per day per violation or a maximum of \$10,000 – and up to two years imprisonment.
Effectiveness:	The program has addressed 29,409 sites. Of those, approximately 50% have been permanently remediated. There are approximately 550 LSPs and, since the start of the program, there have been 48 disciplinary actions that have resulted in affirmative discipline. Some hail the program's success, while others are critical of its over-delegation of authority to the LSPs, the private contractor relationship between the LSP and the property owner, the lack of meaningful public involvement and the few number of meaningful DEP audits
Sources:	<ul style="list-style-type: none"> • http://www.mass.gov/lsp/ • http://www.mass.gov/lsp/files/final.pdf • http://www.astswmo.org/Files/Meetings/2010/2010hazardouswaste/Duff_Collins-Mass_LSP_Program.pdf • http://opim.wharton.upenn.edu/risk/downloads/01-04-HK.pdf • Miriam Seifter, "Rent a Regulator: Design and Innovation in Environmental Decision Making," Freeman And Minnow, Government by Contract (Harvard University Press, 2009)

8. NATIONAL CONTINGENCY PLAN AND REMEDY OPTIMIZATION

Administered by:	EPA
Program Description:	For hazardous waste sites listed on the National Priorities List, EPA utilizes independent technical experts to conduct remedy optimization to identify opportunities to improve the cleanup process and reduce costs. The process results in a report that includes recommendations for improvements. If the recommendations are minor, they can be implemented by EPA or the property owners. If, however, the recommendations are more significant they can only be implemented after EPA's approval of a modified Record of Decision.
Verification of Compliance:	None – EPA approval is required to implement any major recommendations.
Enforcement:	None – To the extent EPA is contracting with private parties, contract remedies would exist.
Effectiveness:	Remedy Optimization has only been implemented at approximately 100 sites. Technical improvements that can be implemented without EPA action had a 70% rate of compliance, whereas more substantive site closure improvement measures had only a 41.7% rate of compliance.
Sources:	<ul style="list-style-type: none"> • http://www.epa.gov/superfund/cleanup/postconstruction/pdfs/0809_optimization_report.pdf • http://clu.in.org/techfocus/default.focus/sec/Remediation_Optimization/cat/Overview/page/3/ • http://www.epa.gov/superfund/cleanup/postconstruction/optimize.htm • http://www.frtr.gov/pdf/meetings/nov11/presentations/biggs-presentation.pdf • http://clu.in.org/consoil/prez/2010/Remedy-Optimization-Through-Remedial-System-Evaluation-Slides.pdf

9. OSHA MACHINE GUARDING AND SAFETY STANDARDS

Administered by:	OSHA
Program Description:	<p>OSHA has thousands of standards in many different categories. Machine Guarding and Safety Standards are treated together because they were among the earliest standards created and shared similar problems (OSHA’s fire safety standards and OSHA’s air toxics standards are discussed below). OSHA was initially authorized to adopt safety standards directly, and adopted machine standards and safety standards summarily in its first two years. OSHA continues to rely on industry standards but now must adopt them through a rulemaking. OSHA has developed procedures called “negotiated rulemakings” in an attempt to reduce adverse comments and expedite the process of adopting and updating standards.</p>
Verification of Compliance:	<p>Inspected directly by OSHA inspectors. Early inspections were ineffective in part because inspectors were paid by the violation, incentivizing them to focus on trivial, easy-to-identify violations. The OSHA inspection process has since been improved. Inspections are now more holistic, and inspectors tour facilities, take pictures, videos, and samples, conduct interviews with both management and employees, and check company records. Inspections of facilities with prior violations, facilities with injuries or deaths, and facilities in certain high-risk industries are prioritized.</p>
Enforcement:	<p>OSHA is authorized under the OSH Act to impose both civil and criminal penalties. Some have suggested, however, that the penalties have not been sufficiently updated so they are currently too low to effectively deter violations.</p>
Effectiveness:	<p>These standards have been historically problematic, but seem to be improving. Many of the standards initially adopted by OSHA were already out-of-date or were not applicable to the broad set of facilities to which they were applied. This illustrates that standards that work in a particular industry can be problematic when made mandatory and broadly applied. OSHA is now more selective about what standards it adopts, but updating standards to keep up with the pace of technology remains problematic.</p>

Sources:	<ul style="list-style-type: none"> • http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=TESTIMONIES&p_id=1062 • http://www.osha.gov/Publications/osha2098.pdf • http://www.osha.gov/OshDoc/data_General_Facts/factsheet-inspections.pdf • http://www.nber.org/papers/w3233.pdf • Robert Hamilton, <i>The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health</i>, 56 Tex. L. Rev. 1329 (1978). • Steven Kelman, <i>Regulating America, Regulating Sweden: A Comparative Study of Occupational Safety and Health Policy</i> (1981).
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10. OSHA FIRE SAFETY STANDARDS	
Administered by:	OSHA
Program Description:	OSHA fire safety standards were examined separately because they have been problematic, particularly OSHA’s standard for grain elevators. OSHA initially adopted an industry standard created by NFPA to address fire hazards in grain elevators. When this standard proved ineffective, OSHA created its own standard from scratch, which was very expensive and took 10 years to complete.
Verification of Compliance:	Same as OSHA Machine Guarding and Safety Standards.
Enforcement:	Same as OSHA Machine Guarding and Safety Standards.
Effectiveness:	Initial failure, but later improved. The NFPA standard was inadequate because NFPA at the time was overly influenced by the management of grain companies and insurers who were worried primarily about keeping costs low (NFPA has since amended its standard-setting procedures to include more input from technical experts, labor, government, and academia). The standard OSHA created to address the problem was sufficiently protective, but was extremely difficult to create and ensured that an inadequate standard remained in place for 10 years. The fire standard creation process could have either through using standards created by a private organization with a more consensus-based focus (e.g. IEEE or ACGIH), or using the “negotiated rulemaking” procedures to expedite the creation of an OSHA standard.

Sources:	<ul style="list-style-type: none"> Ross Cheit, <i>Setting Safety Standards: Regulation in the Public and Private Sectors</i> 39 (1990). http://www.nfpa.org/categoryList.asp?categoryID=161&URL=Codes%20&%20Standards/Code%20development%20process
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11. OSHA AIR TOXICS STANDARDS

Administered by:	OSHA
Program Description:	OSHA initially adopted health and safety standards from ACGIH. ACGIH is a private organization, but it represents the consensus of industry members, government officials, and academics with expertise in industrial hygiene. OSHA currently establishes its own air toxics limits, but relies on standards created by ACGIH and the advice of NIOSH, a federal agency, in developing these standards.
Verification of Compliance:	Same as OSHA Machine Guarding and Safety Standards.
Enforcement:	Same as OSHA Machine Guarding and Safety Standards.
Effectiveness:	ACGIH standards are well-respected and have been viewed as effective. One issue is that the ACGIH standards adopted by OSHA were already out of date, and some OSHA standards lag behind what is currently recommended by ACGIH and NIOSH. Thus, the continual updating of standards is important.
Sources:	<ul style="list-style-type: none"> http://www.osha.gov/SLTC/healthguidelines/index.html http://www.osha.gov/doc/outreachtraining/htmlfiles/fact9214.html http://articles.latimes.com/1988-06-08/news/mn-3910_1_exposure-limits

12. CLEAN AIR ACT RISK MANAGEMENT PLANS

Administered by:	EPA
Program Description:	The EPA passed a Risk Management Plan (RMP) rule pursuant to Section 112(r) of the CAA. Under the rule, facilities manufacturing certain hazardous and flammable substances must create an RMP that includes (1) a hazard assessment that details the potential effects of an accidental release, an accident history of the last five years, and an evaluation of worst-case and alternative accidental releases, (2) a prevention program, and (3) an emergency response program.
Verification of Compliance:	The EPA directly monitors compliance with the RMP rule, through one of four activities depending on the situation: 1) a “completeness check” ensuring that the RMP includes all required data, 2) a “review” for internal inconsistencies in the RMP, 3) an “audit” in which RMP data is verified either through in-depth review of documents or a site visit, and 4) an “inspection” in which EPA staff inspect a plant. The EPA has also started a pilot program for third-party audits, but this program is currently only operating in a small portion of Pennsylvania.
Enforcement:	Failure to comply with the RMP provisions can subject firms to civil and criminal penalties under the CAA.
Effectiveness:	There is very little research on the effectiveness of the RMP program, perhaps because of its overlap with OSHA’s reporting requirements and other provisions of the CAA.
Sources:	<ul style="list-style-type: none"> • 40 C.F.R. § 68 • http://www.epa.gov/oem/content/lawsregs/rmpover.htm • http://www.epa.gov/oem/content/rmp/ • http://www.epa.gov/oem/docs/chem/caa112_rmp_factsheet.pdf • http://www.gao.gov/new.items/d03509r.pdf • http://www.epa.gov/osweroe1/docs/chem/iguidfnl.pdf • http://www.epa.gov/osweroe1/docs/chem/auditfactsheet.pdf • http://www.acusafe.com/Guidance/US-EPA/audit_gd.pdf • http://www.gao.gov/assets/260/258480.pdf

13. UNDERGROUND INJECTION CONTROL

Administered by:	EPA, states
Program Description:	Pursuant to the Safe Drinking Water Act (SDWA), the EPA has promulgated regulations dealing with underground injection wells. The EPA has established different requirements based on the type of well (wells are divided into 5 different classes based on the materials injected and proximity to drinking water sources). The program involves cooperative federalism, in which states can establish their own UIC program if it meets the requirements of the SDWA (if states do not implement such a program, the EPA will administer one). Most classes of wells are required to conduct pressure tests and submit monitoring data to the EPA or the states on an ongoing basis.
Verification of Compliance:	Varies somewhat by state, but typically involves both the reporting of data from pressure tests and monitoring and some direct inspections. The most hazardous classes of are required to submit data more frequently and conduct more rigorous monitoring.
Enforcement:	Varies somewhat by state, but can involve civil and criminal liability.
Effectiveness:	A GAO report found contamination of drinking water in 23 class II wells. Nearly all of these wells were grandfathered out of the pressure testing requirements of the UIC program. These results suggest that the UIC program is effective, but has a significant gap in allowing grandfathered wells to avoid requirements. The results of the program in regulating hydraulic fracturing are not yet clear but are currently being examined.

Sources:	<ul style="list-style-type: none"> • 40 C.F.R. § 144 • http://water.epa.gov/type/groundwater/uic/basicinformation.cfm • http://water.epa.gov/type/groundwater/uic/wells.cfm • http://www.epa.gov/ogwdw/uic/pdfs/rept_uic_statemt_basis_purpose_uic_1980.pdf • http://www.epa.gov/ogwdw/uic/pdfs/guidance/guide-memo_guidance-25_casing_existing_class2_1981.pdf • http://www.epa.gov/ogwdw/uic/pdfs/rept_uic_statemt_basis_purpose_uic_1980.pdf • http://www.gao.gov/assets/150/147952.pdf • http://www.gao.gov/assets/230/220740.pdf • http://www.epa.gov/ogwdw/uic/pdfs/study_uic-class1_study_risks_class1.pdf • http://www.gao.gov/assets/590/587522.pdf • http://pubs.usgs.gov/fs/2009/3032/pdf/FS2009-3032.pdf • http://www.epa.gov/hfstudy/#status
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14. SUBSAFE	
Administered by:	US Navy
Program Description:	In response to the loss of the USS <i>Thresher</i> submarine, the Navy created the SUBSAFE program to assure (a) watertight integrity of submarine's hull and (b) the operability of critical systems to control and recover from flooding hazard. Responsibility under the program is divided among three entities: one creates the design standards, another is responsible for construction, and the final one handles enforcement. This structure was designed such that the three entities provide a system of checks and balances.
Verification of Compliance:	Everything from the submarine design to the construction process and materials must be certified based on "Objective Quality Evidence." Further, certification must be maintained over the life of the submarine. Contractors and shipyards must certify that their work complies with SUBSAFE. Audits are conducted of SUBSAFE facilities are conducted by a team of experts from other SUBSAFE facilities and NAVSEA headquarters.

Enforcement:	Independent Safety and Quality Assurance Authority, the enforcement entity, monitors and can challenge the other two entities on compliance with the standards as well as the standards themselves. Construction cannot progress unless certification is obtained
Effectiveness:	Success. Not a single SUBSAFE certified submarine has been lost since 1963.
Sources:	<ul style="list-style-type: none"> • Nancy G. Leveson, Engineering a Safer World, (The MIT Press) (2011) • http://mitpress.mit.edu/books/full_pdfs/Engineering_a_Safer_World.pdf

15. SURFACE MINING REGULATION UNDER SMCRA	
Administered by:	Office of Surface Mining (OSM), states
Program Description:	OSM passes regulations implementing the Surface Mining Control and Reclamation Act (SMCRA) and issues permits for states that have not established a regulatory program pursuant to SMCRA. In states that have created such a regulatory program, the state regulatory agency has the primary authority, but OSM oversees the state regulation and enforcement efforts. Most coal-mining states have created their own regulatory system for surface mining, but OSM still regulates coal mining in a few states and on federal lands.
Verification of Compliance:	Varies by state.
Enforcement:	Varies by state.
Effectiveness:	Not researched further, due to the inherent difficulty of analyzing varying state regulatory programs.
Sources:	<ul style="list-style-type: none"> • http://www.osmre.gov/rcm/rcm.shtm • http://www.osmre.gov/topic/Oversight/SCM/WhatIsOversight.pdf

IV. STANDARDS ORGANIZATIONS

1. AMERICAN SOCIETY FOR TESTING AND MATERIALS (ASTM)	
Organization Description:	ASTM includes 141 different standards-writing committees, and serves a wide variety of different industries including metals, petroleum, construction, and consumer products. It is now officially name “ASTM International,” rather than the American Society for Testing and Materials, because of its international membership. ASTM has an “open consensus process” for developing standards that includes the use of internet-based procedures that allow for input by members around the world. Anyone with an interest in a particular field can apply to be an ASTM member and thus have input. ASTM has about 30,000 members from more than 100 countries. The members include producers and consumers of particular goods, as well as members with general interests such as government representatives and academics. The technical committees tasked with developing standards have procedures to consider and address dissenting votes and concerns raised by a variety of members during the development process.
Standards Used by:	Adopted voluntarily in numerous industries. Also in mandatory regulations by EPA, FAA, the Coast Guard, and other government agencies.
Effectiveness:	ASTM standards are well-respected, as evidenced by their widespread adoption. Problems with ASTM standards have arisen not from problems with the standards themselves, but from failures to update standards once they have been incorporated in mandatory regulations. For example, an ASTM standard requiring the use of a of mercury thermometers with certain properties become problematic when the EPA did not remove it from a regulation when alternatives to mercury became available. The Coast Guard has attempted to address problems with updating ASTM standards through expedited rulemaking procedures.

<p>Sources:</p>	<ul style="list-style-type: none"> • http://www.astm.org/ABOUT/overview.html • http://www.astm.org/COMMIT/COMMITTEE/E48.htm • http://www.astm.org/ABOUT/faqs.html • http://www.sciencedirect.com/science/article/pii/S0011916405003504 • http://nlquery.epa.gov/epasearch/epasearch?typeofsearch=epa&filterclause=&max_results=100&referer=http%3A%2F%2Fwww.epa.gov%2F&result_template=epafiles_default.xsl&areaname=null&areapagehead=epafiles_pagehead&areapagefoot=epafiles_pagefoot&areasidebar=search_sidebar&stylesheet=s/epa.css&sort=term_relevancy&faq=yes&results_per_page=10&cluster=both&sessionid=448F4FDB809BE1B88BB889E746D9783B&querytext=%22American%20Society%20for%20Testing%20and%20Materials%22 • http://www.faa.gov/search/?omni=MainSearch&q=ASTM&x=0&y=0 • Incorporation of Revised ASTM Standards That Provide Flexibility in the Use of Alternatives to Mercury-Containing Industrial Thermometers, 77 Fed. Reg. 2456 (Jan. 18, 2012) • Update of Standards From the American Society for Testing and Materials (ASTM), 64 Fed. Reg. 67,170 (Dec. 1, 1999).
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<p>2. INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS (IEEE)</p>	
<p>Organization Description:</p>	<p>IEEE develops international standards in the telecommunications, information technology, and power generation industries. IEEE has over 40,000 members in 160 countries, including engineers, scientists, and industry professionals. A proposal to develop of a standard is submitted by an interested party, usually an interested industry member or industry group, but potentially a government or non-profit. If the IEEE approves the request to develop a standard, a “working group” is created that may include individuals from industry, non-profits, and government agencies, who volunteer to help develop the standard. There are then a set of rules and procedures for including input from a variety of members and ensuring that different viewpoints are heard in order to generate consensus. Finally, a standard will need to be approved by a review committee and then the standards board before it is published.</p>

Standards Used by:	IEEE’s standards have been incorporated broadly throughout the electric and electronics industries, including the familiar 802.11 standards for wireless routers. IEEE standards have also been used for the equipment and processes used by government agencies, including the Department of Homeland Security.
Effectiveness:	IEEE standards seem very well respected. A GAO report discussed favorably DHS’s use of an IEEE standards for software verification, and another GAO report criticized the Defense Finance and Accounting Service for its failure to use the same standard.
Sources:	<ul style="list-style-type: none"> • http://www.ieee.org/about/today/at_a_glance.html • http://www.ieee.org/about/organizations/index.html • http://www.ieee.org/documents/organization_summary.pdf • http://standards.ieee.org/about/ieeesa.html • http://standards.ieee.org/develop/process.html • http://www.gao.gov/assets/320/312745.pdf • http://www.gao.gov/assets/330/322032.pdf • http://www.gao.gov/assets/590/587213.pdf

3. UNDERWRITERS LABORATORIES (UL)	
Organization Description:	UL is an independent organization that develops standards and certifies products in five key areas: Product Safety, Environment, Life & Health, Verification Services and Knowledge Services. UL has developed approximately 1,400 standards through an “open, consensus-based methodology” that includes the input of consumers, manufacturers, government agencies, users, regulatory authorities and other interested parties.
Implemented by:	UL standards are widely adopted and mandated through government regulations by agencies such as the FAA. UL also has a highly respected certification program for verifying compliance with UL standards and other national and international standards. Products that pass UL certification receive a “UL” logo mark. OSHA has accredited UL’s certification program by designating it as a Nationally Recognized Testing Laboratory.
Effectiveness:	UL’s standards and its certification program are both respected. The certification program has been given Nationally Recognized Testing Laboratory status by OSHA, and UL certification is frequently considered or required in awards of government contracts.

Sources:	<ul style="list-style-type: none"> • http://www.ul.com/global/eng/pages/corporate/aboutul/ • http://www.ul.com/global/documents/secured/councils/ULOverview.pdf • http://www.osha.gov/dts/otpca/nrtl/index.html • http://ulstandardsinonet.ul.com/catalog/stdscatframe.html • http://www.gao.gov/assets/440/436186.pdf • http://www.fire.tc.faa.gov/pdf/tn89-60.pdf
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4. AMERICAN CONGRESS OF GOVERNMENT INDUSTRIAL HYGIENISTS (ACGIH)	
Organization Description:	ACGIH develops standards in develop standards in several areas of occupational health including: agricultural safety and health, air sampling instruments, bioaerosols, biological exposure indices, industrial ventilation, and threshold limit values for chemical substances. ACGIH initially limited its membership to government officials and academics. The organization, however, is now open to members of industry and any other practitioners in the fields of industrial hygiene or occupational health. Any type of member now has the ability to serve on committees and vote on standards, helping the organization achieve consensus from a variety of interested parties with technical expertise.
Implemented by:	ACGIH's threshold limit values (TLVs) are considered when OSHA designs its standards for air toxics (and in the past, OSHA directly adopted TLVs).
Effectiveness:	ACGIH is viewed as an authoritative source in the area of Air Toxics. In many cases ACGIH's TLVs and OSHA's standards are identical, and in some cases the TLVs are more stringent. One of the problems with the use of ACGIH standards by OSHA is that they have often become out of date. For example, the initial ACGIH standards that were adopted to begin OSHA's air toxics program were almost 20 years old.
Sources:	<ul style="list-style-type: none"> • http://www.acgih.org/about/history.htm • http://www.acgih.org/Members/org_members.htm • http://www.osha.gov/SLTC/healthguidelines/index.html • http://www.acgih.org/about/Approved_ACGIH_Strategic_Long_Range_Plan_2007-2011.pdf • http://articles.latimes.com/1988-06-08/news/mn-3910_1_exposure-limits

5. NATIONAL FIRE PROTECTION ASSOCIATION (NFPA)	
Organization Description:	NFPA creates consensus codes and standards for the prevention of fires and fire safety. NFPA standards are created through an elaborate, consensus-based process. NFPA technical committees have the primary responsibility for developing standards, and these committees must reach certain levels of consensus before taking any action toward approving a standard. The technical committees are composed in such a way that no more than one third of the members are from a particular “interest category.” The interest categories include “manufacturer,” “user,” “labor,” “enforcing authority,” and “insurer.” As discussed below, however, NFPA did not always have this elaborate, consensus-based structure.
Implemented by:	OSHA has extensively adopted or utilized NFPA standards in creating mandatory regulations for fire safety.
Effectiveness:	NFPA has historically produced certain inferior standards, but recently its procedures have improved. As mentioned above, NFPA created a lax standard for grain elevator safety due to the influence of industry management and concerns about costs. This standard led to grain elevator explosions and required OSHA to implement its own grain elevator rule. NFPA’s new procedures, however, will hopefully create better standards by obtaining input from government, academia, technical personnel within industry and others. OSHA currently relies on NFPA standards in a variety of other contexts, and these standards are likely to be significantly better (they have at least not caused OSHA to move to using its own standards as it needed to do with grain elevators).
Sources:	<ul style="list-style-type: none"> • Ross Cheit, <i>Setting Safety Standards: Regulation in the Public and Private Sectors</i> 39 (1990) • http://www.nfpa.org/categoryList.asp?categoryID=495&URL=About%20NFPA/Overview • http://www.nfpa.org/categoryList.asp?categoryID=161&URL=Codes%20&%20Standards/Code%20development%20process • http://www.nfpa.org/assets/files/PDF/classifications.pdf • http://www.nfpa.org/itemDetail.asp?categoryID=589&itemID=18478&URL=Codes%20&%20Standards/Code%20development%20process/Code%20development%20and%20adoption%20partner • http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=18970

6. AMERICAN PETROLEUM INSTITUTE (API)

<p>Organization Description:</p>	<p>API publishes standards on a variety of technical and safety topics in the oil and gas industry, including: refinery equipment, pipeline standards, safety and fire protection, and petroleum measurement (and it created RP 75). Committees who develop standards are made up of industry experts on technical issues. The standards-writing committees, however, are also open to groups who are “materially affected by the standards,” including oil and gas companies, manufacturers and suppliers, contractors and consultants, and representatives of government agencies and academia. API meeting minutes indicate, however, that technical committee meetings are not well-attended by non-industry representatives.</p>
<p>Implemented by:</p>	<p>API standards are adopted voluntarily by industry, and some are adopted through regulations by DOI (specifically, BOEM and the former BOEMRE and MMS). Notably, API’s RP 75 was adopted in BOEMRE’s SEMS rule.</p>
<p>Effectiveness:</p>	<p>API’s standards themselves have been somewhat successful; for example safety standards promulgated by API in the 1970s and 1980s contributed to significantly lowering workplace injuries and deaths. On the other hand, API’s standards clearly failed to address risks of systematic failures like the <i>Deepwater Horizon</i> accident. The report of the National Commission on the BP Oil Spill found that API had set lowest-common-denominator standards in certain areas, and had opposed making RP 75 mandatory. The structure of API and its relationship with its lobbying branch raise questions about both standards it creates and its ability to administer COS.</p>

Sources:	<ul style="list-style-type: none"> • http://www.api.org/publications-standards-and-statistics/committee-information.aspx • http://mycommittees.api.org/standards/ecs/sc2/Meeting%20Materials/2011/September%2028,%202011%20Meeting/Attachment%2001-Meeting%20Attendance%20Sheet%20-%20Sept%202011.pdf • http://mycommittees.api.org/standards/ecs/sc2/Meeting%20Materials/2011/February%2023,%202011%20Meeting/Attachment%2001-%20Attendance%20Sheet%20-%20Feb%202011.pdf • http://mycommittees.api.org/standards/ecs/sc10/Meeting%20Materials/2011/11sc10winterminutes.pdf • http://www.opensecrets.org/lobby/clientsum.php?id=D000031493&year=2011 • http://www.oilspillcommission.gov/sites/default/files/documents/DEEPWATER_ReporttothePresident_FINAL.pdf
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7. AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

Organization Description:	ANSI oversees the design and creation of standards by thousands of Standard Development Organizations (SDOs) by accrediting their procedures. It also accredits certification bodies that assess conformance with certain standards (see discussion of ANAB below). ANSI will accredit an SDO’s procedures if they meet ANSI’s “essential requirements” of “openness, balance, consensus and due process.” ANSI uses a process that is separate from the SDO accreditation, but based on the same principles, to evaluate the creation of particular standards. Standards that are accredited by ANSI become “American National Standards.” ANSI members currently include industry, professional societies, government agencies, and consumer and labor organizations. Each of these groups have input into ANSI’s activities through “member forums.”
Implemented by:	ANSI standards are used throughout industry and government agencies.
Effectiveness:	ANSI is respected, and adds an extra layer of credibility to standards that are created by SDOs that may already have elaborate consensus procedures. API and NFPA, organizations that we have identified as having some issues with the development of standards, are accredited by ANSI. The accreditation of these two groups may raise some questions about the rigor of their accreditation process

Sources:	<ul style="list-style-type: none"> • http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1 • http://www.ansi.org/about_ansi/introduction/introduction.aspx?menuid=1 • http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/ANSI%20Accredited%20Standards%20Developers/MAR12ASD-basic.pdf • http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/U.S.%20Standardization%20System-07.pdf (NOTE: This link seems to be unstable as it is updated frequently, but it can be found from the ANSI website). • http://nlquery.epa.gov/epasearch/epasearch?querytext=ANSI&fld=&areaname=&typeofsearch=epa&areacontacts=http%3A%2F%2Fwww.epa.gov%2Fepahome%2Fcomments.htm&areasearchurl=&result_template=epafiles_default.xsl&filter=sample4filt.hts • http://www.faa.gov/search/?omni=MainSearch&q=ANSI&x=0&y=0
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8. ANSI-ASQ NATIONAL ACCREDITATION BOARD (ANAB)	
Administered by:	ANSI
Program Description:	ANAB accredits auditors to act as independent third-party auditors for various programs that require third-party auditors to be accredited. For example, Responsible Care requires that participating companies be audited by an accredited third-party. ANAB worked with Responsible Care in creating an application and criteria for auditors seeking accreditation to perform such audits. The accreditation period is typically four years. ANAB conducts audits of the applicant's auditing processes, requires corrective action based on the audit, and verifies that any corrective actions were indeed taken. Additionally, a complete reassessment is required every four years.
Accreditation used by:	Both government agencies and the private sector rely on ANSI to accredit third-party auditors.
Effectiveness:	Unclear. While ANAB's accreditation process is extremely thorough and almost certainly improves the auditing process, it is difficult to attribute the successes and failures of the various programs for which ANAB provides accreditation to the role ANAB plays solely as an accrediting body.

Sources:	<ul style="list-style-type: none"> • http://www.anab.org/documents/requirements.aspx • http://www.anab.org/accreditation/responsible-care.aspx • http://www.anab.org/certification-bodies/become-a-certification-body.aspx
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9. INTERNATIONAL ORGANIZATION OF SUPREME AUDIT INSTITUTIONS (INTOSAI)

Program Description:	<p>INTOSAI is an international organization that serves as an umbrella for government auditing organizations (referred to as Supreme Audit Institution or SAI's). INTOSAI issues international standards for how such organizations should conduct financial, compliance, and performance audits, as well as additional guidelines for good governance. The focus of these standards is on creating guidelines for financial audits to combat corruption particularly in developing nations. The United States Government Accountability Office is an INTOSAI member participates in INTOSAI's standard setting process.</p>
Standards used by:	<p>INTOSAI standards are used by national Supreme Audit Institutions (SAIs), such as the GAO in the U.S.</p>
Effectiveness:	<p>Mixed. The GAO has cited to INTOSAI favorably in several documents and has highlighted successful programs of INTOSAI such as investigating the flow of disaster relief aid. The actual impact on INTOSAI on the quality of regulatory decision making is very difficult to assess. The quality is likely to vary widely based on individual government auditing organizations in particular countries.</p>
Sources:	<ul style="list-style-type: none"> • http://www.intosai.org/about-us/organisation.html • http://www.gao.gov/assets/590/587949.pdf • http://www.gao.gov/haiti/audit_reports/ • http://www.issai.org/media(1075,1033)/Purpose_and_authority_of_the_INTOSAI%27s_professional_standards.pdf • http://www.issai.org/composite-344.htm