ENVIRONMENTAL REGULATION: DEVELOPMENTS IN SETTING REQUIREMENTS AND VERIFYING COMPLIANCE

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Summary

Current regulation often appears to promote safety management practices that are neither economical nor adequate for environmental protection. However, the underlying paradigms are beginning to shift in an encouraging direction. Driving this shift is the growing acceptance in regulatory agencies, especially nuclear, of personal decision analysis as a guide to rational action. However, the shift is slowed by the conflicting priorities of key players. For example, regulatory agencies may be charged only with protecting the environment, whereas the public expects their decisions to balance protection with economic and other social concerns.

The effectiveness of environmental regulation is geared to a web of uncertain causal connections between *means* and *end*. The end is the advancement of overall social welfare; the means are the concrete steps a regulated facility takes to meet this end (such as equipment design, or a maintenance procedure). Between them is a hierarchy of consequences in several "tiers". For example, design and maintenance affect equipment reliability; which affects accident risk; which affects release of pollutants; which affects public health; which ultimately affects overall social welfare. Each such item can be affected by others at lower tiers. Uncertainty at lower tiers produces uncertainty at higher tiers.

Regulatory requirements can be set anywhere in this hierarchy. The facility can be told what to do in great detail, i.e. means. Or it can be required to simply "serve the public interest", i.e. the end. Or it can be required to assure that accident risk is acceptable (say, less than one in ten thousand probability), i.e. in-between. The closer the requirement is to means (and further from ends), the easier it is to check compliance; but the less confident one can be that it, in fact, serves the public interest.

It has been sound common practice to set requirements at more than one tier ("defense-in-depth"). However, requirements have usually been set more stringently on means than on the higher tiers, which leads facilities to be preoccupied with satisfying onerous prescriptions, and to neglect risks that these do not address. The reverse practice, where requirements are progressively loosened at lower tiers, is more promising it, since it assures that the facility's dominant priority is the ultimate goal of safety. Within reasonable limits, the facility can then use its discretion to decide how most conveniently to achieve that goal. Intermediate requirements are set comparably.

Requirements can only be enforced if *compliance* with them can be checked, and this demands realistic assessment of performance of the item in question. The prevailing practice of what has been called probabilistic risk assessment (PRA) suffers from certain limitations, at least as a decision aid, that newer so-called comprehensive safety assessment (CSA) might avoid.

- CSA formulate uncertainty as a regulator's personal probability; whereas PRA produces frequencies, difficult for regulators to interpret and use for unique events.
- CSA draws on all available knowledge, however soft, including the regulator's experience and judgments, and on multiple approaches to an assessment, including PRA; whereas PRA draws only on well-documented data (such as experiments or panels of experts) in a single model.
- CSA addresses all recognized sources of risk (including intangibles, such as safety culture); whereas PRA addresses only those risks that can be well documented (such as equipment failure).
- On the other hand, the overtly subjective element in CSA often makes it more vulnerable than PRA to accusations of bias and manipulation in controversial cases.

Subjectivity in comprehensive safety assessment should decline over time, as more impersonal methods for documenting elusive risks mature. This would reduce, and perhaps eventually close, the gap between CSA and PRA. However, for now, decider-specific subjective judgment is unavoidable in responsible regulatory decisions.

1. Introduction

1.1. Problem Background

Even in advanced societies, the regulation of risk—or its converse, safety--is often seriously flawed and may lead to environmental disaster, as at Chernobyl, or immense economic waste, as in the US nuclear waste program. Hazards are misdiagnosed, inadequately protected against, and such protection as there is, is unnecessarily costly. For example, the nuclear industry argues that the US Nuclear Regulatory Commission (NRC) imposes needlessly costly safety measures that threaten the survival of the nation's nuclear energy option. At the same time, public interest groups argue that NRC fails to require prudent and cost-beneficial measures. There is merit in both complaints.

The main causes are inappropriate public policy and research to support it. The first focuses on controlling the means of safety management rather than the ends. The second relies only on documented evidence, often in the form of what is commonly called Probabilistic Risk Assessment (PRA), thereby neglecting much important knowledge.

This chapter seeks to develop guidance for environmental regulators responsible for authorizing hazardous activities, much of the guidance at variance with conventional wisdom. The argument is illustrated primarily in the context of US nuclear reactor regulation, which is already at the technological leading edge of safety assessment, but it is applicable, in principle, to other safety regulation.

1.1.1. The Social Purpose of Safety Regulation

Left to themselves, people can harm the rest of society. Thus, individuals drive dangerously, incinerators pollute, and power companies operate unsafe reactors. In response, society empowers regulators to limit such activities. For example, NRC sets safety requirements for reactor operations and closes them down if it finds that requirements are not met.

1.1.2. Balancing competing interests

Clarity about social objectives should clearly precede determining which regulatory practice will achieve them. Ideally, private rights and public interests will be balanced, but this rarely happens. For example, the regulator charged with environmental protection may act as a single-minded advocate of safety, in effect acting both as prosecutor and judge.

The ultimate purpose of environmental regulation is surely not to minimize risk in any absolute sense, but to serve public interest. Regulatory actions have to take into account conflicting societal interests, including the cost and availability of energy and business viability. For example, if society values a statistical life at US$5 million industry dollars, the regulatory process should result in industry spending up to US$5 million to save an expected life—whether or not regulation explicitly requires it to do so.

1.1.3. Deficiencies in Common Practice

Critics contend that, in practice, environmental regulation is often costly, inconsistent and fails to protect the environment adequately—all at the same time. Consider recent US examples:

- NRC declared a reactor to be dangerously unsafe and required costly improvements, although a major PRA indicated it to be among the safest in the

United States.

- Local Alaskan regulators denied oil company BP permission to build a causeway into the Arctic Ocean, on the grounds of harm to the fish. A Republican administration overruled them on the grounds of public interest. A Democratic Congress protested improper “political interference” by the administration. BP abandoned the causeway, claiming that the permitting process was too unpredictable.
- Environmental Protection Agency (EPA) regulation required a nuclear repository to isolate radioactive waste for 10 000 years, with 90% probability. There was broad scientific consensus that, based on current evidence, a Nevada site met that test. Yet, the Department of Energy spent many years and over a billion dollars to make sure, while waste piled up dangerously.

Critics on all sides agree that current practice needs improving—but not on how.

1.1.4. Policy Criteria

A sound regulatory policy has several desiderata.

Sound regulator judgment: It must go without saying that good regulatory practice should abide by the best judgment of the regulator; let us call him or her R. This requires that R:

- make use of any knowledge R already uses, augmented by any new knowledge;
- draw on value judgments that R adopts; and
- combine knowledge and values logically.

In an ideal world, all parties to a decision would share the same knowledge and values and come to the same conclusion. Failing that ideal, we will try to help all parties to make up their own minds responsibly on the basis of whatever they know and value, by developing tools to aid R’s judgment.

Institutional fit: Good regulatory practice needs to take institutional realities into account. In particular, decisions and the grounds for them must be legally and politically acceptable, which suggests that the rationale should be transparent and reviewable by others. Institutional fit may interfere with sound judgment—by excluding important *unsubstantiated* knowledge—and lead to what has been called “organizational foolishness,” unacceptable to a reasonable individual.

Other institutionally desiderata are:

- to be able to take account of the cognitive needs and capacities of all parties;
- to adapt to existing practices, rather than make radical and disruptive change; and
- to be predictable by a potential “regulatee.”

1.1.5. Distinct Regulatory Tasks

There are three distinct regulatory responsibilities to be aided:

- define objectives
- specify what is required of regulatees
- verify compliance.

Although these tasks are distinct, they interact. For example, deciding what requirements to specify depends on how feasible it is to verify compliance with them.

Different organizations—and people within them—may perform these three roles. The legislature may determine ends, senior agency officials may specify requirements, and agency staff may verify compliance. Several parties in these categories may be involved in making the final enforcement decision, as in the earlier oil construction example. Their positions will inevitably differ, whether aided or not.

1.2. Methodological Perspectives

Two significant decision-aiding paradigms are available (possibly complementing each other).

1.2.1.“Impersonal” Decision Analysis

A paradigm that has dominated safety management practice seeks findings that are impersonal, in the sense that they do not depend on the subjective judgment of any individuals. It relies only on documented knowledge and is limited in scope to issues on which some documented knowledge is available.

For example, the cost–benefit analysis widespread since the 1960s has focused on costs and benefits that can be measured with little controversy. Similarly, the dominant safety assessment practice since the mid 1970s has been PRA, which considers only documented data—thus following classical statistical traditions.

Reliance on “objective” or impersonal findings is well suited to public scrutiny and judicial proceeding. On the other hand it does not do justice to the experience and perceptiveness of competent people active in the field. It may also show consistent biases compared with sound professional judgment. For example, cost–benefit analysis has typically undercounted benefits of environmental protection, which tend to be more intangible—and less objectively measurable—than costs. This favors business interests, by appearing to show that promising regulations are not cost-beneficial. Conversely, PRA may overstate safety, by omitting undocumented sources of risk.

1.2.2. “Personal” Decision Analysis

An alternative—and in some ways complementary—paradigm for evaluating regulatory (and other) options is that of statistical decision theory and its practical implementation—personal decision analysis (PDA), which is basically the formalization of professional judgment.

Any reasonable informal argument can be accommodated and enhanced logically with a quantitative PDA model. The general methodology is well established. It is based on the quantification of personal uncertainty and value—in the form of subjective probability and utility—and derives their logical implications for action.

1.3. Structure of Paper

Section 2 addresses how requirements should be set, considering both their form (e.g., to require some acceptable risk) and content (e.g., where to set the acceptable risk). It draws on the causal linkages between regulatee activities (means) and social ends, and suggests how to model them. Section 3 addresses how to verify compliance with such requirements, through safety assessment. Section 4 offers some concluding comments, including discussion of political issues and technical trends.

2. How Requirements should be set

2.1. Basic Issues

2.1.1. Theory versus Practice

Evaluating regulatory options has two parts: assessing the impact of alternative safety management practices and assessing the impact of regulation on those practices. *Requiring* a safety management practice does not assure that it will be *adopted*—as Three Mile Island (TMI) and Chernobyl testify.

The social meta-problem is to devise a regulatory regime that, *as implemented*, leads to "regulatee" action that serves the public interest. Specifying requirements that, *if met*, would serve public interest may not achieve it, if regulated behavior does not conform. Regulatees who manage to persuade the regulator that they comply with a requirement may not actually do so. Conversely, they may "play it safe" by exceeding requirements.

2.1.2. Conflict between relevant and verifiable requirements

Effective regulation requires both what is important and what is economically enforceable. Regulatory requirements may focus on controlling readily verified features of a regulated activity (like hardware reliability), but neglect features that better protect the public (like a good corporate culture). Beware of "looking for your keys under the street lamp, rather than in the shadows where you lost them." What is needed is a torchlight to help search the shadows of poorly illuminated risks—analytic tools that draw thoroughly on intangible experience and judgment.

2.1.3. Quantitative, Qualitative, and Ambiguous Requirements

Regulatory requirements may be qualitative, at differing degrees of specificity (e.g., low: do not degrade fish habitat, or high: locate a repository in a specific geologic medium). Alternatively, requirements may be quantitative (e.g., allow at most one oil spill in ten years; or assure that groundwater travel from a nuclear repository will not exceed 1000 years).

Qualitative and quantitative performance requirements (especially probabilistic) have complementary appeals. Qualitative requirements are fairly simple for regulator and regulatee to use, but may be subject to controversial interpretation. Quantitative requirements involve more effort, delay, and expertise, but are more verifiable. Both have a role to play. Qualitative requirements can set the stage for operational interpretation in quantitative terms. This chapter's attention is primarily on numerical requirements, but analogous reasoning applies to qualitative requirements.

Current law and regulation often specify requirements that are not only qualitative, but also ambiguous—for example, they may require that risks be "as low as reasonably achievable" (ALARA). This is imprecise enough to give the regulator discretion to adapt to improved knowledge and changing circumstances (like relaxing requirements if energy becomes scarce), but that discretion is also open to inconsistency, arbitrariness, and abuse.

R may also take into account requirements additional to those specified in regulation—i.e. to serve unstated objectives. Some of these objectives may be perfectly legitimate, like addressing deficiencies in regulation (e.g., undervaluing short-term consequences in nuclear waste disposal). Other objectives may be less defensible (e.g., avoiding the bureaucratic embarrassment of a fairly benign accident like TMI). Unambiguous requirements restrict such discretion.

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Biographical Sketch

Rex Brown has spent 40 years alternating policy consulting with research. As a consultant he advised senior environmental regulators on decision aiding methods, and this experience has centrally informed this chapter. Other clients include executives in government and business on foreign and domestic public policy, international business, safety management, regulation, capital investment, defense, education, and law. As an academic, he has held university appointments in public policy, management, statistics, psychology, economics, and systems engineering. His background is interdisciplinary, with a focus on modeling judgment, prescriptive decision theory, and the human context of applying it.

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