The Management of Regulation Development: Out of the Shadows

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On behalf of the IBM Center for the Business of Government, we are pleased to present this report, “The Management of Regulation Development: Out of the Shadows,” by Cornelius M. Kerwin.

This is the second report in the IBM Center’s 2008 Presidential Transition Series. One of the ironies of contemporary public affairs is that while government regulation receives so much attention during presidential campaigns, the processes used to create and implement regulations receive so little. The purpose of Professor Kerwin’s report is to cast light into the shadows of regulation and urge that it be recognized as a core function of contemporary public administration.

In most federal mission areas—from low-income housing to food safety to higher education assistance—national goals are achieved through the use of various policy tools, such as direct spending, grants, loans and loan guarantees, insurance, tax preferences, and regulations. Although policy tools have proliferated in recent decades, knowledge of how to design and manage the federal policy tool set has not kept pace. Policy makers need a better understanding of how individual policy tools such as regulation operate, how to measure their performance and effectiveness, which actors participate in implementing them, and what features are necessary to ensure accountability and oversight.

The air we breathe, the water we drink, the jobs we hold, and the general welfare of our families and friends are increasingly protected and defined by rules issued by federal agencies. Kerwin contends that the greatest challenge facing the management of regulation development is the persistence of its obscurity. His report represents an important step toward removing some of that obscurity and helping raise regulation development management to a level of prominence befitting its impact on public policy.
We hope that this timely and informative report will be useful to external actors, project managers who develop technical content and produce rules, and policy officials who play leading roles in the development of government regulations.

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One of the many ironies of contemporary public affairs is that regulation receives so much attention, but the processes used to create and implement it receive so little.

The management of regulation development occurs in the shadows of public administration. With few exceptions, it operates without serious, sustained attention from scholars, practitioners, or the general public. This lack of attention stands in stark contrast to the large and robust communities of interest that concern themselves with the content and impact of regulation. Studies of regulatory policies and their consequences are numerous and sophisticated. They now constitute important subfields in political science, economics, and public policy analysis. Moreover, interest in regulation is not entirely academic. Regulation is one of our hardy perennials in the issue sets of presidential campaigns and has been for at least the past 30 years. Large sums of money are spent each year by a wide variety of interests in an effort to influence regulatory policy on the Hill, in the White House and agencies, and in the courts.

The reasons for this imbalance of interest between the content of regulation and how that content is created are many. They range from the obvious (regulatory processes are difficult to understand and inherently dull) to the highly technical (cross-agency comparisons of management techniques require sophisticated research designs, data collection protocols, and nuanced analysis). Causes notwithstanding, the current state of knowledge of the architecture of regulation development should be a matter for deep academic and professional concern.

The management of regulation development is crucial to American governance and public administration.

Regulation development—or rulemaking, as it is commonly called—has an immense impact on our quality of life as well as the functioning of our constitutional democracy. Heretical as it may sound, Congress is not the most important source of law and policy. It has not been for decades. It is certainly true that no regulation can be promulgated unless authorized by an act of Congress. In that singularly important sense, rulemaking is a subordinate process. But in virtually every other respect, the development of regulations is a process responsible for America’s most important law and policy. The air we breathe, the water we drink, the jobs we hold, and the general welfare of our families and friends are increasingly protected and defined by rules issued by federal agencies of various sorts. The women and men who develop these rules, these vital instruments of law and policy, were elected by no one. One would think that this confluence of substantive and procedural significance to our physical and political well-being would be sufficient to cause us to take the stewardship of rulemaking very seriously. But we have not.

If regulation development remains obscure because our academic discipline and profession considers it inferior to other forms of lawmaking, the evidence to the contrary is impressive. First, rules and regulations outnumber statutes by more than 10 to 1 in any given year. Second, and far more substantial, regulations contain the most specific statements of our rights and obligations under virtually all government programs that we will ever receive, short of an enforcement action taken against us. Third, the effects of rules are felt immediately upon promulgation, a statement that cannot be made about statutes. In many practical respects, rules and regulations often have even greater impact than statutes on...
the quality of life in the nation. Yet, the management of their development by government agencies remains a matter of minor interest, at best, to scholars and all but a handful of very dedicated practitioners.

The purpose of this report is to cast light into the shadows. Regulation development requires specialized application and coordination of several basic management functions. Most of these functions are well established throughout the federal government. This report considers how those regulation management functions are practiced in federal agencies. At the core of this effort, however, is a fundamental argument. The effective management of regulation development depends disproportionately on the coordination of three related functions: staffing, information acquisition, and participation. In this triad, participation—properly defined and understood—emerges as preeminent. Participation as an element of regulation development is part requirement, part expectation, and part skill. The management of participation, which supports and feeds the other key functions, is the spine of regulation development. If the management of regulation development is to be elevated and recognized as a core function of contemporary public administration, as this author believes it should, the importance of participation must also be fully understood.

The Impact of Regulation

Despite the United States’ steadfast commitment to a free-market economy and its role as a beacon for those around the world seeking the same, regulation is ubiquitous in American life. Our definition of a modern capitalist system embraces extensive and pervasive intervention by government.

That said, the community of discourse on regulation is hardly a peaceable kingdom. There are some who question it, per se; others find it a stifling presence that attacks both freedom and efficiency. When focusing on the cost of regulation to the private and nonprofit sectors, views differ widely and the debate is contentious. A cost estimate prepared by Professor Mark Crain for the U.S. Small Business Administration (SBA) estimated that the direct and indirect cost of regulation is an astonishing $1.1 trillion per year. The Crain estimate, however, is not universally embraced. Although the Crain figure is quoted often by those concerned about the load of regulation on our economy, the number is disputed.

The Center for Progressive Regulation counters that many high estimates cannot be taken at face value since they are politically motivated and analytically flawed. They cite a number of factors they consider responsible for inflated estimates, including reliance on regulated entities as sources of cost estimates and the failure to account for actions that are required by regulation but would be taken by a company’s response to market forces and in the absence of government compulsion. Still, neither they nor others who generally support government regulation would argue that these costs are trivial or insignificant.

The reader will note that the information is presented as a series of ranges rather than a single, precise estimate. This is because the underlying data are drawn from multiple sources that employ diverse methodologies. OIRA takes care to properly account for this diversity of data and method as a complicating factor in their meta-analysis. The estimate by Crain done for the SBA and mentioned earlier is a measure of the accumulated impact of all regulation in effect. Consequently, those numbers are much higher. The OIRA numbers, on the other hand, are estimates of annual compliance costs from a relatively small, albeit significant, portion of the regulatory burden. Notable in these data, issued by a Republican administration, is that taking the highest estimates of costs and lowest estimates of benefits, the net figure is positive in favor of regulation. And
it has been noted that these benefit numbers do not include non-quantifiable or non-monetized positive effects. So, the official view of the current and previous administrations is that regulation produces net benefits to society.

While the controversy over the impact of regulation is serious, legitimate, and important, for this report the details are somewhat beside the point. Whether one adopts, or prefers, the most liberal or conservative views of costs and benefits, the numbers are enormous. That regulation is a significant force in our lives is indisputable. A report by the Mercatus Center at George Mason University that describes the “regulatory day” of the American family—starting with regulated breakfast cereals and ending on mattresses that carry ominous warnings of the consequences of removing labels—is compelling reading.

If one were to ignore the effect on the larger society and focus on regulation simply as a task of government, the rationale for close attention is clear. A report by the Mercatus Center at George Mason University that describes the “regulatory day” of the American family—starting with regulated breakfast cereals and ending on mattresses that carry ominous warnings of the consequences of removing labels—is compelling reading.

The Scope of Regulation Development

The engine that drives regulation, and as such most law and policy, is regulation development—or rulemaking, as it is commonly termed. The amount of public sector activity needed to produce the effects described earlier can be captured in a number of ways. We’ve already noted the budget and personnel dimensions. Figure 1 shows the number of proposed and final regulations or rules issued by federal agencies over the past two decades. The difference between proposed and final rules is significant. Proposed rules are presented to the public by agencies in “notices” that are published in the Federal Register. The purpose of the notice of proposed rulemaking is to inform the public of the agency’s plan to issue a new or amended regulation and to invite comment. At some point following the comment period, and if the agency decides to proceed, a final rule is published. The time period between proposed and final rules may be considerable. The “preamble”

Table 1: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1995 to September 30, 2005

<table>
<thead>
<tr>
<th>Agency</th>
<th>Number of Rules</th>
<th>Benefits (in millions of 2001 dollars)</th>
<th>Costs (in millions of 2001 dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Agriculture</td>
<td>7</td>
<td>3,530 – 6,747</td>
<td>2,215 – 2,346</td>
</tr>
<tr>
<td>Department of Education</td>
<td>1</td>
<td>633 – 786</td>
<td>349 – 589</td>
</tr>
<tr>
<td>Department of Energy</td>
<td>6</td>
<td>5,194 – 5,260</td>
<td>2,958</td>
</tr>
<tr>
<td>Department of Health &amp; Human Services</td>
<td>19</td>
<td>21,313 – 33,268</td>
<td>3,853 – 4,029</td>
</tr>
<tr>
<td>Department of Homeland Security (Coast Guard)</td>
<td>1</td>
<td>44</td>
<td>305</td>
</tr>
<tr>
<td>Department of Housing and Urban Development</td>
<td>1</td>
<td>190</td>
<td>150</td>
</tr>
<tr>
<td>Department of Justice</td>
<td>1</td>
<td>275</td>
<td>108 – 118</td>
</tr>
<tr>
<td>Department of Labor</td>
<td>4</td>
<td>1,138 – 3,440</td>
<td>349</td>
</tr>
<tr>
<td>Department of Transportation</td>
<td>13</td>
<td>2,913 – 4,948</td>
<td>3,212 – 6,622</td>
</tr>
<tr>
<td>Environmental Protection Agency</td>
<td>42</td>
<td>58,670 – 394,454</td>
<td>23,572 – 26,200</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>95</strong></td>
<td><strong>93,899 – 449,412</strong></td>
<td><strong>37,071 – 43,665</strong></td>
</tr>
</tbody>
</table>

*Source: Office of Management and Budget, Office of Information and Regulatory Affairs, 2006 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local and Tribal Entities, p. 3.*
of the final rule will include a summary of the comments received and an explanation of the agency’s actions on those comments.

Care must be taken with these numbers and their apparent downward trend. Counting protocols used by official sources omit whole categories of rules. Some would argue the numbers present a serious undercount of rules. Those arguing the numbers are inflated could make the point that many of the rules counted are so trivial that they do not deserve to be taken seriously. They point to these numbers, compiled by the General Services Administration, and see hundreds, if not thousands, of individual “rules” with quite narrow or temporary effects. As is the case with the impact statistics, whether one picks conservative or liberal protocols for counting, the amount of regulation development activity in agencies is substantial. And, as noted earlier, it occupies significant amounts of time and resources of federal agency personnel, both career and political appointees.

The total number of rules issued is a crude indicator of regulation development activity. Its value is limited because it reveals nothing about complexity, impact, or effort associated with each of these regulation development tasks. One measure that provides insight into all three of these characteristics relates to a given rule’s status as “significant” under prevailing policy. When a rule is deemed “significant,” as defined in various executive orders, it becomes a matter of concern for the White House and triggers review requirements set forth in a number of presidential directives issued over the past 25 years. Rules subject to Office of Management and Budget (OMB) review provide a meaningful indicator of significance because they clearly reflect what the current presidential administration considers to be its highest priorities. Figure 2 on page 10 summarizes the volume of OMB reviews over the last 12 years. The dramatic decrease between 1993 and 1994 is explained by the more selective approach to OMB review that was adopted during the Clinton administration’s National Performance Review.

The significance of Figure 2 is manifold. First, during this 10-year period, the smallest number of rules deemed significant is just under 500; the maximum is over 800. If anything, the graph shows a slightly upward trend since 1997, perhaps not what one would expect in a period of transition from a Democrat to a Republican in the White House. But considering volume alone in OMB reviews is misleading. It is well known that new administrations will be quite active in reviewing rules in the “pipeline” from the previous regime. Until they are secure in their control of departments and agencies, larger numbers of reviews should be expected.
Regulation Development: The Management Challenges

Elsewhere the author has written that regulation development, or rulemaking, is the most important function performed by government agencies. Rulemaking merits this lofty status because of its role in defining our legal obligations and rights and providing the specificity needed to transform policy into working programs for government and the public, as well as the influence of its results on all subsequent government tasks. The author also has noted the "issues and contradictions" that largely define contemporary rulemaking. It is this combination of the importance of regulation development and its persistent problems that define the management challenge.

As the source of our most important law and policy, regulation development is a process under tremendous stress and pressure. As noted earlier, the volume of rulemaking is quite substantial and the demand for more is perpetual. Each legislative enactment of any substance adds to the rulemaking agenda but with only the rare additional appropriation to assist agencies in carrying out the ever-growing rulemaking burden. The mismatch of volume and resources leads to long regulation development cycles, stimulating complaints and concerns about delay in the flow of benefits to society as regulated entities await guidance on how their behaviors and activities must change. Impatient legislators and judges who set deadlines with little regard to the relative importance of their issue of concern in the grand scheme of an agency’s rulemaking agenda do not make matters any easier.

The mismatch of resources and expectations is especially acute in the areas of staffing and information. As discussed below, over the years the technical and procedural aspects of regulation development have grown extraordinarily complex, dramatically increasing the skills, knowledge, and experience needed to develop a major rule. As has been widely reported elsewhere, the historic transitions currently afoot among the federal workforce are affecting regulation development as much as or more profoundly than every other core management function. Unlike so many of those other functions, however, regulation development should not be fully or even substantially contracted out. Lawmaking, after all, is as public as a function gets.

Regulation development demands information of the highest quality if the goals of public policies and programs are to be met. Information acquisition has also become difficult, contentious, and expensive. The same Congress that delegates vast swatches of authority and responsibility to agencies to write the law and policy—law and policy that it cannot or will not write itself—has also seen fit to constrain agencies’ abilities to collect information. Statutes like the Paperwork Reduction Act, the Federal Advisory Committee Act, the Data Quality Act, and a number of others create significant obstacles for agencies engaged in regulation development. Not to be outdone, presidents, who are the ultimate managers of regulation development, have issued executive orders and guidelines establishing standards for the “regulatory analyses” that must accompany major regulations, as well as peer review requirements for analyses conducted.
by or for agencies and used in support of individual rulemaking projects. And, in the face of these constraints, agencies are often forced to the cutting edge of knowledge and beyond for new regulations. They must, in effect, create information in real time and then put it to immediate use when formulating the content of a regulation.

The politics of rulemaking has grown with its prominence. Theodore Lowi’s sage observation that “politics flows to the point of discretion” is well remembered here. Powerful and not so powerful political interests learned long ago that however well or poorly you might fare in Congress, one can accomplish great things by influencing the content of rules. These interests are expert in the nuances of regulation development and seek to use this knowledge to maximum advantage.

Scholars and practitioners alike have decried this procedural and political complexity, arguing that it has “ossified” rulemaking and created a “malaise” that threatens its utility as an instrument of government. These warnings have been voiced for decades but with little obvious effect. The point for this report is that to be conducted in a manner that meets a myriad of formal requirements and political expectations, regulation development is a process that requires sophisticated management.

Another area of challenge for the development of regulations, and in this author’s view the key to effective management, is participation by stakeholders both in and out of government. In its Global CEO Survey 2006, IBM found three emerging themes for public sector leaders to consider:

1. Public sector organizations will need to enhance existing organization capabilities and business models in order to manage the anticipated magnitude of change created largely by budget pressures.

2. The public sector needs to increase both the depth and scope of collaboration with others (i.e., citizens and constituents) to gain flexibility and drive innovation.

3. For maximum impact, it is imperative for the public sector to integrate business and technology, albeit difficult and challenging.

For the management of regulation development, theme 2 is crucial. It provides an answer to theme 1 and a set of tasks for theme 3. Collaboration is the central theme of a gathering movement, commanding nothing less than a recent special issue of Public Administration Review (2006). Collaboration, given the environment that currently surrounds regulation development, is the only realistic approach to developing the information and consensus needed to move a rule to a prompt, economical, and acceptable conclusion. Efforts under way to facilitate collaboration through the use of technology, such as the e-gov initiatives of the current administration, are essential. But, above all else, collaboration must be understood as another way of expressing the elemental importance of participation to the development of regulations. As is argued below, participation skills constitute the single most important cluster of capabilities that a manager of rulemaking can possess.

But the greatest challenge facing the management of regulation development is the persistence of its obscurity. The management of regulation development must rise to a level of prominence befitting its impact on public policy and programs. That means attention in the councils that influence the course of public management. The management of rulemaking deserves a place in the President’s Management Agenda, inclusion in the assessments of the Program Assessment Rating Tool (PART) program, and attention in the strategic plans that lie at the heart of the Government Performance and Results Act. It deserves a place on the research and action agendas of the National Academy of Public Administration, the National Science Foundation, the authorized but unfunded Administrative Conference of the United States, and private entities dedicated to advancing public management, like the IBM Center for The Business of Government. Certainly, if the recently re-authorized Administrative Conference of the United States is ever funded, the management of regulation development must be among the primary elements of its mission. Finally, it means acknowledgment that the management of regulation development is a specialty, a career track, and an essential skill in the federal personnel systems managed jointly by the Office of Personnel Management and all agencies that write rules. More will be said about these points at the conclusion of the report.
Managing the Development of Regulations

The development of regulations has been a function of government since the earliest days of the republic. Beginning early in the last century and accelerating rapidly in the 1960s and 1970s, rulemaking emerged as a truly dominant force in the formulation of law and public policy. Consequently, the development of regulations attracted considerable attention from Congress, the presidency, and the courts. Motivated by concerns for constitutional principles, disciplined decision making, accountability, and their own institutional prerogatives, these institutions have written law, issued executive directives, and handed down decisions that have accumulated and combined to create a remarkably complex process. Responding to these pressures from their “principals,” agencies have fashioned their own internal requirements. The cumulative results of two centuries of these developments are portrayed in the “regulatory map” in Figure 3 on page 14–15. It is also available on the website of the Regulatory Information Services Center of the General Services Administration.

The map is a generic representation of a process that must be customized to a greater or lesser extent for each rule. It succeeds in conveying the formidable challenges that confront any agency serious about the management of this central function of government.

The elements of management required to bring a regulation from start to finish are better known to practitioners than to scholars and other external observers. The first effort to capture these elements comprehensively is found in Rulemaking: How Government Agencies Write Law and Make Policy (Kerwin), published first in 1992 and issued in its third edition in 2003. The most recent attempt to update this information occurred at a one-day conference sponsored by the Center for the Study of Rulemaking described in the sidebar on page 19.

The major elements that compose a management system for regulation development are:

- A process for setting priorities
- A process for initiating rules and providing early guidance
- Early input by senior officials
- Scheduling
- Budget
- Leadership and staffing
- Information collection and analysis
- Participation management
- Drafting
- Concurrences
- Liaison with Congress and the White House

Each of these elements is important, but all are not analyzed here and others get limited treatment. Most attention is paid to what the author considers the major management functions, particularly staffing, information acquisition, and participation. One of these—participation—emerges as first among equals and the single most important element for successful management of regulation development. Accordingly, it is examined in considerable depth.
Priority Setting and Initiation of Regulation Development

When establishing priorities for the development of rules, agencies make important decisions about deployment of resources for the benefit of society. In setting priorities, agencies respond to multiple cues, most of which are external, and attempt to balance legal and political pressures with objective determinations of value, which may or may not be consistent. Initiation of an individual rulemaking project constitutes a critical step in implementing the system of priorities. Done properly, it sets a regulation development effort on the path to accomplishing the goals that made it a priority item in the first place. In Kerwin (2003), priority setting was described in the following way:

Agencies vary considerably in their attention to setting priorities. At one extreme is a fully centralized system in which the priorities are set at the top of the agency, at the other is a fully decentralized system in which no overarching set of priorities is imposed on the operating units of the agency. Between these extremes one might find a system in which agency leadership designates some rules as high-priority projects, leaving the operating units to determine the rest of the rulemaking agenda. Still another is an essentially decentralized approach that allows for intervention by agency leadership when an emergency, political or otherwise, arises....

More recent discussions with agency experts highlight important nuances that add uncertainty and complexity to this basic design and provide the basis for an important observation about the stability of priorities. Variations on the three basic models, outlined in the above quote, are numerous and instructive. The Environmental Protection Agency (EPA), with a number of operating subunits dealing with different media and types of pollution, has a “tiers” system that categorizes individual rulemaking projects according to their significance. Tier 1 consists of rules whose economic impact, controversy, or visibility make them the highest priority. These rules require careful attention from multiple offices at regular intervals and on strict schedules. They constitute only 5 percent of the agency’s rulemaking projects at any given time, but they will consume a disproportionate share of resources. Tier 2 consists of rules with less compelling policy, economic, or political issues but still warrant serious attention from senior officials. These also have set deadlines. It is estimated that these make up about 15 percent of the EPA rulemaking workload. The remaining rules are in Tier 3 and receive no agency-wide attention; their production is entirely in the hands of the responsible program office.

The Animal and Plant Health Inspection Service (APHIS) in the Department of Agriculture also uses a tiering system, but one that more clearly delineates stages of planning. APHIS has four tiers. Tiers 1 and 2 consist of actions already at the rulemaking stage and are considered the highest by the administrator (“1”) or a high priority (“2”) by the deputy administrator. Tiers 3 and 4 consist of actions where rulemaking has not commenced but for which a risk assessment is authorized or under way (“3”) or related to potential imports (“4”) that have been slated for regulatory actions. The Department of Veterans Affairs also places rulemaking projects in three categories: simple, complex, and “hot.” Hot means very high priority and close monitoring.

The Department of Transportation (DOT), another organization consisting of multiple agencies, has no unified priority-setting process, but its component agencies are active. For example, the Federal Aviation Administration (FAA) has a highly disciplined system. The FAA places its rulemaking projects on two lists, A and B, with the former consisting of the highest priority rules for its operating divisions and the latter composed of rules that are important but will be worked on only when time and resources permit. The FAA’s “A-list” rules are ones to which the agency has committed considerable staff expertise and that the agency is prepared to set and adhere to a fixed schedule for completion. The National Highway Transportation Safety Administration (NHTSA) uses risk assessments to determine the priority order of projects. In this respect, the NHTSA practice resembles the APHIS system.

The Nuclear Regulatory Commission (NRC), an independent body with fewer major operating units than EPA or Transportation, also has a unified priority-setting system that may be the most disciplined in government. Points are assigned to
Using The Reg Map

The Reg Map is based on general requirements. In some cases, more stringent or less stringent requirements are imposed by statutory provisions that are agency specific or subject matter specific. Also, in some cases more stringent requirements are imposed by agency policy.

In a typical case, a rulemaking action would proceed from step one through step nine with a proposed rule and a final rule.

However, if a rulemaking action is exempt from the proposed rulemaking procedures under the Administrative Procedure Act provisions (explained under step three) or under other statutory authority, an agency may:
- promulgate a final rule omitting steps three through six, or
- promulgate an interim final rule omitting steps three through six, but providing a comment period and a final rule after step nine.

Also, if an agency determines that a rule likely would not generate adverse comment, the agency may promulgate a direct final rule, omitting steps three through six, but with a duty to withdraw the rule if the agency receives adverse comments within the period specified by the agency.
each rulemaking project based on importance on a number of critical dimensions such as safety and security (awarded the highest number of points), effectiveness, and openness/transparency. Each rule is scored, and the resultant numerical ranking determines priority order.

The Departments of Labor, Treasury, Commerce, and Homeland Security demonstrate additional nuances in setting priorities. The Department of Labor relies on the Regulatory Plan and Regulatory Agenda, established decades ago by executive order, for this purpose. It is the only department that reported using either of these familiar government-wide instruments for serious priority setting. At Treasury, the operating units enjoy nearly complete discretion in determining the order and importance of rulemaking projects, but also reported strong influences from external groups in at least two of their organizations with significant rulemaking responsibilities. The
Department of Commerce also reports that external influence in priority setting is effectively institutionalized for its National Marine Fisheries Service (NMFS) and its international trade agencies. NMFS rulemaking is heavily influenced by input from fisheries management councils, powerful advisory committees established decades ago in its foundation-authorizing legislation. The international trade rulemaking agenda at the Department of Commerce is affected by any changes in treaties, protocols, and other instruments of international trade law.

The Department of Homeland Security (DHS) is a classic example of an agency in need of a capability to alter its priorities on very short notice. The United States Coast Guard, a major DHS operating unit, manages through a system that scores rulemaking projects based on the type and amount of external and internal interest (for example, congressional, judicial, White House, or DHS). At the Coast Guard, it is reportedly less formal and determinative than the system in place at the NRC and used as a device to assist them in keeping track of projects with high political and public salience.

Categories of priority-setting systems are useful heuristic devices, but are by their nature crude and cannot convey the richness and variety of priority setting found in operating systems in federal agencies. Some of this variation depends on the “issue networks” (consisting of interested groups, institutions, and individuals) that surround the department or its subordinate unit and how the agency’s staff and leaders are positioned within them. This highlights another management function—participation. It also leads to an important finding.

Priority-setting systems are susceptible to external disturbance as the concerns of external “principals” and their “agents” inside the agency or department...
Figure 4: Specific Analyses for Steps Three and Seven Mandated by Statute and Executive Order

<table>
<thead>
<tr>
<th>Indian Tribal Governments (E.O. 13175)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the rule a discretionary rule that has tribal implications and imposes substantial unreimbursed direct compliance costs on Indian tribal governments?</td>
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<td>Does the rule have tribal implications and preempt tribal law?</td>
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<th>National Environmental Policy Act (42 U.S.C. 4321-4347)</th>
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<tr>
<td>Is the rule categorically excluded from review?</td>
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<tr>
<td>Does the rule constitute a major Federal action that could significantly affect the quality of the human environment?</td>
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<table>
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<tr>
<th>National Technology Transfer and Advancement Act (15 U.S.C. 272 note)</th>
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<td>Does the rule contain provisions for which the use of voluntary standards is applicable?</td>
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</tbody>
</table>

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<tr>
<th>Governmental Actions and Interference with Constitutionally Protected Property Rights (E.O. 12630)</th>
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<tbody>
<tr>
<td>Does the rule regulate private property use for the protection of public health or safety?</td>
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<tr>
<td>Is the rulemaking a proposed regulatory action that has takings implications (other than regulating private property for the protection of public health and safety)?</td>
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<th>Protection of Children from Environmental Health Risks and Safety Risks (E.O. 13045)</th>
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<td>Is the rulemaking a “covered regulatory action”?</td>
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</table>

<table>
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<tr>
<th>Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)</th>
</tr>
</thead>
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<tr>
<td>Is the rulemaking action a “significant energy action”?</td>
</tr>
</tbody>
</table>

Source: Adapted from the Reg Map—Informal Rulemaking. Copyright ©2003 by ICF Incorporated. The Reg Map was created by ICF with the cooperation of the U.S. General Services Administration’s Regulatory Information Service Center. Permission is granted for use in this publication.

change with shifting events and circumstances. This also means that the departments and agencies with broad regulatory responsibilities that touch the health, safety, or economic well-being of large or powerful interests will struggle with inherently fragile, unstable priority-setting systems. Very recent work undertaken by Professor William West under a grant from the Congressional Research Service also sheds light on the difficulties in priority setting. He notes that whether a given regulation development effort is mandatory (i.e., ordered by Congress in a court) or discretionary (i.e., under agency initiative) is an additional and important factor in priority setting.

Participants in the 2005 symposium at American University were virtually uniform in their assessment of the effects that changing priorities have on the overall rulemaking management system. Changes in priorities divert resources for months or more, making them difficult if not impossible to reassemble. Diversions of resources are momentum killers that also threaten the often tenuous internal and external coalitions that the writers of significant rules rely on to produce the consensus their superiors usually seek to achieve.

The optimal priority-setting system is one that balances the conflicting pressures that put careful planning and the ability to adapt at odds. The priority of regulation development projects must reflect legal obligations but should also consider the relative importance of a given rule to the accomplishment of the agency’s mission and its ability to advance the general welfare. There is no question that solid systems are in place, but instability in priority setting is also common. Hence,
chief among the skills needed for priority setting is the ability to scan and predict, or at least react quickly to, perturbations in the external environment. It is not unreasonable to expect that agencies with substantial rulemaking responsibilities develop plans to buffer high-priority projects that may be at risk if the external environment dictates diversion of resources and effort. This requires, among other things, management of participation by internal and external actors.

**Initiation and Guidance**

Initiation of rules within a larger system of priorities has common features across government and has been described by Kerwin (2003) in the following way:

Virtually all agencies require some form of approval even if it is nothing more than inclusion in the agency’s priorities or a semiannual agenda. Those that require guidance by senior officials for all rules, those that require guidance only on rules deemed important enough for senior management’s attention, and those that have no system of this sort. The devices for providing guidance are as varied as those for priority setting.

Several agencies rely on a formal structure, such as a committee or board, to approve the start of rules. The start of each rulemaking project at the NRC requires an affirmative vote of a majority of the five commissioners. The Department of Veterans Affairs requires initiation authorization by the secretary’s Office of Policy, and for some organizations in the Department of Agriculture, such as APHIS, approval by the under secretary is the norm. Other departments, including Commerce, Treasury, Homeland Security, and Transportation, have no routine department-level initiation requirements, but this does not mean their operating units do not commonly have elaborate processes. For example, within DHS, the Coast Guard requires all proposed projects to be reviewed by their Regulations Coordinating Committee. If this group deems them to be significant, they are forwarded directly to the commandant for approval. In a virtually identical procedure, the FAA’s Rulemaking Council screens all rulemaking projects and sends those considered significant to the associate administrator.

Early guidance from senior management is the more important aspect of regulation initiation. Whether at department or subordinate-unit levels, there is ample opportunity for officials with policy or political interests to provide direction to nascent rulemaking projects. For example, EPA’s tiering procedures contain explicit provisions for varying levels of guidance and subsequent reviews by senior agency officials. Other agencies employ similar arrangements. The critical question with regard to initiation and guidance is how well both work in practice. Setting an early course for rulemaking projects that is then maintained throughout the development process is a fairly modest expectation. Any regulation deemed important enough to be a priority, be it at the department level or lower, deserves attention at the outset of development by those who will ultimately approve its issuance. Early guidance makes explicit the preferences of senior officials and avoids expensive “late hits” by officials who are uninformed about the rule or surprised by its content. This is a simple, common
Agencies Represented at the Center for the Study of Rulemaking Symposium

Many of the observations and insights contained in this report are drawn from the author’s communications with government officials. Among the more important and recent were the discussions that occurred at American University on June 5, 2005, during a one-day symposium sponsored by AU’s Center for the Study of Rulemaking. A group of senior officials with varying but significant responsibilities for the management of rulemaking in their departments and agencies gathered in a “principals only” session to discuss current developments and issues related to the topics covered in this report. The following is a list of the agencies represented at the session. Where noted, with the exception of the Department of Agriculture, representatives from both department-level and subordinate unit offices attended.

- Department of Agriculture
  - Animal and Plant Health Inspection Service
  - Food Safety Inspection Service
- Department of Commerce
  - National Marine Fisheries Service
- Department of Homeland Security
  - United States Coast Guard
- Department of Labor
  - Occupational Safety and Health Administration
- Department of Transportation
  - Federal Aviation Administration
- Department of Veterans Affairs
- Environmental Protection Agency
- Federal Energy Regulatory Commission
- Nuclear Regulatory Commission

More information about the Center for the Study of Rulemaking and similar symposia that it has sponsored can be found at its website, www.american.edu/rulemaking.

sense management device. However, due to the realities of regulation development in complex public organizations, it cannot be taken for granted.

Be it in the context of a sophisticated priority-setting system like those at the NRC, APHIS, and EPA, or one with less department-level discipline, obtaining early guidance is a significant challenge. The senior officials whose views on regulation are needed are hard to reach through normal bureaucratic channels, are busy, and are something less than omniscient on policy matters. Even when the attention of senior officials is secured, the time they spend on the matter will be brief and the preferences they articulate may be superficial or poorly informed. When the technical and policy issues related to the rule are also not fully developed or known, which is frequently the case, serious early involvement by senior officials is compromised. In such circumstances, the initiation stage of rules may not be the best time for senior officials to weigh in with guidance. Relying solely on involvement early or late in the process is fraught with risk. Best practice for complex regulations is a mid-course review by relevant officials. Like early guidance, this requires sufficient clout to gain access to tight calendars and the savvy to use it wisely when it is secured. This, too, highlights the importance of managing participation—in this instance, participation by internal actors.

Scheduling and Budgeting

This author wrote in 2003 that many agencies report setting schedules for rulemaking, and that those who have written on the topic argue persuasively that schedules, whether or not they are rigidly adhered to, can promote a concern for timeliness. Schedules also provide a basis for the appraisal of performance of those responsible for a given regulation development project. This author also noted that schedules routinely slip. Information from the symposium in June 2005 indicates that these general characterizations are still correct. Scheduling using simple word processing or spreadsheet tools is not uncommon in agencies that write rules. But some agencies take scheduling much more seriously. The Department of Transportation and its component, the FAA, are cases in point. A visit to the websites of DOT and the FAA is instructive in this regard. They provide a glimpse into state-of-the-art scheduling for regulation development, complete with the articulation of cultural milestones and decision-point-responsible personnel, as well as documentation of reasons for deviations from original objectives.
Despite these and similar efforts across government, scheduling, like priority-setting rule initiation, is a fragile function. As discussed below, scheduling and its partner function, budgeting, are frequently hostages to larger forces.

Budgeting for regulation development is a matter that virtually all agencies with significant responsibilities for regulation development consider significant but difficult as a management function. In Kerwin (200), the situation was summarized this way:

Of the 35 agencies in the original survey, only four reported that they budget for rule-making, and only one of these did so on an overall, programmatic basis.

Most agencies interviewed reported that the statement about the resources that were likely to be required was expected either during the process of securing permission to start rules or in planning documents.

For these and other reasons, budgeting for rulemaking at the level either of the agency or of an individual rule is fraught with uncertainties.

At the symposium in June 2005, a larger number of officials reported on efforts to budget prospectively for rulemaking, notably those from the NRC and, within the Department of Homeland Security, the Coast Guard. In addition, DHS as a department reports the ability to track the person hours needed to complete the most important rulemakings for the year. They report that this capability not only ensures adequate progress on key projects but also provides information critical to efforts to approach Congress for additional funding for projects that might otherwise slip. DOT reported on their ability to engage in a modest amount of resource reallocation for high-priority projects. But among the agency experts who assembled at American University in 2005, there was a healthy dose of skepticism regarding the value of classical budgeting for rulemaking.

In some cases, budgeting difficulties are a function of technical complexity, such as the inability to assign portions of the cost of large-scale research efforts that support entire regulatory programs to a particular rulemaking proposal. Fish stock analyses done by the National Marine Fisheries Service in the Department of Commerce are good examples of such complexity. Others opined that budgeting is even more difficult when the cost of securing information for a regulation is a complex mix of original research, institutional information, staff expertise, and insights from the public.

The timing of budget preparation and submission requirements is simply not in sync with the dynamic elements of regulation development. Agency budgets are submitted far in advance and according to a firm schedule. The need for rules, prompted by new legislation, court decisions, or emergencies, and the drivers of rulemaking costs, such as the nature and amount of information required or the amount of public participation involved, present themselves without concern for budget schedules. The ability of an agency to correctly predict these dynamics in a timeframe consistent with budget submission schedules and convince Congress to provide the funding needed is, to understate it, very limited. Classical budgeting is simply incompatible with the churning of departmental or agency priorities for regulation development referred to earlier. It makes little sense to attempt to estimate costs with precision when resources are routinely diverted to either other rulemaking projects or completely unrelated agency activities.

Scheduling and budgeting are derivative functions for regulation development and hostage to forces beyond their reach and power. This is not to dismiss or denigrate their importance as management devices. Whatever else, they outline an explicit path of regulation development and the resources needed to complete a rule. Yet their ability to ensure or even influence results is severely constrained. Scheduling and budgeting are determined by staffing, information needs, and participation. If staff are assigned and stay on task, if the resources to secure essential information are adequate, if the public engages the process in a manner that was anticipated at the outset of the rulemaking, and if priorities do not change, then the success of scheduling and budgeting depends solely on the skills and effort of the responsible officials. For major regulation development efforts, those are very real “ifs.” As any one or combination of these factors oscillates, scheduling and budgeting are pushed and pulled, adjusted in an essentially ad hoc manner. This insight alone has value. However useful they are as tools for managers, scheduling and budgeting do cast a bright light on functions even more central to developing a regulation.
The Challenge of Developing Regulations

Staffing

The major components of regulation development management—staffing, information collection and analysis, and participation—are closely related. The number and mix of staff needed for a particular project is determined, in part, by the kind of information needed, its availability in the agency, the programs and areas within the agency affected by the rule under development, and the role that external interests should or wish to play in the process. A simple rule with narrow effect appears to require little more than a single experienced technical expert in the responsible program office who has an effective working relationship with the affected internal or external parties. But even these simple rules must pass through multiple offices for nominal reviews on their way to publication in the Federal Register. Other rules that attract greater attention and carry higher stakes will almost always be developed under wider internal scrutiny.

Over the years, most agencies have used workgroups or teams that bring together essential expertise and affected bureaucratic interests for regulations that are complex, have broad effects, or both. The regulation development task is more challenging in this type of environment since the responsible manager must not only produce a rule that is technically sound but also must manage the organizational dynamics of a workgroup composed of differing perspectives and interests. At this juncture, it is safe to assume that a collective approach typifies the development of significant regulations. Consequently, staffing must be considered on multiple levels.

Agencies have come to recognize the importance of regulation development as a general responsibility that requires proactive management that extends beyond individual projects. According to Kerwin (2003):

“Rulemaking offices” have grown up in so many agencies. The arrival and institutionalization of such management entities as the Regulatory Management Staff at the EPA, the Office of Rulemaking at the FAA, the Office of Regulatory Analysis and Development at APHIS, and the Office of Regulatory Ombudsman at the FMCSA [Federal Motor Carrier Safety Administration] and departmental authorities, exemplified by the work of the assistant general counsel for regulation at the DOT, mark an important milestone in the changing world of rulemaking. These offices [may] shepherd working groups, monitor schedules, expedite concurrence and required analysis, and serve as visible organizational reminders of the importance of rulemaking management. What is not so clear is how well these agency management systems actually work or even the criteria we should use to judge their performance.

Today, one would have significant difficulty identifying a central locus of rulemaking management authority in many agencies by reference to a staff directory or organization chart. The titles of the senior rulemaking managers who assembled at American University in 2005 (listed in the sidebar on page 22) reflect this diversity of approach to whatever management aspects of regulation are centralized.

Despite the general failure to identify rulemaking management by name, it is clear that most agencies recognize the function and staff it. These offices or clusters of responsibility have not been studied
in any systematic manner. What is known about the functions they house is largely anecdotal. They include stewardship of the priority-setting process, scheduling, monitoring of deadlines, working group support (and occasional facilitation), management of the concurrence processes and clearance, liaison with OMB, oversight of compliance with ancillary legal requirements, drafting services and communication with the Office of the Federal Register, and development/delivery of staff training. In most agencies, these offices have limited authority and staffing. But such offices carry the potential to elevate the regulation management function: They have the potential to extend and enhance key aspects of regulation management such as staff development. We will return to this point in the concluding section of the report.

At the level of individual rules, the management of regulation development hinges on two different types of leadership—task and political. Task leaders for regulation development may hold various titles, but they are project managers. The job description, when it exists, varies by agency, but the selection of the right project manager is the essential first step in staffing. Project managers will find themselves in need of a number of skills. Project managers must be competent, and preferably expert, in the area covered by the regulation. They should be intimately familiar with existing or potential sources of information to form the content of the regulation. They must be cognizant of the interests of other offices and agencies in the regulation, as well as of non-governmental actors who are affected or have something important to offer.

In short, the project manager must have strong organizational, technical, and political skills. The regulation development workgroup is a distinctive operating environment. It consists of persons selected to serve on the group by their program areas and offices for a variety of reasons. They may or may not be familiar with rulemaking as a function of government. They may bring any of a number of motives to the table, ranging from meeting the minimum expectations of their superiors to a deep and abiding commitment to a particular result. Almost certainly, the group will be a mixed bag of experience, interests, and motives.

William West, Tom McGarrity, and others have written cogently about the internal dynamics of agencies that develop regulations. West notes that the professional values and perspectives of different offices—program specialties, general counsel, field personnel, policy analysis—can guarantee conflict in the internal deliberations that are at the heart of regulation development. McGarrity observed that different agencies, at different points in their histories, display different norms, or cultures, for the resolution of the inevitable differences of opinion and disputes that arise in regulation development. These and other important insights about organizational culture and regulation development cannot be reviewed in depth here. But the West and McGarrity work clearly establishes that when it comes to writing rules, the arts of the bureaucratic politicians are well matched with the technical skills of the traditional project manager. Suffice it to say that project managers must be, above all else, self-conscious.
catalysts and coordinators of internal participation if they are to be successful. Early mistakes, issues overlooked, or conflicts left unresolved will resurface at the later stages of regulation development when additional work or serious conflict can be most debilitating. The skills to manage internal participation are as difficult to acquire as they are essential, and they are developed at greater length below.

Striking in recent discussions among experts about the craft of regulation development is the consensus that the diplomatic skills of the project manager must be bolstered with political leadership. It may be that the capacity for task and high-level political leadership is found in a single individual, but more often it is not. While the role of the political leader is limited, it may be determinative at a number of critical points in regulation development. The term most often used by experts to capture the essence of the role of the political leader is “champion.” It reflects that widely held perception that the occasional application of clout by an individual committed to the regulation under development can be an indispensable, indeed cathartic, event that breaks a logjam, resolves a key dispute, or simply focuses resources that would otherwise be distracted on the successful completion of the rule. A further discussion of the roles of task and political leaders is found in the section of the report devoted to participation.

Information Acquisition
At its most basic, rulemaking is the transformation of information into authoritative statements of law or policy. For regulations whose development requires significant management effort, the necessary information is only infrequently completely available at the outset of the work and almost never completely in the possession of the person responsible for the project. Every rule, be it major or minor, has five dimensions that determine the types of information that may have to be collected and analyzed:

- **Legal information** includes what is required or allowed by statutes, executive orders, and court decisions.
- **Policy information** includes guidance on the priorities and approaches preferred by the current administration.
- **Content information** consists of the technical or scientific requirements or guidance being established or revised in the rule.
- **Impact information** provides insights to the effects of the regulation on both regulated parties and intended beneficiaries.
- **Implementation and compliance information** details how new requirements will be communicated and enforced.

A critical task in the early stages of regulation development is an assessment of the state of information in each of these categories and the formulation of a strategy for how any gaps in information will be filled.

There are few, if any, systematic studies of the sources of information used by agencies in regulation development. Certainly there is nothing approaching a comprehensive analysis. Yet, the categories of sources available to agencies for this purpose are well-known. Legal information is invariably provided by the agency’s office of general counsel or its functional equivalent, working in closer proximity to the program with primary responsibility for development of the rule. Policy information in the form of guidance on the preferred content or approach is provided by political appointees or, in the case of independent agencies, commissioners or their surrogates. Content information may be provided by a variety of sources either internal or external to the agency.

The internal, or established, sources of these analyses and data include the resident expertise and institutional memory of agency staff, independent academic research, studies previously commissioned by the agency and conducted by a wide range of outside experts, studies conducted by other government agencies or the agency’s own personnel, and data collected during the course of the agency’s implementation and enforcement activities. External sources of information are also varied. Agencies support programs of extramural research whose results may support regulation development efforts, such as the fish stock analyses mentioned previously, or they may commission data collection and analyses that focus specifically on a particular rule by the agency. External parties affected by or otherwise interested in a given rule may supply information or opinion
before, during, or after the public comment phase of rule development. Existing in a status somewhere between purely disinterested, objective research and the input of interested parties is the information provided by formal consultative bodies created under the strict guidelines of the Federal Advisory Committee Act. These too may be launched to provide assistance in the development of a specific rule or cover a much broader area of concern that may affect an entire suite of new regulations.

Impact information may come from the same sources, albeit in a different mix, that provide information for the content information. However, in this area, two internal sources loom large: policy analysis offices within the agency and, for the regulations they have selected for review, the Office of Information and Regulatory Affairs in the Office of Management and Budget.

Implementation and compliance information, an area too often ignored in discussions of regulation development, will be supplied by a given agency’s central enforcement and public communications offices that specialize, respectively, in monitoring of and outreach to regulated entities; by field personnel in regional offices who have the day-to-day responsibilities to manage regulatory programs; and by external interest groups who represent those affected by the new regulations.

Whether a given regulation development effort will rely heavily on internal sources of information, external sources, or some combination of the two, experience and skill are needed to identify and obtain what is needed. As an element in the management of regulation development, the acquisition and use of information should also be understood to include the ability to share what is learned, regardless of the source, with all other stakeholders. Sharing information avoids duplication of effort, misunderstanding, and unnecessary conflict. Information dissemination is a necessary but not sufficient condition for the development of consensus that eases the path of a proposed regulation.

While these categories of information are well-known, what we don’t know is how often, in what combinations, and to what effect agencies actually rely on them during the course of regulation development. Project managers and their regulation development workgroup colleagues confront a very significant challenge in assembling from these varied sources the individual elements of information needed to construct a significant regulation. Once again, we see a central management task hinging on a distinctive set of skills—the identification and tapping of participants as information sources.

Of the types of experience and skills needed to get and use information, participation management is key. Effectiveness in the management of participation requires an understanding of the sometimes subtle differences in skill that need to be applied in work with internal and external actors, plus the ability to identify political leaders—or champions—and access their special talents when needed.

**Participation**

Searches for holy grails appear to be as popular today as they are futile. Scholars of regulation are naturally drawn to simple and elegant theories that seek to explain a complex process and its varied results. However, hard experience fosters skepticism. Promising theories have been tested and disappointments have accumulated. Rigorous empirical inquiry often concludes with disappointingly little variation in results explained by one or even several combinations of variables. But when the focus shifts to the management of regulation development, the participation variable tempts the hardened skeptic to suspend disbelief, albeit temporarily, about the possibility of finding a variable with overwhelming explanatory power.

Participation emerges as the preeminent aspect of regulation development because it is crucial to both mechanics and legitimacy. It suffuses the internal dimensions of rulemaking, affecting every other significant management function. The involvement of those affected by the rule contributes to its content and nothing less than the quality of our democracy.

**Internal Participation.** The internal dimension of participation consists of engaging the right agency personnel in the development of the regulation and modulating their participation to meet the particular needs of the project. Participation management must also take care to ensure that the overall effort, however organized, is managed in a manner consistent with the prevailing decision-making culture of the agency. The project manager should be directing
a workgroup of agency personnel that reflect both the technical and political dimensions of the particular regulation development effort. Establishing a division of labor that includes clear expectations for each member, lines of communication, and venues for deliberation and explicit decision rules are elements of managing internal participation. Project managers must be certain that workgroup members have access to the necessary resources and pertinent positions of their respective organizations and bring them to the regulation development effort. Workgroup members should also be informing and obtaining proper guidance from superiors throughout the process. The project manager must intervene when the wrong people are assigned by a participating office or when the right people are failing to deliver what is expected of them. This may be information needed for the technical content of the rule or the policy preferences of those higher in the various chains of command who hold approval or veto power over the project.

Here collaboration between the task leader and political champion may be needed. When the project manager lacks the clout to convince the leadership of another office or agency to replace or otherwise correct the deficiencies of an inappropriate or under-performing workgroup member, the political leader may have the requisite influence. Similarly, when workgroup members, however assiduous in the conduct of their duties, are unable to move approval of a completed regulation through their chain of command, the political leader, or champion, may be the only recourse for the project manager.

The mix of task and political leaders’ participation skills is particularly important in those cases when multiple agencies must come together to produce a rule. In an era when the formal jurisdictions of departments, agencies, and commissions are often viewed as impediments to the holistic, integrated approaches needed to solve complex social problems, the development of major regulations often requires cross-department collaboration. Areas such as homeland security, environmental protection, and financial services are but a few prominent examples of regulation development that need such an approach. This enriches and broadens deliberations to be sure, but also increases the stakes and challenges for internal participation. The task leader will almost certainly have less knowledge of and influence with participants from other agencies. But the task leader’s political counterpart can be a supplement when the project is threatened by another department’s intransigence arising from significantly different views on the content of a regulation or delay caused by competing priorities. The political leader may have ties to counterparts in these other agencies or may have indirect access through White House policy channels. Here the political leader is a broker of the type of consensus that will also ease the path of the regulation through OMB.

The skills associated with management of internal participation are borne of institutional knowledge and deep experience with regulation development in a given agency. The purpose and goals of a given regulation will drive the search for internal expertise and provide the jurisdictional road map to the affected bureaucratic interests that expect to be involved or consulted. Beyond the many excellent sources of guidance on project management in a workgroup or task force environment, a body of scholarship and professional experience that is most likely to provide useful assistance for the task leader is well summarized in an IBM Center for the Business of Government report, “A Manager’s Guide to Choosing and Using Collaborative Networks” (Milward and Provan). Especially pertinent in this review is the guidance related to networks that function to disseminate information and solve problems. While developed with networks of independent organizations or individuals in mind, the extent of autonomy enjoyed by key offices in many regulatory agencies makes the work quite relevant to regulation development.

No effort will be made here to summarize every crosswalk between the conceptual work on networks and how it applies in the context of regulation development. Table 2 on pages 26–27 summarizes a few salient applications of Milward and Provan’s general principles of managing networks to the specific needs of those managing the writing of rules. For example, Milward and Provan view information diffusion networks as developing between “interdependent government agencies” with a “primary focus” on “sharing information across departmental boundaries” and with the fundamental goal of shaping “government’s response to problems through better communication and collaboration.” This general orientation is fully consistent with what we know about the
The management of regulation development is an environment in which important regulations are developed. One would hope that these types of networks are fully formed and available to project managers and political leaders of a regulation development effort. That said, it is Milward and Provan’s “problem solving networks” that more closely resemble the common situation in rulemaking. They describe problem solving networks as having a focus on tackling existing problems rather than building relationships for future interactions and, as such, may be characterized by temporary groups. Given the issue-driven nature of regulation development.
### Table 2: Management Tasks in Public Networks (continued)

<table>
<thead>
<tr>
<th>Essential Network Management Tasks</th>
<th>Management of Networks</th>
<th>Management in Networks</th>
<th>Application to Regulation Development</th>
</tr>
</thead>
</table>
| **Management of Design (Governance Structure)** | • Determining which structural governance forms would be most appropriate for network success.  
• Implementing and managing the structure.  
• Recognizing when structure should change based on network and participant needs. | • Working effectively with other network participants and with network-level management based on the governance structure in place.  
• Accepting some loss of control over network-level decisions. | • Project manager immediately establishes substantive and procedural guidelines for workgroup operations and decision making. |
| **Management of Commitment** | • Getting the “buy-in” of participants.  
• Working with participants to ensure they understand how network success can contribute to the organization’s effectiveness.  
• Ensuring that network resources are distributed equitably to network participants based on network needs.  
• Ensuring that participants are well informed about network activities. | • Building commitment within the organization to network-level goals.  
• Institutionalizing network involvement so that support of network goals and participants goes beyond a single person in the organization. | • Project manager confirms that all workgroup members understand and agree to goals of the regulation to be developed.  
• Project manager ensures that workgroup communications are effective for members.  
• Project manager determines whether workgroup members are adequately supported by their respective offices and intervenes, with assistance of the political leader/champion when needed, if resources are inadequate. |


Development, it is certain that workgroups or project teams will be temporary.

**External Participation.** The opening section of this report noted that the management of participation in the context of regulation development is part requirement, part expectation, and part skill. All three components are readily apparent when the management of external participation is considered.

The modern era of public participation in rulemaking begins with the passage of the Administrative Procedure Act (APA) some 60 years ago. In fact, participation has been a facet of regulation development since the first rules were written more than 200 years ago. The APA does contain minimum participation requirements that must be met. Beyond legal requirements, the public has come to expect involvement in the development of laws and policies that have a profound effect on their lives. The actual practice of public participation, like so many other aspects of regulation development management, is incompletely understood. On one point there is no question, however. Except in emergency situations, any effort to undertake the development of a regulation important to even a tiny portion of the American people without their opportunity to be involved will likely be met with strong and fully justified protest. Before turning to the deeper and compelling relationship between participation in regulation development and the quality of governance in America, we should begin with more mundane matters, namely its practical utility. Here the linkages between internal and external participation are important.

Internal participation provides focus and is an essential prerequisite to one important dimension of managing external participation. When task managers fully understand the types, amount, and quality of
information available for the regulation from internal sources, they then understand the information deficits that must be filled from external sources. This is the instrumental dimension of external participation, the dimension that relates directly to the technical content of the rule itself. In this sense, effective management of internal participation not only ensures that key bureaucratic interests are properly consulted but allows the task leader to leverage the network of contacts that each of the offices represented on the workgroup can bring to the development process. The same can be said for the networks of external interests that surround other agencies who may be involved. Every office and agency at the table—physically or virtually—must be viewed as a potential point of access to external organizations, firms, and individuals who may be affected by and contribute to the development of a regulation.

To meet legal requirements and ensure the instrumental purposes of external participation are served, the plan for interaction with affected interests should be developed with the same care as that developed for internal participants. The conventional means of outreach are, again, well-known, and include informal communications by phone, e-mail, or face-to-face; written comment; policy dialogues; public hearings; and formal negotiations, or “Reg Neg.” Each of these, with the possible exception of notices requesting comment, requires skills and experience to be used to full advantage. A substantial literature exists on the use of public hearings, policy dialogues, and negotiated rulemaking. Agencies maintain inventories of external parties who are likely to be interested in or hold information pertinent to regulations under development.

The key skill in the management of external participation is the ability to match available forms of outreach and communications venues and techniques with distinctive features of the external interests who are to be engaged with the process. Again, a recent report by the IBM Center for The Business of Government provides an excellent touchstone for the more specific resources that should be developed and maintained by every agency that writes significant rules. The work on public dialogue and engagement is quite varied and rich. A valuable summary of the literature is found in an IBM Center for The Business of Government report entitled “Public Deliberation: A Manager’s Guide to Citizen Engagement” (Lukensmeyer and Torres). Much of what they present and summarize in Table 3 on page 30 is directly applicable to the management of regulation development. As with Milward and Provan’s work, it is not practical to summarize the lessons this work holds for the regulation development project manager. The core lesson of this work and that of others working in the field is to demonstrate that for different elements of the regulation development process, there are different reasons for public participation, different challenges for achieving effective engagement, and different combinations of techniques available to the task or political leader.

Regardless of the means used when information is solicited from the public, the agency must be prepared to deal with what arrives. It is important to note that over the past decade, technology has developed to the point where it can assist in this and other elements of participation management. The literature on “e-rulemaking” (see the sidebar “E-Rulemaking”) is now very substantial. Despite the strength and the promise of e-rulemaking, current research does not indicate that the use of e-rulemaking technology resolves the core issues of internal or external participation in regulation development. While still struggling to get proper funding and the necessary embraces from agencies and the public, e-rulemaking clearly has real potential. But this promise can be fully realized only when more fundamental issues are resolved. Indeed, governance concerns, noted next, can be exacerbated by technology.

Governance is the other, more fundamental dimension of external participation. External participation is linked to basic democratic principles. Just as the electoral connection—representation—confers legitimacy on lawmakers by legislatures, the opportunity to participate directly in the development of regulations provides needed public input and the authority that confers these acts by unelected bureaucrats and political appointees. It is also quite understandable that the instrumental dimension of external participation management often overwhelms concerns for governance. Resources are always limited, and engagement with those portions of the affected public who are not sophisticated, organized, and well resourced is expensive, difficult, and frequently yields little information for the content of a rule. But questions about lawmaking by unelected
E-Rulemaking

No contemporary discussion of the role of participation in the development of regulations is complete without some mention of technology. As part of a larger e-government initiative, the Bush administration launched regulations.gov, designed to be a hub for those seeking information on rules under development at any federal department or agency. The portal can be found at www.regulations.gov. The four-year-old effort has received considerable attention from both the academic and professional public management communities.

But e-rulemaking is a broader topic, encompassing both technologies and techniques bound by the common goal of increasing the frequency of informed and high-quality participation in the development of regulations. The use of information technology to enhance the participation dimension extends far beyond the submission of comments through what is basically a modified e-mail system. It includes sophisticated capabilities that allow for extended “public dialogue” and that are focused on the development of actual regulatory language and tools to assist agencies struggling to keep pace with high volumes of public comment that technology now facilitates. The following resources will be useful to those seeking an introduction to the subject and the current state of e-rulemaking and its various strengths and weaknesses:


... officials without participation by those affected go to the heart of our democratic system.

Existing research on the practice and effects of public participation in regulation development is still in a primitive state when compared with studies of voter turnout or lobbying directed at legislatures. What scholarship is available casts doubt on the frequency with which agencies actually seek public comment and yields inconsistent and inconclusive evidence about the extent to which information and opinions offered by the public alter the content of a regulation that the agency would have otherwise issued. A theme in this literature suggests that two tiers of participation and two classes of participants may characterize some rulemaking. The author’s work with Scott Furlong and more recent work by William West indicate that early involvement in the development of regulations by external interests is indeed an important element in rulemaking. Interest groups report that early and informal communication with agency personnel is a key tactic in their efforts to influence the content of rules. West’s interviews with agency personnel focusing on their practices when developing the content of notices of proposed rulemaking that appear in the Federal Register yield results that are consistent with the findings of Furlong and this author. These findings raise obvious governance questions and concerns.

Project managers develop technical content and produce rules, often under a deadline and while striving for a minimum of external criticism from powerful interests. Organizations, firms, or individuals with specific and the high-quality information that may be unavailable elsewhere or available only at a high cost are likely to be at least as valuable to the project manager as any internal participant.

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Frequently, powerful, organized interests need not be sought out; they are ready, willing, and quite able to engage the process. That is not the case for others with less sophistication, knowledge, or resources. Project managers, in their triage work allocating time and resources, could choose to spend both in the outreach and education of unorganized or poorly resourced interests to advance principles of democratic governance. But they operate in the real world. Given the pressures on project managers and

Table 3: Public Participation and the Stages of Regulation Development

<table>
<thead>
<tr>
<th>Purpose of Activity</th>
<th>Information Acquisition and Analysis</th>
<th>Crafting the Regulation</th>
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<tbody>
<tr>
<td>Establish an inventory of regulations that must or should be developed.</td>
<td>Establish the specific requirements for those regulated by, benefiting from, managing, or administering a public program.</td>
<td></td>
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<tr>
<td>Determine relative importance of rules for use in scheduling and resource allocation.</td>
<td></td>
<td></td>
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<tr>
<td>Provide a policy framework and goals for particular regulation.</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Need/Value of Participation</th>
<th>Priority and Agenda Setting; Early Guidance</th>
<th>Information Acquisition and Analysis</th>
<th>Crafting the Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide guidance from senior political and administrative officials.</td>
<td>Establish an inventory of regulations that must or should be developed.</td>
<td>Establish the specific requirements for those regulated by, benefiting from, managing, or administering a public program.</td>
<td></td>
</tr>
<tr>
<td>External perspectives on need for rules inform initial decision makers.</td>
<td>Determine relative importance of rules for use in scheduling and resource allocation.</td>
<td></td>
<td></td>
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<tr>
<td>Early guidance avoids wasted effort and identifies potential issues.</td>
<td>Obtain information for content of the regulation.</td>
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<thead>
<tr>
<th>Challenges/Issues</th>
<th>Priority and Agenda Setting; Early Guidance</th>
<th>Information Acquisition and Analysis</th>
<th>Crafting the Regulation</th>
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</thead>
<tbody>
<tr>
<td>Number of worthy projects outstrips available resources.</td>
<td>Establish an inventory of regulations that must or should be developed.</td>
<td>Establish the specific requirements for those regulated by, benefiting from, managing, or administering a public program.</td>
<td></td>
</tr>
<tr>
<td>Disagreement on need for rules or relative priority order or approach.</td>
<td>Determine relative importance of rules for use in scheduling and resource allocation.</td>
<td></td>
<td></td>
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<tr>
<td>Conflict among external groups on priority order and approach.</td>
<td>Obtain information for content of the regulation.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Forms of Internal Participation</th>
<th>Priority and Agenda Setting; Early Guidance</th>
<th>Information Acquisition and Analysis</th>
<th>Crafting the Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regularly scheduled meetings related to development of Regulatory Agenda and internal agency priorities.</td>
<td>Establish an inventory of regulations that must or should be developed.</td>
<td>Establish the specific requirements for those regulated by, benefiting from, managing, or administering a public program.</td>
<td></td>
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<tr>
<td>Meetings of project managers and leadership on individual regulations.</td>
<td>Determine relative importance of rules for use in scheduling and resource allocation.</td>
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</table>

<table>
<thead>
<tr>
<th>Forms of External Participation</th>
<th>Priority and Agenda Setting; Early Guidance</th>
<th>Information Acquisition and Analysis</th>
<th>Crafting the Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public comment on departments’ and agencies’ regulatory plans and agendas.</td>
<td>Establish an inventory of regulations that must or should be developed.</td>
<td>Establish the specific requirements for those regulated by, benefiting from, managing, or administering a public program.</td>
<td></td>
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<tr>
<td>Public petitions for rulemaking.</td>
<td>Determine relative importance of rules for use in scheduling and resource allocation.</td>
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<tr>
<td>Use of advisory committees.</td>
<td>Obtain information for content of the regulation.</td>
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**Source:** Modified from Carolyn Lukensmeyer and Lars Hasselblad Torres, “Public Deliberation: A Manager’s Guide to Citizen Engagement.”
without much stronger incentives than are present in the current system, the niceties of democratic theory and constitutional ideals can appear as faint images on the screen.

If there is concern about imbalance in participation by external actors, foreclosure of paths to agency decision makers for informed, organized interests is exactly the wrong way to fix the problem. Indeed, it is imperative that regulation development project managers continue to access knowledgeable external interests as early in the process as possible. Officials who play leading roles in the development of regulations must acquire the knowledge and skills needed to identify and tap these sources of information. They should also possess the talent that allows them to engage these interests at a deeper level to ensure effective dissemination of information throughout the community of interest associated with the rule. At best, and if appropriate under the circumstances, the project managers and political leaders should promote the same type of consensus among external participants that is sought among internal actors.

As for the imbalance mentioned above, the plans for external participation should, in a limited number of high-priority projects, explicitly include participation by those whose awareness or resources would not be sufficient for them to respond to agency outreach without additional assistance. In other words, among the goals for the management of these select regulation development projects is a contribution to governance through education and empowerment of some segment of the affected population that would otherwise not participate. Existing research and expert opinion make a strong case that when the public is engaged in the development of regulations in a substantial and sustained manner, their attitudes toward government and the positions of others in the process, including their adversaries, change for the better. And contributions to good governance should not be listed entirely on the normative side of the ledger. Regulations viewed as legitimate will be easier to enforce since voluntary compliance will be the norm.

This perspective can be easily dismissed as naïve or quaintly idealistic in an environment where rules are developed under intense pressure, with unrealistic expectations and insufficient resources. In defense of the “legitimacy benefit,” as it is termed by Freman and Langbein, one can only offer that these challenging conditions were produced by generations of legislation that effectively rewarded elected representatives for delegating vast responsibilities to agencies with little regard for the “other” legislative process. Regulation development is left with all the remaining work, controversy, and complexity. Be it cynicism or ignorance, this pattern of legislation has never been broken and will not until the American people direct their elected representatives to be better stewards of regulation development. One way to induce that pressure is to bring more people to the process of developing regulations. This is not the stuff of sudden, revolutionary change, but over time and hundreds of regulations the effect could be noticeable. And for those who do engage the process, the effects can be salutary, in terms of both the results achieved and the building of social capital. Involvement in decisions with a direct, immediate, and understandable effect on one’s life is a very meaningful form of participation in governance and a potential antidote for the poisons that have attacked our electoral processes over the past several decades.
Findings and Recommendations

Findings

Finding 1: Regulation Management Lacks Visibility
Regulation management is a well-developed function in federal agencies that bear significant rulemaking responsibilities. As an activity that supports what is arguably one of the most important functions performed by agencies of government, regulation management has little visibility outside the community of specialists that work in the area.

Finding 2: Regulation Development Management Lacks Focused Attention
The management of regulation development enjoys little support in the form of funding, research, technical innovation, and career development from the public management and academic communities.

Finding 3: Regulation Development Is Complex
Regulation development has become a highly complex task requiring the coordination and management of myriad legal requirements and stakeholder expectations in an environment characterized by constrained resources and frequently intense political pressures.

Finding 4: Key Elements Constitute the Management of Regulation Development
Numerous functions make up a fully developed system of regulation management. Three of them—staffing, information acquisition, and participation—are the most important.

Finding 5: Staffing Patterns Challenge Project Management
Staffing a major or significant regulation development process requires involvement of staff from multiple offices within a single agency or department and, due to increasingly cross-cutting issues, multiple agencies with varied missions and jurisdictions. These offices and agencies have discrete missions, jurisdictions, and professional cultures that create significant challenges for the leadership of regulation development efforts.

Finding 6: Regulation Development Requires Multiple Types and Sources of Critical Information
The development of regulations requires the acquisition of five types of information: legal, policy, technical content impact, implementation, and compliance. This information can be secured from multiple sources, but information acquisition must be carried out with careful attention to multiple legal and bureaucratic restrictions.

Finding 7: Participation Management Is the Most Important Function and Skill in Regulation Development
The challenges associated with staffing and information acquisition highlight the importance of participation management to effective regulation development. The knowledge, techniques, and experience needed for effective engagement of internal and external stakeholders is the most important skill set for regulation development managers. Useful tools are available in the areas of collaborative networks and public deliberation to support the participation dimension of the regulation development management.
Finding 8: Participation in Regulation Development Is a Key to Democratic Governance

Participation in regulation development, particularly by affected external parties, is important to the quality and integrity of governance in the United States.

Recommendations

Recommendations for Congress

Recommendation 1: When enacting legislation that creates new or substantially altered regulatory authorities, Congress should routinely authorize and appropriate funds sufficient to ensure effective management of regulation development by responsible agencies. Authorizing legislation should note that all deadlines imposed on agencies for development of regulations are suspended should appropriating committees fail to fund the programs for rulemaking management.

Recommendation 2: Congress should authorize and fund a program of research to support the management of regulation development in federal agencies. The initial priorities should include development of an inventory of best practices and methodologies to determine the linkage between management practices and regulatory outputs and outcomes. To administer this program, recently authorized by the Administrative Conference of the United States, it should be fully funded and directed to draw upon the scholarly and practitioner expertise in all appropriate disciplines.

Recommendations for the Office of Management and Budget

Recommendation 3: The management of regulation development should occupy a more prominent position in major government-wide management initiatives and programs. This includes a place in the President’s Management Agenda initiative, pertinent goals in strategic plans mandated by the Government Performance and Results Act, and analytic inclusion that supports the Program Assessment Rating Tool, or PART, program. Cross-walks between e-government and regulation development management goals should be explicit.

Recommendation 4: When reaching agreements with agencies on major rules they will review under Executive Order 12,866 the Office of Information and Regulatory Affairs should require the regulation development management plan to include information on schedules, budgets, responsible personnel and participation.

Recommendations for Agencies

Recommendation 5: Agencies should include the effective participation by internal and external stakeholders among their goals for rules under development. Specifically, these goals should focus on the building of social capital that enhances the willingness of the public to collaborate with government in the achievement of regulatory objectives.

Recommendation 6: Departments, agencies, and commissions should review the mission, authorities, and resources of central offices that arrange or administer aspects of regulation development.

Recommendations for the Office of Personnel Management

Recommendation 7: The Office of Personnel Management, in collaboration with all federal agencies, should establish regulation development management as an area of specialization, with a career track that includes training and experience standards for each successive level of responsibility. Qualification for the Senior Executive Service should include demonstration of competence in the major areas of regulation development management, with particular emphasis on the ability to facilitate and employ participation by internal and external stakeholders.

Recommendations for the Academic Community

Recommendation 8: The National Association of Schools of Public Affairs and Administration (NASPAA) should consider the inclusion of mandatory coursework in regulation development management among its accreditation criteria.
Appendix: Supporting Data

Table A.1: Number of Proposed and Final Rules (1982–2004)

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Source: U.S. General Services Administration.


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About the Author

Cornelius M. Kerwin is acting president of American University (AU). For seven years, he served as provost of AU, and he has been a member of the faculty since 1975. Dr. Kerwin has held a number of prominent leadership positions within the School of Public Affairs, including his service as dean from 1989 to 1997.


Under Dr. Kerwin’s leadership, the university established the Center for the Study of Rulemaking in July 2004. As part of its mission to better understand and improve the processes and techniques used by government agencies to develop regulations, the Center organizes conferences, symposia, and workshops that bring together scholars, public and private sector personnel, and the larger academic community.

Dr. Kerwin’s experience in the public sector includes work with the Office of Personnel Management, the Environmental Protection Agency, the Administrative Conference of the United States, the Federal Energy Regulatory Commission, the Department of Agriculture, the Nuclear Regulatory Commission, and the Public Health Service. In the private sector, he has served as a consultant to IBM Corporation and General Electric.

Dr. Kerwin was elected as a Fellow of the National Academy of Public Administration (NAPA) in 1996. He was president of the National Association of Schools of Public Affairs and Administration (NASPAA) in 1998 and was the founding chair of the Section on Public Law and Administration of the American Society for Public Administration (ASPA). He is a member of Pi Sigma Alpha and Pi Alpha Alpha national honor societies for the fields of political science and public administration, respectively.

Dr. Kerwin received a B.A. from American University in 1971, his M.A. in political science from the University of Rhode Island in 1973, and his Ph.D. in political science from Johns Hopkins University in 1978.
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