

Agile Regulation

Gateway to the Future

Agile Regulation: Gateway to the Future

*A White Paper by a Study Team of
the National Academy of Public
Administration and the Project
Management Institute.*

National Academy of Public Administration
1600 K Street, NW
Suite 400
Washington, DC 20006
www.napawash.org

Project Management Institute
14 Campus Blvd
Newtown Square, PA 19073
PMI.org

About the Academy

The National Academy of Public Administration (the Academy) is a non-profit, non-partisan, and independent organization of top public management and organizational leaders who tackle the nation's most critical and complex public management challenges. With a network of more than 950 distinguished Fellows and an experienced professional staff, the Academy is uniquely qualified and trusted across government to provide objective advice and practical solutions based on systematic research and expert analysis.

Established in 1967 and chartered by Congress in 1984, the Academy continues to make a positive impact by helping federal, state and local governments respond effectively to current circumstances and changing conditions.

Learn more about the Academy and its work at www.napawash.org.



About Project Management Institute (PMI)

PMI is the world's leading association for those who consider project, program or portfolio management their profession.

Through global advocacy, collaboration, education and research, we work to prepare more than three million professionals around the world for the Project Economy: the coming economy in which work, and individuals, are organized around projects.

PMI works in nearly every country around the world to advance careers, improve organizational success and further mature the project management profession through globally recognized standards, certifications, communities, resources, tools, academic research, publications, professional development courses and networking opportunities.

Visit us at PMI.org, ProjectManagement.com, on Facebook at facebook.com/PMInstitute and on Twitter [@PMInstitute](https://twitter.com/PMInstitute).



Foreword

The National Academy of Public Administration recently presented the results of a year-long effort to identify the [Grand Challenges in Public Administration](#). These 12 challenges across four focus areas represent some of the most significant issues that governments at all levels face from a public administration standpoint over the next decade.

To address these Grand Challenges, the public sector must operate differently and work in new ways. It is our belief that a new agile paradigm has great potential to help government address these issues in a more effective, efficient, and equitable way. This new approach must make end-user satisfaction the top priority, empower teams, and utilize networks and innovation to solve complex problems.

In December 2020, the Academy and Project Management Institute (PMI) jointly released a report, [Building an Agile Federal Government: A Call to Action](#), which examined how agile project management in government differs from current management practices, what major issues and impediments hinder agile adoption, and what various departments and agencies can do to unlock the true potential of agile.

The report included 5 practical recommendations with specific implementation steps to increase agility in the federal government. We were delighted to see that joint report referenced as the foundation for a new federal [workforce priority](#), “Fostering an Agile Organization and the Growth Mindset.” We were also pleased to see that agencies were urged to incorporate our 5 previous recommendations in their activities. Clearly, momentum is building toward a more agile government.

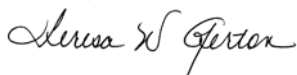
Last fall, the Academy, PMI, and the Samuel Freeman Charitable Trust embarked on an effort to address federal regulation, which many view as the least agile area of public administration and policy. Our Study Team recognized that the federal regulatory process is not going to be fundamentally restructured; however, it is entirely possible for agencies to adopt some agile practices within the existing legal structure.

To document the art of the possible, the team met with different regulatory agencies and other experts. These ideas and other insights, coupled with conversations with the Expert Advisory Group of Academy Fellows, led to the development of an agile regulatory framework with 9 tenets and numerous practices that agencies can implement to improve stakeholder engagement, internal working practices, and regulatory outcomes.

Becoming more agile is a journey, and we aim to practice it ourselves. We want to hear from you—the community of public sector leaders working together to solve the biggest challenges in government—about how this agile regulatory framework works inside agencies and where it can be improved. Based on this feedback, we will make additional revisions to the framework and practices on our website - and possibly through an updated version of this report.

This report could not have been produced without many contributing people and organizations. All of these stakeholders and partnerships were vital to this effort’s success, including The Freeman Trust, the partnership between the Academy and PMI, the contributions of our Agile Government Network, and the input from federal agencies and other interviewees.

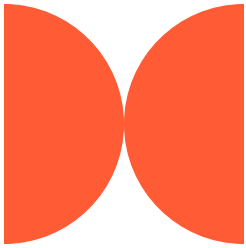
We express our deepest appreciation to these contributors, to the Academy Fellows, and to the study team members who worked mightily to synthesize information and develop an innovative and practical framework. We hope that leaders and managers across federal regulatory agencies will not only find this framework useful, but also let us know how it can be strengthened in the coming years.



Teresa W. Gerton
President and Chief Executive Officer
National Academy of Public Administration



Michael DePrisco
Interim President & CEO
Project Management Institute



Acronyms

AI	Artificial intelligence
APA	Administrative Procedure Act
CFPB	Consumer Financial Protection Bureau
CFR	Code of Federal Regulations
EO	Executive Order
FAA	Federal Aviation Administration
FACA	Federal Advisory Committee Act
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
FDIC	Federal Deposit Insurance Corporation
FinCEN	Financial Crimes Enforcement Network
FOIA	Freedom of Information Act
GQM	Goal-Question Metric
HHS	US Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
IT	Information technology
ML	Machine learning
NAPA	National Academy of Public Administration
NARA	National Archives and Records Administration
NLP	Natural Language Processing
NRC	Nuclear Regulatory Commission
NTSAC	National Towing Safety Advisory Committee
OECD	Organization for Economic Cooperation and Development
OCR	Office of Civil Rights
OKR	Objectives and key results
OSHA	Occupational Safety and Health Administration
PMI	Project Management Institute
PRA	Paperwork Reduction Act
SED	Standards Evaluation and Development
USCG	US Coast Guard
WEF	World Economic Forum



Introduction

In the first 22 years of the 21st century, the United States and the rest of the world have had no shortage of once-in-a-lifetime events:

- Terrorist attacks on September 11, 2001
- Wars in Iraq, Afghanistan, and elsewhere in the Middle East and North Africa
- Global financial crisis in 2007-2009
- Ongoing Russian war in Ukraine
- Ongoing global COVID-19 pandemic
- Inflation, workforce, energy, and supply chain disruptions in the wake of the pandemic

These are the equivalent of many “100-year floods,” now occurring every few years.

Social, cultural, economic, environmental, and technological developments are putting pressure on federal regulatory agencies as they seek to protect the public, advance social equity, protect the environment, and foster an innovative market economy. New complex technologies—drones, self-driving cars, genomics—are being developed at a rapid pace, and the public increasingly expects that federal agencies provide a user-friendly and responsive customer experience similar to leading private sector companies.

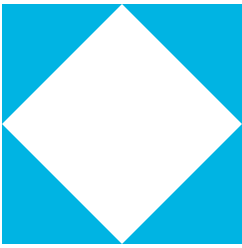
To keep up with these demands, federal agencies can adopt agile practices to increase stakeholder satisfaction, allow for more iteration on outputs to learn lessons about what works best, empower staff members, and maximize team and network performance to meet critical public needs.

During the COVID-19 pandemic, all federal agencies have gained considerable experience operating in a more agile way. For example, they have updated their modes of working, adopted new workforce models, developed new collaboration mechanisms, and modernized some regulatory guidance and requirements. Moving forward, we believe that federal agencies can leverage this experience by more systematically implementing agile tenets and practices as they serve the American public.

This paper presents an Agile Regulatory Framework that we believe can help federal agencies meet public needs in an increasingly fast-paced and dynamic environment. This framework is offered in the spirit of a deep and abiding belief in the public sector’s importance and the need for regulation. We neither seek legal changes to the regulatory process itself nor expect that legal reforms are required for agencies to become more agile. As always, agencies should review their statutory authorizations and requirements and consult their counsel to determine what is permitted and what is not. By implementing the proposed agile tenets and practices, we expect federal agencies will become more anticipatory and forward looking, innovative and experimental, data driven, responsive, and transparent. Consistent with existing legal requirements, we hope that federal agencies use this framework where possible to support the conduct of their vital public missions.

Structure of the Report

- The Agile Regulatory Framework with nine tenets across four key categories
- A more detailed description of each tenet and specific practices that federal agencies could consider adopting
- Appendices with specific agency examples of operating in an agile way, list of people interviewed in this study, and the biographies of the Expert Advisory Group and Study Team members



Agile Regulation Framework

Table 1 presents the key tenets of Agile Regulation across four categories that generally correspond with the regulatory process, timeline, and activities.

We do not presume that every tenet and practice will apply in every situation. We understand that agencies have legal constraints, established practices and expectations, and competing objectives. Although we expect that the tenets and practices will apply in many or most situations, agencies must make their own decisions about when and how to use them. For the sake of simplicity, we decided against incorporating “as appropriate” or “as needed” or “consistent with legal requirements” into the wording of each tenet—but these caveats are a critical part of the agile regulatory framework and should be thought of as such.

Table 1. Key Tenets of Agile Regulation

Category	Tenet
Public Need	1. Understand changing external conditions and evolving societal, economic, and environmental needs.
Regulatory Design	2. Think comprehensively about how to best meet the agency’s regulatory goals. 3. Incorporate innovative methods that address economic, environmental, and societal needs. 4. Collaborate early and often during regulatory development.
Internal Processes	5. Construct small yet inclusive teams to manage the regulatory development process. 6. Make the agency’s work and workflows visible as regulations are developed. 7. Automate processes and use modern technological tools. 8. Conduct parallel processing of activities.
Continuous Learning	9. Foster continuous learning about regulatory impacts and internal processes.



1. Understand changing external conditions and evolving societal, economic, and environmental needs.

While agencies use strategic plans to plan 5 to 10 years in the future, the rapid pace of change both domestically and internationally requires a nimble, agile approach to even the most solid plans. The immediate need to work from home during the COVID-19 pandemic, for example, illustrated the challenge uncontrollable external conditions place on federal agencies. Many regulatory agencies face technology cycles that outpace the current regulatory process. Increased recognition of the importance of diversity, equity, inclusion, and accessibility at all levels of society has led to policy changes and ongoing dialogue about future needed changes. Agencies must continually monitor the external environment to identify changing conditions and future scenarios. This can be done by scanning the environment, using scenario planning methodologies, soliciting input from a wide range of stakeholders, and remaining culturally sensitive and socially equitable.

Key questions an agency should consider as part of this tenet:

- What processes can we put into place to prepare for the future?
- What are the most significant emerging issues and challenges?
- What existing regulations address these issues?
- How, if at all, can additional or updated regulations assist?

PRACTICES

1.1. Adopt an agile mindset that embraces needed change and adapts quickly to emerging conditions.

Agencies must first acknowledge that change may be necessary. For some, this might mean implementing small-scale changes to improve effectiveness, efficiency, equity, transparency, and/or responsiveness. For others, change might entail a more comprehensive, full-scale reimagining of their regulatory development process. Agencies may seek change for a wide range of reasons, including to reduce the time between drafting and implementing a rule, increase stakeholder input, or to develop innovative compliance metrics. An organization needs buy-in from employees, including subject matter experts who carry out the agency's work and those who can implement large-scale change. Regulators should review existing authorities and elicit creative ideas from their stakeholders, both internal and external, about how best to address modern needs.

The Department of Homeland Security's Procurement Innovation Lab is guided by the Federal Acquisition Regulation (FAR) 1.102-4(d) which states, "If a policy or procedure, or a particular strategy or practice, is in the best interest of the Government and is not specifically addressed in the FAR, nor prohibited by law (statute or case law), Executive order or other regulation, Government members of the Team should not assume it is prohibited." Agile begins by asking whether the current way of doing things is limited by statute or if innovation is allowable, but simply not currently utilized.

1.2. Conduct environmental scans and scenario planning to identify and understand emerging issues.

According to the Society for Human Resource Development, environmental scanning "is a process that systematically surveys and interprets relevant data to identify external opportunities and threats that could influence future decisions" (Society for Human Resource Management, n.d.). Agencies can do comprehensive scans of the environment, and they can use scenario planning to identify key drivers, decision factors, and possible futures. Scenario planning can help increase agility and allow an agency to adapt to multiple eventualities. Reports like the Government Accountability Office's [Trends Affecting Government and Society](#) can also focus agencies on important issues on the horizon. With these processes, stakeholder engagement is key. Stakeholders can include

industry leaders, trade associations, small businesses, nonprofit advocacy organizations, and the general public. Other observers, like economic and market analysts, journalists, and academics, may also provide critical insights on emerging issues for the government to address in some way. In some industries, such as emerging technology, the pace of change is so fast that it can be difficult to keep up without a concerted focus on the future and how to address it.

1.3. Remain culturally sensitive to the impact of regulations and regulatory design on marginalized communities.

The current administration has placed increased emphasis on diversity, equity, inclusion, and accessibility across the federal government, including in the regulatory process and the evaluation of the impacts of regulation on marginalized communities. As society changes, agencies must adapt both new and existing rules to address the needs and impacts on various communities. The use of human-centered design helps agencies tailor rules to the needs of end users and ultimate beneficiaries by bringing them to the table to develop solutions. This may help alleviate disproportionate impacts on specific groups. Regulatory reviews of existing rules can determine if there are negative or unbalanced impacts on specific groups of people that need to be mitigated. Developing a continual focus on identifying the real-world effects of regulations on individuals can help promote fair and equitable outcomes.

Regulatory Design

2. Think comprehensively about how best to meet the agency's regulatory goals.

Concerns about such issues as the environment, the economy, occupational safety and health, equity, and fairness underlie many federal agency missions. As they regulate so many aspects of modern life, agencies must determine how best to protect the public's interests. An agency also needs to have a sense of what it thinks the end state should be and keep in mind how it will be achieved.

Key questions an agency should consider as part of this tenet:

- Do we need to regulate?
- How do we best meet our regulatory goals?
 - Should we use Notice and Comment rulemaking, guidance, or some other form of regulation?
- What do we know about our current regulations' effectiveness, efficiency, and equity impacts?
- Would there be advantages in thinking differently about enforcement and compliance mechanisms in future regulations?
- Are there opportunities for pilot programs, sandboxes, and other test-and-learn processes?
- How do we ensure that social equity issues are addressed?

PRACTICES

2.1. Explore a wide range of types of regulatory interventions.

Agencies can look for solutions (both regulatory and nonregulatory) that provide needed flexibility and promote innovation. In some cases, non-legally binding interventions may appropriately address the regulatory concern, including actions like increasing information and education, where consumers opt into preferred behaviors without a regulation requiring them to do so (Organization for Economic Cooperation and Development, 2006). These types of regulatory interventions have historically been supported throughout the Executive Branch. Previous administrations have issued executive orders (EO) encouraging a variety of regulatory interventions, including the Obama Administration's EO 13563 that urged agencies to "Identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or

marketable permits, or providing information upon which choices can be made by the public.” Market-oriented approaches such as permit systems, emission fees, and subsidies can be useful where authorized by statute (Environmental Protection Agency, n.d.).

As federal agencies consider which regulatory strategy to use, agencies may wish to consider using one or more of the approaches recently identified by the World Economic Forum (2020):

- Anticipatory regulation: Regulators can use anticipatory regulation to identify innovations and their implications.
- Outcome-focused regulation: Similar to a project team using agile management, regulators can use outcome-focused regulation with a focus on defining and assessing desired outcomes instead of listing compliance “tick boxes.”
- Experimental regulation: Regulators can use experimental regulation to adapt more quickly to novel innovations through the provision of regulatory advice to innovators, the enablement of testing the product under regulatory supervision, and the setting of regulatory challenges for innovators.
- Data-driven regulation: Regulators can use data-driven regulation to take advantage of new data-driven technologies that provide monitored outcomes in real time to target their interactions at critical junctures and update regulatory boundaries accordingly.
- Self- and co-regulation: Facing a disparity in information between themselves and businesses, regulators can use self- and co-regulation to foster responsible industry-led governance that allows industry to communicate its opinion on the most efficient and effective risk management for the specific innovation.

In 2017, the Federal Aviation Administration (FAA) began a 3-year pilot program, the [Unmanned Aircraft Systems \(UAS\) Integration Pilot Program](#), which brought together nine participants including local and tribal governments, state departments of transportation, universities and industry. Data from this pilot program helped the FAA develop rules by “identifying ways to balance local and national interests related to drone integration; improving communications with local, state and tribal jurisdictions; addressing security and privacy risks; and accelerating the approval of operations that currently require special authorizations.”

- Joined-up regulation: Regulators can use joined-up regulation to coordinate across agencies and levels of government in a “whole-of-government” approach to manage the risks associated with such areas as emerging technologies.
- International regulatory cooperation: Since digital innovations are inherently cross-border, regulators can use international regulatory cooperation to collaborate with each other across international borders to facilitate a more efficient and lower-cost trade environment.

2.2. Pilot regulations first to learn lessons before applying them more broadly.

Regulations can impact thousands of businesses and millions of individuals. Pilot testing allows the government to gain insights into the social benefit and resources required before implementing regulations on a larger scale. Pilot testing can help eliminate unnecessary administrative and financial burdens and increase dialogue between the regulated, the regulators, and the broader public. Examples of pilot testing include regulatory sandboxes, which may be most applicable for financial and technology areas or for other industries where innovation is so fast that government agencies struggle to keep pace.

2.3. Incorporate flexibility into the regulations themselves as appropriate.

Building flexibility into a regulation—and tailoring them to the characteristics of specific sectors—can benefit the regulated, the agency, and the public. The public interest is sometimes best served when agencies establish the broad goals and objectives (the “what”) while providing the regulated with flexibility on how to manage themselves to ensure compliance (the “how”). Agencies may find that several of the approaches identified above—especially outcome-focused regulation, data-driven regulation, and self- and co-regulation—can be especially helpful methods that allow for flexibility to be incorporated into regulations themselves.

Enforcement discretion and interpretive flexibility, where agencies update the enforcement regime for specific requirements based on compelling public needs or changing circumstances or adapt their interpretation to improve compliance, may allow agencies to react more swiftly to the changing environment and meet agency goals (Fernandez Lynch et al., 2020). These actions may obviate the need to formally alter existing regulations by issuing a new rule (a process that can be both costly and time consuming).

3. Incorporate innovative methods that address economic, environmental, and societal needs.

Regulated entities operate in an increasingly complex world in which citizens need every tool possible to navigate economic, environmental, and societal issues. To produce the maximum public benefit, regulatory agencies often must balance safety and fairness concerns with the opportunity cost of limiting such innovations as new technologies and processes. Including modern management techniques in the regulatory process can help meet modern public needs, reduce risks, and respond to a rapidly evolving external context.

Key questions for agencies to consider:

- To what extent can we build flexibility into the regulations?
- What are the best ways to ensure compliance?
- How can we use high-quality data for compliance and evaluation purposes?
- What metrics should be incorporated into the regulations to ensure we can learn lessons about effectiveness, efficiency, and equity?

PRACTICES

3.1. Harness the opportunities offered by digital technologies and big data to develop metrics while focusing on more innovative and outcome-focused regulatory approaches.

Federal regulatory agencies can use new tools, especially those related to data collection and analysis, to keep pace with advancements in technology while enhancing their regulatory processes. As discussed earlier, the World Economic Forum (WEF) identified several leading regulatory practices and lessons learned from its participating countries, and many of these practices can be adapted for American agencies. These include both outcome-focused regulation—which focuses on defining and assessing desired outcomes instead of listing compliance “tick boxes”—and data-driven regulation (World Economic Forum, 2020).

3.2. Enable greater experimentation, testing, and trials to stimulate innovation under regulatory supervision.

Many regulated entities have unique subject matter expertise that can be leveraged to find the best solutions to meet public needs. This process may work most effectively when a regulated entity can communicate with regulators in a context that encourages experimentation, testing, and trials. When working alongside its industry partners, a regulatory agency must take great care to not give special treatment to particular entities, which would risk harm to the American public, create distrust of the regulatory agency, and undermine the mission of the regulatory process. Experiments, tests, and trials can facilitate the learning and the adaptation required to produce the best regulatory outcomes.

The Japanese government has [recently created](#) an outcome-focused, technology-neutral regulatory framework for autonomous vehicles (AVs). The framework defines the desired goals for AVs and measures performance against them. This regulation includes a system of exemptions to permit the testing of AVs, voluntary technical requirements, and continuous revision of regulation based on trials. It allows companies to continue to develop their unique technologies and test them in an environment that is safe for consumers. Recently, this forward-thinking approach has helped companies like Honda test their technology in Japan and adapt their vehicles to Japan's distinct traffic environment, regulations, and laws.

3.3. Innovate to provide user-friendly regulatory compliance mechanisms.

Whatever the ultimate level of regulation, user-friendly regulatory compliance mechanisms can advance the public interest. For example, agencies can consider:

- Creating or expanding online portals that regulatory entities can use to submit applications and documents.
- Establishing mobile sites or virtual consultation options.
- Using software that allows for system-to-system communications to ensure data gets to the right regulator.
- Streamlining internal regulatory compliance processes by using simultaneous review or expedited approvals under certain circumstances.

Transparency and clarity are also vital to user-friendly regulatory compliance mechanisms to ensure that regulated entities are informed about requirements and how to comply.

The Consumer Financial Protection Bureau (CFPB) [implemented](#) an Advisory Opinions Policy that regulated businesses or other stakeholders can use to request clarification of a regulation. Entities requesting the opinion may find legal safe harbor in the opinion or conversely enforcement if they stray from it in the future. The Advisory Opinions increase the value in the regulation as entities can feel more comfortable innovating within the regulation while the agency can ensure the desired outcomes of the regulation remain intact. In other cases, Advisory Opinions clarify that particular conduct is prohibited, or is governed by a particular set of requirements.

4. Collaborate early and often during regulatory development.

For regulatory agencies to develop the necessary regulations, they must understand both the environment in which regulated entities operate and the effects of potential regulatory options. Collecting input from the public, including regulated entities, provides insight into the “value” of potential regulatory tools and techniques. This feedback loop is essential for regulations and agencies to remain relevant in sectors with rapidly changing environments.

Key questions for agencies to consider:

- How can we get input from stakeholders on what our regulatory goals in a particular area should be?
- How can we get input from stakeholders on their proposed regulatory solutions?
- How can we get input from stakeholders on how to achieve the regulatory goals while minimizing compliance costs?
- How can we get timely feedback not just from industry, but also from the individuals and households that the regulations are meant to benefit, throughout the development process?

PRACTICES

4.1. Actively engage stakeholders during the regulation design phase.

Consistent with existing law, agencies should involve stakeholders in a variety of ways: information gathering sessions, writing sessions, and validating regulations. Several feedback mechanisms, when conducted correctly, can produce this necessary input. They include but are not limited to the following:

- Surveys: a way to obtain information from multiple, diverse data sources at a relatively timely pace.
- Focus Groups: a way to obtain more expansive qualitative data while also allowing for different opinions to be heard in the same session.
- One-on-One Meetings: a way to have an in-depth discussion between the agency and the various other stakeholders, although prone to agency time consumption and bias if not carefully planned.

When in-person or virtual sessions are conducted, a wide range of diverse stakeholders—including members of the public, nongovernmental organizations, and industry—should be included. These sessions can be particularly helpful for industries like emerging technology, where the environment is rapidly changing, and regulators must stay up to date with the advancements. Each feedback mechanism must meet the various requirements of the Administrative Procedure Act (APA), Paperwork Reduction Act, Freedom of Information Act, and the Federal Advisory Committee Act. Training agency staff on facilitation techniques will further raise the impact of these discussions and the value of the final regulation. Although using innovative approaches for gathering public feedback requires agency resources, the return on investment to the American public can justify the upfront resources.

In an effort to measure the effectiveness of digital identity proofing, the Federal Deposit Insurance Corporation (FDIC) and the Financial Crimes Enforcement Network (FinCEN) conducted a ‘tech sprint’ designed to help inform firms and regulators. Eight teams worked to answer the question, “What is a scalable, cost-efficient, risk-based solution to measure the effectiveness of digital identity proofing to ensure that individuals who remotely (i.e., not in person) present themselves for financial activities are who they claim to be?” The FDIC and FinCEN used this problem-solving session to help improve the safety and security of digital banking.

4.2. Strengthen collaboration and cooperation across departments and independent agencies to ensure a sound and concise set of rules.

Regulated entities must comply with multiple regulations from various agencies. To reduce administrative burdens, the previously mentioned Executive Order 13563, “Improving Regulation and Regulatory Review,” requires “greater coordination across agencies” to reduce the number of redundant regulations, thus reducing costs and simplifying and harmonizing rules (Executive Order No. 13563, 2011). Agencies are also expected to confer with one another to minimize regulatory conflict. Agencies can learn from each other as they experiment with and then prove new ways of working in practice.

Internal Processes

5. Construct small yet inclusive teams to manage the regulatory development process.

Small teams can work in a more streamlined manner and respond to change more quickly than larger teams. These small teams should include a diverse group of subject matter experts tailored for the specific regulatory challenge. Diverse teams make better decisions and produce better results than more homogenous teams. Agencies may be challenged to balance the need to keep teams small and manageable with the need to ensure that they are sufficiently representative. One way to address this issue is to establish multiple small teams for different issues and manage these teams as a network.

Key questions for agencies to consider:

- How should we create cross-functional teams for each regulation?
 - Do we tailor the team for individual regulations?
- Is there a skill set that we seem to be missing? If so, how can we incorporate it?
- Is there a voice or stakeholder group that we are missing? If so, how can that group best be represented?
- What training does the regulatory workforce need to ensure that they have the necessary knowledge, skills, and abilities to utilize these techniques?

PRACTICES

5.1. Develop empowered, highly skilled, cross-functional teams with the skills and resources required to complete their mission.

Congress delegates the rulemaking authority to agencies to harness agency-specific expertise and experiences. Creating diverse, highly skilled teams ensures that regulations are developed in a rigorous manner that leverages the team members' expertise, perspective, and functions. The role of management is to help build such teams, support them, and remove roadblocks. Teams should be "whole" in the sense of having the skills and resources required to complete their mission.

5.2. Clearly communicate the desired outcome and map the business process to understand the required way of working process.

Teams should identify their "north star." What are they trying to achieve? What benefits do they hope to create? Agile teams must have a clear set of goals with the understanding that the team can adjust desired outcomes over time as new information is gathered. An effective business process diagram can identify what actions are to be completed, when they are due, and who will complete each task. Ways of Working (WoW) include the practices and processes followed throughout the team's life cycle. Creating a picture of the overall process from the beginning and then updating it as it evolves will help streamline both the agency's and the team's work.

5.3. Manage and improve processes based on lessons learned while remaining flexible and responsive to the team.

Typically, the people doing the work are in the strongest position to determine how their work should be done. Ideally, teams should be self-managing. Leaders should provide guidance and the resources they need to succeed and to help eliminate roadblocks and hindrances. Situations will change, the people involved will change, and their understanding of what needs to be done will evolve. As a result, teams should regularly reflect on how they can improve their WoW and then make needed changes. This reflection can take place as a formal retrospective or as an informal appraisal of the process. This iterative process allows for nonvalue-added steps to be eliminated over time.

6. Make the agency's work and workflows visible as regulations are developed.

Transparency supports effective governance and facilitates collaboration by enabling all participants to see what others are currently working on. Effective teams make their work visible to their key stakeholders to communicate their status. They make their workflow visible so that everyone knows how everyone else is working.

Key questions for agencies to consider:

- What public dashboards can be created to ensure that the public knows where we are in the regulatory development process?
- How do we communicate our regulatory agenda, our working process, and any changes to the substance and timeline of proposed regulations?
- What recommendations does our agency have for improving the website, regulations.gov, and increasing the transparency of the regulatory design process?

PRACTICES

6.1. Use plain language.

Jargon-free language that clearly and thoroughly explains a regulation is essential. This helps the general public and stakeholders, including regulated entities themselves, fully understand the purpose of the regulation and what is required. Writing in plain language can also help agencies determine early on if the regulation addresses the right issues and how it could be interpreted or misinterpreted.

6.2. Adopt task boards to manage and communicate the work of the team.

Task boards are a visual representation of a team's completed work and work in progress. They are a great way for an agile team to manage its own work. Task boards can be a simple whiteboard with sticky notes or an online whiteboard tool. By showing what work has been completed and where the team is in the process, task boards provide real-time status reports that keep teams organized, promote transparency, and strengthen communications. Task boards can also identify key impediments and dependencies.

6.3. Regularly update an agency's regulatory agenda.

Using a public dashboard or status board can provide key information on an agency's overall regulatory agenda and the status of individual rules. Online dashboards can allow the public to provide comments, click on links for more details, and view agency metrics necessary for compliance. These online dashboards can be developed to supplement the Unified Agenda of Regulatory and Deregulatory Actions that is only published in the fall and spring of each year.

7. Automate processes and use modern technological tools.

Teams should apply existing and emerging technologies to streamline the work of developing and implementing regulations. These technologies cover the spectrum from "mundane" technologies such as chat and discussion forums to leading-edge artificial intelligence (AI) tools. Technology can increase transparency, increase the speed of regulatory development, allow an agency's staff to focus on higher-value work, and improve collaboration among all stakeholders.

Key questions for agencies to consider:

- How does our current technology allow us to engage with our stakeholders, and what changes should be implemented to allow for greater engagement?
- Can we adopt agile management tools, such as task/scrum boards, to capture and communicate the work and workflow of the team?
- Given the changes to workspaces over the last two years, have we made changes that increase automation (e.g., eSignatures, etc.) that should be kept in place once we return to an in-office setting?
- How can natural language processing and machine learning improve the quality of our regulatory process? For example, what benefits might come from using natural language processing and more advanced technology to sort and categorize public comments?

PRACTICES

7.1. Adopt Artificial Intelligence-based tools such as natural language processing to quickly process large volumes of information and analyze evolving information.

The notice-and-comment period is an essential step in the regulatory process, but it can be burdensome for agencies to sift through thousands of comments by hand. With natural language processing, an agency can use technology to categorize comments, allowing for deduplication and grouping of similar comments based on semantics. Once grouped, these comments can be distributed to experts on the team to evaluate and consider as they revise the proposed regulation to respond to public concerns.

7.2. Adopt tools such as digital/eSignature technologies to support signoffs during the rule writing process and the resulting compliance process.

Simple digital tools like eSignature technology reduce administrative burdens, streamline compliance, and address potential inequities caused by required in-person signatures. They can also advance diversity, equity, inclusion, and accessibility. For example, individuals with disabilities or those without the ability to travel to brick-and-mortar agency locations can use digital tools to access or comply with regulatory requirements.

7.3. Invest in enterprise modernization strategies to replace or enhance existing, antiquated systems with modern technology.

We are now 2 decades into the 21st century, but much of the federal government IT infrastructure is based on 20th century solutions. Agencies face budgetary and procurement constraints that often prevent large-scale enterprise modernization updates. To the extent possible, agencies should prioritize the inclusion of technology that promotes agile regulation in their IT modernization budgets. Investing in new technology can provide new and essential functionality. Maximum agility requires up-to-date technology and continued investment for upgrades and innovation.

The National Archives and Records Administration's [Electronic Code of Federal Regulations](#) provides an up-to-date list of federal regulations and also allows users to see a regulation at two points in time, back to January 2017. Instead of waiting for the annual update to the Code of Federal Regulations (CFR), agencies can see daily updates to regulations across all subject areas.

7.4. Employ social-media platforms, where appropriate, to reach out to a broader audience.

Transparency, a hallmark of agile practices, can be increased by using social media platforms like Twitter and Facebook. Quick, short updates on process timelines, changes to draft regulations, or reminders to submit comments can easily increase transparency and public participation in the rulemaking process and improve regulations and compliance.

8. Conduct parallel processing of internal activities.

Within the roadmap of the Administrative Procedure Act (APA) for developing regulations, agencies have some flexibility to design and manage their internal processes and activities. Working various internal processes in parallel can speed up regulatory timelines, allow for real-time collaboration, and improve outcomes through iteration.

Key questions for agencies to consider:

- Are we required to complete our internal review, development, and evaluation activities sequentially, or do we complete activities sequentially out of habit?
- Can we do virtual or in-person collaboration internally “in real-time?”

PRACTICES

8.1. Identify where an agency has the discretion to conduct parallel processing of its internal activities.

The first step to implementing parallel processing is to fully understand an agency's regulatory design process. Identifying legal requirements clarifies the tasks and activities that must occur in a specific order or for a specified amount of time. The remaining discretionary tasks and activities can now be evaluated to determine the most efficient sequencing. It is imperative to receive buy-in from internal stakeholders such as an agency's Office of General Counsel and senior leaders during this step. Their support, along with those carrying out regulatory development, can include adequately resourcing agile teams to carry out parallel processing successfully.

8.2. Sequence steps to produce the best outcome most efficiently and effectively.

Consistent with the APA framework, agencies may find that they can use parallel processing techniques to manage internal development, review, and approval processes. Agile teams can collaborate across boundaries in real time, using communication tools that best suit the circumstance. For example, organizational units and functions responsible for different aspects of regulatory design and approval can send representatives to virtual or in-person meetings where the group collaborates on documents in real time and addresses issues of concern.

Nondependent activities can often be performed concurrently to optimize time and responsiveness. Such a simple change to traditional work processes can save significant time, minimize internal miscommunication, improve working relationships, and allow public needs to be met more effectively and efficiently.

In response to the COVID pandemic, the Food and Drug Administration [issued guidance](#) that allowed vaccine companies to use data from similar products to inform manufacturing decisions. This allowed companies to prepare for the large-scale manufacturing that would be required once vaccines received approval.

Continuous Learning

9. Foster continuous learning about regulatory impacts and internal processes.

The best way to improve effectiveness is to experiment with, and then adopt where appropriate, new ways of working. Agencies can use a strategy called "validated learning" to structure their experimentation with new ways of working and assess how effective they were. Being willing and able to experiment is critical to process-improvement efforts. Evaluating the regulatory process and the impact of regulations is necessary to further and more fully understand what worked well and what can be improved (either the regulations themselves or the processes for developing, implementing, and enforcing them).

Key questions for agencies to consider:

- How do we evaluate the effectiveness, efficiency, and equity impacts of existing regulations?
- How do we receive feedback on the impact of existing regulations?
 - What do we do with this information once it is received?
- Do we have metrics for assessing our agency's regulatory development process's effectiveness, efficiency, and equity? How can these metrics be improved?

PRACTICES

9.1. Collect feedback on current regulations to identify lessons learned and inform future development.

Agencies use Regulatory Impact Analyses (RIAs) for “significant regulatory actions” to determine whether they should regulate and how that regulation may positively or negatively impact those who are regulated (Executive Order No. 12866, 2011). While RIAs are vital tools for regulators at the outset of regulation development, they can be supplemented with retrospective analyses to foster continual learning and improvement. Administrations have often supported retrospective analyses to identify “rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned” (Executive Order No. 13563, 2011). These retrospective analyses can both identify issues with existing regulations and provide insights for regulatory development teams.

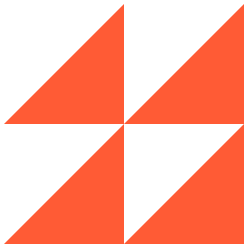
9.2. Create adaptive, iterative, and flexible assessment cycles.

Moving from “regulate and forget” to “adopt and learn” allows for continuous learning and improvement of new and existing regulations. Stakeholder engagement, regulatory impact assessments, and regular internal evaluations of team processes provide a complete picture of what did and did not work throughout the regulatory development life cycle. This cyclical process helps tailor regulations to meet the desired outcomes more effectively.

The Occupational Safety and Health Administration (OSHA) [Strategic Partnership Program](#) reaches out to unions, trade associations, employers, and employees in the interest in sharing best practices and improving safety outcomes. OSHA’s partnership program’s focus on end-user feedback provides continuous learning for the agency and those they regulate. OSHA brings the “customer” or, in this case, the business into its policy process. In theory, this allows for a more pragmatic approach to workplace safety as the business can identify and focus its resources and efforts on the most prevalent or dangerous workplace hazard.

9.3. Adopt assessment strategies such as objectives and key results or goal-question metric to drive improvement.

Objectives and key results ask what is to be achieved and what are the key results. Goal-question metric is the same basic idea, with the addition of “questions to ask” that identify how to determine success. Regardless of the strategy employed, agencies should set objectives early and start tracking progress by gathering data and making refinements over time as new information is learned.



Appendix A: Agency Examples of Agile Regulatory Practices

The Nuclear Regulatory Commission

Created as an independent agency by the US Congress in 1974, the US Nuclear Regulatory Commission (NRC) regulates the use of radioactive materials for beneficial civilian purposes while protecting people and the environment (Nuclear Regulatory Commission, 2022).

As NRC regulates commercial nuclear power plants and other uses of nuclear materials, it is dedicated to transparency and openness by providing stakeholders with regular opportunities to participate in the regulatory process before issuance of a license, construction permit, early site permit, design certification, or combined license (Nuclear Regulatory Commission, 2008). NRC uses agile tenets in the following ways:

- Holds meetings with the public or other external stakeholders both in the vicinity of nuclear facilities and at its headquarters and regional offices (Nuclear Regulatory Commission, 2008).
- Provides documents and correspondence related to licensing renewals, license applications, and inspection findings on its website (Nuclear Regulatory Commission, 2008).
- Issues press releases when it receives license applications and announces public meetings, opportunities for hearings, and other avenues for public involvement (Nuclear Regulatory Commission, 2008).
- Copies of key documents and notifications are sent to federal, state, local, and tribal authorities, published in the Federal Register, and made available electronically on the NRC website (Nuclear Regulatory Commission, 2008).

The Department of Health and Human Services

The Department of Health and Human Services (HHS) is a federal agency dedicated to improving Americans' health, safety, and welfare. Soon after the global COVID-19 pandemic hit the United States, healthcare workers had to shift from in-person appointments to virtual telehealth appointments with patients wherever possible to avoid the risk of spreading the virus. HHS had to quickly adapt their regulations to allow telehealth providers to use products like Zoom, Google Hangouts, Apple FaceTime, and Skype for patient visits to facilitate telehealth services (Health and Human Services, 2020). Previously, this would not have been compliant with Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. In March 2020, HHS's Office of Civil Rights provided the *Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, which waived specific HIPAA penalties for using these products (in good faith) (Health and Human Services, 2020).

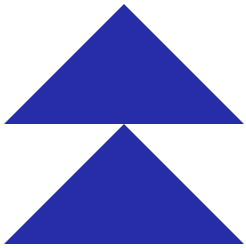
This flexibility allowed healthcare providers to continue providing patient services in the midst of office closures. HHS accompanied this notification of enforcement relaxation with clarification that included outlining the entities covered, the specific parts of HIPAA rules covered by the notification, and when the notification enforcement discretion would expire. Frequently asked

questions include outlining the entities covered, the specific parts of HIPAA rules covered by the notification, and when the notification of enforcement discretion would expire (Health and Human Services, 2020).

The United States Coast Guard

The United States Coast Guard (USCG)—a uniformed military service housed within the US Department of Homeland Security and part of the US Armed Forces—actively engages stakeholders during the regulation design phase by working with Federal Advisory Committees. Consistent with the Federal Advisory Committee Act, USCG has established committees of industry partners who provide input via a public process that it can use to shape regulations and policy decisions. For example, the National Towing Safety Advisory Committee (NTSAC) submits advice, reports, and recommendations to the Secretary of Homeland Security on rulemaking and other matters related to coastal waterway navigation, shallow-draft inland navigation, and towing safety (United States Coast Guard, n.d.). NTSAC's feedback has been vital in ensuring the USCG's regulations are up to date, effective, and fair.

USCG also has used innovative practices for regulatory design and internal processes. For example, the USCG's Office of Standards Evaluation and Development requires the creation of matrix teams who work through the life cycle of the rulemaking process together. At the initiation, the team is created with a minimum of six people; most groups include the project manager, a lawyer, a subject matter expert from the sponsor's office, an economist, an environmental specialist, and a technical writer. In addition, the members of these teams are treated as equals, meeting frequently and providing input at all stages of the regulatory process. The team is also encouraged to work with the legal office to update the legal structures to improve the process. Additionally, the environmental expert typically works in parallel with the legal and economic experts to maximize efficiency.



APPENDIX B: Individuals Contacted for this Study

While conducting this study, we received important input from group meetings with:

- Interagency Roundtable of the Administrative Conference of the United States
- Shared Services Leadership Coalition
- Agile Government Network

In addition, we conducted virtual interviews with the following individuals:

Steven Balla, Associate Professor of Political Science, Public Policy and Public Administration, and International Affairs, George Washington University; Co-Director, George Washington Regulatory Studies Center

Michael Blair, Project Management Division, United States Coast Guard

Maggie Colvin, Innovation Officer, Office of Innovation, Office of the Comptroller of the Currency

Soraya Correa, President & CEO, Soraya Correa & Associates, LLC

Joe Defee, Senior Vice President and Manager of the Advanced Systems Division Group, CACI International Inc

Roslyn Docktor, Vice President, Technology and Science Policy, IBM Government & Regulatory Affairs and Vice President, Middle East and Africa

Susan Dudley, Director, George Washington University Regulatory Studies Center

Allison Hester-Haddad, Special Counsel, Office of the Comptroller of the Currency

Virginia Huth, Assistant Deputy Commissioner for eRulemaking, Technology Transformation Services, General Services Administration

Stephen Laurence, Vice President of Software Engineering and Growth, CACI International Inc.

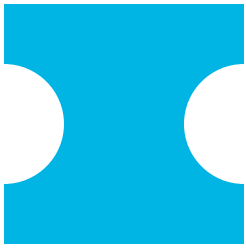
Catherine Sharkey, Professor, New York University School of Law

Rebecca Orban, Senior Attorney and Team Leader, Office of Regulations and Administrative Law, United States Coast Guard

Mitchell Plave, Special Counsel, Legislative & Regulatory Activities Division, Office of the Comptroller of the Currency

Paul Verkuil, Senior Fellow, Center for American Progress

Miriam Vincent, Web Manager, Office of the Federal Register, National Archives and Records Administration



APPENDIX C: Study Team and Expert Advisory Group Biographies

Study Team Members

Dr. Joseph P. Mitchell, III is Director of Strategic Initiatives & International Programs at the National Academy of Public Administration. He leads the Grand Challenges in Public Administration initiative, co-leads the Agile Government Center along with Academy Fellows from the IBM Center for the Business of Government, and advances cutting-edge thought leadership. He served at the General Services Administration to help set up the Office of Shared Solutions and Performance Improvement and built and led a team there to manage multi-functional and cross-agency projects and initiatives in support of the President's Management Agenda. From 2011 to 2017, he led and managed the Academy's organizational studies program. He serves on the National Science Foundation's Business and Operations Advisory Committee. He was named a Fed 100 awardee in 2022 for his contributions to improving the federal government. He holds a PhD from the Virginia Polytechnic Institute and State University, a Master of International Public Policy from the Johns Hopkins University School of Advanced International Studies, a Master of Public Administration from the University of North Carolina at Charlotte, and a BA in History from the University of North Carolina at Wilmington.

Kate Connor is a Senior Analyst at the Academy and has served on several studies, including work for the Agricultural Research Service, US Department of Commerce Office of Inspector General, and the Defense Nuclear Facilities Safety Board. Prior to joining the Academy, she served as an intern on the US Senate Committee on the Budget and taught high school social studies for several years before graduating from Georgetown University with a Master of Public Policy. Ms. Connor also holds a BA in History and Political Science and a Master of Arts in Teaching from the University of North Carolina at Chapel Hill.

Scott Ambler is a software engineer, consultant, and author. Mr. Ambler currently serves as a Senior Advisor, Vice President, and Chief Scientist for Disciplined Agile at the Project Management Institute. He is also an advisory board member with the Architectural Thinking Association, ScaleFree Inc., and SEMAT. Mr. Ambler has authored or coauthored 21 books, typically centered around topics such as the Disciplined Agile® Delivery tool kit, the Unified Process, and agile software development. Prior to joining PMI, Mr. Ambler held executive positions with the Disciplined Agile Institute and IBM. Mr. Ambler also holds a BS in Computer Science and an MA in Information Science from the University of Toronto.

Mark Fabian is the Business Lead for the Public Sector at the Project Management Institute. In the past, he served as Director of Federal Consulting at SD Solutions LLC, Vice President of Federal Consulting at the Ambit Group and as Partner of the Sales & Market Development at The EndGoal Group, Inc. Mr. Fabian previously worked as a Strategic Account Executive at CA Technologies.

Karen Holloway has served as the Project Management Institute's Lead Instructional Designer and Content Developer since January 2012. Since 2013, Ms. Holloway has researched and developed educational products focused on agile approaches to project management. Prior to joining PMI, Ms. Holloway was a senior healthcare risk analyst and educator for ECRI, where her research focused on patient safety and regulatory compliance in healthcare settings. Ms. Holloway has a MS in Education from California State University and a BA in Social Sciences from Thomas Edison State University.

James Higgins is a Senior Research Associate for Strategic Initiatives & International Programming at the National Academy of Public Administration. Mr. Higgins has previously worked on studies for the Bureau of Transportation Statistics, the United States Trade and Development Agency, and the project Increasing the Agility of the Federal Government. Prior to joining the Academy, Mr. Higgins interned with the Cohen Group and the Army War College; he also externed with the US Patent and Trademark Office. Mr. Higgins graduated with a BA in International Studies with a focus on Asia from Dickinson College and earned an MA in Global Policy with a focus on Security and Foreign Policy from the University of Maine School of Policy and International Affairs.

Jillian McGuffey is a Research Associate for Strategic Initiatives & International Programming at the National Academy of Public Administration. Ms. McGuffey realized she had a profound interest in working at the Academy when she interned there in the summer of 2020, where she contributed to studies for the Office of Space Commerce and the National Park Service. Ms. McGuffey previously interned with the US Census Bureau and the US Citizenship and Immigration Services. Ms. McGuffey graduated from the University of Maryland with a Master of Public Policy after earning a BA in Government and Politics with a minor in Creative Writing.

Expert Advisory Group Members

Edward DeSeve* is the Coordinator of the Agile Government Center at the National Academy of Public Administration and the Agile Visiting Fellow at the IBM Center for The Business of Government. Mr. DeSeve has served at all three levels of government and in the private sector during his illustrious career. At the federal level, he was responsible for implementing the \$800 billion American Recovery and Reinvestment Act as a Special Advisor to President Barack Obama. He was also Deputy Director for Management and Controller at the Office of Management and Budget and Chief Financial Officer of the Department of Housing and Urban Development. At the state and local levels, Mr. DeSeve was a Special Assistant to the Governor of the Commonwealth of Pennsylvania and Director of Finance for the City of Philadelphia. In the private sector, he was a managing director at Merrill Lynch Capital Markets and the founder and president of Public Financial Management, which is the nation's largest independent financial advisor to the government.

Michael Fitzpatrick* serves as Director of Strategy & Innovation at Google Global Affairs. He previously led Google's Regulatory Affairs Center of Excellence. Prior to joining Google, Mr. Fitzpatrick served for over 7 years as Head of Regulatory Advocacy at General Electric. During the Obama Administration, he served as Associate Administrator in the White House's Office of Information and Regulatory Affairs. Mr. Fitzpatrick also held several roles within the Obama transition team. He is a member of the American Law Institute, a Senior Fellow of the Administrative Conference of the United States, and a member of the American Bar Association Administrative Law Section's Governing Council. Mr. Fitzpatrick was a partner at Akin Gump LLP. He was also a law clerk for the Office of Judge William Norris in the US Court of Appeals, Ninth Circuit.

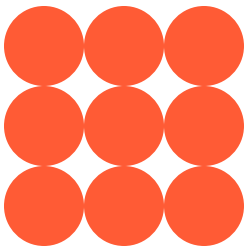
Dr. Suzanne Logan* is self-employed and serving government as a member of the Board of Visitors at the National Defense University and as a member of the Board of Trustees at the U.S. Coast Guard Academy. Dr. Logan formerly served as the Deputy Associate Director at Human Resources Solutions, the Executive Director of the Center for Leadership Development, and the Director of the Federal Executive Institute at the US Office of Personnel Management. Prior to these roles, Dr. Logan was a Chief Academic Officer for the US Air Force Spaatz Center for Officer Education, a Deputy Commandant for Academic Affairs, and the Senior Education Advisor to the Air War College Commandant at the USAF Air University. She was also the former Vice Provost and Associate Vice Provost at Texas Tech University. Dr. Logan has held additional leadership positions in the private sector and in non-profit organizations.

Anne Joseph O'Connell,* a lawyer and social scientist, is the Adelbert H. Sweet Professor of Law at Stanford University, where her research and teaching focuses on administrative law and the federal bureaucracy. Outside of the law school, she is a contributor to the Center on Regulation and Markets at the Brookings Institution and an appointed senior fellow of the Administrative Conference of the United States, an independent federal agency dedicated to improving regulatory procedures. Before joining the Stanford faculty in 2018, she taught at Berkeley Law as the George Johnson Professor of Law.

Anne Rung* is Senior Vice President for Public Sector at Varis, a procurement technology company. Prior to joining Varis, Ms. Rung worked as Director, Public Sector, for Amazon Business. She is the former US Chief Acquisition Officer for the Office of Management and Budget, Chief Acquisition Officer at the General Services Administration, and Senior Director of Administration at the US Department of Commerce. Ms. Rung has also served as Deputy Secretary for Procurement & Administration at the Pennsylvania Department of General Services.

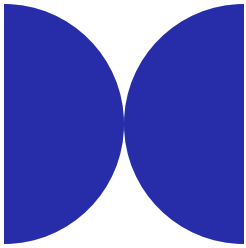
Dan Sokolov* is a Deputy Associate Director at CFPB. He formerly served in several roles at the Department of Treasury including Counselor to the Deputy Secretary, Senior Counselor to the Assistant Secretary for Financial Institutions, Senior Advisor to the General Counsel, and Attorney Advisor. He also has served as Counsel for the Board of Governors of the Federal Reserve System and an Associate at Williams & Connolly. Prior to that, he worked as a judicial law clerk for the United States District Court (Massachusetts).

*Academy Fellow



Appendix D: Agile Regulation Tenet and Practice Checklist

Category	Tenet	Practice	Status
Public Need	Understand Changing External Conditions	Adopt an agile mindset	
		Conduct environmental scans	
		Remain culturally sensitive	
Regulatory Design	Think Comprehensively to Meet Goals	Explore regulatory interventions	
		Pilot regulations	
		Incorporate flexibility	
	Incorporate Innovative Methods to Address Needs	Harness digital technologies	
		Enable greater experimentation, testing, and trials	
		Provide user-friendly compliance mechanisms	
	Collaborate During Regulatory Development	Engage stakeholders in the design	
		Strengthen collaboration and cooperation across departments and agencies	
Internal Processes	Construct Small Yet Inclusive Teams	Develop cross-functional teams	
		Communicate desired outcomes and map the process	
		Manage and improve processes through lessons learned	
	Make Work and Workflows Visible	Use plain language	
		Adopt task boards	
		Regularly update the regulatory agenda	
	Automate Processes and Use Technology	Adopt AI-based tools	
		Adopt digital/eSignature technologies	
		Invest in enterprise modernization strategies	
		Employ social-media platforms	
	Conduct Parallel Processing of Internal Activities	Identify parallel processing opportunities	
		Sequence steps	
Continuous Learning	Foster Continuous Learning about Regulatory Impacts and Internal Processes	Collect feedback on current regulations	
		Create adaptive, iterative, and flexible assessment cycles	
		Adopt assessment strategies	



References

- Society for Human Resource Management. (n.d.). *What are the basics of environmental scanning as part of the strategic planning process?* Retrieved from <https://www.shrm.org/resourcesandtools/tools-and-samples/hr-qa/pages/basics-of-environmental-scanning.aspx>
- Organization for Economic Cooperation and Development. (2006). *Alternatives to traditional regulation*. Retrieved from <https://www.oecd.org/gov/regulatory-policy/42245468.pdf#page=7>
- Environmental Protection Agency. (n.d) *Economic incentives*. Retrieved from <https://www.epa.gov/environmental-economics/economic-incentives>
- World Economic Form. (2020). *Agile regulation for the fourth Industrial Revolution: A toolkit for regulators*. Retrieved from https://www3.weforum.org/docs/WEF_Agile_Regulation_for_the_Fourth_Industrial_Revolution_2020.pdf
- Fernandez Lynch, H., Dickert, N. W., Zettler, P. J., Joffe, S., & Largent, E. A. (2020). Regulatory flexibility for COVID-19 research. *Journal of Law and the Biosciences*, 7(1):2-8. Retrieved from <https://doi.org/10.1093/jlb/l5aa057>
- World Economic Forum. *Toolkit for Regulators*.
- Executive Order No. 13563, 76 FR 3821 (January 21, 2011). Retrieved from <https://obamawhitehouse.archives.gov/the-press-office/2011/01/18/executive-order-13563-improving-regulation-and-regulatory-review>
- Executive Order No. 12866, 58 FR 51735 (October 4, 1993). Retrieved from <https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf>
- Nuclear Regulatory Commission. (January 25, 2022) *About NRC*. Retrieved from <https://www.nrc.gov/about-nrc.html?msclkid=464264facfd511ec8632383a6e7bf9f7>
- Nuclear Regulatory Commission. *Strategic plan fiscal years 2008-2013*. (2008). Retrieved from <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1614/v4/sr1614v4.pdf#page=20>
- Department of Health and Human Services, 45 CFR Parts 160 and 164. (2020). *Notification of enforcement discretion for telehealth remote communications during the COVID-19 nationwide public health emergency*. Retrieved from <https://www.govinfo.gov/content/pkg/FR-2020-04-21/pdf/2020-08416.pdf>
- United States Coast Guard. (n.d.) *National towing safety advisory committee*. Retrieved from <https://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/Commercial-Regulations-standards-CG-5PS/Office-of-Operating-and-Environmental-Standards/vfos/TSAC/msclkid/0d3e5a55c28011ecb1bd1befef8edd77/>



PMI.org

