

EPA's Action Development Process

Guidance for EPA Staff on Developing Quality Actions



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Acronyms Used Throughout This Document

AA: Assistant (or Associate) Administrator
RA: Regional Administrator
ABP: Analytic Blueprint
ADP: Action Development Process
ANPRM: Advance Notice of Proposed Rulemaking
AO: Administrator's Office
APA: Administrative Procedure Act
CCP: Courtesy Copy Policy
CFR: Code of Federal Regulations
CPRC: Conflict Prevention and Resolution Center
CRA: Congressional Review Act
DAA/DRA: Deputy Assistant Administrator/Deputy Regional Administrator
DABP: Detailed Analytic Blueprint
DFRM: Direct Final Rulemaking
EFSC: Economic Forum Steering Committee
EO: Executive Order
EPA: Environmental Protection Agency
FACA: Federal Advisory Committee Act
FAR: Final Agency Review
FDMS: Federal Docket Management System
FR: *Federal Register*
GAO: Government Accountability Office
IAC: Innovation Action Council
ICR: Information Collection Request
NCEE: National Center for Environmental Economics
NoA: Notice of Availability
NODA: Notice of Data Availability
NPRM: Notice of Proposed Rulemaking
NRA: Negotiated Rulemaking Act
NTTAA: National Technology Transfer & Advancement Act
OAR: Office of Air and Radiation

OCHPEE: Office of Children's Health Protection and Environmental Education
OCIR: Office of Congressional and Intergovernmental Relations
OCSPP: Office of Chemical Safety and Pollution Prevention
OD: Office Director
OECA: Office of Enforcement and Compliance Assurance
OEI: Office of Environmental Information
OEJ: Office of Environmental Justice
OEX: Office of the Executive Secretariat
OFR: Office of *Federal Register*
OGC: Office of General Counsel
OIRA: OMB's Office of Information and Regulatory Affairs
OMB: Office of Management and Budget
OPA: Office of Public Affairs
OP: Office of Policy
ORC: Office of Regional Counsel
ORD: Office of Research and Development
ORPM: Office of Regulatory Policy and Management
OSWER: Office of Solid Waste and Emergency Response
OW: Office of Water
PABP: Preliminary Analytic Blueprint
PRA: Paperwork Reduction Act
PRAD: Policy and Regulatory Analysis Division
QIC: Quality and Information Council
RAPIDS: Rule and Policy Information Development System
RFA: Regulatory Flexibility Act
RIA: Regulatory Impact Analysis
RIN: Regulation Identifier Number
RMD: Regulatory Management Division
ROCIS: Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated
RPC: Regulatory Policy Council
RPO: Regulatory Policy Officer
RRC: Regional Regulatory Contact
RSC: Regulatory Steering Committee
SAN: Start Action Number
SBO: Senior Budget Officer
SBREFA: Small Business Regulatory Enforcement Fairness Act
SNPRM: Supplemental Notice of Proposed Rulemaking
S&EO: Statutes and Executive Orders
SPC: Senior Policy Council
UMRA: Unfunded Mandates Reform Act

Introduction to this Guidance

This section introduces the reader to the guidance’s purpose and use, as well as identifying what is not covered in the guidance.

What is the Purpose of This Guidance?

The purpose of this document is to ensure that Agency actions are of consistently high quality, involve senior managers early in the development process, are supported with strong analysis, and are developed via an open process. This document lays out the Action Development Process (ADP) and tells you where to get additional information and guidance as you develop Agency actions.

How is “Agency Action” Defined and Used throughout This Guidance?

Agency actions include certain rules, policy statements, risk assessments, guidance documents, models that may be used in future rulemakings, reports to Congress that go beyond narrow budgetary issues (see Action Aid 15), certain other regulatory documents (e.g., some petition responses), and regulatory-related strategies. In this document, the terms “action” and “Agency action” are used in their broadest sense; they are not limited to their statutory definitions.

The Administrative Procedure Act defines a “rule” as “the whole or a part of an Agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy ... (5 CFR 1.551(4)).” “Rulemaking” is defined as an Agency process for formulating, amending, or repealing a rule. (5 CFR 1.551(5)).” The terms “rule,” “rulemaking,” and “regulation” are used synonymously through this guidance.

How are the Terms “You,” “Manager,” “Senior Management,” and “Lead Program Office” used Throughout This Guidance?

“You” is the term used for EPA staff who are assigned to work on some aspect of an action development project. The term “manager” refers to the manager of an EPA staff member who is assigned to participate in the development of an action, either as a workgroup chair or as a workgroup participant. “Senior management” usually refers to AA/DAA/RA/DRA-level managers who have EPA staff that are assigned to participate in the development of an EPA action. “Lead office” or “lead program” usually refers to the office that has primary responsibility for the development of an EPA action.

What is Not Covered in This Guidance?

This guidance is intended to provide a complete guide to the ADP, but makes no attempt to comprehensively address topics which, while they may be necessary to develop a quality action, are thoroughly addressed in other Agency guidance, such as:

- Specific guidance on the various Statutes and Executive Orders (S&EO) that govern rulemaking (e.g., Children’s Health, Environmental Justice, Federalism, etc.) Please refer to the ADP Library for this guidance at <http://intranet.epa.gov/adplibrary>.
- Establishing and populating a public docket in the Federal Docket Management System (FDMS). For this guidance, please refer to the Office of Environmental Information at <http://intranet.epa.gov/fdmsinfo/index.html> and “Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers” at the ADP Library at <http://intranet.epa.gov/adplibrary>.
- Preparing a detailed economic analysis. Please refer to the National Center for Environmental Economics (NCEE) at <http://yosemite.epa.gov/ee/epa/eed.nsf/Webpages/Guidelines.html>.
- Preparing a risk assessment. Please refer to the National Center for Environmental Assessment’s (NCEE) portal at <http://www.epa.gov/risk>.
- Performing a scientific analysis with peer review. Please refer to the Office of the Science Advisor in the Office of Research and Development at <http://www.epa.gov/osa/spc/2peerrev.htm>.
- Developing and maintaining information collections. Please refer to the Office of Environmental Information, Office of Information Collection at <http://intranet.epa.gov/icrintra/>.
- Recordkeeping and document storage requirements. Please refer to <http://www.epa.gov/records/>. Similarly, this guidance does not cover other Agency processes, such as:

- Agency's Directives Clearance Review Process, which addresses procedures for developing Delegations of Authority, Agency Manuals, EPA Orders, etc. More information on these and other processes is available on the Agency intranet at: <http://intranet.epa.gov/ohr/rmpolicy/>.
- Agency's Product Review process, which governs the development of communication materials (e.g., booklets, fact sheets, brochures, guidance documents, etc.) More information on the product review process is available at <http://www.epa.gov/productreview/faqs.html>.

Overview of EPA's Action Development Process

This section identifies the ADP's purpose, stages, participants, primary users, and available resources.

What is the Purpose of EPA's Action Development Process (ADP)?

Actions covered by the ADP represent the Agency's public face. The Agency's public documents form the basis of its reputation among its external stakeholders: regulated entities, State and local governments, Congress, environmental groups, and the public at large.

EPA is one of the most active regulatory agencies in the Federal government. A substantial proportion of ADP actions are regulatory in nature or directly related to a regulatory program. Thus, developing environmental regulations is one of the Agency's principal tasks. In fact, much of EPA's environmental success and organizational credibility is directly linked to the quality of this work. Therefore, it is important for EPA's actions to be based on sound scientific, economic, legal, and policy analyses and for the Agency to involve the public throughout development. Through the ADP, the Agency aligns its actions with its stated goals made in EPA's strategic plan, budget requests, and commitments under the Government Performance and Results Act.

As an EPA rulewriter, or as the manager of an EPA rulewriter, you assume an important professional role as a public servant. The gravity and scope of responsibility borne by Federal rule writers is too often underestimated. Regulations are one of the most important sources of law in the United States. Congress enacts statutes that provide the legal framework. The Executive Branch, through the regulatory process, establishes the substantive and procedural details and promulgates the enforceable requirements of the law.

Due to the seriousness of these tasks, over 25 years ago, EPA designed a comprehensive process for developing quality actions; this process is called the Action Development Process. At various intervals, these procedures have been reviewed, reinforced, and strengthened by the Agency's senior management and professional staff. With each effort, the Agency has sought to encourage better planning and analysis, promote improved collaboration among

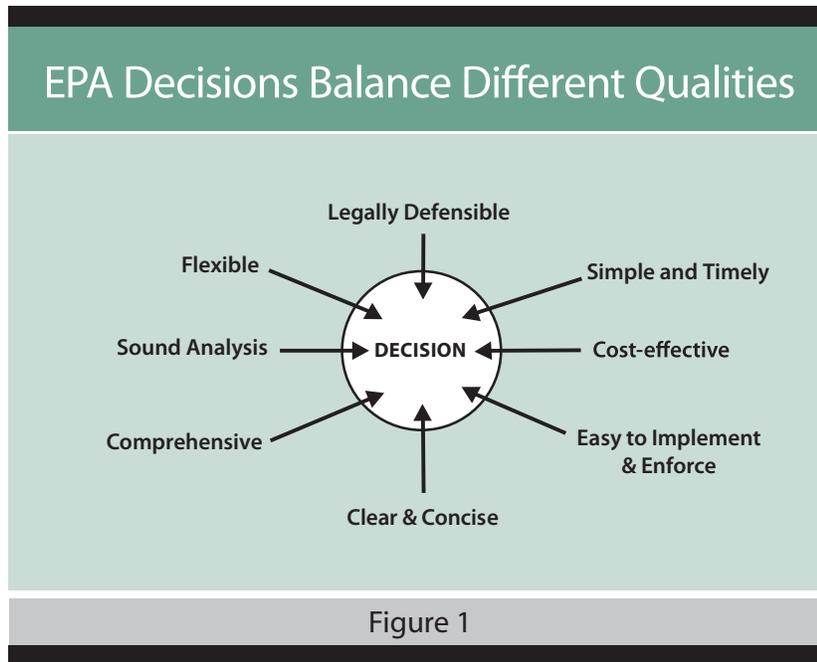
offices and agencies, and foster a creative problem-solving environment where EPA can develop cost-effective and scientifically sound solutions to our environmental problems.

The ADP relies on a multi-disciplinary, collaborative, cross-office and cross-media approach to ensure that a variety of perspectives are incorporated and expertise from EPA offices is encouraged throughout the process. EPA's Office of Policy (OP) coordinates the ADP and serves as liaison to other agencies when they become involved in the ADP (e.g., when the Office of Management and Budget (OMB) reviews an EPA action). The ADP is designed to bring together a diverse group of professionals to develop and deliver quality actions that are based in sound science, promote economic efficiency, and accelerate the progress of protecting human health and the environment. EPA has a long, impressive history of producing superior actions, and the ADP is the mechanism by which we can ensure this legacy is carried into the future.

The ADP is a method for producing quality actions. It serves as a comprehensive framework to ensure the use of quality information to support our actions and an open process. It also makes certain that scientific, economic, and policy issues are adequately addressed at the appropriate stages in action development. It provides opportunities for senior management to get involved early and to provide guidance and direction to staff at key points in the process.

EPA prepares and releases hundreds of actions a year that define the technical and operational details of environmental programs. Some actions are fairly narrow and routine, while others may be broad and complex, but all must be of consistently high quality. Quality actions have the following common characteristics; they:

- Achieve environmental objectives cost-effectively.
- Are consistent with legal requirements, executive orders, directives, Agency guidance, and national policies.
- Reflect EPA-wide involvement as appropriate.
- Reflect appropriate solicitation and consideration of views outside EPA.
- Consider multimedia effects.
- Consider pollution prevention principles and innovative alternatives during the investigative and development process.
- Are based on sound economic, scientific, legal, policy, and technical analyses.
- Can be efficiently implemented and effectively enforced.
- Are clear, concise and written in plain language.
- Are timely.



While all of these are important characteristics to produce quality actions, we must recognize that we do not always have the resources to maximize all of these characteristics in every action. Recognizing that tradeoffs are often necessary and frequently give rise to issues needing resolution, the ADP calls upon the Agency’s managers to:

- Give early consideration to the full range of characteristics.
- Ensure input from internal and external stakeholders on any tradeoffs necessary.
- Provide early guidance on what tradeoffs, if any, are appropriate.
- Be explicit about any tradeoffs made.

In cases where tradeoffs among the quality characteristics are necessary, lead AAs/RAs are responsible for achieving a balance that results in quality actions (see Figure 1).

It is important to recognize that the ADP, although presented here as a step-by-step guide, is not intended to be a rigid process. Flexibility is often appropriate during the application of the ADP when developing a quality action and should be worked out among the workgroup and lead AA/RA in consultation with OP.

What are the Five Key Elements of the ADP?

1. It includes steps for planning sound scientific and economic analyses to support the action, including peer review, when necessary.

EPA’s actions often address complex environmental problems. To do this effectively, EPA’s decisions should be based on sound science, robust economic analysis, and quality research.

2. It includes steps for developing and selecting regulatory and non-regulatory options based on relevant scientific, economic, and policy analyses.

EPA often has a range of options for addressing and solving environmental problems. In order to choose the best possible option, EPA looks at different aspects of an action, legal, scientific, social, public health, economic, and environmental, and takes them into account when developing the action. Strong analysis in these areas allows EPA to develop options for the action and then choose the best one based on relevant factors.

3. It calls upon affected Headquarters and Regional managers to get involved early in developing an action and stay involved until the final action is completed.

Actions must be developed with appropriate management involvement to be successful. This involvement ensures that actions fully reflect EPA's priorities and that significant issues are raised early and resolved efficiently. Investing management time early in the process saves time and work in the long run. Management provides guidance, addresses issues, guides development of the action, selects preferred options, and approves the final product throughout the ADP.

4. It ensures active and appropriate cross-Agency participation.

The ADP relies on collaborative and collegial involvement across the Agency to ensure actions are discussed and developed using all of the available and appropriate Agency expertise.

5. It encourages appropriate and meaningful consultation with external stakeholders in the process through substantive consultative procedures.

In order to develop quality actions that can be implemented, the ADP encourages you to involve State, Tribal, and local partners, regulated entities, environmental groups, and other concerned individuals at appropriate points during the process. EPA's Public Involvement Policy (PIP) encourages managers and staff to provide opportunities for public involvement above and beyond the minimum requirements. However, such involvement does not replace internal Agency deliberations. Moreover, the ADP facilitates consultation with other Federal agencies via the interagency review process defined in Executive Order (EO) 12866.

Who Needs to Know About the ADP?

All EPA staff and managers who work on Agency actions are responsible for working together to produce quality actions. They should be familiar with the ADP, this guidance, and be aware of the available resources related to the ADP.

■ EPA managers

Managers provide policy direction and ensure the integrity of the process. Therefore, they should be familiar with their role in the ADP and with the statutes, Executive Orders (EOs), and Agency guidance, policies, and procedures that apply to action development.

They are also relied upon to provide direction, whether as a manager of the lead office or, as a manager of a workgroup member, on policy approaches and activities fundamentally related to action development (e.g., consultation, research, analysis, public meetings, and/or resource investment).

- **EPA staff who develop actions**

It is important that you be familiar with the ADP, your role and responsibilities under the ADP, and any related laws or EOs and Agency guidance, policies, and procedures that apply to actions being developed. You should use the ADP and follow the applicable steps to ensure development of quality regulatory and non-regulatory actions.

What are the Five Major Stages of the ADP?

Stage 1. Tiering the Action and Obtaining Commencement Approval

Prior to initiating substantive development activities, the lead office prepares and submits a tiering form describing the new action. This information is used (1) to solicit the approval of the Agency's Regulatory Policy Officer (RPO) to proceed and (2) to assign the action to one of three tiers based on the nature of the anticipated issues and the level of cross-Agency interactions needed to ensure a quality action. The first process is called "commencement approval." The second is called "tiering."

The commencement approval and tiering processes should be initiated as soon as a program knows that it may need to develop some type of action on an issue, or as early in the process as possible. For additional information about this process, visit the ADP Library at <http://intranet.epa.gov/adplibrary>

Stage 2. Developing the Proposed Rule or Draft Action

Once commencement and tiering have been approved by the RPO and OP/AA, respectively, you use a standard process for the assigned tier to develop the proposed rule or draft action. The number of steps and level of management approval varies by tier.

Stage 3. Requesting OMB Review (if necessary) for Proposed (and Final) Actions

EO 12866 requires EPA to work with the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) to determine in advance which actions will be reviewed by OMB. If OMB review is necessary, the Agency must submit a regulatory package to OMB and address OMB's comments. All actions requiring interagency review are transmitted by OP via OMB's Regulatory Information Service Center and Office of Information and Regulatory Affairs Consolidated (ROCIS) database. The ROCIS database accepts agency submissions for OMB review, as defined by EO 12866. These documents are also displayed on OMB's RegInfo.gov website, thus allowing the public to see which actions are under review.

Stage 4. Requesting Signature, Publishing an Action in the *Federal Register*, and Soliciting and Accepting Public Comment

After an action is developed, there are still several tasks you should complete before it can be published, or otherwise released by the Agency. Depending on the type of action, these steps may include ensuring the docket is complete, requesting the signature of the proper Agency official, publishing an action in the *Federal Register* (FR), if necessary, and soliciting and accepting public comment (refer to “Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers”, visit the ADP Library at <http://intranet.epa.gov/adplibrary>). Most regulatory actions are signed by the Administrator unless that authority is placed with someone else by law or regulation, or otherwise delegated by the Administrator.

Stage 5. Developing the Final Action and Ensuring Congressional Review

After public comments have been received and considered, the workgroup should recommend any changes to the proposal and senior management decides the approach the Agency will take for the final action. This will likely require repeating some, if not all, of the steps in the process for developing the proposed action. The final step in this process is submitting final rules to the FR for publication and to Congress and the Government Accountability Office (GAO) under the Congressional Review Act (CRA) (available on the ADP Library at <http://intranet.epa.gov/adplibrary>) or the Courtesy Copy Policy (CCP); see Action Aid 13).

What are the Products of a Quality Action?

Workgroups using the ADP generally produce a number of basic documents along the way. The following documents are typically required for a Tier 1 or Tier 2 action. The list is somewhat shorter for Tier 3 actions, and non-regulatory actions will vary further based on type and prominence. The list includes:

- Tiering Form.
- Preliminary Analytic Blueprint (PABP).
- Early Guidance Briefing Package.
- Early Guidance Memorandum.
- Detailed Analytic Blueprint (DABP).
- Options Selection Briefing Package.
- Draft action (e.g., rule text, report to Congress, policy or guidance).
 - For rules, draft preamble addressing applicable S&EOs.
 - For rules, draft economic and scientific supporting analysis (as necessary).
- Action Memorandum.
- Communications Plan, coordinated with the Office of Public Affairs (OPA).
- Information Collection Request (ICR), if necessary, coordinated with the Office of Environmental Information (OEI).

The documents listed above, as well as other forms and documents that may be needed, are referenced throughout this guidance with added information about where to find specific instructions for preparing them.

Who is Involved in the ADP?

During a typical action development project, the Agency's Action Development Workgroup for the particular project is involved in the primary day-to-day activity.

Action Development Workgroup

The Action Development Workgroup includes the Workgroup Chair (representing the lead office), core office representatives for all Tier 1 and 2 actions (discussed below), representatives of other interested Offices or Regions, and for economically significant rules, an Economics Subgroup. As part of the tiering process, workgroups are formally chartered and workgroup representatives are assigned to the groups. Workgroups are sometimes called "teams" for Tier 3 actions, but in this document the term "workgroup" is used to refer to individuals working together to develop an action. Workgroups are responsible for working together on:

- Preparing planning documents for the action.
- Obtaining appropriate management guidance.
- Collecting data, consulting with external constituencies, conducting analyses, and developing options.
- Complying with any applicable laws and EOs, and considering relevant guidance documents that govern action development.
- Preparing the action, e.g., preamble and rule, report to Congress, or significant policy or guidance document, and supporting documents.

Core Offices

The core offices are the Office of General Counsel (OGC), the Office of Policy (OP), the Office of Enforcement and Compliance Assurance (OECA), and the Office of Research and Development (ORD). Core offices should have a representative on all Tier 1 and 2 workgroups. Their functions include assuring that appropriate options are considered and that actions are based on sound legal, policy, economic, and scientific analyses.

- **Office of General Counsel**

OGC's Cross-Cutting Issues Law Office facilitates the assignment of an OGC workgroup member to every Tier 1 and 2 workgroup and many Tier 3 workgroups to participate in the development of Agency actions.

Note:

A Core office may opt out of a Tier 1 or 2 action if there appears to be no relevant issues for that office (e.g., no science issues, so ORD could choose not to participate). However, this option must be exercised explicitly during the tiering process and periodic check-in is expected to confirm that new relevant issues haven't arisen.

The OGC attorney assigned to the workgroup provides legal and, where appropriate, policy advice to the workgroup and EPA managers. The OGC attorney also ensures that decision makers are well informed about available regulatory options and associated legal issues.

■ Office of Policy

OP is involved in action development in many ways (discussed in more detail below), but in the context of typical workgroup activities, two divisions in OP's Office of Regulatory Policy and Management (ORPM) are particularly active. ORPM's Office of Policy and Regulatory Analysis Division (PRAD) assigns a workgroup member to participate in virtually all tiered actions (including Tier 3 actions) to generally serve as OP's primary point of contact and provide policy analysis, advice, and cross-media perspective. ORPM's Regulatory Management Division (RMD) assigns a Desk Officer to each program office to serve as the point of contact and resource regarding all management and procedural aspects of the ADP related activities. Furthermore, RMD transmits all documents to OMB for interagency review via OMB's ROCIS database.

■ Office of Enforcement and Compliance Assurance

OECA assigns a workgroup member to all Tier 1 and 2 actions when necessary to ensure that actions are clear and concise, that compliance measures can be understood and that final actions can be enforced.

■ Office of Research and Development

ORD assigns a workgroup member to all Tier 1 and 2 actions, in addition to providing scientific expertise to all actions that have science issues. ORD is a resource for, and a steward of, sound science in Agency decisions. ORD ensures that science is considered at all points in the decision-making process.

How is the ADP Managed?

The ADP's management structure reflects its central relationship to the success of the Agency's mission. A senior management council provides overarching ADP policy and direction, a mid-level committee serves as a vital communication and implementation link, and OP staff manages the day-to-day operations and information systems that underpin the whole process. The management structure includes:

- Regulatory Policy Officer.
- Regulatory Steering Committee.
- OP's Office of Regulatory Policy and Management.
 - Regulatory Management Division.
 - Policy and Regulatory Analysis Division.

Regulatory Policy Officer (RPO)

The Regulatory Policy Officer (RPO), who is also the AA for OP, is the primary decision-maker for the ADP. The RPO engages with OMB and other Federal Agencies on regulatory matters and manages the interpretation and implementation of the main executive orders and statutes that apply to the ADP.

Regulatory Steering Committee (RSC)

The Regulatory Steering Committee (RSC) is a standing body with representation from each Assistant Administrator, the General Counsel, and each Region, as well as representatives from certain advocacy offices (e.g., OCHPEE and OEJ). It is the primary mechanism for coordinating, integrating, and carrying out the operational details of the ADP. The RSC meets regularly to:

- Oversee the ADP.
- Develop related guidance and training materials.
- Implement the monthly tiering process.
- Monitor the progress of action development workgroups (especially regarding cross-media or inter-office problem-solving).
- Ensure that significant issues are resolved or elevated to the Regulatory Policy Council.

The RSC is chaired by the Director of the Regulatory Management Division (RMD) in OP's Office of Regulatory Policy and Management.

In addition to their role as members of the RSC, these representatives play an important role within their offices (this may differ depending on each program office). They typically serve as a first-line information resource for staff in their offices working on action development; direct the flow of documents into and through the ADP's review systems (including early guidance, analytic blueprint, options selection, FAR and FR activities); serve as their Assistant Administrator's liaison with OMB; and direct their program's review of other offices' action development activities. This list does not cover all responsibilities of RSC representatives for any particular office. Their responsibilities will vary by program. A list of RSC representatives can be found at the ADP Library at <http://intranet.epa.gov/adplibrary>

Office of Regulatory Policy and Management (ORPM)

The Office of Regulatory Policy and Management (ORPM) is responsible for ensuring that EPA uses the most appropriate analytic information to determine regulatory policy and serves as the liaison to other Federal Agencies for all actions. ORPM also manages the regulatory infrastructure, and analyzes priority and cross-media regulatory and policy actions. To accomplish this, ORPM works with program offices as early as possible in the regulatory and policy development processes. Its goal is to increase the range of regulatory and policy options considered in decision-making, incorporate input from the Agency's consultations with advisory groups, State, local and Tribal governments, and other external stakeholders;

and to strengthen the quality and consistency of regulations and other significant non-regulatory decisions. ORPM's Director serves as the Agency's Small Business Advocacy Chair to ensure EPA's compliance with all aspects of the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (RFA/SBREFA).

ORPM's staff in RMD and PRAD are involved in numerous facets of the ADP beyond the typical workgroup process. ORPM's staff is tasked with representing OP's AA, who among other things serves as the Administrator's chief policy advisor, OMB liaison, Federalism Official, Economics Advisor, and overall regulatory manager. ORPM staff participate to some extent on all ADP workgroups, but when the workgroup concludes its work at a Final Agency Review (FAR) meeting, ORPM's work on the draft document is far from over. ORPM goes on to receive, review, and transmit action packages when a program submits the package for OMB review, the Administrator's signature, or publication in the *Federal Register*. ORPM ensures, on behalf of the Administrator, that each action package is complete and ready in all respects for signature and/or publication.

Regulatory Management Division (RMD)

RMD's goal is to protect EPA's investment in regulation and policy-making by ensuring effective flexible administration of the many procedural requirements that govern rulemaking by improving action development tools for Agency staff and by earning public respect through sensible advocacy for small entities subject to environmental regulation. Specifically, RMD:

- Manages the Agency's ADP.
- Develops and provides training to Agency management and staff at Headquarters and in the Regions on regulation development and the ADP.
- Maintains liaison with the regulatory and information management offices within other Federal agencies (e.g., the Office of the *Federal Register*, GAO, etc.), as well as with OMB for administration of Executive Order 12866.
- Provides support to the Agency's Small Business Advocacy Chair in administering the requirements of the RFA/SBREFA.
- Chairs and staffs the RSC.
- Maintains RAPIDS, the database supporting the ADP and the ADP Library website (<http://www.epa.gov/adplibrary>).
- Maintains an online overview of laws related to EPA and general regulatory information. See the Laws and Regulations website <http://www.epa.gov/lawregs>) and the Rulemaking Gateway (<http://www.epa.gov/rulemaking>).

Policy and Regulatory Analysis Division (PRAD)

PRAD participates in workgroup development of Agency actions to make certain that decision processes are invested with high-quality and timely information. PRAD ensures that appropriate consideration is given to all relevant scientific, economic, and policy factors and that an appropriate range of alternatives is considered to achieve the best overall environmental results. The Division's responsibilities are to:

- Participate in action development workgroups to ensure that:
 - Managerial decision points occur in an appropriate and timely manner;
 - A broad range of policy alternatives are considered; and
 - Agency decision-making includes science and economic analysis.
- Ensure that a transparent process exists for the presentation of scientific, economic, and other technical issues, including uncertainties.
- Identify and help resolve cross-Agency issues.
- Support the Administrator and Deputy Administrator's general discussions with the National Program Managers and Headquarters Programs with data related to the timeliness of actions.
- Monitor and maintain the integrity of information in the SCOUT (see description below) database.
- Develop, evaluate, and recommend policy approaches that achieve more cost-effective environmental regulations, policies, or programs.
- Support the implementation of the Administrator's priorities into Agency actions and programs.

What ADP Resources are Available?

Many resources are available to help you develop quality actions, including:

- **The ADP Library (<http://intranet.epa.gov/adplibrary>)**
Contains information about the ADP process, including this guidance, S&EOs, other Agency guidance documents concerning the development of actions, template language for preambles, forms that apply at various stages in the ADP, and contact information for your RSC representative/RRC and your office's Desk Officer.
- **Rule and Policy Information and Development System (RAPIDS)**
Is a database used to manage actions in the ADP. The RSC uses RAPIDS and other linked IT systems to manage creating, tracking, approving, and reporting on Agency actions.

RAPIDS data (e.g., timelines for critical milestones in the process) are used to prepare reports for the Agency's senior management (SCOUT system) and certain data are extracted twice a year for publication in the Semi-annual Regulatory Agenda to inform the public about our rulemaking activities. For rules that appear in the Rulemaking Gateway (generally, Tier 1 and Tier 2 rules), certain data are extracted from RAPIDS on a monthly basis—or even daily basis. Therefore, it is important to keep the data in RAPIDS current as you proceed through the ADP. All Agency staff may be granted reader access rights to RAPIDS upon request. Editor access varies from office to office; check with your RSC representative/ RRC.

- **Action Aids**

Are provided in Appendix A; they contain a series of more detailed guidance on key areas of the ADP.
- **The Preamble Wizard**

Is a tool that will help you prepare *Federal Register* documents. Before using the Wizard, you should familiarize yourself with the Agency guidance on statutory and Executive Order reviews. The Wizard asks you a series of questions designed to efficiently identify the correct preamble template that you require. When you finish entering responses, the Preamble Wizard will compile all the required template language and export it as a Microsoft Word file to which you can then add other parts of the preamble and regulatory text.
- **Links to websites**

With additional resource information are provided throughout this document. All of the links are also collected and listed in Appendix C.
- **RSC Representatives and Regional Regulatory Contacts**

Can provide guidance at any stage of the ADP. Every AA-ship and Region has a representative assigned to the RSC. The Headquarters representatives are known as RSC representatives, while each Region has a Regional Regulatory Contact (RRC). You can contact your RSC representative/RRC at any time in the process of developing an action, but particularly if you have questions or concerns pertaining to the ADP, S&EOs, guidance, office-specific questions, or issues that may call for senior management attention. The list of RSC representatives/RRCs can be found at: <http://intranet.epa.gov/adplibrary>.

Stage I.

Tiering the Action

Agency actions developed through the ADP are assigned to one of three tiers. This section describes the three tiers and discusses the criteria for assigning a tier to an action.

Step I: Understanding Tiering and Commencement Approval

This step defines tiering, describes what actions are tiered, and explains how they are tiered. It also describes commencement.

What is action tiering?

Tiering is the approach we use to determine which process should be used to develop an action. Actions are assigned to one of three tiers according to the criteria in Table 1, below. Under the ADP, each new regulatory action is assigned a tier level that appropriately corresponds to the level of complexity, needed cross-Agency input, controversy/visibility, and need for involvement by top-level managers. The particular steps and approving officials for each tier are different, but the approaches for all tiers ensure that we develop high quality actions. In addition, EPA's RPO needs to approve the commencement of each action.

In order to request a tier level for an action under the ADP, the lead office completes a form describing the new action to be developed and submits the form to OP for processing and approval via the lead office's RSC representative/RRC.

What is commencement approval?

The same form used for action tiering initiates commencement approval. EO 12866, as amended by EO 13422 requires a Presidential Appointee to serve as the Agency RPO. The RPO's approval is needed to commence any regulatory development activity, and the RPO may then choose to be involved in all stages of the regulatory process or assign it to an AA or RA.

What actions are tiered?

The following regulatory actions should be tiered:

- All rules signed by the Administrator.
- Rules not signed by the Administrator, but of sufficient importance to appear in the Semi-Annual Regulatory Agenda. (See Action Aid 1 for more information on the Regulatory Agenda).
- Significant guidance documents. The process for preparing and submitting significant guidance documents is available at the ADP Library at <http://intranet.epa.gov/adplibrary>. (See Action Aid 12 for a summary reference guide for preparing and submitting significant guidance documents).

In general, all other regulatory and non-regulatory actions that meet the Tier 1 or Tier 2 criteria should be developed through the Agency's ADP, including, but not limited to:

- Policy statements.
- Guidance documents.
- Risk assessments.
- Models that may be used in future rulemakings.
- Regulatory-related strategies.
- Reports to Congress that go beyond narrow budget issues. (For information on Reports to Congress, see Action Aid 15).
- Certain other regulatory documents (e.g., some petition responses).

If an action will be developed through another established Agency process, (e.g., one established for developing documents by the Science Policy Council (SPC), or Quality and Information Council (QIC)) the lead office is expected to note this on the tiering form. During the review process for the tiering form, other offices will have an opportunity to concur or question the use of this other process. If the use of an alternative process is challenged, the challenging RSC representative/RRC should work with the lead office to resolve the issue. If this is not possible, OP/AA, in consultation with the lead office's AA/RA, will determine the process that will be used.

If your action is not a rule that will be signed by the Administrator, will not appear in the Semi-Annual Regulatory Agenda, and does not meet the Tier 1 or Tier 2 criteria, you may choose to develop it through the Tier 3 process or any other approach you prefer -- within the general outlines of the Agency's generic side-agreement for Tier 3 actions (see Action Aid 10). The generic side-agreement calls for the lead office and representatives of other interested offices on the workgroup to discuss and come to agreement on the appropriate process steps for a Tier 3 action.

If the lead office wishes to use a process that is not already established and that differs from the ADP for developing a non-regulatory action, that office may note this on the tiering form.

The workgroup that is formed to develop the action is expected to evaluate whether an alternative process is appropriate and propose what the alternative process might be. The RSC is responsible for approving/disapproving the alternative process. It is expected that the workgroup will develop the alternative process within 90 days of tiering approval; otherwise it will be assumed that the ADP applies to the action.

If you would like advice on how tiering applies to your action, you should consult your RSC representative/RRC.

When are actions tiered?

Actions are tiered as soon as a program knows that it may need to develop some type of action on an issue, or as early in the process as possible. Agency actions should be tiered even if the available information is scarce and the date the action will be finalized is expected to be far in the future.

Regulatory actions need commencement approval by the RPO before substantive work begins, so if the lead office plans to gather data and analysis in order to decide whether or not a regulation or other Federal intervention is warranted – that exploratory work may also be appropriate for tiering. Commencement approval takes place on a monthly basis in conjunction with the tiering process and occurs before tiering approval. For more information on commencement and tiering approval see Stage 1, Step 3, below.

In some instances, rather than submitting a new tiering request, circumstances may dictate that an action is appropriate for “splitting” from an already tiered action. There are several situations when “splitting” might be appropriate; for example, when a program office has issued a proposal and then decides not to finalize all issues in a single final action. Splitting an action allows each of those final actions to be tracked separately but to retain original tiering and commencement approval. See Action Aid 2 for information on tiering a new action vs. splitting an action.

Step 2: Placing the Action in the Appropriate Tier

In this step, you determine which tier is appropriate.

How do you decide which tier is most appropriate for your action?

The table below will help you determine the appropriate tier for your action. If you have questions, contact your RSC representative/RRC. This table explains the criteria for each tier and the cross-Agency procedural interactions for each.

Tiering Criteria

The table that follows shows the criteria that should be used when tiering actions.

Tier 1: "Administrator's Priority Actions"	Tier 2: "Cross-Media and/or Actions with Significant Issues"	Tier 3: "Lead Office Delegation"
<p>This tier will include top actions that demand the ongoing involvement of the Administrator's office and extensive cross-Agency involvement on the part of the AAs/RAs.</p>	<p>These actions are targeted for extensive cross-media or cross-Agency involvement or are single media actions with significant issues. Primary decision authority rests with the lead AA/RA.</p> <p>In general, actions which include significant science, policy, economic and/or implementation issues should be placed in Tier 2.</p>	<p>Actions in this category are those for which there is little or no need for cross-Agency participation. A workgroup may not be needed. For the most part, lead offices have the flexibility to design their own processes. While there are few system requirements, the lead AA/RA is responsible for cross-Agency staff linkages and external stakeholder involvement to produce a quality action.</p>
<p>Factors to consider in making a judgment about placing an action in Tier 1 are:</p> <ul style="list-style-type: none"> ■ major cross-Agency or cross-media policy implications or precedents; ■ potential for major or precedent-setting implementation issues; ■ potential for major cross-Agency, cross-media, or inter-agency controversy; ■ potential for major economic impact on other levels of government or the regulated community; ■ highly controversial in terms of external interest; ■ ongoing, formal involvement of the Agency's highest level of management (Administrator, Deputy Administrator) is necessary or desired; ■ presents a significant opportunity for the Agency to advance the Administrator's priorities. 	<p>Factors to be considered for this Tier are:</p> <ul style="list-style-type: none"> ■ significant policy decisions that may be precedent-setting, even if primarily within the lead office; ■ potential for significant or controversial implementation issues; ■ cross-Agency or cross-media policy implications; ■ potential for cross-Agency or cross-media controversy; ■ major interest from a variety of external groups, which suggests the need for cross-Agency representation and a workgroup; ■ necessity for senior management (AAs, RAs) involvement from other than the lead AA or RA. 	<p>Factors to be considered for this Tier are:</p> <ul style="list-style-type: none"> ■ quality of the actions does not depend on formal, extensive cross-Agency interactions; ■ implementation issues are routine; ■ the action is routine, is not controversial, has broad-based support, or implements statutory provisions with little or no discretion; ■ the concerns of those outside the originating office can be addressed through informal discussions and/or formal agreements (e.g., side-agreements) made during the tiering process.
<p>Your Action should be placed in Tier 1 if...</p> <ul style="list-style-type: none"> ■ science issue(s) are precedent setting and controversial; ■ it is economically significant per E.O. 12866 (i.e., > \$100 million). It should be placed in Tier 1 unless the program office can justify placement in Tier 2; ■ economics issue(s) are precedent setting and controversial. 	<p>Your Action should be placed in Tier 2 if ...</p> <ul style="list-style-type: none"> ■ it involves a significant new use of science; ■ science issues are controversial, unresolved or unaccepted; ■ it includes an action or decision made based on a risk assessment; ■ a non-routine use of science is interpreted or characterized in the document; ■ it involves a significant new use of economics not covered in the Agency's Economic Analysis Guidelines; ■ economic issues are controversial, unresolved or unaccepted; ■ a non-routine use of economics is interpreted or characterized in the document. 	<p>Your Action should be placed in Tier 3 if...</p> <ul style="list-style-type: none"> ■ use of science is well known and accepted; ■ it generally involves the routine use and application of science; ■ use of science is new, but minor and not controversial; ■ use of economics is well known and accepted; ■ it generally involves the routine use and application of economics; ■ use of economics is new, but minor and not controversial.

Step 3: Obtaining Tiering Approval

This step describes the process for completing the tiering form and obtaining tiering approval.

How does the tiering process work?

Actions are assigned to tiers through a monthly cross-Agency tiering process. The major steps in the process are:

1. The lead AA/RA's office (or the AA/RA designee) identifies an action to be developed and completes the tiering form in RAPIDS. Program leads for developing actions should check with their RSC representative/RRC to confirm who has responsibility for completing the tiering form in their office.

Note:

Information from your tiering form is used to issue Action Initiation Lists (AILs) and to import information to the Rulemaking Gateway.

AILs are used to notify the public about new rules and other regulatory actions. AILs are posted on the EPA website at roughly the end of each month. The AIL describes those actions that were approved for commencement during the given month. This process gives the public more up-to-date information about upcoming regulatory actions. In the past, the public had to wait for EPA's Semiannual Regulatory Agenda, which is updated only every six months. You may view the AIL at <http://www.epa.gov/lawsregs/search/ail.html>

The Rulemaking Gateway is an EPA website that provides a transparent way to keep track of the Agency's priority rulemakings (i.e., generally Tier 1 and Tier 2 actions). It provides users with earlier and more targeted information as well as special filters that will allow users to find rules and related documents that interest them. Updates are generally made on a monthly basis; some timeline updates (e.g., publication dates) are made on a daily basis. You may view the Rulemaking Gateway at: <http://www.epa.gov/rulemaking/>

2. After the lead AA/RA (or the AA/RA designee) approves the tiering form, the RSC representative/RRC forwards the tiering form to RMD.
3. RMD assigns a Start Action Number (SAN), compiles all tiering forms, and disseminates them to all RSC representatives/RRCs on a monthly basis. Each RSC representative/RRC coordinates the response from their organization to:
 - Approve or recommend changes to the proposed tiering placements.
 - Indicate interest in serving on a workgroup.
 - Identify their office/Region's representative(s) for the workgroup.

4. Each month, while the RSC is reviewing proposed tiering actions, OP will review the tiering forms for clarity and conciseness to ensure the public's understanding of what the action will do when it appears in the Rulemaking Gateway and on the Action Initiation List. These comments will be provided to the workgroup chair and the RSC representative for the action. Also at this time, OP works with the RPO who is responsible for approving the commencement of applicable actions.
5. Each RSC representative/RRC provides their comments to the lead office and RMD, including the names of their representative(s) for the workgroup.
6. Upon commencement approval, the tiering coordinator in RMD will compile approval and tiering responses and meet with OP management for final tiering approval.
7. If a tiering level is challenged, the challenging RSC representative/RRC should work with the lead office to resolve the issue. If this is not possible, OP/AA, in consultation with the lead office's AA/RA, will determine the appropriate tier level.
8. After tiering approval, RMD sends a tiering approval report to the RSC representatives/RRCs.
9. If at any time during the development of an action, the lead office or a participating office concludes the tiering designation needs adjusting, the RSC representative/RRC for the requesting offices should submit a tiering change request, including a justification for the up-tiering/down-tiering of the action. The tier change request will then go through the same review/approval process as the original tiering action--alerting the Agency of the request and providing an opportunity for other offices to concur. Note that the participating office submitting a tier change request should discuss the matter with the lead RSC prior to any tier change request being submitted.

Note:

In lieu of the formal workgroup and ADP milestones called for under Tier 1 and 2, all Tier 3 actions, use as a starting point the side agreement, which establishes the ground-rules for the development process for Tier 3 actions. See Action Aid 10 for details.

Stage 2.

Developing the Proposed/Draft Action

Once the action has been tiered, the lead AA-ship/Region convenes the workgroup and begins developing the action. The process varies depending on the tier to which the action has been assigned.

Developing Tier 1 & 2 Actions

Step 1: Chartering the Workgroup

In this step, a workgroup is established consisting of representatives from interested AA-ships and Regions. This workgroup develops the action and supporting documents.

When should a workgroup be chartered?

Typically, workgroups are formally chartered as soon as the tiering process is completed. However, if discussions need to occur prior to formal chartering, all interested Offices should be involved.

How do programs/Regions select workgroup members?

After the tiering form has circulated through the RSC representative/RRC as part of the tiering process, interested AA-ships/Regions designate representatives to the workgroup by notifying the RSC representative/RRC of the lead office and RMD. When an AA-ship/Region wants more than one member assigned, it should designate a primary representative. This primary representative is expected to provide the AA-ship/Region's position during workgroup deliberations and an official position at particular ADP milestones (e.g., Final Agency Review (FAR)).

Who should be on the workgroup?

The membership of any given workgroup is determined by the AAs/RAs who respond to a tiering request. Workgroups need to involve all participants from the earliest stages

and throughout development of the action. Involvement by the following participants is particularly important:

- **Core Offices**

Core offices should have a representative on all Tier 1 and 2 actions. The core offices are OGC, OP, OECA, and ORD. Their functions include assuring that appropriate options are considered, that actions are enforceable, and that actions are based on sound legal, policy, economic, and scientific analyses.

In limited cases, a core office may determine that an action does not include any significant issues relevant to that core office and may decide to have minimal participation during the workgroup process. The core office RSC representative/RRC will notify the lead office RSC representative/RRC of these actions during the tiering process. Since the ADP for a particular action may span over several years and the scope of an action could change, the lead office RSC representative/RRC will notify (i.e., key milestones) the core office RSC representative/RCC that the scope of the action has not changed and that issues involving the core office have not surfaced. Based on this notification, the core office RSC representative/RRC will reconfirm their participation is not necessary. It is expected that core offices will be notified at the following milestones: early guidance, analytic blueprint approval, options selection, and FAR.

- **Regional Offices**

The workgroup should have adequate representation from Regional offices, when appropriate. Because of the Regions' critical role in implementing most actions, their experience is often vital in developing effective actions that can be enforced. Where full-time participation of Regional offices cannot be arranged, lead offices should find other ways to ensure they can produce a quality action that addresses implementation and related issues of Regional expertise. Such means might include contacting the Office of Regional Operations in the Office of Congressional and Intergovernmental Relations (OCIR) or the OCIR RSC representative for assistance.

- **State, Tribal and Local Government Representatives**

Lead offices should consider having the workgroup consult with State, Tribal and local government representatives (i.e., elected officials or their designated employees) when developing rules for which States, Tribes or local governments are charged with actual day-to-day management of the program or regulation. There are several ways to conduct such consultation without interfering with the Agency's internal decision-making processes. For example, the work group could consult regularly with the State, Tribal, and local governments to solicit input from the government representatives. Or the lead office could establish an advisory group made up of State, Tribal, and local governments and solicit their recommendations on specific issues that the rulemaking workgroup is considering. Finally, in limited circumstances the work group could consider including State, Tribal and local government representatives as work group members.

Expectations regarding the scope of State, Tribal and local government representatives' involvement, including involvement in inherently internal processes (e.g., early guidance, options selection, etc.), should be made clear at the outset of deliberations. When considering State, Tribal and local government participation, the lead office should consult with its RSC representative/RRC and OGC to evaluate the policy and legal issues related to such participation. For example, meetings involving non-federal participants may trigger the Federal Advisory Committee Act (FACA). Although the Unfunded Mandates Reform Act exempts meetings with State, Tribal and local government representatives from FACA requirements, this exemption applies only to certain meetings. Some meetings involving State, Tribal and local governments are not covered by this exemption. OGC can help you determine if FACA requirements would be triggered for meetings involving State, Tribal and local government representatives. Also, it is important to remember that documents shared with State, Tribal, and local governments may have to be released should someone from the public submit a FOIA request. It is important to consider the ramifications on EPA's internal deliberative process when deciding how to involve State, Tribal and local government representatives, especially when they serve on your workgroup.

OCIR is available to assist with identifying potential State and local government representatives. The Office of International and Tribal Affairs (<http://www.epa.gov/indian>) is available to assist with identifying potential Tribal participants. For additional information on consultations, please visit the ADP Library at <http://intranet.epa.gov/adplibrary> or contact your RSC representative/RRC. See Step 5 below for more information regarding public involvement.

What are the expectations for workgroup members?

To function effectively, all workgroup members are expected to fulfill the following responsibilities:

- **Represent the positions of their AA-ships/Regions.**

You should represent the positions of your AA-ship/Region as the action is developed (if more than one workgroup member is assigned by an AA-ship/Region, the primary workgroup member should provide all positions). You may raise concerns and ensure that those issues are addressed or elevated in a timely manner so the lead AA-ship/Region can formulate an appropriate response, when needed. This may include elevating the issue formally. To elevate an issue formally, you should notify the workgroup chair of your intent and then raise the issue to your own management at the appropriate level. Your management should then contact the workgroup chair's management for resolution. If the dissenting office is not satisfied at this level, they may pursue the issue up the management chain in similar fashion. Ultimately, they could elevate the issue to the Administrator, through a dissent memorandum. For more information on elevating and resolving issues, see Action Aid 4.

- **Contribute to developing the action.**

You are expected to be an active participant on the workgroup. You should contribute a meaningful degree of work to the process of developing and writing the action. Additionally, while lead offices have ultimate responsibility for producing quality actions, other workgroup members share in that responsibility by participating actively in discussions and reviews, by providing meaningful comments, and by contributing relevant data and analysis.

- **Pay attention to timeliness.**

You are expected to work with the workgroup chair to establish reasonable timelines and meet them. You should raise issues as early as possible in the process so there is sufficient time for those issues to be addressed and resolved. You are expected to be a part of the process of developing the action until it is finalized and should participate in all workgroup meetings and review all drafts in a timely fashion. In order to make this task easier, you should use redline/strikeout, or similar tools i.e., wikis or the EPA Portal, when reviewing draft documents to highlight comments or changes since the prior draft. The lead office should provide for these tools when requesting review and needs to allow sufficient time for review.

- **Identify changes in representation in the workgroup.**

If you find you cannot fulfill your obligations to the workgroup, or you are reassigned, then you are responsible for letting your RSC representative/RRC and the workgroup chair know of the change so a replacement can be assigned.

For additional information on workgroup responsibilities, see Action Aid 3.

Step 2: Getting the Workgroup Underway

In this step, the workgroup begins meeting to develop the action.

When should the first meeting take place?

In general, the workgroup chair should hold the first meeting soon after tiering approval, even if concerted effort on the action will not start for some time. As noted above under RPO commencement and tiering approval, an ADP workgroup should be convened before the lead office prepares a detailed workplan, determines its use of contract resources, or receives early guidance from senior management.

What happens at the first meeting?

The workgroup will begin the following:

- **Discussing and reaching agreement on a problem statement.**

The workgroup defines the issue or problem they are being asked to address or solve; they develop a problem statement. A shared understanding of the problem helps the workgroup avoid misunderstandings later in the process.

- **Setting expectations.**

The workgroup begins to discuss goals, schedule, issues, process requirements, S&EOs affecting action development, expectations of the chair and members, and anticipated analytic needs. Setting clear expectations for the workgroup based on an open discussion with all participants at the beginning avoids surprises later.

- **Identifying key constituencies.**

The workgroup identifies key external stakeholders (such as States, Tribes, local governments, small entities, public interest groups, and other members of the regulated community) to begin making plans (choosing consultation methods and identifying schedules) for consulting with these groups.

- **Identifying preliminary issues and questions for senior management.**

The workgroup identifies preliminary issues or questions for senior management to begin the process of developing the preliminary analytic blueprint (PABP) and getting early management guidance (see Step 4 below).

How often should the workgroup meet?

Workgroups need to meet frequently enough to ensure that all significant issues and options are fully discussed and agreed upon by all members. These workgroup discussions are essential because one-on-one meetings may result in one office reaching a satisfactory resolution while creating unanticipated problems for another. The workgroup should meet often enough to ensure a cross-Agency understanding of issues and options prior to management-level meetings and decisions (e.g., early guidance, analytic blueprints, options selection, and general agreement on drafts of the action before Final Agency Review).

If an action is being developed in conjunction with a related Federal Advisory Committee Act (FACA) process, such as negotiated rulemaking, workgroups should meet to prepare before FACA meetings, circulate the results of such meetings, and discuss any findings or considerations, as well as the overall direction of the Committee. For more information on Agency policy regarding public involvement, FACA, and other consultative procedures, visit <http://www.epa.gov/publicinvolvement>

What should meetings focus on?

Workgroups should hold meetings to discuss issues, make decisions, and help meet the milestones for each step of the ADP. The workgroup chair should prepare and circulate agendas before and summaries of decisions and action items after each meeting. Materials should be prepared and shared in advance to allow sufficient time for review. You should adequately brief your management prior to major milestone meetings so that each AA-ship/Region's position is represented.

Step 3: Preparing the Preliminary Analytic Blueprint and Getting Early Guidance from Senior Management

In this step, the workgroup creates a preliminary blueprint for developing the action and gets initial guidance from senior management.

What is an analytic blueprint?

An analytic blueprint (ABP) is a document which spells out a workgroup's plans for the data collection and analyses that will support development of a specific action. The ABP describes how this information will be collected, peer reviewed, and used to craft the action within a specific budget and time frame. In addition, the ABP process serves to expand EPA's opportunities to consider a broad range of possible regulatory (and non-regulatory) strategies, including alternative or innovative approaches that complement traditional methods. ABPs are developed in two phases, a Preliminary ABP (PABP), and a Detailed ABP (DABP). In this section we will discuss the PABP. The DABP is discussed below in Step 4.

The Agency prepared a detailed stand-alone guidance on developing Analytic Blueprints (ABPs) available on the ADP Library at <http://inranet.epa.gov/adplibrary>

What actions call for an ABP?

ABPs are expected for all Tier 1 and Tier 2 actions and are encouraged for Tier 3 actions (some AA-ships expect them for Tier 3 actions too—check with your RSC representative/RRC).

Who is responsible for developing the ABP?

The workgroup develops the ABP as a collaborative effort; it is not just a product of the lead office. The workgroup is expected to follow it once it is adopted. Since the ABP is a living document, the workgroup, in consultation with management, can modify the ABP throughout the process as necessary.

When is an ABP expected?

Development of the ABP should commence with the convening of the workgroup, which should occur as soon as is practicable after tiering approval. The PABP is generally expected to be completed within 60 days of tiering approval. Every effort should be made to complete the PABP within the 60 days; however, sometimes circumstances may prevent this from occurring. The DABP should be completed and approved within approximately 150 days of tiering approval.

What is a PABP?

A PABP is a project management tool intended to help the workgroup manage its work—it's an outline that helps the workgroup organize itself and prepare for the early guidance discussion with senior management. The PABP should define the problem the action will address and provide the context for the action (e.g., statutory requirements, EOs affecting development, deadlines, and previous actions). It should also identify broad analytic areas that the workgroup will address, including an outline of possible economic and scientific issues, areas of research to be addressed, plans for dealing with applicable S&EOs, plans for consultation with stakeholders, and how the workgroup will focus on each topic. Guidance and templates on how to consider the S&EOs while developing Agency actions are available on the ADP Library <http://intranet.epa.gov/adplibrary>. When feasible, a PABP also describes possible broad approaches for addressing the problem (e.g., regulatory, voluntary, and/or innovative approaches) and any other issues important to senior management.

What is early guidance?

Early guidance is usually a meeting with senior managers, although it can sometimes take the form of a speech or memorandum from a senior manager. Early guidance is used to establish policy priorities and communicate expectations for the workgroup. Senior managers identify issues of significant concern and guide the process of developing the action.

What is the role of the PABP in early guidance?

The workgroup develops the PABP and submits it to senior management within 60 days of the date the tier designation was approved by OP. All members of the workgroup should agree that the PABP is ready to be provided to senior management before this occurs. Providing the PABP to senior management in advance of early guidance allows for senior management consideration and an opportunity for workgroup members to consult with them on general direction for the action. If workgroup members cannot agree, the issues of disagreement should be presented to management for resolution. The expectation is that management will give early guidance within 30 days of receiving the PABP.

How can the workgroup prepare for the early guidance meeting?

Upon completion of the PABP, the workgroup turns its attention to early guidance meeting preparations. To ensure a predictable and productive early guidance meeting, it helps if the workgroup discusses and prioritizes the issues on which to seek senior management input. The lead office may then choose to prepare a draft early guidance briefing document and share it with the workgroup for a quick review. The resulting briefing document can then be used by you to pre-brief your management for the early guidance meeting. At that pre-brief, you can also give your manager a copy of the PABP to review prior to the early guidance meeting.

Who should provide early guidance to the workgroup?

Early guidance always comes from senior management, although the level of management giving guidance differs for Tier 1 and Tier 2 actions:

■ **Tier 1 Actions**

The Administrator or Deputy Administrator provides early guidance, with input from participating AAs/RAs from across the Agency. The lead AA/RA is responsible for assuring that it is communicated to the workgroup in writing.

■ **Tier 2 Actions**

The lead AA/RA, in consultation with other participating AAs/RAs, gives early guidance to the workgroup. The lead AA/RA should consider policy issues and priorities of other AAs/RAs when giving early guidance. In some cases, the AAs/RAs may delegate this authority explicitly to an Office Director (OD), but whoever is authorized to provide the guidance is also responsible for assuring that it is communicated directly to the workgroup in writing.

For both Tier 1 and Tier 2 actions, the lead office should provide participating AAs/RAs with meaningful opportunities to contribute to early guidance decisions and should obtain agreement from participating offices on issues that affect them. The recommended way to accomplish this is to have an early guidance meeting involving all of the participating offices to discuss significant issues and to mutually agree on the priorities and general direction for the action.

If the workgroup agrees there are no significant issues, and the direction for the action is clear, it may recommend that an early guidance meeting is not necessary. The decision-maker (A/DA or AA/RA) should make this determination.

What topics might be considered when preparing early guidance?

Early guidance is the opportunity for EPA's management to make its priorities clear—it is not where final decisions on options are made (see Step 7: Selecting Options below). Management should consider giving guidance on a range of issues, including:

- Priority policy and key analytic issues.
- Research and scientific analysis to be undertaken.
- How, and by whom, the Agency action should be implemented (States, Tribes, Regions, and/or Headquarters).
- Significant cost issues, such as administrative burden associated with implementing the Agency action both for the regulated community and the regulators, or the potential for significant economic impacts.
- Opportunities to consider nontraditional approaches, such as non-regulatory alternatives, voluntary programs, or approaches that differ from the command and control paradigm.

- Schedule and resource constraints.
- Key external constituencies to consult with, including consultation methods and schedules, and related issues/concerns.
- Critical issues or points in the process that might need special attention from management.

For more information on early guidance, see “Issues to Consider when Giving Early Guidance” in Action Aid 5 and contrast with the information provided in Action Aid 7: Options Selection Meetings.

Step 4: Preparing the Detailed Analytic Blueprint

In this step, the workgroup incorporates the early guidance it received and develops a DABP describing the scope of the action and the analytical work necessary to develop the action, as well as key milestones.

What is the DABP?

The DABP is based on the PABP. It is modified as necessary as a result of early guidance and provides greater detail than the PABP. It should identify the key activities, analyses, consultation activities (including those called for by relevant S&EOs), contributors, and timelines. The DABP should discuss the plan for peer review of major scientific and technical products. This should include a schedule for the review and identify the resources that will be needed to conduct it. Because sound analyses (economic, scientific, technical, and legal), consultation, and peer review are important elements of good decision-making and a quality action, the DABP allows workgroups to lay out all of the tasks needed to complete those analyses. It should also identify resource needs, individual workgroup assignments, and timelines. Additionally, it can raise issues the workgroup may need to elevate to management for decision. Essentially, the DABP identifies the information that will be available to decision makers at options selection and the timeline for developing it.

How are DABPs approved?

In contrast to the relatively informal approach to PABP approval, DABPs go through a more formal approval process similar to the process currently used for Final Agency Review (see Step 9 below) involving participating AA/RA-level approval. For detailed information on this step and the rest of the ABP process, please refer to the Analytic Blueprint guidance document on the ADP Library at <http://intranet.epa.gov/adplibrary>.

Step 5: Completing Data Gathering, Consultation, Analyses, Peer Review, Options Development and Establishing a Docket

In this step, the workgroup investigates the problem, gathers relevant information, and develops options for resolving the problem.

At this point, members of the workgroup implement the DABP they prepared in Step 5 and complete the following tasks:

- **Data Gathering**

The workgroup gathers data and information about the problem they are addressing. The data may suggest alternatives to a regulatory approach.

- **Consultation**

The workgroup consults with key stakeholders potentially affected by the action. Key constituencies may include: Tribal representatives, State representatives, local government representatives, public interest groups, small entities, and industry. In some cases, it may also be necessary for management to consult with State, local and/or Tribal elected officials or their designated employees or authorized representatives, as may be required by various S&EOs (e.g., UMRA, Federalism EO, Tribal Governments EO, etc.). Similarly, consultations with small business, small governments and/or small non-profits may be required under the RFA; for guidance and further information on these S&EOs, see the ADP Library at <http://intranet.epa.gov/adplibrary> For more information on planning for and conducting stakeholder involvement processes, see “Involving Stakeholders in Rulemaking and Other Actions” Action Aid 6.

- **Analyses**

Under lead office oversight, the workgroup conducts the scientific, economic, policy and legal analyses called for in the DABP. Generally, the lead office will control and direct the analyses, but when appropriate, and with workgroup agreement, other involved offices may take the lead on particular analytic efforts to support the action.

- **Peer Review**

Any major scientific and/or technical work product that supports an action should undergo peer review. Peer review is a documented, critical review of a work product, performed by experts who are independent of those who developed the product. Peer review should be completed as early in the process as possible. In addition, the Action Memorandum accompanying each action submitted for signature must explicitly address the use of peer review.

For more information on peer review, visit the ADP Library at: <http://intranet.epa.gov/adplibrary>.

■ Options Development

The workgroup identifies and scopes out the costs and benefits (even if the available information allows for only a qualitative assessment), pros and cons, and feasibility of different options they have identified. The options presented to senior management at the options selection meeting are based on this work.

■ Establishing a Docket

A docket can be established at any time during the ADP (i.e., created in the EPA Federal Docket Management System (FDMS).) The docket should become publicly available and open no later than the date of issuance/publication of the action or FR document (e.g., notice, proposed or final rule). For additional information on dockets, see “Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers” at the ADP Library <http://intranet.epa.gov/adplibrary>.

Step 6: Selecting Options

In this step, the workgroup identifies significant issues and a range of options to resolve each issue. Senior management then selects those options that would best achieve the goals of the action.

What is options selection?

Options selection is the last formal step for senior management to provide input in the development process before the workgroup completes drafting of the action. At this point, the workgroup has usually completed its research, consulted with stakeholders, conducted analyses, completed peer review, identified issues, weighed the costs and benefits, considered the pros and cons and assessed the overall feasibility of the options available. (See Action Aid 7 for additional information on options selection.) After doing this the workgroup is ready to present several possible options for each issue, and to the extent practicable, identify and discuss any options with workgroup consensus and provide recommendations that would achieve a quality action. For more information on the characteristics of a quality action, see page 11 & 12.

The lead office schedules an options selection meeting either with the Administrator or Deputy Administrator (A/DA) for Tier 1 actions or with the lead AA/DAA for Tier 2 actions. Ideally, an options selection meeting should be held no later than six months before the action is scheduled for signature. After options selection and before signature occurs, the schedule should allow enough time for you, the workgroup member, to circulate several drafts of the action, preamble, and supporting documents for review and comment. The completion of Final Agency Review (FAR) meeting and OMB review, if necessary will also occur before the action is signed. For additional information on scheduling key milestone meetings, see Action Aid 8.

AA/RAs from all offices participating on the workgroup should be invited to the options selection meeting, with a simultaneous notice provided to all the RSC representatives/RRCs

and workgroup representatives of the participating offices. The A/DA chairs the meeting for Tier 1 actions and the lead AA/DAA chairs the meeting for Tier 2 actions. Lead AAs/DAAAs are encouraged to hold preliminary options selection meetings prior to an A/DA option selection for a Tier 1 rule and to invite participating AAs and RAs. Such preliminary meetings should help ensure efficient decision meetings with the Administrator or Deputy Administrator.

If the workgroup agrees there are no significant issues and no options that require senior management involvement, it may recommend that an options selection meeting is not necessary. The decision-maker (A/DA or AA/RA) should make this final determination.

What do offices do to prepare for an options selection meeting?

To prepare for the options selection meeting, the lead office should:

- Have a workgroup meeting to discuss the regulatory options and policies to be considered at the options selection meeting.
- Include the workgroup chair and other members in any pre-briefs of senior managers, in particular when important issues affecting their office's interests are discussed.
- Prepare a summary of other offices' positions on the options, and include it with the background information for the meeting.
- Prepare a summary of the views of stakeholders as a result of any stakeholder involvement or consultation processes.
- Schedule the options selection meeting.
- Distribute background materials that lay out issues and options to be discussed preferably two weeks, but no later than one week, before the meeting.

To prepare for the options selection meeting, non-lead offices participating on the workgroup should pre-brief their senior management so that every participating office is appropriately represented at the options selection meeting. For recommendations on the scheduling and timing of key milestone meetings in the ADP, see Action Aid 8.

What happens at an options selection meeting?

At the options selection meeting, the workgroup and senior management review and discuss all of the identified issues and proposed options. Then, senior management will either:

- Select a final option for the action, or
- Narrow the list of potential options to be presented in the proposed action.

What does the lead office do after an options selection meeting?

The lead office will draft a memorandum that documents the options discussed, decisions made, and follow-up actions agreed to and distribute it to all participants in the meeting.

Step 7: Drafting the Proposed Action

In this step, the workgroup will prepare the action under the leadership of the workgroup chair.

What parts of the action does the workgroup prepare?

Once options are selected or narrowed down, the workgroup is responsible for drafting the action and supporting materials under the leadership of the workgroup chair. For most actions, this will include preparing the following:

- The action itself, which may be regulatory text and preamble language, report to Congress, policy or guidance documents, relevant FR documents where appropriate, and supporting documents, which may include risk assessments, environmental impact assessments, and/or economic impact analyses.
- Draft action memorandum transmitting the action for signature (for guidance on how to prepare an Action Memorandum, visit the ADP Library at <http://intranet.epa.gov/adplibrary>).
- Communication strategy or plan (which should be coordinated with your communication director in OPA).
- ICR(s) (if required, this should be coordinated with your information officer in OEI).

ANPRMs:

Sometimes an Advance Notice of Proposed Rulemaking (ANPRM) may be issued. An ANPRM is a “notice” intended to solicit comments and/or information from all segments of the public interested in a particular issue prior to an agency determining whether an action will be proposed. As such, it does not propose or impose any regulatory requirements. Workgroups may choose to develop an ANPRM for actions which are still in the early stages of development and for which public input may be particularly helpful to the ADP. Additional information for developing ANPRMs is available at the ADP website: <http://intranet.epa.gov/adplibrary>

All of the documents listed above should be completed before the materials are distributed for FAR. You are encouraged to provide timely responses at every opportunity. Every attempt should be made to identify and resolve issues before FAR. If the lead office and participating offices have carefully followed the ADP, ideally, no new issues should be raised at FAR.

What format do I use to write a document to be published in the FR?

The Office of the *Federal Register* (OFR) has specific requirements for documents they publish. You will find templates for formatting the preamble, including the “Summary” “Dates” and “Addresses” sections on the ADP Library website at <http://intranet.epa.gov/adplibrary>. For specific information on FR requirements, you may visit the OFR website at http://www.archives.gov/federal_register. OFR’s Document Drafting Handbook can be found at the website and provides specific guidance and procedures for drafting and formatting a document for publication in the *Federal Register*.

Step 8: Conducting Final Agency Review

In this step, the action goes through a Final Agency Review.

What is FAR?

FAR is the last point for internal EPA review of an action. FAR meetings are chaired by the Director of RMD, or his/her representative, and are held to confirm that:

- All issues have been resolved, or elevated.
- The action package is ready for OMB submission (if required) or signature.
- All EPA and external requirements have been met.

During FAR, you are expected to present the position of your AA/RA, unless the AA/RA has expressly designated another management level to have that authority. Positions must be submitted in writing. An email from the AA/RA or their designee stating an office or Region's position is acceptable.

How do workgroups decide that an action is ready for FAR?

During the course of developing the action, you typically have several opportunities to review and comment on the drafts of materials that are included in the FAR package. When the workgroup chair believes the FAR package (described in the next section) is complete, the workgroup is polled to seek agreement that the package is ready for FAR. Once the workgroup agrees the package is ready to move forward, the workgroup chair will ask you to identify and report any unresolved issues which have been vetted by the workgroup or possible non-concurrences. These concerns are reported to management and RSC representatives/RRCs to consider prior to FAR initiation. Because the FAR meeting is the last point for Agency input before OMB review or signature, it is important that unresolved issues are addressed prior to the FAR meeting whenever possible. Your RSC representative/RRC can assist you in elevating unresolved issues to the appropriate levels of management.

Once the workgroup agrees the package is ready, the workgroup chair will work with their RSC representative/RRC to schedule the FAR meeting. The package should be in a state where the lead AA/RA would be comfortable publishing it under his/her signature. For recommendations on the scheduling and timing of milestone meetings in the ADP, see Action Aid 8.

What does the workgroup need to include in the package that goes to FAR?

For a package to go through FAR, it should include each of the following items:

- FAR announcement memorandum from lead RSC representative/RRC (a sample memorandum is available on the ADP Library at <http://intranet.epa.gov/adplibrary>).
- Draft action memorandum (for guidance on how to prepare an Action Memorandum, visit the ADP Library at <http://intranet.epa.gov/adplibrary>).

- Current workgroup membership list.
- Draft action (e.g., rule, report to Congress, policy or guidance document).
- For rules, draft preamble that addresses S&EOs, if any, and the text of the action.
- For rules, draft Regulatory Impact Analysis (RIA), or other appropriate economic and scientific supporting analysis (as necessary).
- For rules that are economically significant, an OMB Circular A-4 (economics) table.
- Draft ICR (if required, this should be coordinated with your information officer in OEI).
- Draft communications strategy or plan (this should be coordinated with your communication director in OPA).

What happens once the FAR package is complete?

The lead RSC representative/RRC schedules the FAR meeting through the RMD Desk Officer. (RMD assigns a staff Desk Officer to each program area; the current list of Desk Officers is available on the ADP Library at <http://intranet.epa.gov/adplibrary>). The FAR meeting should be scheduled no sooner than 15 working days after the FAR package is distributed to the participating AAs and RAs. There could be times when this isn't possible. If this occurs, a request for an expedited FAR process is necessary. See Action Aid 9 for more information on expedited FARs. The lead AA-ship/Region is responsible for distributing the package to the workgroup members as well as the RSC representatives/RRCs affected.

In order to prepare for FAR, it is important for you to brief your senior management on the action and obtain your AA's/RA's position on the action. The AA's/RA's (or their designee's) position should be provided in writing no later than at the time of the FAR meeting. Only the AA/RA or their designee may submit a written position; office designees must be on file with RMD in order for the position to be accepted. A hardcopy of a signed FAR memorandum or a PDF of a signed memorandum is acceptable as long as the memorandum is signed by the AA/RA or their designee. RMD will accept positions in the text of an email if it is sent directly from the AA/RA or their designee.

What happens at a FAR meeting?

The RMD Director will chair the FAR meeting and request the position of each participating AA-ship/Region. As stated above, the position should be in writing and approved by the AA/RA or their designee and sent to the lead AA/RA. Copies should be sent to the workgroup chair, the RSC representative/RRC for the lead AA/RA, and the appropriate RMD Desk Officer. The AA/RA or their designee may take one of the following positions:

- If an office has minor, non-substantive comments, they may concur without comment.

- If an office has substantive comments, they may concur with comment. The lead office is responsible for consulting with the workgroup to determine how to address substantive comments. If the workgroup cannot agree on a way to address the comments, the lead office should include the comments in the Action Memorandum with an explanation of why it cannot satisfactorily address the comments. For guidance on how to write an Action Memorandum, visit the ADP Library at <http://intranet.epa.gov/adplibrary>. While the lead office should try to resolve the issue(s) raised by the comments, it may choose to go forward to OMB for review, or to the Administrator for signature, without resolving the issues.
- If an office feels that a major issue remains unresolved (e.g., the action lacks legal authority or conflicts with other EPA rules or policies), it may non-concur. Non-concurrence indicates that the AA or RA objects to the action being forwarded to OMB, or to the Administrator for signature. Non-concurrences should be submitted to the lead AA/RA and copies should be sent to the workgroup, the RSC representative/RRC for the lead AA/RA, and the relevant RMD Desk Officer.

The lead office is responsible for consulting with the workgroup to determine how to address the comments. If the lead office and the workgroup (including their AA/RA) cannot agree on how to resolve the non-concurrence(s,) then the following process applies depending on the given situation: if more than one office non-concurs, and no agreement was reached on how to proceed, OP will alert the RPO about the non-concurrence. The RPO may pursue any of the following options:

- Authorize the rule to proceed to OMB review, or to the Administrator for signature, without further changes.
- Determine how to revise the rule to meet concerns raised in the non-concurrences.
- Defer the decision to the lead AA/RA.

If one office non-concurs and no agreement is reached on how to proceed, the lead office should include the comments in the Action Memorandum with an explanation of why it cannot satisfactorily address them.

What if a participating office does not provide a written position from the AA or their designee at the FAR meeting?

The appropriate RMD Desk Officer will contact the RSC representative/RRC for the participating AA-ship/Region to obtain its position. If a written position is not provided by the AA/RA or their designee within two working days after the FAR meeting, RMD may record their position as “no position provided.” In the event there are extenuating circumstances that prevent an AA/RA or their designee from providing their position in writing, the RMD Director may extend this timeframe. See Action Aid 9 for the process in the case of an expedited FAR.

How is the FAR process recorded?

The RMD Desk Officer prepares a memorandum summarizing the FAR meeting providing the position of each participating office at the time of FAR and will attach all written comments, including non-concurrences. This memorandum is signed by the Chair of the meeting and distributed to all workgroup members and their RSC representatives/RRCs. It accompanies the package when it is submitted to OP for approval to go to OMB (if necessary), or to the Administrator for signature. The FAR summary memorandum will not be transmitted to OMB, but gives the AO information about any substantive issues at the time of the FAR meeting. The Action Memorandum also provides the information on how non-concurrences were resolved and any remaining issues.

What happens after FAR?

After FAR the proposed rule, or draft action, will be submitted, via OP, to OMB, if required, or to the Administrator for signature. The process for submitting your action to OMB is discussed under Stage 3 of this guidance as outlined below. The process for submitting your action for the Administrator's signature is discussed under Stage 4 of this guidance as outlined below.

General Management of Tier 3 Actions

Lead offices have considerably more discretion to decide what methods are appropriate for developing Tier 3 actions. This is usually referred to as the side agreement and is described below. Although Tier 3 actions allow more discretion and flexibility, it is still built on the same foundation of collaboration as Tier 1 and Tier 2 actions. Most Tier 3 actions still need to be transparent and inclusive, and should typically include OGC and OP in the development of the action, as well as all other offices expressing an interest in participating. If a lead office believes an action warrants senior management attention in offices other than OGC and OP, the Tier 3 designation should be reconsidered.

Step 1: Understanding Side Agreements

In this step, the lead office and interested offices establish the side agreement.

What is the “side agreement”?

Side agreements establish the ground rules for interested offices to take part in the development of an action for which no formal workgroup is convened. The agreement defines a relationship between the lead office and other offices and Regions that asked to be involved in developing a Tier 3 action. For a copy of the side agreement, see Action Aid 10.

What does the side agreement do?

The side agreement ensures that concerns outside the lead office/Region are appropriately considered during development of the action. The AA-ships/Regions that ask to participate

in the development of a Tier 3 action are consulted and given an opportunity to participate in specific and discrete parts of the development and decision making process for these actions.

The Agency's side agreement is suitable for most Tier 3 actions, but may be modified and tailored by the individual offices to suit their needs. In those rare circumstances where additional agreements must be added, those agreements will need to be clearly documented to avoid any surprises or misunderstandings later in the process.

Step 2: Managing Tier 3 Actions

In this step, the lead office consults early, promotes quality actions, and ensures management involvement.

The management of Tier 3 actions rests primarily with the lead office. The lead office has considerable autonomy to decide how it will develop an action, but it also has the responsibility for making sure that whatever the process, it has been agreed upon, and the end result is a quality action that addresses the agreements reached with other participating offices. The lead office is responsible for:

- **Consulting early.**

The lead office should consider what consultation and stakeholder involvement is needed. They should consult with workgroup members from participating offices to identify their specific areas of interest or concern and define the level of their participation. The lead office should also identify key external stakeholders, including State, Tribal, and local governments, industry, small entities, and public interest groups for consultation where appropriate. (See page 37 for issues to consider when consulting with State, Tribal, and local governments). Once the lead office identifies these stakeholders, it should begin making plans for appropriate consultation and stakeholder involvement processes or methods and scheduling outreach activities. Effective consultation and stakeholder involvement should precede major decisions in action development. For more information on the Public Involvement Policy and stakeholder involvement, see Action Aid 6.

- **Ensuring that actions meet the characteristics of quality.**

The lead office is accountable for producing an action that meets the characteristics of a quality action. For the characteristics of a quality action, go to page 11 & 12. The lead office is also responsible for conducting the necessary analyses and peer reviews to support the actions.

- **Establishing a management structure to provide guidance and internal closure.**

Since there is flexibility in the internal Agency process for developing Tier 3 actions, the lead office needs to make sure that the action stays on track. To do this, the lead office may want to establish consistent internal procedures for developing and managing Tier 3 actions, adhering to the side agreement for Tier 3 actions and ensuring closure/approval of Tier 3 actions.

Tier 3—Lead Office Actions

Lead AA ensures:

- Early consultation (e.g., state, local & tribal govts., industry, interest groups)
- Actions meet definition of “quality”
- “Side agreements” are honored
- Management structure is in place to provide team with
 - early guidance
 - internal closure

Lead Office develops Tier 3 actions—with participation from other offices



OMB Review—if required



Administrator Signature



FR Publication

Figure 3

Step 3: Developing a Tier 3 Action

In this step, the lead office should consider involving other offices, using available Agency expertise, developing an ABP, and providing participating offices with copies of the proposed action for their review.

What should the lead office consider in developing Tier 3 actions?

■ Involving other offices.

Even though Tier 3 actions do not require workgroups, the lead AA/RA is expected to take steps to involve the AA-ships/Regions that expressed an interest in participating when the action was tiered, consistent with the Tier 3 side agreement. In most cases, OGC and OP will be involved in the development of a Tier 3 action. The lead office should consider the level of assistance needed from Regions and other offices to produce a quality action. The Regions are in a particularly good position to assist the lead office in ensuring actions can be enforced and implemented in the field. The lead office should invite workgroup members to workgroup meetings and to key management briefings if they are held.

■ Using EPA expertise to develop the action.

Lead offices should develop in-house expertise and/or consult early with EPA experts (e.g., attorneys, RSC representatives/RRCs, Federal Register Liaison) regarding applicable laws, EOs, and *Federal Register* drafting guidance, well in advance of signature and other deadlines to ensure they develop quality actions. Additional information can be found at the ADP Library at <http://intranet.epa.gov/adplibrary>

- **Developing an analytic blueprint.**

An analytic blueprint is not required for Tier 3 actions, but it is encouraged. Some program offices may require it; please contact your RSC representative/RRC for more office specific information. Lead offices may find an informal blueprint helpful for effective planning. The analytic blueprint is an early agreement on the scope of the action and the analytical work required to develop the action.

- **Providing other offices with copies of the proposed action.**

Tier 3 actions are not required to go through FAR. At a minimum, however, the lead office should provide all participating offices with an opportunity to review issue papers, briefing documents, and options selection papers prepared for management. The lead office should also provide workgroup members opportunity to review the action's draft and final documents, and ensure sufficient time is provided to permit a meaningful review. The lead office should work with participating offices to address comments and issues raised during the reviews.

- **Resolving issues.**

The lead office and the participating offices should work together to resolve issues and to quickly elevate unresolved issues to management for resolution.

Stage 3.

OMB Review under EO 12866 for Proposed and Final Regulatory Actions and Significant Guidance Documents (if necessary)

This section describes the process for determining if OMB review under EO 12866 is necessary for proposed and final regulatory actions and significant guidance documents. It also explains how to prepare your action for submission to OMB, and how to address OMB's comments.

Step 1: Determining if EO 12866 Review for Proposed and Final Regulatory Actions and Significant Guidance Documents is Necessary

In this step, the lead office will determine if EO 12866 review is necessary and how the lead office should proceed based on this determination.

Does EO 12866 review apply to all regulatory actions?

Not all EPA actions must undergo EO 12866 review. Only those regulatory actions and some guidance documents designated “significant” under EO 12866, “Regulatory Planning and Review” are subject to EO 12866 review. This section discusses how EO 12866 applies to regulatory actions. See Action Aid 12 for detailed information on how EO 12866 applies to significant guidance documents.

What makes a regulatory action significant under EO 12866?

There is no direct relationship between a determination of significance under EO 12866 and placement of EPA actions in tiers. Under EO 12866, significant regulatory actions are those that meet at least one of the following four criteria:

- Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;

- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this EO.

Who determines if a regulatory action is significant?

The lead program offers a significance determination. Via the following process, OMB either agrees or disagrees with the lead program's determination. Twice a year, RMD issues a call letter to the programs soliciting information on regulatory actions currently under development by the Agency. RMD compiles a list of upcoming regulatory actions including the title of the action, the Agency's significance determination, justification for a non-significant determination if warranted, the stage of the action (e.g., NPRM or Final Rule), the timeline for the action (including statutory or judicial deadlines), and a description (abstract) of the action under development. This list is subsequently submitted to OMB, and they have 10 days to agree or disagree with the Agency's significance determination.

Step 2: Preparing Your Regulatory Action for Submission to OMB under EO 12866

In this step, if EO 12866 review is necessary, the lead office must prepare a regulatory package for submission to OMB.

What should be included in the package sent to OP for EO 12866 review?

When a package is ready for EO 12866 review, the lead AA/RA submits it to OP/RMD. OP is the only organization authorized to formally submit packages to OMB for EO 12866 review. The package should contain one original and one copy of the following items

(Note: Lead AA-ships/Regions may call for additional copies)

- The draft Action Memorandum (for guidance on how to write an Action Memorandum, visit the ADP Library at <http://intranet.epa.gov/adplibrary>);
- For actions developed under Tier 1 or 2, the FAR Summary Memorandum and copies of any non-concurrences or substantive FAR comments;
- The action itself (e.g., regulatory text and preamble, report to Congress, policy or guidance document, and relevant *Federal Register* document or notice of availability, as applicable);
- For economically significant rules, the OMB Circular A-4 (economics) table.
- For economically significant rules, the Regulatory Impact Analysis;
- An Electronic version of all the above.

Note: Documents submitted to OMB should follow the format for labeling documents as outlined in EPA's "Guidelines for Documenting EO 12866 Review and Consistently Labeling Documents in FDMS." These guidelines are available in the ADP library at <http://intranet.epa.gov/adplibrary>

What should the lead office do to prepare a regulatory action for submission to OMB under EO 12866?

If a significant regulatory action will be formally submitted to OMB for review under EO 12866, then the lead office needs to prepare a package for submission to OMB. For Tier 1 and 2, this package is prepared after the FAR meeting and submitted to OP. Tier 3 actions do not require a FAR and may go directly to OP for review and transmittal to OMB when that is necessary.

Who approves the action for submission to OMB for review?

Actions that do not go through FAR are submitted to OP for review and submission to OMB. For actions that do not have more than one non-concurrence, the AA/OP approves submission. For actions where more than one participating office/Region has non-concurred, OP will alert the RPO about the non-concurrence. The RPO will either:

- Authorize the action to proceed to OMB for review, without further changes.
- Determine how to revise the action to meet concerns raised in the non-concurrences, or
- Defer the decision to the lead AA/RA.

How long will EO 12866 review of a significant action last?

EO 12866 gives OMB 90 days to review regulatory actions (other types of actions will have a shorter review period). However, EO 12866 authorizes EPA to request a one-time 30-day extension. Requests for extensions should be prepared by the lead office in the form of a memorandum and should be submitted to the RMD Desk Officer for transmittal to OMB. For an example of a memorandum requesting an extension from OMB, visit the ADP Library at: <http://intranet.epa.gov/adplibrary>

Step 3: Addressing OMB's Comments for Regulatory Actions

In this step, the lead office will address questions and comments raised by OMB, or in response to other Federal agencies that participate in inter-agency review of your regulatory action.

How are OMB questions and comments on the draft regulatory action addressed?

During OMB review, the lead office may make changes to the regulatory action in response to questions and comments raised by OMB, or in response to other Federal agencies that participate in the inter-Agency review process under EO 12866. Any discussions with OMB should include the OP workgroup representative. The representatives of the other core offices should be included when significant issues relevant to those programs are being discussed.

Whenever time permits, the lead office should consult with OP and other members of the workgroup prior to making significant changes to the regulatory package or guidance document while it is at OMB. When time does not permit, the lead office should inform the workgroup members, as soon as possible after the fact, but before the regulatory package goes to the Administrator for signature. The workgroup chair should let the workgroup members know about these changes. Workgroup members are then responsible for informing their management of these changes.

Step 4: Docketing Changes Made During EO 12866 Review of Regulatory Actions

This step discusses how to identify and docket EO 12866 review material and changes made during that review.

What EO 12866 related materials are docketed?

If your regulatory action is reviewed by OMB under EO 12866, you should identify and place each of the following in the public docket:

- The draft action and any other documents sent to OIRA for review, such as analyses and assessments.
- The substantive changes, if any, between the draft action sent to OIRA for review and the action subsequently made available to the public, regardless of who requested the changes.
- The subset of changes made at the suggestion or recommendation of OIRA.

Note:

Certain provisions of the Clean Air Act and the Toxic Substances Control Act impose additional docketing requirements related to interagency reviews, including reviews under EO 12866. For more information about these requirements, contact your RSC representative and/or the OGC attorney assigned to your workgroup.

For additional information on compliance with EO 12866 docketing requirements, please visit the ADP Library at: <http://intranet.epa.gov/adplibrary>.

For additional information on documenting EO 12866 review, refer to the “Guidelines for Documenting EO 12866 Review and Consistency Labeling Documents in FDMS” document located at the ADP library, <http://intranet.epa.gov/adplibrary>.

Stage 4.

Requesting Signature, Publishing an Action in the *Federal Register*, and Soliciting and Accepting Public Comments

This section describes the procedures for requesting signature on proposed and final actions, publishing actions in the *Federal Register* as well as soliciting and accepting public comments.

Step 1: Requesting Signature

In this step, the lead office prepares the action for signature.

What actions are signed by the Administrator?

In general, most regulatory actions are signed by the Administrator unless that authority is placed with someone else by law or regulation, or otherwise delegated by the Administrator. You should have written evidence of delegation of signature authority before someone other than the Administrator signs a regulatory action.

What if your action will be signed by an EPA official other than the Administrator?

For those actions where the signature authority has been delegated, you should contact your RSC representative/RRC for information about the signature process in your AA-ship/Region. Sometimes a delegation may allow the AA/RA to further delegate signature authority. See the Agency's Delegations Manual for more information about who can sign what at the website: <http://intranet.epa.gov/ohr/rmpolicy>.

What should be done if an action will be signed by the Administrator?

The lead office should do the following before the Administrator signs an action:

- 1. Request preliminary review of a regulatory action by EPA's Federal Register Liaison, if appropriate.**

The lead office should have the Federal Register Liaison review the preamble and the rule at the same time that OMB is reviewing it. If OMB does not need to review the regulatory action, then a copy should be provided to the Federal Register Liaison after the FAR for Tier 1 or 2 actions, or after workgroup approval for Tier 3 actions. You may send your

action to the Federal Register Liaison via email. The Federal Register Liaison assures that actions comply with *Federal Register* publication standards and requirements. The Federal Register Liaison for all EPA offices is located in OP's RMD (with the exception of the Office of Chemical Safety and Pollution Prevention (OCSPP), which has an office-specific liaison.) The Federal Register Liaison always reviews the action after signature, but preliminary review avoids problems and delays at this stage.

2. Address OMB's concerns and issues.

Generally, the Administrator signs significant EPA regulatory actions after the lead office has addressed OMB's concerns and has resolved any outstanding issues, and after OMB has cleared the action. It is the responsibility of the RMD Desk Officer to confirm OMB's clearance of an action before moving it forward for signature.

3. Assure a complete docket.

A docket can be established at any time during the ADP, but should open no later than the date of issuance/publication of the first action or FR document to be published (e.g., notice, proposed, or final rule).

A docket should contain:

- All information relied upon by EPA in developing an action.
- All public comments.
- EPA's response to significant public comments (e.g., a response to comment document).
- Other information EPA considers relevant to the development of an action (e.g., environmental or public health assessments, cost and benefit analyses, technical support documents, etc.) with the exception of confidential business information and other information whose public disclosure is protected by statute.
- Information concerning changes made during EO 12866 review (see Stage 3, Step 4).

The docket generally should not include internal documents that capture pre-decisional discussions that were deliberative in nature. This includes materials generated prior to the making of a decision such as day-to-day staff notes, briefing papers, action memoranda and other staff advice and recommendations. Confidential business information and other information whose public disclosure is protected by statute should not be included in the public docket. The docket process may vary by program. For more information about what to include in your docket, please consult experts in your program such as your RSC representative/RRC contact or the OGC or Regional attorney assigned to your action.

For additional information on docketing see "Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers" at <http://intranet.epa.gov/adplibrary>.

Note:

Some statutes require the docket to be established no later than the date of signature.

Dockets for regulatory actions are posted in the Agency's official electronic docketing system, the Federal Docket Management System (FDMS). Non-regulatory actions have more discretion (i.e., may be posted on the Internet). For more information about FDMS, visit the FDMS information Web page at <http://intranet.epa.gov/fdmsinfo>.

What does the lead office include in the package requesting the Administrator's signature?

When an action is ready to be signed by the Administrator, the lead office submits a signature package to RMD which includes, the original and two copies (unless otherwise noted) of the following items

(Note: Lead AA-ships/Regions may call for additional copies):

- The draft Action Memorandum (for guidance on how to write an Action Memorandum, visit the ADP Library at <http://intranet.epa.gov/adplibrary>);
- For actions developed under Tier 1 or 2, the FAR Summary Memorandum and copies of any non-concurrences or substantive FAR comments;
- The action itself (e.g., regulatory text and preamble, report to Congress, policy or guidance document, and relevant *Federal Register* document or notice of availability, as applicable);
- For economically significant rules, the OMB Circular A-4 (economics) table.
- Fact sheets, if available;
- A disk or CD that contains an electronic version of any action to be published in the *Federal Register*;
- A letter (original only) to the OFR certifying that the hardcopy of an action to be published in the FR is identical to the one on the disk, if needed; and
- A typesetting request (one copy) (EPA Form 2340-15), if needed.

Note: Some parts of this process may be different for OCSPP since that Office has its own *Federal Register* staff.

Who is responsible for requesting the Administrator's signature?

The lead AA/RA is responsible for requesting the Administrator's signature via an Action Memorandum. The lead AA/RA submits the complete package to OP for final review and approval. OP reviews the package and if no outstanding issues remain, seeks approval from either the AA/OP, or the RPO. The AA/OP approves packages that do not have more than one non-concurrence at FAR. OP transmits the package to the Office of the Executive Secretariat (OEX) for the Administrator's signature.

Note:

Lead AA-ships/Regions may call for additional copies.

What happens if changes are made after an action has been signed by the Administrator?

Occasionally, it is necessary to make changes to a regulatory action after it has been signed by the Administrator, but before it has been published in the *Federal Register*. If these changes are only clerical or typographical and do not affect the substance of the action, authorized EPA staff can make the changes and initial them without further review by the Administrator, however, these changes should be reviewed by OP.

Proposed substantive changes should be submitted by the lead AA/RA with concurrence from OGC and OP through a memorandum to the Administrator. Substantive changes must be approved by the Administrator before transmitting the action to the *Federal Register* for publication.

Any questions regarding whether a change is substantive should be discussed with OGC, since in some cases, even a clerical, typographical, or format change, such as a change to a regulatory citation, may affect substance. (More information on this topic is available at the ADP Library: <http://intranet.epa.gov/adplibrary>)

When can I post my action on the Internet?

After the Administrator, Deputy Administrator, or Assistant Administrator has signed your action, your office may decide to post it on the Internet before it is published in the *Federal Register* (see Step 2 below). The workgroup will review and approve the documents prior to posting. When your office decides it is necessary to release a signed, pre-publication version of a document on the Internet, or mail it directly to external parties, a disclaimer should be added to the document and the document should match the subsequent *Federal Register* publication. Minor stylistic or formatting discrepancies are acceptable. For additional information about posting on the Internet and the specific disclaimer to use, visit the ADP Library at <http://intranet.epa.gov/adplibrary>.

Step 2: Publishing an Action in the *Federal Register*

In this step, OEX sends the action to the Federal Register Liaison for review and submission for publication in the *Federal Register*, if appropriate.

When is the action sent to the *Federal Register*?

After the Administrator signs the action, OEX sends it to the Agency's Federal Register Liaison, if appropriate. The Federal Register Liaison conducts a final review of the action and transmits it to the *Federal Register* for publication. Regulatory actions generally are published in the *Federal Register*.

How does the *Federal Register* process work?

Once actions are sent to the *Federal Register*, they are usually published within four business days if they are under fifty pages and do not contain tables. Otherwise, it will likely take longer.

For specific information on the *Federal Register* process you should visit the OFR website at http://www.archives.gov/federal_register/write/handbook. OFR's Document Drafting Handbook, which can be found at the website, provides specific guidance and examples for drafting and formatting a document for publication in the *Federal Register*. The manual also includes guidance on how to request an expedited publication or "withdrawal before publication" of an action from the OFR.

Step 3: Soliciting and Accepting Public Comments

In this step, the public responds to solicitations for comments and sends comments to the Agency.

How does the public comment process work?

Each action published, or otherwise released for public comment, must include clear instructions for the public on when, where, and how to submit comments to EPA. These instructions are usually included in the preamble for your regulatory action. Template language for use in regulatory packages is available on the ADP Library at <http://intranet.epa.gov/adplibrary>.

An electronic public docket may also be established in the Federal Docket Management System (FDMS) for some non-regulatory actions that will solicit public comment. For guidance on establishing and populating a public docket in FDMS, please refer to OEI's website at <http://intranet.epa.gov/fdmsinfo/index.html>, as well as OP's "Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers" also available on the ADP Library at <http://intranet.epa.gov/adplibrary>.

In addition to accepting public comments in writing, the Agency may also choose to hold one or more public meetings during the comment period. If you think public meetings would be appropriate for your action, work with your OGC workgroup representative and your RSC representative or RRC to ensure you take the appropriate steps to notify the public of the meeting and properly record public comments.

Stage 5.

Developing the Final Action and Ensuring Congressional Review

In this step, the workgroup reconvenes to finalize the action. This section also describes how to comply with the Congressional Review Act or the Courtesy Copy Policy

At this point in the process, the workgroup should consider any comments received and determine which, if any, present substantive issues which may impact the development of the final action. If the Agency receives substantive comments on the proposed Tier 1 or Tier 2 action, the workgroup should return to the early guidance step and seek direction from senior management on how to proceed. At the early guidance meeting, senior management will hear the workgroup's recommendations on the substantive issues raised and plan for proceeding to a final action. As part of early guidance, senior management may also decide whether procedural steps like revising the DABP and/or options selection are necessary for the final action. If the workgroup agrees that there are no significant issues following the public comment period, and the direction for the final action is clear, it may not be necessary to have an early guidance meeting or option selection meeting. The lead AA/RA should make this final determination, and the lead office should share that decision in writing with the workgroup. After that point, the workgroup proceeds to complete development of the final action and ultimately concludes the workgroup with a Final Agency Review process.

Step 1: Addressing Public Comments

In this step, the workgroup considers public comments and may reconsider options, based on the public comments received.

How does the workgroup address public comments?

Following solicitation of public comments on a proposed rule or draft action, the workgroup first reviews and considers the comments and any other relevant new information that may have come to its attention since it published the proposed action. Based on its assessment of the comments, the workgroup develops recommendations on how to proceed, including whether to reconsider the preferred options and/or analyze new options.

Does the workgroup have to respond to every comment received?

No, when developing a final action, the workgroup should consider all significant public comments that are relevant to the proposal and submitted during the applicable comment period. Sometimes, the same comments may be received by numerous commentors and need to be addressed only once. The consideration of significant comments is documented consistent with legal requirements and applicable docket policies. Depending on the nature and extent of public comments received, you may choose to prepare a separate “response to comments” document or simply address them in the preamble to the final action. For assistance with docketing, please see “Creating and Managing Dockets: Frequently Asked Questions for EPA Action Developers”, visit the ADP Library at <http://intranet.epa.gov/adplibrary>.

Sometimes, an office may elect to consider a comment that was submitted after the formal comment period has ended. Generally, if you consider one comment received after the close of the comment period, you must consider all such comments. Consult the OGC attorney assigned to your action and your RSC Representative/RRC for guidance. They may advise you to issue a Supplemental NPRM.

How many comments can the Agency expect to receive?

The volume of comments varies tremendously from action to action. In some cases there can be tens of thousands of comments; in others, only a few. While the number of comments may be indicative of the general interest in the action, it is the substantive content of the comments, not merely the number, that is most important. Commenters may, for example, submit new information prompting reconsideration of options or supporting material, including economic analyses prepared for the proposed rule. New information and data should be reconsidered in the development of the final action.

Should others be involved in the response to comments?

If clarification or discussion of public comment is useful, the workgroup can consider whether the Agency may want to contact stakeholders to discuss the comments further, but you will need to work with OGC to ensure that any such post-proposal outreach is managed and documented properly.

Step 2: Determining Next Steps

In this step, the workgroup briefs management and receives guidance on how to proceed in developing the final action. The level of management involvement will depend on the tier level of the action.

How does the workgroup determine what the next steps are for developing the final action?

At the end of the comment period, the workgroup will brief management on the scope of the comments received and provide recommendations on how they believe the Agency should respond to the comments. Management will consider the recommendations and provide guidance on how to proceed in developing the final action.

Management guidance should come from the A/DA for Tier 1 actions, AA/DAA for Tier 2 actions, and AA/DAA or designated OD for Tier 3 actions. In light of public comments and any new data, a workgroup might face a range of possible approaches—everything from making minor rule changes and clarifications to new data gathering and possible re-proposal. Below are some ways that a workgroup may be directed to address the different types of comments it receives in response to a proposed action.

- **Comments indicate that the preferred option presented in the proposed action is acceptable.**

In this case, the workgroup may recommend to management that the final action use the proposed option. If management agrees, there may be no need to make changes to the action and the workgroup may be able to proceed expeditiously to FAR.

- **Comments indicate that another option presented in the proposed action should be considered.**

This would involve another round of management decisions based on the new information received, which would be accomplished by having an options selection meeting prior to the FAR process.

- **Comments indicate that an option not identified in the proposed action should be considered.**

This is an unusual, but not an unheard of circumstance. In this case, the workgroup may need to revisit the Analytic Blueprint and update it in order to plan additional analysis and options development. New options would subsequently be presented to management in an options selection meeting. In addition to considering the substantive options, management will also need to evaluate procedural options, i.e., how to provide notice to the public that the Agency is considering an approach other than one previously proposed, which could include a re-proposal, known as a Supplemental NPRM for rules. A Notice of Data Availability (NODA) may be issued if comments have provided new data or additional information on the action. (See Action Aid 14 for detailed information on NODAs.)

How does the workgroup develop the final action?

After receiving management guidance, the workgroup employs the particular ADP steps as directed using the procedures outlined earlier in this document. For Tier 1 and 2 actions, preparing the final action will include FAR, and for all tiers, submission to OMB if necessary. As with the draft or proposed stage, during final action development the workgroup should continue as a transparent collaborative body – collegially generating and sharing documents for internal review and comment prior to seeking senior management and approval or sign-off.

Step 3: Submitting Actions to Congress and GAO under the Congressional Review Act or the Courtesy Copy Policy

In this step, actions are submitted to Congress and GAO for Congressional review after they are signed, but before they are published in the *Federal Register*, or otherwise issued.

Many of the Agency's final actions are submitted to Congress and the Government Accountability Office (GAO) under either the Congressional Review Act (CRA) or the Courtesy Copy Policy (CCP). Proposed rules are not subject to Congressional review.

The CRA and CCP are discussed below. In addition, a separate guidance document was written for the CRA, while the CCP is the subject of Action Aid 13, included at the end of this document. Both documents are available on the ADP Library at <http://intranet.epa.gov/adplibrary>.

What is Congressional Review?

Federal agencies must submit most final rules (see exceptions below) to Congress and GAO under the CRA. The CRA provides an expedited way for Congress to review and potentially disapprove final rules issued by Federal agencies. Under the CRA, a member of Congress can introduce a joint resolution to disapprove a particular rule within a specified period of time and have that joint resolution considered using expedited procedures. It also generally prohibits any rule meeting the CRA definition of "major rule" from taking effect until 60 days after publication in the *Federal Register*.

What EPA actions are subject to Congressional Review under the Congressional Review Act (CRA)?

Final rules, with few exceptions, are subject to Congressional review, including actions that may contain legally binding requirements regardless of their title or whether they are published in the "Rules and Regulations" section of the FR.

Examples of rules that are not subject to Congressional review include:

- Rules of particular applicability (i.e., entities subject to the requirements of the rule are specifically named in the rule).
- Rules relating to Agency management or personnel.
- Rules of Agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-Agency parties.

What is a "Major Rule" for the Purposes of the CRA?

- A "major rule" is a rule that the Administrator of OMB/OIRA finds has resulted in, or is likely to result in:
- An annual effect on the economy of \$100 million or more.

- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

This is similar to the definition of an economically significant rule under EO 12866. Thus, an “economically significant” rule under EO 12866 is likely (but not certainly) to also be designated as “major” under the CRA. It is important to note that a rule can be a “significant regulatory action” (i.e., is reviewed by OMB) under EO 12866 **without** being a major rule under the CRA. This is because EO 12866 has more criteria for making a rule “significant” than the CRA does for making a rule “major.” In addition, a rule that EPA finds is not economically significant under EO 12866 may be determined by OMB to be major under the CRA.

For more information on CRA and CCP, visit the ADP Library at <http://intranet.epa.gov/adplibrary> or contact your RSC representative/RRC.

When is an action submitted to Congress and GAO under the CRA?

In general, before a final rule can take effect, EPA must submit a rule report, as defined in the CRA, to each house of Congress and the Comptroller General of the Government Accountability Office (GAO). According to Agency policy, RMD submits a rule report on or before the date of their publication of the rule in the *Federal Register*.

Congress and GAO sign a “receipt of delivery” for actions submitted under CRA/CCP, and a copy of this receipt is sent to the lead RSC representative/RRC within about a day of delivery. Program offices should put receipts in the docket for the relevant action. RMD keeps the original receipts for CRA/CCP submissions as official documentation that the action was submitted to both houses of Congress and GAO.

What are the consequences of not submitting a CRA rule prior to the effective date?

Even though a rule subject to the CRA may be published in the *Federal Register*, the rule will not be effective on the cited date unless EPA has submitted the rule to Congress and GAO (unless the Agency invokes the good cause exception from the CRA’s effective date provision.) This is a particularly important issue for rules that are expected to be effective upon or before the date of publication in the *Federal Register*.

What office submits EPA actions for Congressional review?

RMD is the only EPA office authorized to submit final rules under CRA and other documents under CCP to Congress and GAO. Regional and Headquarters program offices must not submit rules, policies, and other guidance documents under the CRA/CCP directly to Congress, GAO for any reason. There are no exceptions.

Note:

Legislative and Appropriations reports to Congress are not submitted to Congress and GAO under the CRA or CCP. They are submitted to Congress and GAO through the normal procedures for such reports to Congress, through OCIR or OCFO.

What should the lead office provide to RMD so that it can submit a regulatory action for Congressional review under the CRA?

The lead office needs to submit the regulatory action to RMD only if it is not signed by the Administrator. RMD automatically gets a copy of final rules signed by the Administrator. Once RMD receives the action, it will complete a Congressional submission report for the action. This report should contain:

- A copy of the action.
- A concise general statement explaining the action (included in the rule's "Summary" section), and indicating whether the action is a "major action," i.e., has an economic impact of \$100M or more.
- The proposed effective date of the action, which is included in the action's preamble.

What is the Agency's Courtesy Copy Policy (CCP)?

The Agency's Courtesy Copy Policy took effect in July 1999. The policy states that the Agency will send courtesy copies of non-binding policy, guidance, and interpretive documents to Congress and GAO as they are issued to inform them of newly developed Agency guidance at the same time the Agency informs the public at large.

How does it relate to CRA?

The CCP complements our official submissions to Congress and GAO under the CRA.

What actions are submitted under the CCP?

EPA submits to Congress guidance and policy documents that are used to implement statutory and regulatory programs.

What is the process for CCP submittal?

The lead office submits these documents through their RSC representative/RRC to RMD for transmittal to Congress and GAO. If the program is submitting a paper copy, RMD will need four copies of the guidance or policy document. However, if the program is submitting their guidance or policy documents electronically, RMD will need the URL for the document. In either case, RMD will also need a statement from OGC/ Office of Regional Counsel (ORC) indicating the document does not include legally binding requirements.

Note:

Policies and guidance documents that do not implement statutory or regulatory requirements are not submitted to Congress and GAO (e.g., voluntary programs, or miscellaneous information documents)

For more information on CRA and CCP and for copies of the preamble template language and forms, visit the ADP Library at <http://intranet.epa.gov/adplibrary> or contact your RSC representative/RRC.

Appendix A.

Additional Information for Action Developers on Specific Topics

This section includes numerous Action Aids to assist you in developing actions.

This section contains several “Action Aids” about the following topics:

- Action Aid 1: EPA’s Semi-Annual Regulatory Agenda and Regulatory Plan
- Action Aid 2: Tiering a New Action vs. “Splitting” an Action
- Action Aid 3: Workgroup Responsibilities
- Action Aid 4: Elevating and Resolving Workgroup Issues
- Action Aid 5: Issues to Consider when Giving Early Guidance
- Action Aid 6: Involving the Public and Other Stakeholders in the ADP
- Action Aid 7: Options Selection Meetings
- Action Aid 8: Recommendations for Scheduling Key Milestone Meetings
- Action Aid 9: Procedures for Requesting an Expedited Final Agency Review Process
- Action Aid 10: Side Agreement for Tier 3 Actions
- Action Aid 11: Ordering of Statutes and Executive Orders, and Discussions for Rule Preambles
- Action Aid 12: A Reference to EPA’s Implementation of OMB’s Good Guidance Practices Bulletin
- Action Aid 13: EPA’s Courtesy Copy Policy
- Action Aid 14: Notices of Data Availability (NODA)
- Action Aid 15: Reports to Congress – Procedures for Internal Review and Submission to OMB

For more information about the ADP, please visit the ADP Library at <http://intranet.epa.gov/adplibrary> or contact your RSC representative.

Action Aid I: EPA's Semi-Annual Regulatory Agenda and Regulatory Plan

What is the Regulatory Agenda?

The Regulatory Agenda is an information tool to give stakeholders an opportunity to be effectively involved in developing regulations. Each spring and fall, OMB sends out a request to all Federal agencies involved in regulation development. This request asks agencies to provide information on all regulatory actions under development that may be submitted to OMB for review under EO 12866. All agencies provide information to OMB as part of the Unified Regulatory Agenda. In addition to regulatory actions, agencies have the discretion to include entries on important policies, strategies, and guidance documents that may be of particular interest to the public.

As part of the fall Regulatory Agenda some agencies, including EPA, also publish an Annual Regulatory Plan. The Plan highlights a very limited number of the most significant actions the Agency intends to publish in the coming year. Plan entries include everything that is in Agenda entries plus additional required information fields on alternatives, costs and benefits, risks, and a statement that addresses why a regulation is necessary.

What kind of information is published in the Regulatory Agenda?

Agenda entries generally include the following:

- A brief description of the action, the abstract.
- Legal authority.
- Contact information.
- A timetable of upcoming dates related to the action (e.g., NPRM, projected publication date in the FR, etc.).
- Where to find supporting documents for the regulatory action, or the docket location.
- North American Industry Classification System (NAICS) codes associated with the action.
- Links to additional information.
- Up to 20 other types of information related to the action.

How is EPA's Regulatory Agenda information updated?

OMB sends an Agenda call letter to OP with directions and a schedule. The Chair of the RSC then sends a call letter to the RSC requesting the program office to update Agenda entries in RAPIDS. Agenda updates are reviewed by OGC and OP/PRAD. They are then submitted to the GSA's Regulatory Information Service Center (RISC) which coordinates review with OMB before providing EPA a galley version about six weeks later for final revisions. If the program office needs assistance during this process, they should contact their RSC representative/RRC or their RMD Desk Officer. Contact information is available at the ADP Library at <http://intranet.epa.gov/adplibrary>.

OP pays for the basic *Federal Register* typesetting, reprinting, and distribution costs for the Agenda. If a correction notice has to be published, as occasionally happens for entries that did not receive an adequate and timely review, the FR costs for the correction are generally charged to the program office account requesting the change.

How is the Regulatory Agenda used?

The Regulatory Agenda provides information to citizens to give them the opportunity to be involved in the rulemaking process. It also helps to coordinate regulatory activity within the Executive Branch of the government. Users include OMB, Congress, EPA and other Executive Branch agencies, the media, trade associations, interest groups, State and local governments, the general public, and interested foreign parties.

How do I get a copy of the Semi-Annual Regulatory Agenda and Annual Regulatory Plan?

EPA's Regulatory Agenda and Regulatory Plan can be accessed at <http://www.epa.gov/lawsregs/search/regagenda.html>.

Action Aid 2: Tiering a New Action vs. “Splitting” an Action

The RAPIDS and Scout systems track actions that follow the ADP and were created for consistency of planning and development of regulatory or related activities. Actions are divided into stages, and stages, in turn, are composed of specific milestones. The structure assumes that each stage has one end point, typically signature or management approval, which culminates as a single final action. The most common pattern or development track for Agency actions is a proposal stage followed by the final stage. Occasionally, however, an action begun with an expected single final stage changes course and it becomes necessary to add differing action stages. When that occurs, program offices should work with OP to determine the most appropriate way to track the actions in RAPIDS/Scout, either by tiering a new action or by “splitting” the current action.

When is it appropriate for an action to be tiered as a new action vs. splitting an action?

A new action or activity is tiered at the beginning of the ADP which typically commences as an NPRM and is commonly referred to as the proposal stage. In some cases, the program office will initiate a new action by first issuing preliminary data in the form of an ANPRM and in other cases by issuing a Direct Final Rulemaking (DFRM). For any action or activity that uses an ANPRM, NPRM or DFRM, or their functional equivalents, the action developer should submit a commencement/tiering approval form in order to obtain a new SAN. For more information about tiering or about when to directly issue a DFRM, see <http://intranet.epa.gov/adplibrary>.

It is generally not appropriate to add any additional stages in RAPIDS to an action that has been completed in the final action stage. There should be only one final stage per SAN in RAPIDS. Completed actions should not be split or used to add stages for subsequent actions based merely on a similarity or close relationship of subject matter. Instead, a commencement/tiering approval form for a new action should be completed and submitted to OP for approval.

When is splitting an action appropriate?

The most common and straightforward case for “splitting” an action is when a program office has issued a proposal and then decides that it will not finalize all issues in a single final action. Splitting an action allows each of those final actions to be tracked separately but to retain original tiering and commencement approval. It may be appropriate to split an action under the following circumstances:

- When an Agency-initiated correction to the final rule will be issued.
- When a minor amendment will be issued and the amendment is temporally close to the promulgation of the original rule. Significant amendments or those that will be proposed substantially after the final rule (e.g., more than 12 months following the final rule) should be tiered as new actions.

- When a “generic” action has multiple stages that are part of an on-going effort. For example, a singularly tiered action, such as a Federal Implementation Plan, may have frequent but unpredictable changes when State Implementation Plans are developed. In this circumstance, split actions can be created to avoid adding duplicative stages to the original action.
- For some petitions when they are covered by a generic SAN.

How do I request approval to split an action?

The initiating office’s RSC representative/RRC should contact the appropriate RMD Desk Officer to request a split action. The request should include:

- A new title.
- An edited or revised abstract for both the original and new action.
- A timetable for the new action.
- Any other information normally required on a tiering form that varies from the original action, e.g., court deadlines, workgroup members, etc.
- A reference to the original action (title & SAN) for the maintenance form of the new action.

The RMD Director is the approving authority for split action requests.

What happens after a “split” is approved?

As with tiering approval notifications, RMD will notify the RSC representatives/RRCs once a split is approved. The commencement approval, tier level, workgroup members, OMB significance level, and other key data elements will be applied to the new action, unless requests are made otherwise. The split action will receive a new SAN, which will appear as a decimal point to the related existing action. For example, SAN 6100.1 would be newly created from the existing SAN 6100. In addition, if the action is a rule, it will receive a new Regulation Identifier Number (RIN) and title. Once the RMD Desk Officer has assigned the new split SAN, the requester will be notified via email and will have 5 business days to complete the maintenance form for the new action in RAPIDS. Failure to complete the form will result in the split action being deleted from the system and the need to tier it as a new action.

Action Aid 3: Workgroup Responsibilities

Workgroups are formed soon after tiering and workgroup members are assigned through the tiering process. Workgroups consist of a workgroup chair (representing the lead office developing the action) and workgroup members (representing the AAs/RAs who responded to the tiering request). Whether you are the workgroup chair or a workgroup member, if you have been assigned to a workgroup, you will need to be involved in the development of the action throughout the ADP.

What are the workgroup members' responsibilities?

Workgroup members and the chair share the same responsibilities for participation, although the workgroup chair has some additional responsibilities.

Responsibilities the workgroup members and the chair share are:

- Being prepared for meetings by having reviewed materials and discussed issues and positions with management;
- Contributing a meaningful amount of work to the process of developing the action;
- Regularly attending meetings or ensuring that a qualified alternate attends workgroup meetings (the use of alternates should be minimized and workgroup representatives should be sure they support any positions taken by alternates in their absence);
- Representing their office's or Region's management positions on issues;
- Helping to find solutions on issues;
- Raising timely issues within their individual offices or Regions and ensuring the issues raised are documented, elevated, and resolved as soon as possible, preferably before options selection and Final Agency Review;
- Implementing the issue elevation and resolution process when necessary;
- Honoring decisions the lead office senior management or other upper management makes, unless they are appealed to a higher level in the Agency in a timely manner;
- Seeking outside assistance when the workgroup needs vital information;
- Using redline/strikeout or similar tools to highlight comments on or revised language in draft documents to expedite the review process;
- Ensuring products meet Agency quality standards; and
- Contacting the appropriate lead AA/RA representative (for example, a RSC representative/RRC) for help with problems in the workgroup.

Additional responsibilities of the workgroup chair are:

- Involving the workgroup throughout the process;
- Facilitating a meaningful and responsive workgroup process at all times, including times when dissenting members have asked for senior management decisions;

- Facilitating attendance at workgroup meetings by scheduling meetings with sufficient notice and providing meeting materials well in advance of the meeting;
- Documenting workgroup meetings, issues addressed, and decisions made;
- Determining whether the package is complete and ready for Final Agency Review, including polling workgroup members to determine if they think it is ready for Final Agency Review;
- Sharing early drafts of documents for workgroup input before they are approved by management (e.g., PABP, DABP, options selection briefing);
- Maintaining all documentation throughout the workgroup process (including decisions, issues, and participation);
- Ensuring consistency with the ADP and compliance with the S&EOs addressing rulemaking;
- Producing a comprehensive and comprehensible action that complies with all internal and external administrative processes and requirements;
- Ensuring that issues are identified and resolved at the appropriate management level in a fair and open manner;
- Seeking additional members for workgroup, if needed;
- Informing your management and RSC representative/RRC of any changes to workgroup membership;
- Guaranteeing that lead office management is routinely informed of issues and agreements reached at the workgroup level as they occur;
- Documenting and distributing changes made to the package during and after FAR to workgroup members; and
- Considering whether a neutral facilitator might be useful to manage discussions and assist in preventing or resolving issues or disagreements.

Action Aid 4: Elevating and Resolving Workgroup Issues

Throughout the ADP, issues that arise that workgroup members cannot resolve. When this occurs, it is important for workgroup members to elevate these issues to a higher level of management in a timely fashion.

How do workgroups effectively deal with issues that arise?

Workgroup procedures can help achieve the goal of a timely, quality product even while allowing members to raise and work through significant issues. To do this, workgroup procedures should:

- Encourage members to raise issues;
- Provide for open discussion and timely resolution of issues;
- Progress toward resolving issues while encouraging diverse views;
- Seek agreement with the workgroup while being mindful of deadlines;
- Document resolved issues and dissents; and
- Develop a means to quickly elevate issues to management if the workgroup hasn't resolved them in a reasonable time period.

Workgroups can avail themselves of the services of an internal facilitator or contract a neutral facilitator in order to assist in laying out operational ground rules, managing productive discussions and airing and resolving differences. For guidance in locating a neutral facilitator, see the OGC's Conflict Prevention and Resolution Center's (CPRC) website at <http://intranet.epa.gov/adr/>.

How does the workgroup process help workgroups elevate and resolve issues?

Workgroups should try to resolve issues within that forum. If they can't, they should act quickly to elevate issues to their management for resolution. The workgroup should avoid two extremes: (1) unreasonable delays because of unresolved issues, and (2) failure to address legitimate substantive issues which were raised by workgroup members.

The workgroup process includes four elements that help strike the right balance between open discussion and resolution of issues. These elements are:

1. Building a spirit of teamwork and collaboration

It is the responsibility of the lead AA-ship/Region to produce a quality action that addresses all relevant information and issues. For this reason the lead AA-ship/Region should make the best possible use of the expertise available on the workgroup. A successful workgroup that functions as a collaborative team will be able to resolve most issues through internal discussions in a reasonable time period. The workgroup chair can help foster collaboration by scheduling regular meetings for the workgroup with his or her management to get continuing feedback and resolve issues. At these meetings any member of the workgroup should feel free to raise issues. Sometimes it is useful for the chair to access a neutral facilitator to assist the group in airing and resolving differences in a timely and collegial manner.

2. Implementing lead office prerogative

There may be some issues that a workgroup cannot reach agreement on in a reasonable time. If these are major issues, the chair and workgroup members should agree to elevate the issue to managers for resolution. In some rare cases, however, when the lead office/Region feels an issue needs to be resolved by the workgroup in order to avoid delay, the lead office/Region has the following options:

- If the workgroup is unable to reach agreement on the issue within a reasonable time, the lead office/Region has the prerogative to propose a solution and move forward based on the proposal without accommodating all of the concerns of the dissenting office(s).
- If the lead office/Region chooses to exercise the prerogative, the workgroup chair should document the decision and the reasons for the selected approach, and communicate it to all workgroup members and to lead office management.

3. Elevating issues quickly

Issues can be elevated informally, in a meeting with the lead office/Region's management; or formally, with a dissenting member's management. When workgroup members can't elevate the issue informally, they should elevate the issue formally through their management chain.

Elevating issues informally

Workgroups are encouraged to elevate important issues to management when they can't resolve the issue themselves or when they want management guidance. Informal elevation takes place with the workgroup chair's management in a feedback session. Workgroup chairs should schedule workgroup feedback sessions with their management periodically during the development process, and particularly when substantive disagreements are impeding workgroup progress.

Elevating issues formally

To elevate the issue formally, the dissenting workgroup member should notify the chair of their intent and then raise the issue to their own management at the appropriate level. The dissenting member's management should then contact the workgroup chair's management for resolution. If the dissenting office is not satisfied at this level, they may pursue the issue up the management chain in similar fashion, depending upon their degree of concern regarding the issue. Ultimately, they could elevate the issue to the Administrator, but this would be unusual except for Tier 1 rules.

4. Documenting agreements and dissents

Carefully documenting issues and their resolution helps the workgroup focus on the most important issues and keeps all members aware of important decisions.

- To facilitate discussion or elevation of an issue, a workgroup member may submit a dissent memorandum to the workgroup chair to object to the lead office's

solution. The memorandum should outline the nature of the objection and the rationale for it, and propose an alternative approach.

- If a program or Region submits a dissent memorandum with an OD or AA/RA-level signature, the lead office OD or AA/RA must respond to it and indicate how the concern was addressed or why it was not. If the issue(s) in the dissent memorandum are not resolved by the time of Final Agency Review, an AA/RA-level dissent memorandum and the lead office/Region response to it should be attached to the package circulated for Final Agency Review.

The CPRC offers training to improve negotiating and consensus building skills. For a list of their courses as well as additional conflict prevention and resolution resources, visit their site at <http://intraent.epa.gov/adr>.

Action Aid 5: Issues to Consider when Giving Early Guidance

Early guidance is the opportunity for senior managers to raise questions that will focus the direction of the workgroup. Listed below are suggested questions for consideration; however, this list is not inclusive. Only a few of the questions may be pertinent to a particular situation and there may be other relevant questions to consider that are not listed here.

Have you considered the Administration's Priorities?

- Does this action involve climate change?
- Will this action help to improve air quality?
- Is this action assuring the safe use of chemicals?
- Will this action help clean up communities?
- Will this action help in protecting waters?
- How can we expand involvement on environmentalism and work toward environmental justice with this action?
- Will this action help to build stronger State and Tribal partnerships?

What are the general management issues?

- What is our expected product?
- Is there a particular schedule to which we should (or must) adhere? How will that affect the level of analysis and selection of options or alternatives?
- How often do I need to receive briefings on this action? At particular decision points?
- Is this action likely to need OMB review?
- Should we involve other Federal agencies, and if so, how and when?
- What kinds of stakeholder involvement will improve the quality and durability of the rule?
- Is this action appropriate for some type of negotiated or consensual rulemaking?
- What are the quality characteristics that are of particular interest? (For a list of quality characteristics, go to page 11 & 12 of this guidance document.)
- What does our action's assigned tier determine about our process?

What policy and procedural issues do we need to examine?

- Do statutory mandates limit our policy options?
- Are there cross-media implications?
- What type of scientific data and research will be required?
- Should we examine market-based incentives or other innovative approaches as an option to regulation?

- In what ways could we encourage pollution prevention?
- What public participation provisions can we include?
- In what ways should we involve the regulated community?
- In what ways could we encourage other levels of government (co-regulators) to have input into the rulemaking process?
- What further information and/or briefing does management want from the workgroup? At what points?
- What documents might require peer review?
- What do we need to do to ensure the quality of the information supporting the action?

What other S&EOs may require analysis?

- Is this action “significant” under EO 12866, as amended? If so, what kinds of economic analysis do we need to do?
- Does this rule have energy impacts under EO 13211?
- Will this rulemaking affect small entities (i.e., small businesses, small governments, and non profits)? Specific guidance on how to make this determination is available at the ADP Library <http://intranet.epa.gov/adplibrary>
- Will this rulemaking impose a reporting or record keeping burden on the regulated community?
- Will this rulemaking impose mandates on States or local governments? If so, it may require consultation with affected parties or federal funding for activities under the Unfunded Mandates Reform Act (UMRA).
- Will this rulemaking require consultation with State, local, or Tribal elected officials?
- Will this rulemaking show an actual or potential lack of fair treatment for any group, including minority or low-income populations? EPA’s guidance on how to determine if your action will have Environmental Justice concerns will be available soon on the ADP Library at <http://intranet.epa.gov/adplibrary>.
- Will this rulemaking require special consideration of its impact on children? Specific guidance on how to make this determination is available at the ADP Library, <http://intranet.epa.gov/adplibrary>
- Will it have a significant or unique impact on small governments?
- Are there voluntary technical standards that may apply?

Action Aid 6: Involving the Public and Other Stakeholders in the ADP

When should the public and stakeholders be involved in the ADP?

Under the Public Involvement Policy (PIP), “whenever possible” Agency officials should strive to provide opportunities for public involvement above and beyond the minimum regulatory requirements when actions are expected to be classified as “significant” under terms of EO 12866. You can access the PIP at <http://www.epa.gov/publicinvolvement/public>

Involving outside stakeholders at the earliest practicable time in constructing an EPA action or EPA decision provides additional viewpoints, data, and options that can be valuable in designing the most effective and implementable regulations and programs. These public involvement activities may be in addition to efforts under certain statutes, regulations and executive orders which require more formal consultation. The efforts and timing of public involvement activities should be such that the information that is presented, sought, and obtained can be integrated in a timely way with the Agency’s internal deliberation and decision-making processes.

Who are stakeholders?

Stakeholders are those members of the public who may have an interest in a specific decision or action the Agency is about to take. They may include Tribal, State, and local governments; regulated industry and their suppliers; and/or economic, social, environmental and public interest groups. While the general public is invited to participate in the notice and comment process when the NPRM is published, during the rule development stage you may find it useful to actively seek out and engage groups of people or organizations which can be identified as affected either directly or indirectly. They may be able to provide additional viewpoints, data, information, options, or insights that you don’t already have access to. Since stakeholders provide real world experiences that can improve the effectiveness of our regulatory actions, the PIP encourages EPA officials to conduct outreach to the public to ensure that all who may be interested or affected have an opportunity to participate.

How do we get stakeholders involved in the ADP?

The workgroup should work together to develop a plan for stakeholder involvement during the ABP process and solicit feedback on the plan from management at the early guidance meeting. Getting stakeholders involved requires planning to achieve identified goals; identifying the interested and affected parties; conducting the involvement process; and using the results of the involvement process. It should be connected to the development of the action in a way that helps inform the action at the earliest possible stage and continues throughout the ADP in order to produce a quality action that is both durable and effective. In order to be credible and productive, processes for conducting public involvement should be carefully selected and the goals and endpoints of the process should be communicated clearly to the stakeholders. The CPRC has many resources for rulewriters trying to design and manage stakeholder participation. Visit their website at <http://intranet.epa.gov/adr>.

What are the four stakeholder involvement processes?

There is not a single preferred method of stakeholder involvement. EPA has identified four stakeholder involvement processes applicable to action development that may be appropriate based on the desired goal or end product of the process. Involving stakeholders in the ADP may include one or several types of processes.

Outreach - Used when EPA wants to inform stakeholders about the information, data, options, and direction of the rulemaking or other action. This is a one-way information sharing process. Outreach is an important component of most other stakeholder involvement processes.

Information Exchange - Used when EPA wants to share, discuss, and exchange information, data, and options with stakeholders. This is a two-way process that can be conducted in a collaborative manner and can recognize convergence in views, but it does not build consensus.

Recommendations - Used when EPA wants to engage in a dialogue with stakeholders identifying or narrowing down potential options. This process involves continuing discussion with and between stakeholders. Design of a recommendations process should involve an analysis of the applicability of the FACA.

Agreements - Used when EPA wants to engage in negotiations with stakeholders to develop mutually acceptable options for the action. This process is known as negotiated rulemaking. It typically involves establishment or use of a FACA with EPA taking the lead in the negotiations.

How does the workgroup know which stakeholder involvement process to use?

The primary factors to consider in determining which stakeholder involvement process to use include: the amount of information already available to the Agency and stakeholders, the degree of controversy, the degree of complexity, and the time and resources available to EPA and the stakeholders. For assistance in deciding which stakeholder involvement process is appropriate, you can contact the Conflict Prevention and Resolution Center at <http://www.epa.gov/adr>.

What is the timing of stakeholder involvement?

Planning for stakeholder involvement occurs during the development of the PABP and the DABP. Although the stakeholder involvement process could occur earlier, ideally it occurs during the period after the approval of the DABP and before options selection. The information and/or recommendations obtained from stakeholders may be used in developing the options for the options selection meeting.

How does FACA affect public involvement in action development?

FACA generally applies whenever EPA establishes or utilizes (that is, manages or controls) a group that includes one or more non-federal members to obtain group or collective advice or

recommendations. FACA's public notice and transparency requirements mirror best practices normally used in public involvement processes. A more detailed discussion of the FACA and collaboration with the public can be found at <http://www.epa.gov/publicinvolvement/pdf/facaguide.pdf>. Advice on how to design public involvement activities taking FACA into consideration can be obtained from OGC's FACA attorney or the Office of Cooperative Environmental Management.

Action Aid 7: Options Selection Meetings

Options selection is the last formal step for senior management to provide input in the development process before the workgroup completes drafting of the action.

How do I prepare for an options selection meeting?

- Prior to the options selection meeting, there is a workgroup meeting to discuss the options and policies to be considered in advance of distributing the background materials for the options selection meeting. The lead office prepares a summary of other offices' positions on the options and includes it with the background materials for the options selection meeting.
- The discussion and any material distributed for such a meeting are considered deliberative and should not be discussed or released outside of EPA.
- The lead AA-ship/Region distributes the options selection briefing package and background materials to the participating AAs/RAs and their RSC representatives/RRC at least one week prior to the meeting.

Who should be invited to the options selection meeting?

- All participating AAs/RAs are invited to the options selection meeting. The participating AAs/RAs should decide which staff member(s) they want to accompany them to the meeting. The invited AA/RA may ask someone else to represent him/her at the options selection meeting; however, the representative must be fully able to commit the invited principal.
- Core offices (i.e., OP, ORD, OGC and OECA) are expected to participate on Tier 1 and Tier 2 workgroups. Staff from these offices do not have to attend the workgroup meeting on the options, and the AAs from these offices do not have to attend the options selection meeting if they have no issues or concerns. Recognize, though, that the office will miss its chance to contribute its views if an issue does come up and the office elected to be absent.

How do I notify invitees?

- The workgroup chair advises his or her RSC representative/RRC as soon as planning for an options selection meeting begins, but no later than two weeks in advance of the meeting and provides him/her a list of participating AA-ships/Regions and workgroup members identified by each office/Region.
- Lead RSC representatives then notify all RSC representatives/RRC from AA-ships/Regions that are participating on the workgroup of the upcoming meeting and include names of workgroup member(s) identified by each AA-ship/Region.
- RSC representatives/RRC will notify their RMD Desk Officers when an options selection meeting is scheduled.
- RMD will notify RSC representatives/RRC of upcoming options selection meetings in conjunction with the distribution of RSC meeting agendas.

What is the protocol for an options selection meeting?

- The meetings are chaired by the Administrator or Deputy Administrator for Tier 1 actions, or the lead AA or Deputy AA for Tier 2 actions.
- The meeting focuses on selecting the approach and/or policies, identifying any unresolved issues, and agreeing on follow-up actions.
- The lead office drafts a memorandum that documents the options discussed, the decisions made, and the follow-up actions agreed to. It distributes this memorandum to all participants.
- The memorandum is included in the FAR package and marked as an “internal deliberative document.”

Action Aid 8: Recommendations for Scheduling Key Milestone Meetings

It is important that your office’s early guidance, options selection, and FAR meetings (i.e., milestone meetings) are clearly described and communicated to the necessary staff to ensure proper cross-Agency participation. This Action Aid describes recommended procedures for scheduling your meetings in a manner that benefits all participating Program and Regional offices. These procedures are not required. They simply help document some of the best practices that offices have used in the past.

What is the appropriate time for scheduling key milestone meetings?

Notify participating offices of milestone meetings early enough that they are able to schedule pre-briefs with their senior managers. Notify participating offices according to the following time frames. (See “What should I include in my meeting notice?” section below for recommended content of meeting notices.)

Early Guidance	Options Selection	FAR
<ul style="list-style-type: none"> Notify participating offices of the meeting 2 weeks in advance. Distribute the PABP briefing materials a minimum of 5 working days beforehand. 	<ul style="list-style-type: none"> Notify participating offices of the meeting 2 weeks in advance. Distribute background materials a minimum of 5 working days beforehand. 	<ul style="list-style-type: none"> Notify participating offices and distribute the FAR package a minimum of 15 working days prior to the meeting. For exceptions to 15-day notification, see Action Aid 9.

Who are the recipients of meeting notices?

For early guidance and option selection meetings, meeting notices should be sent to the AAs/RAs of the participating offices. The following individuals should be included in the “Optional/cc” line:

- All workgroup members.
- The RSC representative or RRC for every participating office, as well as their alternates. You can find a current list of RSC representatives and RRCs at <http://intranet.epa.gov/adplibrary>.
- The Office Director responsible for the action.
- Other program office experts, as determined by the workgroup chair or the RSC representative/RRC.
- The RMD Desk Officer for lead program and the RMD Director.

For FAR meetings, the lead office should notify the workgroup members rather than the RAs/AAs as indicated above. All others listed in the bulleted list above should be added to the “Optional/cc” line. Consult your Desk Officer in RMD for help. Desk Officers are listed at <http://intranet.epa.gov/adplibrary>.

What should I include in the subject line of my meeting notification?

- The subject line of your meeting notice should include these four elements:

- Type of milestone meeting (e.g., early guidance, options selection, FAR).
- Name of action.
- Stage of action when appropriate (e.g., NPRM, Final Rule).
- SAN.

What should I include in my meeting notice?

All meeting notices should include the following information in the body (i.e., the “description” in a Lotus Notes meeting scheduler):

- The type of milestone meeting. (Restate it here even though it is in the Subject.)
- The name and SAN for the action. (Restate it here even though it is in the Subject.)
- Meeting purpose. (Limit this to 3-5 short bullet points.)
- A list of the workgroup members, RSC representatives/RRCs, and other program office participants. Identify, all by office.

You may not have all of your materials prepared when first scheduling a meeting, but you should distribute them as soon as possible. (See the “Timing” section for guidance on deadlines to follow.) Meeting participants should receive the following materials:

Early Guidance	Options Selection	FAR
<ul style="list-style-type: none"> ■ Background material. ■ PABP. ■ Major questions to be addressed. ■ Specific issues where other AA-ships or agencies may differ. 	<ul style="list-style-type: none"> ■ Background material. ■ Options (try to limit to 4-5) identified by the workgroup. For each option, describe: <ul style="list-style-type: none"> • Preliminary scope of costs, benefits, and risks. • Overview of how stakeholders may benefit or be adversely affected. 	<ul style="list-style-type: none"> ■ FAR announcement memorandum. ■ Draft action memorandum. ■ Draft action. ■ For rules: <ul style="list-style-type: none"> • Draft preamble. • Draft Regulatory Impact Analysis, or other analyses. ■ Economically significant rules must also include the OMB Circular A-4 table. ■ Draft information collection request, if required. ■ Decision Memorandum from options selection.

What are some things that have worked for key milestone meetings in the past?

RSC representatives and RRCs have a great deal of experience in scheduling and attending milestone meetings. Here are their tips on what has worked well in the past:

- Request a meeting with the DA 2 months prior to your desired date, if it is a Tier 1 action.
- Schedule pre-briefs with senior managers at least 2 weeks before milestone meetings.
- Make sure your workgroup list is up to date, and update the list in RAPIDS if it changes. The lists in RAPIDS are often not current.

- In most offices, the AA's staff assistant schedules milestone meetings. Help the staff assistant by including these elements in the meeting request you send to them:
 - 3 prioritized options for the meeting date/time.
 - The preferred location of the meeting.
 - Audio/visual needs.
 - A mailing list for the meeting notice that clearly indicates who should be in the "Required/To" field and who should be in the "Optional/cc" field.
 - The exact content of the meeting notice, so the staff assistant can cut and paste your text. (See the above "What should I include in my meeting notice?" section for more information.)

Action Aid 9: Procedures for Requesting an Expedited FAR Process

Sometimes, it may be necessary to request an expedited FAR. This Action Aid establishes procedures for requesting an expedited FAR. This procedure will be used whenever an office believes they will not be able to provide the standard 15 working days to complete review of the FAR package.

When is it okay to request an expedited FAR?

This expedited process is limited to those circumstances in which there is no other option, given a deadline, or in cases where all participants agree to a shortened period. Typically, the lead office provides participating offices/Regions with the complete FAR package (action memorandum, *Federal Register* documents, economic assessment, information collection request, communications strategy, decision memorandum, etc.) a minimum of fifteen working days before the FAR meeting. In exceptional circumstances, it may be necessary for this standard review period to be shortened (e.g., court-ordered deadline, etc.). An expedited FAR does NOT mean that all documents in the FAR package do not have to be complete. Quite the opposite, a truncated review period increases the importance of having a complete package in hand when the review period begins.

What is the process for requesting an expedited FAR?

To shorten the FAR review period, the workgroup chair should follow the approach below:

1. The workgroup chair will seek agreement from all workgroup members to expedite the FAR process. The chair will find out whether the workgroup members agree, or if they have any concerns.
2. If the workgroup agrees, the workgroup chair will transmit the following information to their RSC representative/RRC:
 - Title and SAN for the action.
 - The number of working days requested for the expedited FAR process.
 - A justification for expediting the FAR process.
 - A list of workgroup members, with Office and Regional affiliates.
 - The position of all participating offices on the request to expedite the FAR process; and
 - Any concerns raised by other offices.
3. The lead RSC representative/RRC will then advise and seek agreement from the RSC representatives/RRCs for all participating offices/Regions and address any remaining concerns.
4. If the participating offices/Regions agree to an expedited FAR, the lead RSC representative/RRC should provide the bulleted information in #2 above to the Director/RMD.
5. Expedited FAR concurrences/non-concurrences must be submitted and will be addressed according to the procedures outlined in Stage 2, Step 9 of this guidance document.

Action Aid 10: Side Agreement for Tier 3 Actions

The lead AA-ship/Region is responsible for consulting with the identified representatives of the other AA-ship/Regions that ask to participate in a Tier 3 action and for affording them an opportunity to participate in the development and decision-making process. In those rare circumstances where this side agreement needs to be supplemented with additional agreements, those agreements will need to be clearly documented.

What are the responsibilities of the lead AA-ship/Region Workgroup Chair?

- Consult with the identified representative of the participating AA-ship/Region shortly after tiering to identify specific interests/areas of concern and/or expertise, and define the level of desired participation, i.e., full participation, reviewer, consultant.
- Invite the identified representative of the participating AA-ship/Region to workgroup meetings, if held, and to key management briefings, if held.
- Provide an opportunity for the identified representatives of the participating AA-ships/Regions to participate in review (and where appropriate, the development) of related issue, briefing, and option selection papers prepared for management.
- Provide an opportunity for the identified representative of the participating AA-ship/Region to participate in the review (and where appropriate, the development) of the action's draft document(s), i.e., the rule and preamble, *Federal Register* document, guidance, policy statement, report, etc.
- Ensure that the participating AA-ship/Region has the opportunity to participate in the final review of the document(s), and is informed of any distribution of a final draft so that the participating AA-ship/Region can ensure that they provide their final comments.
- Work with the participating AA-ship/Region to address comments and issues raised.
- Ensure that sufficient time is provided to the identified representative of the participating AA-ship/Region, so that they may undertake a meaningful review and complete any necessary discussions with their management.

What is expected of the participating AA-ship/Region staff contacts?

- Communicate and discuss with the workgroup chair shortly after tiering the specific interests/areas of concern and/or expertise related to the Tier 3 action, along with the level of their desired participation, i.e., full participation, reviewer, consultant.
- Respond to meeting invitations. This will ensure that the workgroup chair knows that they have received the message and confirms their continued involvement even if they do not attend the meeting or briefing.
- Actively participate in the review (and where appropriate, the development) of materials.

- Ensure that comments and advice provided are representative of the AA-ship/Region and program that they represent, and clearly indicate when that is not the case.
- Participate and comment in a timely manner, making sure to represent management's position, and work with the lead office to resolve comments and issues raised.
- Inform their RSC representative or RRC and the workgroup chair for the action when they are reassigned, and provide the name of a replacement contact, even if that person will only be an interim contact.

How are issues resolved?

The workgroup chair and the Participating AA-ship/Region Staff Contacts will work together to resolve issues and to quickly elevate unresolved issues to management for resolution (see Action Aid 4).

What if a participating office would like to discontinue its participation?

The participating contact may determine at any time that their office should no longer participate in the action. In such cases, they must inform their RSC representative or RRC that they recommend that their office withdraw from further participation in the action. The RSC representative/RRC will determine whether the AA-ships/Regions will withdraw from the activity. If so, that RSC representative/RRC will notify the RSC representative/RRC for the Lead AA-ship/Region and OP that they are withdrawing from further participation in that activity. The RSC representative/RRC will inform their workgroup chair, and OP will document the withdrawal in RAPIDS.

Action Aid II: Ordering of Statutes and Executive Orders, and Discussions for Rule Preambles

Discussions of the S&EOs affecting rulemaking are included in a section at the end of the preamble entitled “Statutory and Executive Order Reviews.” This discussion is included in the preamble of both your proposed and final rule. It may also appear in an ANPRM or other type of notice. Consult your RSC representative/RRC contact or OGC attorney for advice in these instances. The information presented in these discussions is developed as part of the data collection and analysis portion of the ADP process (see Stage 2, Sep 3).

Is there a particular order the S&EO should follow?

Use the following standard ordering of the discussion of the “Statutory and Executive Order Reviews” section that appears at the end of rule preambles for both proposed and final rules.¹

- Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
- Paperwork Reduction Act
- Regulatory Flexibility Act
- Unfunded Mandates Reform Act
- Executive Order 13132: Federalism
- Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
- Executive Order 13045: Protection of Children from Environmental Health & Safety Risks
- Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- National Technology Transfer and Advancement Act
- Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

As necessary and appropriate, you may also include a discussion of the following:

- Executive Order 12630: Governmental Actions and Interference with Constitutionally Protected Property Rights (Takings)
- Executive Order 12988: Civil Justice Reform

For all rules and non-rule notices published in the Final Rules Section of the *Federal Register* and not for any notices published in any other section of the *Federal Register*:

- Congressional Review Act

¹ Exceptions will be considered on a case-by-case basis. Contact your RSC representative or RRC for guidance on exceptions.

Where can I get information on how to prepare language for S&EOs?

For more information on the S&EOs listed above and preamble template language for each, visit the following websites:

- ADP Library: <http://intranet.epa.gov/adplibrary>
- ICR website: <http://intranet.epa.gov/icrintra>
- RFA/SBREFEA website: <http://www.epa.gov/sbrefa>

Action Aid 12: A Reference for OMB Review of Significant Guidance Documents under EO 12866 Review

A guidance document can be defined as an agency statement of general applicability and future effect, other than a regulatory action, that sets forth policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue. The definition of a significant guidance document¹ is similar to the definition of a “significant regulatory action” under EO 12866, and includes guidance documents that may reasonably be anticipated to “raise novel legal or policy issues arising out of legal mandates, presidential priorities, or the principles set forth in EO 12866...” An economically significant guidance document includes guidance that “may reasonably be anticipated to...have an annual effect on the economy greater than \$100 million or adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities...”

See <http://www.epa.gov/regulations/guidance/byoffice.html> for a list of documents by program or Regional offices the Agency has already determined are “significant”.

How do I tier a significant guidance document?

Significant guidance documents should be tiered and should follow a written procedure for development that includes core offices, where appropriate. The procedures for developing a significant guidance document can be found at <http://intranet.epa.gov/adplibrary>. We encourage you to use the ADP to develop significant guidance documents. If you use the ADP as your process, the following information should be included on the tiering form: title of document, program office, proposed tier level, desired development procedure, projected dates for OMB review (if that becomes necessary), and signature or issuance date. Note that all significant guidance documents should receive approval at the AA-ship/Region level. Generally, once you have determined that a new guidance document under early development could meet the definition of a “significant guidance document” you should contact your RSC representative or RRC if you have questions about which procedure to follow for developing your significant guidance document.

What should be included in my newly developed significant guidance document?

A number of elements that should be included in each newly-developed significant guidance document can be found in a checklist on the ADP Library website at: <http://intranet.epa.gov/adplibrary>.

Will OMB review a significant guidance document?

When a program is nearing completion of the significant guidance document and is preparing for its release, RMD will notify OMB that a guidance document determined as “significant” is under development and OMB will determine if it should be transmitted for interagency review. OMB instructed agencies to notify it about any significant guidance

¹See OMB’s “Final Bulletin for Agency Good Guidance Practices,” http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/m07-07.pdf

documents no later than 10 days prior to intended dissemination,¹ but as a practical matter, if OMB wishes to review the guidance document, it may take 30 days or more. We recommend that you allow sufficient time prior to release of a significant guidance document to allow for potential interagency review. Be sure to work with your RSC representative/RRC when developing a significant guidance document.

Two weeks prior to finalizing the significant guidance document or transmitting it to OMB, lead program or Regional offices should submit the following materials to the appropriate RMD Desk Officer:

- One paper original and one hard copy of the significant guidance document;
- One hard copy of any other supporting materials;
- One electronic version; and
- A transmittal memorandum.

The RMD Desk Officer will transmit the significant guidance document in the ROCIS interagency database system.

Do I have to post a significant guidance document on EPA's website and do I have to create a docket for a significant guidance document?

Yes, OMB has instructed each Agency to allow for public comment on all final significant guidance documents. Agencies are under no obligation to respond to comments made specifically about a significant guidance document. However, for economically significant guidances, Agencies are expected to respond to comments. EPA has elected to use the federal electronic rulemaking docket (<http://www.regulations.gov/>) to receive comments on each Agency-issued significant guidance document. For detailed instructions on how to post your significant guidance document to EPA's website and on how to establish the docket, including the specific abstract text, see <http://intranet.epa.gov/adplibrary>.

¹See OMB's implementation memo on Agency Good Guidance Practices, http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/m07-13.pdf.

Action Aid 13: EPA's Courtesy Copy Policy

Program offices may develop guidance and interpretive documents that are not legally binding and make them available to the public. In order to inform Congress and the GAO about the availability of these materials, RMD sends courtesy copies to both Houses of Congress and GAO under the CCP. Program offices should not post new policy, guidance, or interpretive documents on the internet or otherwise disseminate the documents without concurrently (or earlier) following the CCP submission process.

What is the CCP submission process?

Program offices and Regions are responsible in the first instance for determining whether a document should be submitted under the CCP. The program office or Region should obtain concurrence from OGC/ORC that the document does not contain binding legal requirements. EPA Regions should receive concurrence from the appropriate Headquarters program office that the document does not conflict with existing national guidance. After internal reviews are complete and concurrences have been obtained, lead offices should forward four courtesy copies or a website URL to the CRA Coordinator in RMD. (If you don't know who your CRA Coordinator is, ask your RMD Desk Officer, who is listed at <http://intranet/epa.gov/adplibrary/contacts>.) This submission should include a short note from OGC/ORC indicating that there are no legally binding requirements in the document. RMD will keep the OGC/ORC statement on file and attach a short cover note to accompany the submission before delivering it promptly to both Houses of Congress and GAO.

How do I know what to send under the CCP?

In general, any non-binding policy, guidance, or interpretive document that reflects the first written instance in which EPA publicly announces its approach to the implementation of or offers an explanation for a given statutory or regulatory program would be submitted to Congress and the GAO under CCP. However, a public document that merely reiterates statutory or regulatory requirements should not be submitted under CCP. Included within the scope of "non-binding guidance" documents that should be submitted under CCP are those:

- Containing recommendations used to draft permit conditions, variances, or waivers.
- Explaining EPA's view of what is included in or excluded from a requirement.
- Containing guidance that is directly communicated to the public and used by program offices to implement or explain EPA's regulatory programs.
- Directed to Regions, States and/or the regulated community to:
 - Explain what the regulated community should do to comply.
 - Explain how EPA will exercise its discretion in implementing statutory or regulatory requirements.
 - Offer direction to the Regions on how to implement statutory or regulatory provisions pursuant to a specific statutory authority or program (e.g., memorandum from Headquarters office to Regions).

- Define multi-media or cross-program EPA positions explaining the treatment of certain kinds of regulated entities.
- Offering technical guidance directly related to a regulatory requirement;
- Including “stand-alone” policy, guidance, and interpretive documents; or
- Containing non-binding guidance relating to grants or contracts.

Is the CCP different for Regional Offices?

In short, no. Any non-binding policy, guidance or interpretive document that implements or explains a statutory or regulatory program, and could be applied more broadly to cases or parties in other EPA Regions or offices, is covered under the CCP. This includes guidance documents that:

- Further define, clarify, or explain statutory or regulatory requirements, or Agency policy or guidance and cover a class or group of entities, directly or by implication.
- Are significant, precedent-setting, or historic.
- Are relevant to more than one facility and used by EPA to implement, describe or explain a statutory or regulatory program.
- Are specific applicability determinations or jurisdictional letters sent to a facility or source, or to a State regarding a facility/source, if they contain broadly applicable policy statements of interest to regulated entities.
- Have been communicated to affected parties, in addition to the original inquirer.

Are there any general categories of documents not included in the CCP?

Yes. Documents that are exempted from the Congressional Review Act (CRA) (see question 6) are not included. Deliberative or otherwise privileged documents, enforcement-sensitive documents, and scientific information used to support agency programs but not directly related to a regulatory requirement, are not covered by the CCP. In addition, site-specific and individual determinations that do not meet the criteria described in question 4 are not covered by the CCP.

How does CCP differ from CRA?

The CRA (5 U.S.C. §§ 801-808) imposes a statutory requirement to submit rules to Congress and the GAO. In accordance with the CRA, EPA submits all documents that contain binding legal requirements, regardless of their title, unless the document falls within one of the exemptions to the CRA. Guidance and interpretive documents generally should not contain legally binding requirements, and thus would not fall within the scope of the CRA. However, EPA’s policy is to provide to Congress and GAO copies of our non-binding guidance documents under the CCP. The following types of documents are expressly exempted from the CRA under 5 U.S.C. §804(3) and are also not included in CCP:

- Rules of particular applicability (i.e., those applicable to specifically named entities).
- Rules related to Agency management or personnel.
- Rules related to Agency organization procedure or practice that do not substantially affect the rights or obligations of non-agency parties.

Check with your OGC/ORC attorney for more information about exemptions from the CRA. For additional CRA guidance, see <http://intranet.epa.gov/adplibrary>.

Does RMD track CCP submissions?

Yes. RMD tracks CCP submissions in the CRA/CCP database. In addition, RMD keeps signed receipts for these submissions on file. Contact RMD's CRA coordinator for more information about specific CCP submissions or to get read-only access to the CRA/CCP database.

Action Aid 14: Notices of Data Availability (NODA)

What is the purpose of this action aid?

This Action Aid provides policy guidance and recommendations for Agency staff who are considering using a NODA in a pending Agency rulemaking. NODAs do not impose legally binding requirements. If you work on regulatory actions, you should consider how a NODA would be used. Some past uses of NODAs resulted in criticism from stakeholders asserting that the Agency appeared to be imposing new requirements without going through normal rulemaking procedures. EPA's rulemaking activities are subject to public scrutiny, as well as judicial review under various statutes, including the RFA and APA. Questions have arisen in the past concerning the use of NODAs after the comment period on a proposed rule has closed and before a final rule has been issued. Agency staff should be aware of potentially applicable requirements of these statutes, especially when developing a NODA between the proposed and final rule stages.

How does EPA use a NODA?

EPA can use a NODA in a variety of situations to provide notice to the public of data developed or received by EPA on a particular issue or topic. The data may be contained in the FR notice itself, or more commonly posted in the docket or on the web with information in the FR notice on how the public can access the data.

The type of NODAs addressed by this Action Aid are NODAs that both:

- Make the public aware of new data EPA is considering during the development of a rulemaking that is subject to notice and comment in the rulemaking procedure under the APA or any other statute.
- Relate to a rulemaking that has already been proposed.

For example, EPA may use a NODA to make available to the public a new technical study that has been developed or received by EPA and is related to a proposed rule. The NODA serves to inform the public that the data may be considered in developing the final rule. Although placing the data in the public docket makes the data publicly available even without a NODA, the NODA is a way to call attention to the addition of the data to the docket.

How does OFR categorize NODAs for publication in the FR?

The OFR considers NODAs to be rule-related actions when they make available to the public information relating to a previously proposed rule. OFR will generally publish such NODAs in the "Proposed Rule" section. Other NODAs that are not related to a rulemaking may be published in the "Notices" section.

In addition, the OFR allows agencies to issue a Notice of Availability (NoA), which makes the public aware of a particular document – as opposed to data. Like a NODA, if a NoA is related to a pending rulemaking, OFR generally will publish it in the "Proposed Rules" section, and if a NoA is not related to a rulemaking, then it generally will be published in the "Notices" section.

What is a “new regulatory alternative”?

A new regulatory alternative is a substantive or enforceable rule provision or regulatory option that was neither included in the original regulatory text of the proposed rule nor with the scope of the discussion in the preamble.

What is the difference between Supplemental NPRMs (SNPRMs) and NODAs?

A SNPRM typically proposes a new regulatory alternative. In addition, a SNPRM may present new data that EPA intends to consider in developing the final rule. A SNPRM that contains a new regulatory alternative usually is signed by the same level of agency official as the original proposal and may be subject to OMB review under EO 12866. A SNPRM should address in the preamble EO 12866, RFA and other S&EO reviews applicable to the rulemaking. A SNPRM may require a supplemental analysis, for example, under the RFA, if a new regulatory alternative would have economic impacts that were not addressed in the RFA analysis or certification for the original proposal. You should work with your OGC or ORC attorney to ensure that the requirements of the RFA, as well as other S&EO reviews, are satisfied.

EPA's policy is that a NODA, on the other hand, should **only** announce the availability of the new data and should not otherwise propose or identify additional regulatory alternatives or change the original proposed rule. Therefore, no additional economic analysis should generally be needed.

Is EPA required to request public comments when it releases new data post-proposal?

When EPA releases new data that merely reinforce the supporting information for the rule provisions or regulatory options presented in the proposed rulemaking, EPA does so in a NODA. The APA does not require EPA to request additional public comment. However, when EPA proposes or identifies a new regulatory alternative, EPA's policy is to do so in a SNPRM, not in a NODA.

The APA, as interpreted by the courts in certain instances, may require EPA to provide the public with notice and an opportunity to comment on new data that serve to expand the scope of the rule provisions or regulatory options presented in the original proposal and upon which EPA may rely in a final rule. As a result, a SNPRM is an important tool for providing an additional opportunity for public comment on a new regulatory alternative or new data that, in effect, expand the scope of the regulatory options in the original proposal. If you have questions concerning whether to seek public comment on new data being made available to the public after an initial public comment period has closed (or shortly before it will be closing), you should consult your OGC or ORC attorney.

Do NODAs undergo formal Agency review?

NODAs do not need to undergo all the same steps in the ADP as the proposed rule, but they should still undergo a FAR-like process and otherwise be processed as you would a standard regulatory action. This will help to ensure the NODA policy is addressed consistently across the Agency.

Does OMB review NODAs?

OMB generally does not review NODAs under EO 12866. If you follow this guidance and your NODA doesn't propose new regulatory alternatives, the AO review performed by OP should be sufficient.

Action Aid 15: Reports to Congress – Procedures for Internal Review and Submission to OMB

Congress often requests or directs the Agency to report on specific topics. Congress typically makes these requests either through authorizing statutes (e.g., Clean Air Act or Clean Water Act), or via appropriations legislation (i.e., the bills that provide the Agency with its operating funds). OP may be involved in the development of the report to Congress in either of these circumstances, and this Action Aid discusses the process for our involvement in detail.

Are reports to Congress Tiered?

Reports to Congress are considered “non-regulatory” actions under the ADP and should be developed according to these guidelines:

- Reports to Congress mandated by authorizing statute should all be tiered and should follow the ADP for the designated Tier level.
- Reports to Congress called for by appropriations legislation, or requested through committee reports, should be tiered if the substantive content of the report would establish or amend policy or otherwise provide new or revised interpretations of statutory, regulatory, or policy requirements. If the report to Congress called for by appropriations legislation is tiered, it should follow the ADP for the designated Tier level.

In RAPIDS, there is a specific tiering form available for reports to Congress, which is a condensed version of the tiering form for regulatory actions. Program offices should complete this form for each new report to Congress. The completed form should be submitted via the lead office RSC Representative/RRC so that it can be included in the Agency’s monthly tiering exercise for review by the RSC and assignment of workgroup representatives. Once the tiering is approved by OP management, each tiered report to Congress should follow the appropriate steps in the ADP.

Unlike the ADP for regulatory actions, the ADP for reports to Congress differs in stipulating that the office coordinating the end of the development process varies based on the source of the Congressional request. The office selected to coordinate OMB review and final sign-off for transmittal to Congress varies based on the following criteria:

- The Office of Congressional and Intergovernmental Relations (OCIR) coordinates reports to Congress called for by authorizing statutes.
- The Office of the Chief Financial Officer (OCFO) coordinates reports to Congress called for through appropriations language or committee reports.

It is important to note that before such reports are submitted to either OMB or Congress (without regard to the source of the Congressional request, internal coordinating office, or ADP tier level), OP/ORPM is tasked with reviewing and approving all reports to Congress that address substantive issues that could establish or amend policy or otherwise provide new or revised interpretations of statutory, regulatory, or policy requirements.

Reports to Congress Mandated by Authorizing Statute

Submitting the report to OMB

- When a report to Congress is ready for submission to OMB, the lead program/Regional office should prepare an Action Memorandum requesting OMB/Interagency clearance of the report. The Memo should summarize the primary conclusions and recommendations in the report and the process used for the development and review of the report. The Memo should be:
 - From the lead program office AA/RA.
 - Through the AA/OP.
 - To the AA/OCIR.
- The originating office should submit an original and one copy as well as an electronic version of the Action Memorandum and the report to OP/ORPM with a “cc” on the electronic version to OCIR at least ten weeks prior to the date the report is due for submission to Congress. When the original schedule cannot accommodate this target submission date, please contact your RSC representative/RRC to work with OP and OCIR to identify a workable schedule for completing your report on time.
- Upon receiving the report to Congress, OP/ORPM will review it for any resource implications. If there are resource implications, OP/ORPM will forward an electronic copy of the report to the OCFO for review and include a due date for completion of OCFO’s review.
- OP/ORPM will promptly review the submitted reports to Congress and, in consultation with OCIR, will recommend whether to forward the report to OMB for OMB/Interagency clearance. Once approved by management to go to OMB, OP/ORPM will electronically transmit the report to OCIR for immediate submission to OMB and deliver a hard copy of the report to OCIR.
- OCIR will transmit the report to OMB with “cc’s” to OP/ORPM and the lead office/Regional Office (including the RSC representative/RRC). The report to Congress should be forwarded to OMB for review at least six weeks prior to the due date. OMB has up to 30 days to review the report.
- OP/ORPM will enter the date of transmittal to OMB in RAPIDS.
- During OMB review, OCIR will work with the originating program office, including the RSC representative/RRC, and OP/ORPM to consider OMB comments and will inform, as necessary, other interested AA/RAs regarding any revisions requested through interagency comments. Any discussions with OMB should include the OP/ORPM workgroup representative. The representatives of the other core offices (i.e., OECA, OGC, & ORD) should be included when significant issues relevant to those programs are being discussed.

Submitting the report for Signature

When a report to Congress has cleared OMB and is ready to be transmitted to Congress, OCIR will work with the originating office to prepare transmittal letters for signature. Letters will be sent to the President of the Senate and the Speaker of the House of Representatives, and, as appropriate, to the chair and ranking member of committees of jurisdiction.

- The program office should finalize the Action Memorandum, including discussion of any changes requested by OMB. The Memo should be:
 - From the lead program office AA/RA.
 - Through the AA/OP.
 - To the AA/OCIR.
- The program office AA/RA should submit a complete package for review and approval for signature to OP with a cc to OCIR. The package should include the original and 3 hard copies, as well as electronic versions of:
 - The Action Memorandum.
 - The transmittal letters.
 - The final report to Congress.
- OP/ORPM will review reports to Congress and, in consultation with OCIR, will recommend whether to forward the report to Congress. Once approved, OP/ORPM will electronically transmit the report to OCIR and deliver the hard copies of the report package to OCIR.
- OCIR will submit the transmittal letters for signature along with the report to Congress, “cc” the originating program office (including the RSC representative/RRC) and OP, and subsequently, transmit the report to Congress.
- OP/ORPM will enter the date of transmittal to Congress in RAPIDS.

Reports to Congress Mandated through Appropriations or Requested in Committee

Reports:

OCFO manages the reports to Congress requested via appropriations language or committee reports. OCFO maintains and regularly updates a database which tracks Congressional report requests, the status of each Agency response, and whether OP has ‘flagged’ a report as being of interest. OCFO works directly with the Senior Budget Officers (SBOs) in each Agency office and has issued written guidance regarding the development of the reports to Congress under its purview, i.e.: Standard Operating Procedures for reporting Requirement reports Mandated by the Appropriations Committees (included below).

Many of the reports to Congress OCFO coordinates do not deal directly with issues that would establish or amend policy or otherwise provide new or revised interpretations of statutory, regulatory, or policy requirements and the ADP will not apply to those actions. However, to ensure offices represented on the RSC have an opportunity to get involved as early as possible in the development of reports to Congress that do appropriately fit under the ADP, the following procedures will be observed by OP/ORPM:

- Utilizing the brief summary information available in OCFO’s database, OP/ORPM will preliminarily identify reports to Congress that might warrant OP attention/involvement.
- OP/ORPM will flag its interest in OCFO’s database, assign an OP/ORPM analyst and notify the lead program office RSC Representative/RRC who then notifies their office’s SBO (per OCFO’s guidance, below).
- The OP/ORPM analyst is tasked with looking into the charge from Congress and communicating with the program lead.
- If the OP/ORPM analyst concludes OP does not have a role to play on a particular report, OP/ORPM will update the entry in OCFO’s database to reflect that decision.
- If the OP/ORPM analyst believes OP does have a role, the analyst is to engage with the program in the same capacity as if it were a rule, i.e.:
- If they believe milestones are necessary, they will suggest that to the program.
- If they believe the report should be tiered, they will raise it to the OP RSC Representative to pursue through RSC channels.
- Whether tiered or not, OP/ORPM analysts will encourage programs to enter each report into Scout to improve transparency during development.

Standard Operating Procedures for Reporting Requirement Reports, Mandated by the Appropriations Committees

The Congress acts on the various Budgets by developing, amending, and, ultimately, passing bills which enact the Budgets into law. The Congressional Committees will then develop Congressional (House, Senate, Conference) reports language to identify guidelines for Agency's spending.

Within these Congressional reports, the Committees may request that a report(s) be produced and provided to them by a specific date. These reports are designated as reporting requirement reports (RRR) which may be either an Agency or in association with another Agency (e.g., National Academy of Sciences, Army Corps of Engineers, etc.) report.

Reporting Requirements Issuance

The Office of Budget's (OB) Formulation Team reviews and updates the OB database with the new reporting requirement reports (RRR) that are included in the House, Senate and Conference reports. OB sends a memo to the Agency's Senior Budget Officers (SBOs), OP contacts and the Office of Budget (OB) identifying the reporting requirements reports, office assignments and due dates. The memo is notification that the database has been updated with the new requirements.

With issuance of the memo, this is the Senior Budget Officers' (SBOs) opportunity to review the database for due dates and accuracy of office assignments. If an office assignment is incorrect, the designated SBO and media analyst will need to negotiate the reassignment. After the SBOs agree upon the reassignment, the newly assigned SBO will advise the Formulation Team via e-mail that both SBOs agree. The Formulation Team will then update the database if a new assignment is required.

OP will review the OB database and flag any reporting requirements that fall within their stated task of "substantive issues regarding protection of human health and the environment" in which they wish to track. OP will contact the Regulatory Steering Committee (RSC) representative within that office. The RSC representative within that office should work with their SBO to ensure the office is aware of OP's interest.

OB media analysts and SBOs should read the entire House, Senate and Conference reports, provided by OB's Formulation Team, for further details on reporting requirements and other mandates (e.g., Congressional directives) directed by the Committees.

Development of the Report

The SBO coordinates the development of the report, in coordination with OP, if applicable, and other interested parties to ensure that the report has been properly reviewed and answered in accordance with the timeline below. RSC representatives may contact the program office if the requirement deals directly with issues that establish or amend policy or otherwise provide new or revised interpretations of statutory, regulatory or policy requirements. OB media analysts will review and update the database with the report prior to transmittal to OMB and in accordance with the timeline below.

Extensions

If the SBO determines that the report will be late, the OB Office Director should be notified in writing no later than five weeks prior to the due date. The SBO should include the media analyst and Formulation Team as a cc. This note should include a justification for the delay and an achievable, realistic due date that the program office is prepared to meet without further extension. The media analyst prepares a formal request for an extension of the deadline to the House and Senate Appropriations Subcommittees, for signature by the OB Office Director. The media analyst provides copies of the requests and its results to the SBO, Formulation Team, and OP if appropriate.

OMB Review

Six (6) weeks before the due date established by the Appropriations Committee, the SBO office submits the report to the OB Media Staffs and OP (for RRRs of interest) for comment and review. The OB media analyst reviews the report and coordinates a broader OCFO review if necessary and ensures that all requirements identified in the Committees' request have been satisfied. OP provides any comments to the SBO and OCFO.

Four (4) weeks prior to the Committee's due date, the media analyst provides the report to OMB for clearance. The media analyst prepares a brief transmittal letter to OMB's Environment Branch Chief, signed by the OB Office Director, and then forwards it to OMB. The routing slip should include the Formulation Control and Policy Staff Director's name for concurrence. In addition, the media analyst ensures that the OB database is updated with a copy of the complete package and the database status is changed to indicate "Sent to OMB." This letter should request that OMB review the report and return it to the OB in two weeks. The letter should identify the responsible media analyst, including the telephone number for all questions, comments, edits, etc.

The Media Analyst works with the SBOs and OP, if appropriate, on all revisions or additional information requested by OMB and has one week to resolve all issues.

Submission to Congress

One week prior to the due date, the OB Media Analyst prepares a cover letter for signature by the Chief Financial Officer. Please include the Agency's Appropriations Liaison as the point of contact. If necessary, the media analyst works with the SBO to develop the transmittal letter. The transmittal letter should include a short (e.g., one to two paragraphs) summary of the report. The SBO's Deputy Assistant Administrator must concur with the report and transmittal letter and sign the routing slip.

Identical copies of the letter and report, as prepared above, should be individually addressed to the Chairs and Ranking Minority Members of both House and Senate Appropriations Subcommittees:

U.S. Senate

Chairman, Subcommittee on Interior, Environment, and Related Agencies Committee on Appropriations United States Senate Washington, DC 20510	Ranking Member, Subcommittee on Interior, Environment, and Related Agencies Committee on Appropriations United States Senate Washington, DC 20510
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U.S. House of Representatives

Chairman, Subcommittee on Interior, Environment, and Related Agencies Committee on Appropriations U.S. House of Representatives Washington, DC 20515	Ranking Member, Subcommittee on Interior, Environment, and Related Agencies Committee on Appropriations U.S. House of Representatives Washington, DC 20515
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The Agency's Appropriation Liaison ensures that the signed transmittal letter and report are delivered to the Members listed above.

The OB media analyst will ensure that a final update to the RRR section in the OB database includes: 1) a scanned copy of the dated and signed Congressional transmittal letter and report; 2) a final statement, "This fulfills EPA's requirement and serves as the final update related to this requirement" which will acknowledge that the requirement is complete; and 3) the report status is changed to "Final" in the OB database. The OB database will be the repository for all House and Senate Appropriations Committee final reports.

Reporting Requirement Responsibilities

DUE DATE	ASSIGNMENT	OFFICE OF BUDGET		OCFO	SBOs	OP
		Formulation Team	Media Analysis			
At Time of Issuance of Committee Reports	Review Congressional Reports For Reporting And Other Requirements	X			X	
	Updates OB database With new requirements	X				
	Assign Reports and due dates to NPMs	X				
	Identify report in database that they wish to track and inform RSC representative					X
	Coordinate the programmatic review and development of report				X	
Six Weeks Prior to Due Date	1) Transmit Report to OB and OP 2) Notify OB if Report Will Be Delayed				X	
	Request Congressional Extension, if Report Delayed		X			
	Coordinate OCFO Review		X			
Four Weeks to Due Date	1)Transmit to OMB Review 2)Update the OB Database		X			
Two Weeks Prior to Due Date	Coordinate OMB Review and any Necessary Revisions		X		X	
One Week Prior to Due Date	Prepare and Develop Four Cover Letters and Reports to Congress		X		X	
Due Date	Transmit to Congress			X		
Final Steps	Updates database		X			

Appendix B:

Overview of the ADP

The flowchart on the following two pages summarizes the “ADP” for Tier 1 and Tier 2 proposed rules as discussed throughout the text of this document. The lead office develops the proposed rule, which may take months to years depending on the complexity of the rule, priorities, and court/statutory deadlines.

EPA initiates the following steps upon identifying a cause for rulemaking, such as the issuance of a new statute, court order, presidential initiative, or administrator priority.

- Step 1. Commencement and tiering the action
- Step 2. Preparation of the PABP
- Step 3. Receipt of early guidance from management
- Step 4. Preparation of the DABP
- Step 5. Senior management approval of the DABP
- Step 6. Development of regulatory options with appropriate analyses and consultations
- Step 7. Selection of preferred regulatory option
- Step 8. Preparation of preamble, rule and support documents
- Step 9. Final Agency review by senior management in participating offices and Regions
- Step 10. OP review for regulatory actions deemed “significant” under EO 12866
- Step 11. OMB review for significant regulatory actions
- Step 12. OP approval and the signature of the Administrator (or his/her designee)
- Step 13. Publication in FR and opening of dockets
- Step 14. Public comments received

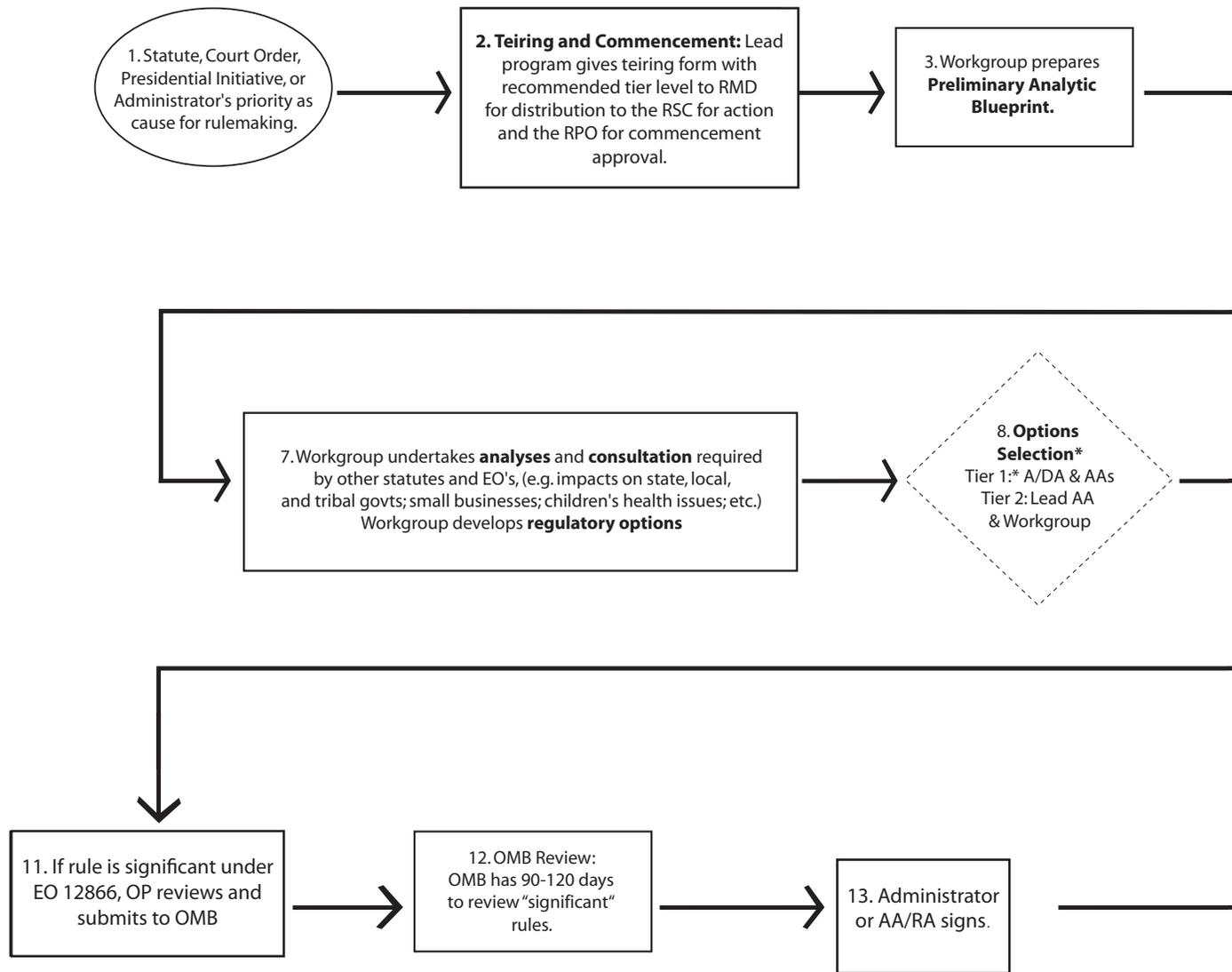
For final rules, EPA adds three additional steps:

- Consideration of and response to public comments
- Repetition of appropriate rulemaking steps (Steps 4 through 14)
- Simultaneous with FR submission, EPA submits a copy of the rule to Congress and GAO under the CRA.

Flowchart of Rule Development

For the purpose of illustration, the next 2 pages include a flowchart demonstrating the process for developing a rule. Please note that the ADP also applies to the development of other significant non-regulatory actions.

Tiers 1 & 2—Proposed Rules

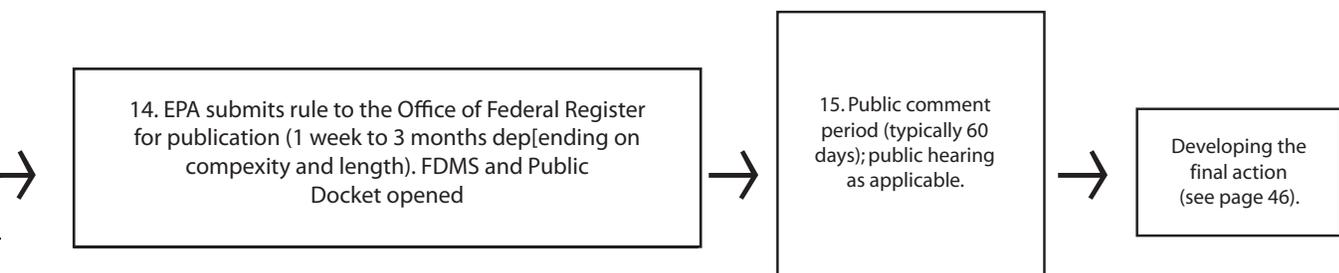
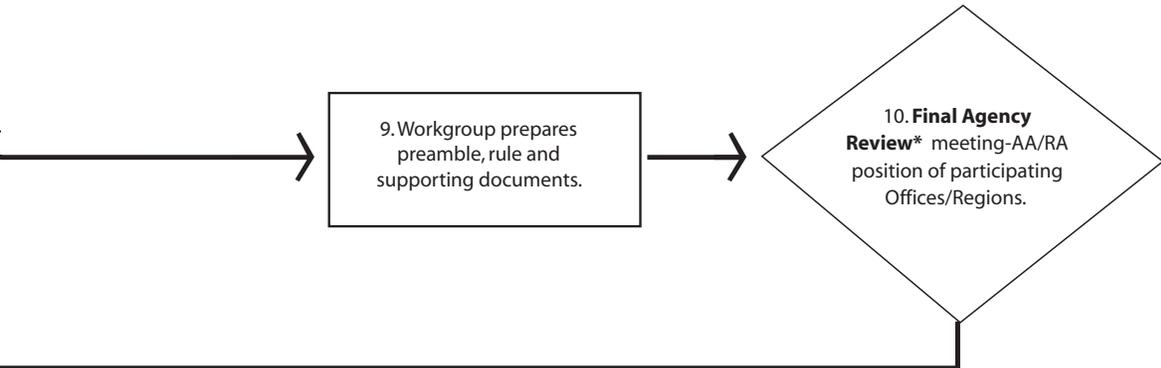
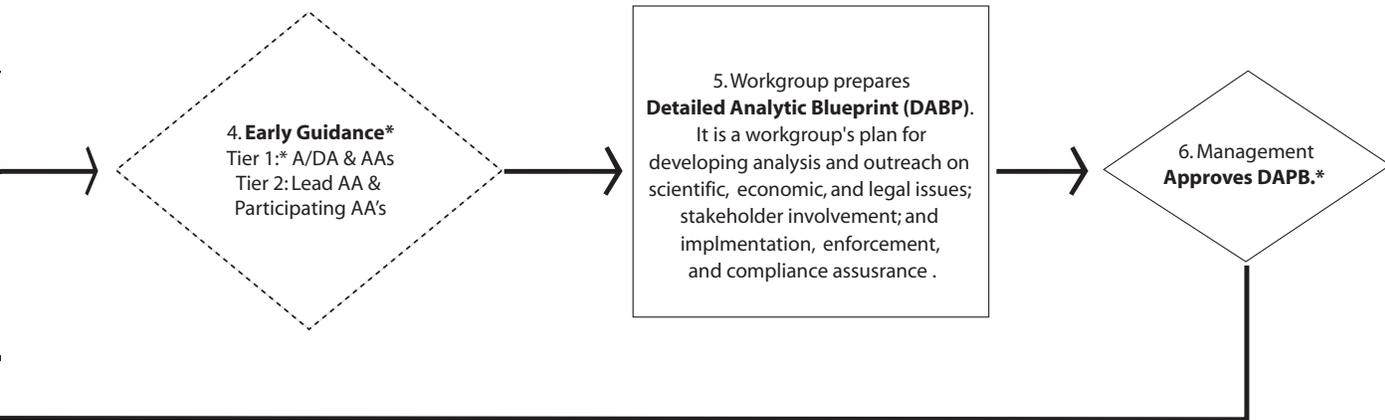


Legend

◇ = Critical Senior Management Input

* Cross-Agency Decision

** The Agency may request a one-time 30 day extension



Appendix C:

Other websites That May Be Of Assistance to EPA Action Developers

Other websites of interest:

1. <http://www.epa.gov/publicinvolvement>
2. http://www.archives.gov/federal_register/document
3. <http://www.epa.gov/indian/>
4. <http://intranet.epa.gov/fdmsinfo>
5. <http://www.regulations.gov/>
6. <http://www.epa.gov/sbrefa>
7. <http://www.epa.gov/quality/informationguidelines>
8. <http://intranet.epa.gov/ohr/rmpolicy>
9. <http://www.epa.gov/osa/spc/2peerrev.htm>
10. <http://intranet.epa.gov/icrintra>
11. <http://www.epa.gov/regulations/guidance/byoffice.html>
12. <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-13.pdf>
13. <http://www.epa.gov/lawsregs/search/regagenda.html>
14. <http://intranet.epa.gov/adr/> (publically available site: <http://www.epa.gov/adr/>)



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