ADS Chapter 156

Agency Rulemaking

New Edition Date: 04/10/2012
Responsible Office: M/MPBP/POL
File Name: 156_041012

Functional Series 100 – Agency Organization and Legal Affairs
ADS 156 – Agency Rulemaking

This is a new ADS Chapter.

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ADS 156 – Agency Rulemaking

156.1 OVERVIEW
Effective Date: 04/10/2012

This chapter provides the Agency's policy directives and required procedures for developing, reviewing, issuing, and amending rules that will be published in the Federal Register and codified in the Code of Federal Regulations (CFR), primarily in Titles 22 and 48.

The **Administrative Procedures Act (APA)** defines a rule as an agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the organization, procedure or practice requirements of an agency. USAID must publish rules to inform the general public when the Agency is considering a specific regulatory change that will affect the rights and interests of outside parties. Rulemaking is the process the Agency uses to create, amend, or repeal a rule that involves notifying the public and providing the opportunity for the public to comment.

156.2 PRIMARY RESPONSIBILITIES
Effective Date: 04/10/2012

a. Assistant Administrator, Bureau for Management (M/AA) serves as the Agency's Regulatory Policy officer and provides oversight for the rulemaking process.

b. The Bureau of Management, Office for Management Policy, Budget and Performance, Policy Division (M/MPBP/POL) coordinates the rulemaking process and ensures that Agency rulemaking activities comply with all statutory and regulatory requirements.

c. The USAID Initiating Program Office (IPO) develops rules that affect their programs.

d. The Federal Register Liaison Officer (FRL) or alternate coordinates the submission of rulemaking documents to the Federal Register for publication. The Agency FRL is located in M/MS/IRD.

e. The Rules Coordinator (RC), among other responsibilities, acts as the liaison concerning USAID's rule development and review process with IPO. The RC is a staff member of M/MPBP/POL.

f. The Docket Manager is an official assigned by the IPO with the subject-matter expertise and the judgment needed to produce rulemaking documents. The Docket Manager will coordinate with the RC during the rulemaking process.

g. The Federal Docket Management System (FDMS) Agency Administrator is responsible for the application of Agency-specific configurations and user

administration. USAID Agency Administrators are in the Bureau for Management Office of the Chief Information Officer (M/CIO) and Office of Acquisition and Assistance (M/OAA).

h. **The Office of General Counsel** provides guidance on legal and procedural requirements during the rulemaking process.

156.3 POLICY DIRECTIVES AND REQUIRED PROCEDURES

Effective Date: 04/10/2012

USAID must develop, issue, and amend rules in accordance with all applicable statutes, Executive Orders (EO), and regulatory policy. A rule must usually be issued when the Agency is considering a specific regulatory change that will alter the rights and interests of outside parties. Pursuant to **EO 12866, Regulatory Planning and Review** and **EO 13563, Improving Regulation and Regulatory Policy**, USAID must:

(1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and

(5) Identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

156.3.1 Preparing and Issuing Rules

Effective Date: 04/10/2012

USAID's internal procedures for preparing and issuing rules must foster the development of effective, innovative and efficient regulations. The Assistant Administrator, Bureau for Management (M/AA), serves as USAID's Regulatory Policy Officer and provides oversight for the rulemaking process. The responsible organizations and detailed procedures for implementing rulemaking policies and procedures outlined in this chapter are:

a. M/MPBP/POL is the primary point of contact with the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB). The Rules Coordinator (RC) will work with the Initiating Program Office (IPO) to assist with each step of the rulemaking process. M/MPBP/POL will communicate and obtain the necessary approvals and clearances from OIRA prior to publication of a rule in the Federal Register. (See **ADS 516** on Federal Register Notices for USAID's policy directives and procedures for preparing and submitting documents to publish in the Federal Register.)

M/MPBP/POL recommends changes to preliminary rules and determines the necessity and effectiveness of the rule and whether the rule is in the best interest of the Agency. When developing and issuing a rule, M/MPBP/POL will:

(1) Communicate and obtain the necessary approvals and clearance from OIRA prior to publication in the Federal Register;

(2) Obtain a Regulatory Identification Number;

(3) Assist the USAID IPO in drafting rules and training personnel to draft rules;

(4) Advise IPO on resources, priorities, and coordination of USAID rules development;

(5) Advise IPO of the eRulemaking requirements pursuant to the President's eGovernment initiative;

(6) Provide support to IPO on regulatory matters and coordinate the analysis and review of proposed and final rules;

(7) Work with the IPO to submit a copy of final rules to Congress and the Comptroller General, General Accountability Office (GAO); and

(8) Coordinate with the IPO and approve any documents that USAID must transmit to outside organizations.

The IPO may submit a formal appeal to the Director of M/MPBP in the event of a disagreement regarding M/MPBP/POL preliminary determinations on new rules. If the first appeal is denied by the Director of M/MPBP then the IPO can further appeal to the Regulatory Policy Officer (M/AA) for final determination.

b. The IPO is the USAID office that determines the need for rulemaking. The IPO drafts the rule and is responsible for the progression of the rule through the rulemaking process from inception through completion. The IPO has the specific technical knowledge of the purpose for the rule and should be prepared to explain the rule and provide arguments in support of the rule to internal and

external stakeholders who have questions, comments or request further information about the rule. The IPO must:

1. Consult with M/MPBP/POL as soon as the potential need for a rule is identified. M/MPBP/POL, in coordination with the Office of the General Counsel (GC), will determine whether the rule is necessary and if there are any special legal requirements. M/MPBP/POL may also coordinate a consultation with OIRA, who can provide guidance on whether or not the action warrants a new rule.

2. Prepare a memorandum signed by the Assistant Administrator (AA) of the operating unit of the IPO justifying the need for the rule, in consideration of Executive Orders 12866 and 13563.

3. Assign a Docket Manager with the subject-matter expertise and the judgment needed to produce rulemaking documents. The Docket Manager will coordinate with the RC during the rulemaking process.

4. Develop the technical content of rules and draft the rulemaking documents.

5. Ensure that regulatory evaluations and analyses are conducted.

6. Clear the rulemaking documents with stakeholder bureaus and offices, complete the **Rules Checklist**, and submit the checklist to M/MPBP/POL along with the rulemaking documents.

7. Upon notification of OIRA clearance, work with M/MS/IRD to publish the rule in the Federal Register.

c. The Federal Register Liaison Officer (FRL) in M/MS/IRD coordinates the submission of rulemaking documents to the Federal Register for publication. The FRL:

(1) Serves as the official liaison with the Federal Register and coordinates all publication in the Federal Register.

(2) Ensures that format and technical requirements are met and that the necessary documents and clearances are included in the package sent to the Federal Register for publication.

(3) Submits the rule package and tracks the publication of the rule.

156.3.2 Stages of Rulemaking

Effective Date: 04/10/2012

156.3.2.1 Advanced Notice of Proposed Rulemaking

Effective Date: 04/10/2012

An Advanced Notice of Proposed Rulemaking (ANPRM) is an information gathering document issued to the public prior to the development of a specific proposed rulemaking. An ANPRM notifies the public that USAID is considering an area for rulemaking and requests written comments on the appropriate scope of the rulemaking or on specific topics. The ANPRM allows the Agency to receive information from the public that will assist in the development of a Notice of Proposed Rulemaking (NPRM) or the determination that a rulemaking is not appropriate. It is an option, not a required step in the rulemaking process. The Agency may issue an ANPRM to

- Identify entities that may be affected,
- Identify unique procedures,
- Assess the issues and potential public impact, and
- Gather technical or economic data that USAID does not possess.

The notice and comment period for an ANPRM is generally 60 days, but may be as short as 30 days. Pursuant to **EO 12866: Regulatory Planning and Review**, OMB will take up to ten working days to review an ANPRM.

The IPO must contact M/MPBP/POL to determine whether issuing an ANPRM is appropriate to ensure the efficient use of Agency resources since the ANPRM can provide a platform for increased public comment, but is not a required step in the rulemaking process. If USAID chooses to issue an ANPRM, it must subsequently issue an NPRM before issuing a Final Rule on the subject, since the NPRM is the formal notice that will appear in the Federal Register.

156.3.2.2 Notice of Proposed Rulemaking

Effective Date: 04/10/2012

A Notice of Proposed Rulemaking (NPRM) is a formal notice, published in the Federal Register, that USAID is considering a specific regulatory change or action. The NPRM notifies the public of the proposed rulemaking, describes the proposed rule modifications, and informs the public how it may participate in the rulemaking process.

Except when a notice or hearing is specifically required by statute, an NPRM is not required for the following:

- Interpretive rules, general statements of policy, rules of agency organization, practice, or procedure; or

- When USAID for good cause finds that the notice and comment procedure is impracticable, unnecessary, or contrary to the public interest. M/MPBP/POL must explain this good cause in a brief statement which will be placed in the preamble of the final rule. USAID can then proceed directly to issuing an interim final rule. (See 156.3.2.3b regarding the good cause exception.)

156.3.2.3 Final Rule

Effective Date: 04/10/2012

The Final Rule announces to the public a new or revised rule and the date on which it will take effect. By this stage, the IPO has addressed all comments and made all modifications. Generally, a Final Rule does not go into effect until at least 30 days after its publication in the Federal Register. There are circumstances when the rule may not go into effect until a later date (see 156.3.2.3a), and circumstances when it may go into effect at an earlier date (see 156.3.2.3.b). In accordance with the **Congressional Review Act,** USAID must submit a Final Rule to each House of Congress and to the Comptroller General before the rule is effective. USAID must submit a concise general statement describing the rule, including whether it is a "major rule" and the proposed effective date of the rule. The IPO must coordinate with M/MPBP/POL in preparing this statement and in completing a **Submission of Federal Rules Under the Congressional Review Act form**. The IPO must also:

- Work with the Office of Legislative and Public Affairs, Congressional Liaison Division, to submit a copy of the Final Rule to Congress; and

- Work with M/MPBP/POL to submit a copy of the Final Rule to the Comptroller General.

A Final Rule may take effect at any time after it is submitted to Congress and the Comptroller General unless it is determined to be a Major Rule.

a. Major Rule

A "major rule" for purposes of Congressional review is defined as one that OIRA finds has resulted or is likely to result in the following:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) 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.

A major rule does not take effect until 60 calendar days after its publication in the Federal Register or its submission to Congress, whichever is later. If Congress passes a joint resolution of disapproval and the President vetoes the resolution, the major rule is not effective until the earlier date of:

(1) The date on which either House of Congress votes and fails to override the veto, or

(2) 30 session days after the date on which Congress receives the veto and objections from the President.

If the President does not veto the resolution of disapproval, the Final Rule may not take effect and is essentially withdrawn by the Agency.

b. Expedited Final Rules – Interim Final Rule and Direct Final Rule

The 30-day effective date requirement does not apply to: (1) interpretive rules or statement of policy; (2) rules that grant or recognize an exemption or relieve a restriction; or (3) an Agency finding that "good cause" exists for an earlier effective date which is published in the preamble to the final rule.

The notice and comment procedures do not apply when the Agency finds, for "good cause," that those procedures are impracticable, unnecessary, or contrary to the public interest. When the Final Rule is published, USAID must state that it is using the good cause exception and provide a rationale for the exception's use. Two procedures for expedited rulemaking under the good cause exception are the Interim Final Rule and the Direct Final Rule.

(1) Interim Final Rule. The Final Rule is issued without advance notice and opportunity for public comment, i.e., without first issuing an ANPRM or NPRM. The Interim Final Rule is effective immediately, but with an opportunity for the public to comment after the rule is issued and takes effect. If public comments persuade the Agency that it should make changes in the Interim Final Rule, USAID may revise the rule by publishing a Final Rule reflecting those changes. The IPO must consult with M/MPBP/POL regarding use of an Interim Final Rule. OIRA makes the final determination on whether the Interim Final Rule is appropriate.

(2) Direct Final Rule. The rule is published in the Federal Register with a statement that the rule will be effective on a particular date unless an adverse comment is received within a specified period of time. If the public files any adverse comments, the Agency must withdraw the Direct Final Rule and may publish that rule as an NPRM. A Direct Final Rule is

generally used for administrative changes, such as implementation of statutory changes, for which adverse comments are unlikely.

156.3.3 Exceptions to Rulemaking Requirement

Effective Date: 04/10/2012

The **Administrative Procedures Act** provides exceptions to the rulemaking requirement in the following situations:

- When there is a military or foreign affairs function of the United States involved;
- A matter relating to agency management and personnel; or
- When the Agency finds that good cause exists to forgo the rulemaking process and publishes a statement of its finding of good cause when it publishes the rule.

The exceptions to rulemaking are construed narrowly. For example, the foreign affairs exemption applies if the subject matter of the rule is clearly and directly related to a foreign affairs function, such as matters which would affect the U.S. Governments relationship with foreign governments or would clearly provoke undesirable international consequences. The IPO must consult with M/MPBP/POL and GC to determine whether an exception applies.

156.3.4 Legal and Procedural Requirements for Rulemaking

Effective Date: 04/10/2012

USAID must comply with various legal and procedural requirements during the rulemaking process. The IPO drafting a rule must ensure that the required regulatory evaluations and analyses have been conducted. The IPO must consult with M/MPBP/POL and GC regarding any of the legal and procedural requirements described in this chapter.

156.3.4.1 "Significant" Regulatory Actions

Effective Date: 04/10/2012

EO 12866, Regulatory Planning and Review requires USAID to determine whether a regulatory action is "significant". A significant regulatory action is likely to result from a rule that may:

(1) Have an annual effect on the economy of $100 million or more;

(2) Have an adverse material affect on the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;

(3) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(4) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs; or

(5) Raise novel legal or policy issues.

M/MPBP/POL will submit the proposed rule to OIRA stating whether USAID believes the rule is significant. OIRA makes the final determination on whether the rule is significant pursuant to **EO 12866**. If the rule is determined to be "significant" then the IPO should consult **OMB Circular A-4, Regulatory Analysis**, which outlines the best practices for preparing an economic analysis of significant regulatory actions under EO 12866. Then M/MPBP/POL must submit the rules to OIRA before publication in the Federal Register at both the proposed and final rulemaking stages. M/MPBP/POL in consultation with the IPO must give OIRA:

(1) An explanation of the need for the rule and how the rule will meet that need;

(2) An assessment of costs and benefits of the rule;

(3) An explanation of how the rule is consistent with a statutory mandate;

(4) How the rule promotes the Administration's priorities;

(5) How the rule avoids undue interference with state, local, and tribal governments; and

(6) An assessment of alternative costs and benefits, and why the rule is preferable to such alternatives.

OMB/OIRA is required to notify an agency of the results of its review of a proposed or final rule within 90 calendar days after the rule and related analyses are submitted. The review period is reduced to ten working days if OIRA reviews an ANPRM or other preliminary regulatory action prior to a NPRM. Either review process may be extended once for 30 days at the request of the Agency Administrator and upon the written approval of the Director of OMB.

If OIRA has previously reviewed the information, and USAID has made no material change since that time, OIRA has only 45 days to complete its review. An agency may not publish in the Federal Register until OIRA has waived or completed the review, or the applicable time period for review has expired.

156.3.4.2 Significant Economic Impact on Substantial Number of Small Entities

Effective Date: 04/10/2012

The Regulatory Flexibility Act (RFA), 5 U.S.C. requires USAID to review proposed rules for their impact on small entities (small businesses, small organizations, and small governmental jurisdictions) and to consider less burdensome alternatives. The IPO

must prepare a regulatory flexibility analysis if the proposed rule could "have a significant impact on a substantial number of small entities."

Under **EO 13272, Proper Consideration of Small Entities in Agency Rulemaking**, USAID must notify the Small Business Administration's (SBA) Chief Counsel for Advocacy of any draft rules that may have a significant economic impact on a substantial number of small entities. The IPO must address any comments received from the SBA in the text of the Final Rule.

The RFA requires analysis of a proposed regulation only where notice and comment is required. Therefore, RFA analysis is not required for interim final rules and direct final rules that meet the good cause exception.

The IPO should consult SBA's **Procedures for Compliance with the Regulatory Flexibility Act** and **Executive Order 13272** and the Office of Advocacy's publication **"A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act"** for more detailed guidance regarding compliance with the RFA.

156.3.4.3 "Collection of Information" Requirement

Effective Date: 04/10/2012

The **Paperwork Reduction Act, 44 U.S.C. 3501-3520** is intended to:

- Minimize the federal paperwork burden on individuals and small entities;
- Minimize the cost to the Federal Government for collecting and disseminating information; and
- Maximize the public benefit of the information collected.

The Act requires an agency to justify to OMB its proposed "collection of information" (COI) and to show that:

- It is as least burdensome as possible,
- It is not duplicative of other federal information collections, and
- The collected information will have practical utility.

A COI means obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties, or the public of information by or for an agency by means of identical questions posed to or identical reporting, recordkeeping, or disclosure requirements imposed on ten or more persons.

If there is a COI requirement, M/MPBP/POL must obtain permission from OIRA before implementing the COI requirement and seek periodic extensions for existing rules with

ongoing COI requirements. The IPO must consult with M/MPBP/POL on COI requirements.

If the proposed rule has no COI requirement, the NPRM must state the provisions of the Paperwork Reduction Act do not apply.

156.3.4.4 Unfunded Mandate

Effective Date: 04/10/2012

The **Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4)** requires agencies to give special consideration to proposed rules imposing mandates on state, local, and tribal governments without providing adequate Federal funding. If a rule contains an unfunded mandate that results in an annual expenditure of $100 million or more (adjusted annually for inflation), the IPO in consultation with M/MPBP/POL must prepare a budgetary impact statement and include it in the preamble to the proposed rule sent to OIRA.

156.3.4.5 Federalism Implications

Effective Date: 04/10/2012

Rules that have federalism implications are those that have substantial direct effects on

- The states,
- The relationship between the Federal Government and the states, or
- The distribution of power and responsibilities among the various levels of government.

Often this means the proposed rule would preempt state law. Under **EO 13132, Federalism**, if a rule has federalism implications, an analysis of those implications, in the form of a “federalism summary impact statement,” must be included in the NPRM. The IPO must coordinate with M/MPBP/POL to prepare this statement. If the rule has no federalism implications, the NPRM does not include a statement.

156.3.4.6 Constitutionally Protected Property Rights

Effective Date: 04/10/2012

The Federal Government could be required to pay just compensation to a property owner for any “taking” of private property resulting from a government rule or regulation. **EO 12630, Government Actions and Interference With Constitutionally Protected Property Rights** requires any proposed rule with significant “takings” implications to include a discussion of those implications in the NPRM. The IPO must coordinate with M/MPBP/POL to prepare that statement, if required.

156.3.4.7 Adverse Health and Environmental Effects on Minority and Low Income Populations

Effective Date: 04/10/2012

Under **EO 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations** agencies must develop an environmental justice strategy for any rule that produces disproportionately high and adverse human health or environmental effects on minority and low income populations. The IPO must coordinate with M/MPBP/POL to prepare the statement, if required.

156.3.4.8 Environmental Health and Safety Risks for Children

Effective Date: 04/10/2012

If a rule concerns an environmental health risk or safety risk that may disproportionately affect children, **EO 13045, Protection of Children From Environmental Health Risks and Safety Risks** requires agencies to provide OIRA with

- An evaluation of the effects on children, and
- An explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives.

The IPO must work with M/MPBP/POL to prepare the documentation, if required.

156.3.4.9 Indian Tribal Governments

Effective Date: 04/10/2012

Under **EO 13175, Consultation and Coordination With Indian Tribal Governments** agencies are required to employ a process that ensures meaningful and timely input by tribal officials in the development of rules that have tribal implications.

156.3.5 Public Participation in Rulemaking

Effective Date: 04/10/2012

Pursuant to **EO 13563**, USAID must promote public participation and an open exchange of information in rulemaking. Public comments may be sent to USAID

- Via the US Postal Service,
- Via email to the IPO, or
- Submitted online through the official U.S. Government Web site **www.regulations.gov**.

All comments within the scope of the rule from interested parties must be addressed by the author of the rule as a preamble to the next stage of rulemaking, regardless of the

stage of rulemaking. The author of the rule may group comments based on the topic addressed, in the event that multiple comments reflect a common idea, concern, or topic. The IPO will receive public comments for 30-60 days after publication of the ANPRM or NPRM. The IPO must post the comments in the Federal Docket Management System as outlined in **156.3.5.1**.

156.3.5.1 Federal Docket Management System

Effective Date: 04/10/2012

The **E-Government Act of 2002** requires that agencies be transparent and accountable by providing Web-based access to records and by allowing a broader spectrum of the public to participate in the rulemaking process. The Web site **www.regulations.gov** is the public face of the U.S. Government's eRulemaking Initiative, and facilitates public participation in the federal regulatory process by providing a single location where the public can view and comment on federal regulatory actions.

The Federal Docket Management System (FDMS) is the “behind the scenes” on-line regulatory system where agencies create and organize electronic files through which rules and notices published in the Federal Register are posted, public comments can be received, and agency comments can be posted to be viewed by the public.

The FDMS requires each agency to designate FDMS Agency Administrators who are responsible for the application of Agency-specific configurations and user administration. USAID Agency Administrators are in the Bureau for Management, Office of the Chief Information Officer (M/CIO) and the Bureau for Management, Office of Acquisition and Assistance (M/OAA).

The designated IPO must request access to the FDMS via the following sites:

a. **www.fdms.gov**

b. **http://fdms.erulemaking.net/fdms-web-agency/component/main?__dmfClientId=1305654632092&__dmfTzoff=240**

Once a request has been made via the Web site, the request is sent to the USAID FDMS Administrator who will grant access to the FDMS system.

156.3.5.2 Limitations on Ex Parte Contact With the Public

Effective Date: 04/10/2012

An ex parte contact is a communication between USAID and an interested party outside the government concerning a specific rulemaking proceeding before a final rule is published. All ex parte contacts must be avoided, unless authorized by M/MPBP/POL.

USAID staff must not engage in individual and/or inappropriate contact with interested persons -- through meetings, phone conversations, or e-mail dialogues -- during the rulemaking process. Ideally, a rulemaking should proceed with all interested persons

given an equal opportunity to provide comments on the record through the notice-and-comment process established in the NPRM. Any ex parte contact could raise questions about the fairness of a rulemaking and jeopardize the legal effect of the rule.

If the topic of the proposed rule is highly controversial then M/MPBP/POL may authorize a public meeting to discuss the matter with interested parties and stakeholders. These meetings are usually announced via the Federal Register in order to give notice to the public and to provide an effective means of discussing the matter with stakeholders.

156.3.6 On-Going Responsibility Regarding Rules

Effective Date: 04/10/2012

Executive Order 13563, Improving Regulation and Regulatory Review, requires agencies to develop plans to continuously review existing significant regulations in order to determine whether any regulations should be modified, streamlined, expanded, or repealed. The IPO must review all rules within its program area to determine whether they continue to serve the purpose for which they were originally issued or whether they should be modified or eliminated.

Under the **Regulatory Flexibility Act**, USAID must review existing rules that have a significant economic impact on a significant number of small entities within ten years of their publication as Final Rules. The review is to determine whether such rules should be continued without change, or should be amended or rescinded in order to minimize the economic impact on small entities. This review should consider the following:

- The continued need for the rule;
- The nature of complaints or comments received concerning the rule;
- The complexity of the rule;
- The extent of duplication or conflict with other Federal, state, or local regulation; and
- Any relevant economic or technological changes that have occurred since the last review.

USAID must report on the status of the rule reviews to OMB/OIRA on the second Monday of January, May, and September until September 2012 and semi-annually on the second Monday of January and July for each year thereafter. The reports must describe past progress, anticipated accomplishments, and proposed timelines for relevant actions. The reports must be made available to the public within two weeks of submission to OMB/OIRA. M/MPBP/POL must work with IPOs to review USAID rules, submit reports to OMB/OIRA, and make the reports available to the public.

156.3.7 Semi-Annual Unified Agenda Report
Effective Date: 04/10/2012

Pursuant to **EO 12866**, USAID must prepare a Semi-Annual Agenda of rules that are under development. The Agenda is published in the Federal Register every April and October. To complete the Agenda, M/MPBP/POL will contact each IPO to obtain a description of the rulemaking activities each office plans to undertake in the next six months. The IPO must provide the following:

- A description of each proposed or final rule under development,
- Target dates for completion of steps in the development of each such rule, and
- The status of any such rules previously listed in the Agenda.

M/MPBP/POL must compile the information provided by the IPO and prepare a Unified Regulatory Agenda of all regulations under development or review. For each rulemaking activity, the Unified Regulatory Agenda must include the following:

- A regulatory identification number (RIN),
- A brief summary,
- The legal authority for the action,
- Any legal deadline, and
- The name and telephone number of a knowledgeable USAID point of contact.

M/MPBP/POL will notify the IPO each Spring and Fall to begin the process to complete the Semi-Annual Regulatory Agenda with a timetable for review and completion. Each IPO must adhere to the timetable to ensure timely submission of the report.

156.4 MANDATORY REFERENCES

156.4.1 External Mandatory References
Effective date: 04/10/2012

a. **Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701 et seq.**

b. **Congressional Review Act, P.L. 104-121 (the Act is a part of the Small Business Regulatory Enforcement Fairness Act of 1996, also called the Contract with America Advancement Act of 1996)**

c. **Regulatory Flexibility Act, 5 U.S.C. § 601 et seq.**

d. **Paperwork Reduction Act, 44 U.S.C. 3501-3520**

e. **Unfunded Mandate Reform Act of 1995, 2 U.S.C. §§ 1501-1571**

f. **EO 13272, Proper Consideration of Small Entities in Agency Rulemaking (67 Fed. Reg. 53461, August 16, 2002)**

g. **EO 13175, Consultation and Coordination with Indian Tribal Governments (65 Fed. Reg. 67249, November 9, 2000)**

h. **EO 13132, Federalism (64 Fed. Reg. 43255, August 10, 1999)**

i. **EO 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 Fed. Reg. 19885, April 23, 1997);** amended by **E.O. 13299 (66 Fed. Reg. 52013, October 11, 2001)** and **E.O. 13296 (68 Fed. Reg. 19931, April 23, 2003)**

j. **EO 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 Fed. Reg. 7629, February 16, 1994)**

k. **EO 12866, Regulatory Planning and Review (58 Fed. Reg. 51735, October 4, 1993);** amended by **E.O. 13258 (67 Fed. Reg. 9385, February 28, 2002)**

l. **EO 13563, Improving Regulations and Regulatory Review**

m. **Plain Writing Act of 2010**

n. **EO 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights (53 Fed. Reg. 8859, March 18, 1988)**

o. **OMB Circular A-4, "Regulatory Analysis"**

p. **E-Government Act of 2002**

q. **Federal Register Document Drafting Handbook**

r. **FDMS Frequently Asked Questions**

156.4.2 Internal Mandatory References

Effective date: 04/10/2012

a. **Check List of Special Considerations**

b. **ADS 516, Federal Register Notices**

156.4.3 Mandatory Forms
Effective date: 04/10/2012

a. **Submission of Federal Rules Under the Congressional Review Act Form**

156.5 ADDITIONAL HELP
Effective Date: 04/10/2012

The documents listed below contain optional information for you to consider. The author is citing these documents because they would like you to know more about the subject matter or provide helpful, non-mandatory guidance.

a. **Memorandum from John D. Graham to the President's Management Council on "Benefit-Cost Methods and Lifesaving Rules," (May 30, 2003)**

b. **Federal Register**

c. **SBA Office of Advocacy - A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act**

d. **SBA's – Procedures for Compliance with the Regulatory Flexibility Act and Executive Order 13272**

e. **Government Printing Office Style Manual**

f. **OMB OIRA: Reg Map: Informal Rulemaking Flow Chart**

g. **OMB OIRA: Reginfo.gov- Frequently Asked Questions**

h. **OMB OIRA Regulatory Impact Analysis: Frequently Asked Questions (FAQs)**

i. **OMB Memorandum on Guidance for Regulatory Review, March 4, 2009**

156.6 DEFINITIONS
Effective date: 04/10/2012

The terms and definitions listed below have been incorporated in the ADS Glossary. See the ADS Glossary for all ADS terms and definitions.

Advanced Notice of Proposed Rulemaking (ANPRM)
An information gathering document issued prior to the development of a specific proposed rulemaking. (Chapter 156)

Federal Docket Management System (FDMS)
An on-line regulatory system and a component of the federal e-Rulemaking Initiative that began with the E-Government Act of 2002, which directed the Federal government to become more transparent and accountable by providing Web-based access to agency records and by allowing a broader spectrum of the public to participate in the rulemaking process. (Chapter 156)

Initiating Program Office (IPO)
Any USAID office that initiates a rule. (Chapter 156)

Rule/Regulation
An agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or to describe the organization, procedure, or practice requirements of an agency. A rule issued by an agency alters rights and interests of outside parties. (Chapter 156)

The terms rule and regulations are interchangeable and synonymous. Both rules and regulations are subordinate to statutes, especially to the specific statute under which they are issued. (Chapter 156)

Rulemaking
The process that an executive agency uses to create, amend, or repeal a rule that involves notice to the public and the opportunity for public comment. (Chapter 156)

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