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ADS 156 – Agency Rulemaking

156.1 OVERVIEW

Effective Date: 06/17/2020

This chapter provides the Agency’s policy directives and required procedures to develop, review, issue, and amend rules that will be published in the Federal Register and codified in the Code of Federal Regulations (CFR), primarily in Titles 2, 22, and 48.

The terms “rule” or “regulation” are often used interchangeably in discussions of the Federal regulatory process. The [Administrative Procedure Act \(APA\)](#) 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 or describing 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, in most cases, providing the opportunity for the public to comment.

The [Office of Federal Procurement Policy Act \(41 U.S.C. 1707\)](#) requires agencies to provide notice and comment for certain procurement policies, regulations, procedures, and forms. Procurement regulations that have “a significant effect beyond the internal operating procedures of the agency” or that have “a significant cost or administrative impact on contractors or offerors” may generally not take effect until 60 days after publication for public comment in the Federal Register.

[Executive Order \(E.O.\) 12866](#) establishes presidential review of rulemaking of covered agencies within the Office of Management and Budget’s Office of Information and Regulatory Affairs (OMB/OIRA). E.O. 12866 requires covered agencies to submit their significant rules to OMB/OIRA for review before they become final and requires those rules to meet certain minimal standards. A covered agency under this E.O. is any “agency” defined in 44 U.S.C. 3502(1), except those defined in 44 U.S.C. 3502(10) as being “independent regulatory agencies.”

156.2 PRIMARY RESPONSIBILITIES

Effective Date: 06/17/2020

a. The **Deputy Administrator** serves as USAID’s Regulatory Reform Officer (RRO). The RRO oversees implementation of regulatory reform initiatives and policies to ensure USAID effectively reduces regulatory burdens, consistent with applicable law. The RRO approves USAID’s semi-annual regulatory unified agenda (“Unified Agenda”) and any proposed and final rules for publication in the Federal Register. The Administrator delegates to the Deputy Administrator the authority to certify that a rule will not have a significant economic impact on a substantial number of small entities.

b. The **Assistant Administrator, Bureau for Management (AA/M)** serves as the Agency’s Regulatory Policy Officer (RPO) and provides oversight for the rulemaking

process. The RPO must be involved in each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations.

c. The **Bureau for Management, Office of 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.

d. The **USAID Initiating Program Office (IPO)** is the Bureau or Independent Office (B/IO) that provides subject matter expertise on regulatory matters that impact the IPO's programs. The IPO identifies new or revised technical requirements, requests changes to the Code of Federal Regulations (CFR), and utilizes its technical expertise to develop the requirements and supporting documentation for review during the rulemaking process (e.g., analysis of regulatory costs and impact on the public). The IPO serves as the Agency lead on drafting sections of the rule that require technical expertise or analysis to support the basis for the rule, responding to technical or subject matter queries raised during the rulemaking process, and updating supporting documentation on the rule based on input received during the rulemaking process.

e. The **Office of General Counsel (GC)** provides guidance on legal and procedural requirements during the rulemaking process.

f. The **Bureau for Management, Office of Acquisition and Assistance (M/OAA)**, works with the IPO, CFR Owner and General Counsel on the development rules that may impact contractors or grantees.

g. The **Code of Federal Regulations Owner** (referenced in this chapter as the **CFR Owner**) is the B/IO and/or the statutory official for the CFR subject matter that advises and assists the IPO by determining the need for changes to the CFR that require rulemaking, establishing rulemaking requirements, and identifying any regulatory analysis required to support rulemaking. The CFR Owner develops the rule that impacts their regulation, ensuring that the rule is necessary, appropriate and complies with regulatory drafting requirements and fits within the structure and format of the regulation codified in the CFR. The CFR Owner serves as the Agency's main point of contact during the rulemaking process and approves editorial or other changes to the rule proposed by USAID, OMB/OIRA, the interagency, the public, or the Office of the Federal Register (OFR). The CFR Owner also performs the docket manager and/or rule writer roles within the Federal Docket Management System (FDMS), the system of record for managing rulemaking documents for public review and comment on Regulations.gov.

h. The **Rules Coordinator (RC)**, among other responsibilities, acts as the liaison between the IPO, CFR Owner, and OMB/OIRA concerning USAID's rule development and review process and serves as the Agency representative on the eRulemaking Program Advisory Board. The RC is a staff member of M/MPBP/POL.

i. 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 the Bureau for Management's Office of Management Services, Information and Records Division (M/MS/IRD).

j. The **Federal Docket Management System (FDMS) Agency Administrator** is responsible for the application of Agency-specific configurations and user administration. USAID's Agency Administrators are located in the Bureau for Management's Office of the Chief Information Officer (M/CIO) and M/MPBP/POL.

156.3 POLICY DIRECTIVES AND REQUIRED PROCEDURES

Effective Date: 06/17/2020

USAID must develop, issue, and amend rules in accordance with all applicable statutes, E.O.s, 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 [E.O. 12866, Regulatory Planning and Review](#) and [E.O. 13563, Improving Regulation and Regulatory Review](#), USAID must comply with the following requirements as specified in the E.O.s:

- 1) "In deciding whether and how to regulate all costs and benefits of available regulatory alternatives, including the alternative of not regulating;
- 2) Recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs;
- 3) Tailor regulations to impose the least burden on society, consistent with obtaining the regulatory objectives, considering, among other things, and to the extent practicable, the costs of cumulative regulations;
- 4) 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), unless a statute requires another regulatory approach;
- 5) To the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and
- 6) 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."

Pursuant to [E.O. 13771, Reducing Regulation and Controlling Regulatory Costs](#), and [OMB Memorandum M-17-21, Guidance Implementing E.O. 13771](#), USAID must comply with the following requirements:

- 1) For every new rule issued, the Agency must identify at least two existing rules for elimination; and
- 2) Any new incremental costs associated with a new rule must, to the extent permitted by law, be offset by eliminating existing costs associated with at least two prior rules.

E.O. 13771 only applies in the event that USAID issues a new rule that OMB/OIRA considers a significant regulatory action. In such circumstances, USAID is not required to issue “deregulatory actions” that satisfy the requirements in 1) and 2) above at the time the new rule is issued. OMB/OIRA will assess the Agency’s rulemaking activities at the end of each fiscal year to determine if deregulatory actions are necessary. If so, USAID must formulate a plan to eliminate the existing rules in the next Fiscal Year. For further information on significant regulatory actions, please refer to **156.3.2.1** in this chapter.

156.3.1 Preparing and Issuing Rules

Effective Date: 06/17/2020

USAID’s internal procedures for preparing and issuing rules must foster the development of effective, innovative, and efficient regulations. The AA/M serves as USAID’s RPO and provides oversight for the rulemaking process. The responsible organizations and detailed procedures for implementing rulemaking policies and procedures outlined in this chapter are as follows:

- a. M/MPBP/POL is the primary point of contact with OMB/OIRA. The Rules Coordinator (RC) will work with the IPO, CFR Owner, and GC to assist with each step of the rulemaking process. M/MPBP/POL will communicate and obtain the necessary approvals and clearances from OMB/OIRA prior to publication of a rule in the Federal Register (see [ADS 516, Federal Register Notices](#) to reference USAID’s policy directives and procedures for preparing and submitting documents to publish in the Federal Register). For further information about the rulemaking process, contact the Rules Coordinator by emailing **rulemaking@usaid.gov**.

M/MPBP/POL and the CFR Owners recommend changes to preliminary rules and determine the necessity and effectiveness of the rule and whether the rule is in the best interest of the Agency.

During the rulemaking process, M/MPBP/POL will:

- 1) Communicate with and obtain the necessary approvals and clearance from OMB/OIRA prior to publication in the Federal Register;
- 2) Obtain a Regulation Identifier Number (RIN);

- 3) Assist the CFR Owner and IPO in drafting rules and training personnel to draft rules;
- 4) Advise the CFR Owner, IPO, and GC on resources, priorities, and coordination of USAID rules development;
- 5) Provide support to the CFR Owner, IPO, and GC on regulatory matters and coordinate the analysis and review of proposed and final rules;
- 6) Work with the CFR Owner to submit a copy of final rules to Congress and the Comptroller General, General Accountability Office (GAO); and
- 7) Coordinate with the CFR Owner, IPO, and GC to approve any relevant documents that USAID must transmit to outside organizations.

The CFR Owner or 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 CFR Owner or IPO can further appeal to the Regulatory Policy Officer (AA/M) for final determination.

- b. The IPO has the specific technical knowledge of the purpose for the rule and should be prepared to explain the rule and provide justifications to support the rule to internal and external stakeholders who have questions or comments or request further information about the rule. The IPO must:
 - 1) Consult with the CFR Owner and M/MPBP/POL as soon as the potential need for a rule is identified. The IPO must consult with the Bureau for Management's Office of Acquisition and Assistance (M/OAA) when considering development of a rule that may impact contractors or grantees. M/MPBP/POL, in coordination with the CFR Owner, will determine whether the rule is necessary and whether any specific analysis is required. M/MPBP/POL may also coordinate a consultation with OMB/OIRA to obtain guidance on whether or not the action warrants a new rule. If M/MPBP/POL and the CFR Owner recommend proceeding with rulemaking, M/MPBP/POL will add the rule to the semi-annual Unified Agenda. A rule is generally published in the Federal Register for public comment after it has been included in the published Unified Agenda. In limited circumstances, when a rule must be published ahead of the Unified Agenda, the RRO must approve a waiver request to OMB/OIRA to approve publication of the rule prior to its inclusion in the published Unified Agenda (see **156.3.7** for more information).
 - 2) Prepare an action memorandum signed by the Assistant Administrator (AA) of the Operating Unit of the IPO justifying the need for the rule, in consideration of E.O.s 12866 and 13563.

- 3) Develop the technical content of the rule and assist the CFR Owner in drafting the rulemaking documents, referencing the [Document Drafting Handbook](#) as appropriate.
 - 4) Prepare the regulatory evaluations and analyses, as necessary.
- c. The CFR Owner is the B/IO that determines the need for rulemaking. The CFR Owner, in coordination with the IPO, drafts the rule and is responsible for the progression of the rule during the rulemaking process, from inception through completion. The CFR Owner must:
- 1) Obtain clearances from GC and other stakeholder B/IOs. M/MPBP/POL will review the rulemaking documents and submit them to OMB/OIRA for E.O. 12866 significance review and input.
 - 2) Upon M/MPBP/POL's notification of OMB/OIRA clearance, coordinate with M/MPBP/POL to obtain internal Agency clearance of the action memo described above in Step 2.
 - 3) Upon RRO approval of the action memo, in coordination with M/MPBP/POL, work with M/MS/IRD to publish the rule in the Federal Register.
- d. 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 Office of the Federal Register (OFR) and coordinates publication in the Federal Register;
 - 2) Submits the rulemaking package to the OFR;
 - 3) Notifies the CFR Owner, IPO, and RC if the OFR requests changes to the rule; and
 - 4) Obtains the CFR Owner's approval for any changes proposed by OFR.

156.3.2 Stages of Rulemaking

Effective Date: 06/17/2020

For an overview of the Agency's rulemaking process, reference [ADS 156mab, USAID Rulemaking Timeline](#) and [ADS 156mad, Business Process Mapping of Rulemaking at USAID](#).

156.3.2.1 OMB/OIRA Regulatory Action Review Under E.O. 12866

Effective Date: 06/17/2020

a. OMB/OIRA Significance Determination

Prior to publishing any regulatory action in the Federal Register, M/MPBP/POL must send a draft copy of the proposed rule to OMB/OIRA to determine whether the rule is “significant” pursuant to [E.O. 12866: Regulatory Planning and Review](#). E.O. 12866 defines a significant regulatory action as one that is likely to result in the following:

- 1) “Have an annual effect on the economy of \$100 million or more;
- 2) 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;
- 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 the rights and obligations of recipients thereof; or
- 5) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in E.O. 12866.”

M/MPBP/POL will submit the proposed rule to OMB/OIRA stating whether USAID believes the rule is significant. OMB/OIRA makes the final determination on whether the rule is significant pursuant to [E.O. 12866](#). If OMB/OIRA determines that the rule is significant, the IPO should consult [OMB Circular A-4, Regulatory Analysis](#), which outlines best practices for preparing an economic analysis of significant regulatory actions under E.O. 12866. M/MPBP/POL must submit the rule to OMB/OIRA before publication in the Federal Register at both the proposed and final rulemaking stages. During the proposed rule stage and the final rule stage, the IPO, in consultation with the CFR Owner, must provide the following to M/MPBP/POL for submission to OMB/OIRA:

- 1) Text of the draft rule;
- 2) An explanation of the need for the rule and how the rule will meet that need;
- 3) An assessment of the potential costs and benefits of the rule;
- 4) An explanation of how the rule is consistent with a statutory mandate;
- 5) How the rule promotes the Administration’s priorities; and
- 6) How the rule avoids undue interference with state, local, and tribal governments in the exercise of their governmental functions.

“Economically significant” regulatory actions are a subset of those designated by OMB/OIRA as significant. A regulatory action is “economically significant” if OMB/OIRA determines that it is likely to have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities. For all “economically significant” regulations, E.O. 12866 requires a more detailed cost-benefit analysis, including an assessment of the costs and benefits of potentially effective and reasonably feasible alternatives to the planned rule.

b. OMB/OIRA Major Determination

In addition to including a proposed significance determination with submission of a rule to OMB/OIRA for E.O. 12866 review, pursuant to [Memorandum M-19-14, Guidance on Compliance with the Congressional Review Act](#), USAID must include a proposed determination of whether the rule is “major” under the Congressional Review Act (CRA) (5 U.S.C. § 804(2)). The CRA creates a special category of “major” rules and requires OMB/OIRA to determine whether a rule is major based on a finding by OMB/OIRA that the rule has resulted in 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.

For all rules, USAID should include a CRA compliance statement in the body of the rule to provide transparency and notice to Congress, including language as to whether OMB/OIRA designated the rule as “major” or “not major.” For instance, “Pursuant to the Congressional Review Act (5 U.S.C. § 801, et seq.), OMB/OIRA designated this rule as not being a major rule, as defined by 5 U.S.C. Section 804(2).” For regulatory actions submitted pursuant to E.O. 12866 review, OMB/OIRA will continue to incorporate the CRA major determination into its standard process. The major designation triggers a report by the U.S. Government Accountability Office and a delayed effective date while Congress may consider whether it will disapprove the rule.

c. OMB/OIRA Review Process under E.O. 12866

Under E.O. 12866, OMB/OIRA is required to notify USAID of the results of its review of a rule within 90 calendar days after the rule and related analyses have been submitted. The review period is reduced to 10 working days if OMB/OIRA reviews any notice of inquiry, an Advanced Notice of Proposed Rulemaking (ANPRM), or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking (NPRM). Either review

process may be extended once for up to 30 calendar days at the request of the Agency Administrator and upon the written approval of the Director of OMB.

If OMB/OIRA has previously reviewed the information, and USAID has made no material change in the facts and circumstances upon which the rule is based since that review, OMB/OIRA has up to 45 days to complete its review. USAID may not publish in the Federal Register until OMB/OIRA has waived or completed the review, or the applicable time period for review has expired.

156.3.2.2 Advanced Notice of Proposed Rulemaking

Effective Date: 06/17/2020

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 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; or
- 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 E.O. 12866, OMB will take up to 10 working days to review an ANPRM.

The IPO must contact the CFR Owner 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 a Notice of Proposed Rulemaking (NPRM) before issuing a final rule on the subject, since the NPRM is the formal notice that will appear in the Federal Register.

156.3.2.3 Notice of Proposed Rulemaking

Effective Date: 06/17/2020

USAID publishes a Notice of Proposed Rulemaking, or NPRM (also known as a proposed rule), in the Federal Register to notify the public that the Agency 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.

Agency Rulemaking Clearance Procedures

Once OMB/OIRA completes its significance review under E.O. 12866, the RC notifies the CFR Owner to send an action memo to the RRO requesting authorization to publish the NPRM in the Federal Register. The action memo should (1) originate from the CFR Owner's authorizing official serving as the signatory of the rule; and (2) include a copy of the rule and any relevant supplemental documentation accompanying the rule. The CFR Owner must obtain clearances from GC, M/MPBP, RPO, and other B/IOs as appropriate prior to sending the action memo to the RRO for approval. Clearing officials have 10 business days from the date of the clearance request to provide clearance or comments or request additional information. The clearance period may be extended for an additional five business days upon written request to the CFR Owner's authorizing official. If the clearing official or designated alternate does not respond within the comment deadline, the B/IO forfeits its right to clear on the material. Once the CFR Owner sends the action memo to the RRO for approval, the CFR Owner should receive approval for publication of the rule within 10 to 20 business days.

After the RRO approves the NPRM for publication, the CFR Owner must submit the following to the FRL at least seven business days prior to the desired publication date in the Federal Register to allow time to make corrections in the event that the OFR requests formatting and/or technical changes to the rule:

- An electronic copy of the rule in Microsoft Word with a digital signature from the CFR Owner's authorizing official serving as the signatory of the rule (see [ADS 516sae, Preparation of Documents for Electronic Submission to the Office of the Federal Register](#));
- An electronic copy of the action memo signed by the RRO approving the rule for publication, including the clearance sheet;
- A [letter](#) to the OFR requesting emergency publication of the rule, if applicable; and
- Any supplemental documentation accompanying the rule for public comment, as appropriate.

If the OFR provides edits or comments on the rule, the FRL promptly forwards those edits and comments to the CFR Owner for resolution. Upon the CFR Owner's approval, the OFR publishes the rule, and the public may provide comments within the timeline specified in the Federal Register notice (generally up to 60 days). The proposed rule and the public comments received on it form the basis of the final rule.

a. Exceptions

Unless a notice or hearing (*e.g.*, notice and comment period) is specifically required by statute, NPRMs are not required for certain categories of rules, although such rules must still be published in the Federal Register. Categories of rules that require publication but are not subject to NPRMs include the following:

- Notice and comment procedures generally do not apply when USAID finds, for “good cause,” that those procedures are impracticable, unnecessary, or contrary to the public interest. When using this exception, the Agency must explicitly indicate this and provide a rationale for the exception’s use within the preamble of the final rule. USAID can then proceed to issue an Interim Final Rule (see **156.3.2.5b** regarding the good cause exception).
- Interpretative rules; general statements of policy; or rules of agency organization, procedure, or practice.

In the event that, following consultation with the IPO, GC, and M/MPBP/POL, the CFR Owner proceeds with rulemaking without providing the public with the opportunity to comment, the rule must include analysis of why public comments were deemed to be unnecessary. OMB/OIRA will review the analysis and determine whether or not an NPRM, which includes the notice and comment period, is required. In general, agencies may pursue an Interim Final Rule to implement statutory requirements with a specific near-term implementation date. Non-statutory revisions to the CFR that impact the public, such as contractors or recipients, should be issued using the standard NPRM process.

156.3.2.4 Comments on Rulemaking

Effective Date: 06/17/2020

The RC coordinates with the CFR Owner to provide user access to the Federal Docket Management System ([FDMS.gov](https://www.fedms.gov)), an electronic docket management system that provides U.S. Government agencies with the ability to post documents routinely included in rulemaking dockets, including supporting documents for public review and comment, such as reports, summaries, and transcripts of public meetings and hearings.

FDMS is publicly accessible through www.regulations.gov, the external-facing website where the public can provide comments, including written opinions, data, and other information submitted to the Agency, to agree or disagree with the rulemaking and/or to suggest alternatives to the proposed action. The RC is responsible for creating the docket where comments are submitted and for ensuring that comments from the regulations.gov website are sent to the appropriate docket in FDMS.gov. Once the comment period for rulemaking has ended, the CFR Owner should retrieve the comments from FDMS.gov by docket identifier (not by an individual commenter’s identifying information) and coordinate with GC to determine which comments are relevant to the rulemaking and require an Agency response. In consultation with the IPO and GC, the CFR Owner should:

- 1) Identify the issues raised in the substantive comments and categorize the comments by issue area;
- 2) Develop the Agency's response to each set of comments, rather than addressing each comment individually; and
- 3) Determine the extent to which the proposed rule language may need to be modified.

The final rule must summarize all substantive issues raised by commenters in the preamble of the rule and provide the Agency's response to each substantive issue raised by commenters. In addition, the CFR Owner must publish all substantive comments on the Regulations.gov website for public review prior to publishing the final rule.

156.3.2.5 Final Rules

Effective Date: 06/17/2020

The final rule announces to the public a new or revised rule and the date on which it will take effect. Prior to publishing the final rule, the CFR Owner, IPO, and GC must review and develop responses to public comments for inclusion in the preamble. If OMB/OIRA has deemed the final rule to be significant, the CFR Owner, IPO, and GC, in consultation with the RC, must address substantive comments in developing the final rule, and the RC will coordinate submission of the draft final rule to OMB/OIRA for approval before publication. If OMB/OIRA does not deem the final rule to be significant, then USAID does not need to submit responses to comments to OMB/OIRA for review prior to publishing the rule in the Federal Register, although the RC should advise OMB/OIRA when the final rule will be published. The CFR Owner and IPO should seek to publish the final rule according to the timeline proposed in the Unified Agenda, but the timeline may vary depending on the nature and scope of the public comments, the time required to address substantive public comments, and the time required to review and approve the final rule for publication.

Once OMB/OIRA has approved the final rule for publication in the Federal Register, the RC notifies the CFR Owner to send an action memo to the RRO requesting authorization to publish the final rule. The internal Agency clearance and submission process for publication of the final rule is the same as the process for a proposed rule. See **156.3.2.3** for further information on requirements related to the action memo and submission of rulemaking documentation for publication.

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 **156.3.2.5.a**), and circumstances when it may go into effect at an earlier date (see **156.3.2.4.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 becomes effective (e.g., upon publication of the final rule in the Federal Register). 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 Rules

A major rule may take effect no sooner than 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 interpretive rules or statements of policy; rules that grant or recognize an exemption or relieve a restriction; or an agency finding that “good cause” exists for an earlier effective date, which is published in the preamble to the final rule.

Per the APA, notice and comment procedures generally 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 Rules.** When issuing an Interim Final Rule, an agency invokes good cause and issues the rule 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 USAID that it should amend the Interim Final Rule, the Agency may revise the rule and publish a final rule that incorporates the revisions made in light of those comments. The IPO and CFR Owner must consult with M/MPBP/POL regarding use of an Interim Final Rule. OMB/OIRA makes the final determination on whether the Interim Final Rule is appropriate.

- 2) **Direct Final Rules.** Direct final rulemaking may be used when USAID deems a rule to be routine or noncontroversial. A Direct Final Rule is generally used for administrative changes, such as implementation of statutory changes, for which comments are unlikely or from which the Agency has little or no discretion to deviate. Under direct final rulemaking, USAID issues a final rule without prior notice and comment. The rule may take effect unless at least one adverse comment is received, in which case the Agency must withdraw the rule and proceed with notice and comment procedures (*e.g.*, an NPRM). If the Agency does not receive any comments, the rule will become effective. In certain circumstances, in coordination with M/MPBP/POL, the IPO and CFR Owner may need to consult with OMB/OIRA to clarify whether comments received are “adverse,” which would require that USAID withdraw the rule and proceed with an NPRM or notice and comment rulemaking.

156.3.3 Exceptions to Notice and Comment Rulemaking Requirement

Effective Date: 06/17/2020

The Administrative Procedure Act provides exceptions to the notice and comment rulemaking requirement in the following situations:

- When there is a military or foreign affairs function of the United States involved;
or
- A matter relating to Agency management or personnel or to public property, loans, grants, benefits, or contracts.

The exceptions to notice and comment rulemaking are construed narrowly. For example, the foreign affairs exception applies if the subject matter of the rule is clearly and directly related to a foreign affairs function, such as matters that could affect the U.S. Government’s relationship with foreign governments or that could clearly provoke undesirable international consequences.

Although the Administrative Procedure Act provides exceptions to notice and comment rulemaking for matters relating to Agency management or personnel or to public

property, loans, grants, benefits or contracts, the [Office of Federal Procurement Policy Act \(41 U.S.C. 1707\)](#) requires notice and comment for procurement policies, regulations, procedures, or forms that (1) relate to the expenditure of appropriated funds; (2) have a significant effect beyond the internal operating procedures of the agency; or (3) have a significant cost or administrative impact on contractors or offerors.

The CFR Owner must consult with M/MPBP/POL and GC to determine whether an exception applies. If the CFR Owner decides to pursue an exception, OMB/OIRA must approve the exception.

156.3.4 Legal and Procedural Requirements for Rulemaking

Effective Date: 06/17/2020

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

156.3.4.1 Significant Economic Impact on Substantial Number of Small Entities

Effective Date: 06/17/2020

[The Regulatory Flexibility Act \(RFA\)](#) requires USAID to prepare a regulatory flexibility analysis if its rule could “have a significant economic impact on a substantial number of small entities,” including small businesses, small not-for-profit organizations, and small governmental jurisdictions, and to consider less burdensome alternatives. The IPO must prepare an initial regulatory flexibility analysis upon issuance of the proposed rule and a final regulatory flexibility analysis upon issuance of the final rule.

The analytical requirements do not apply to final rules for which USAID does not publish a proposed rule (e.g., interim final rules and direct final rules that meet the “good cause” exception).

In addition, the analytical requirements are not triggered if the RRO certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities. The IPO should coordinate with the CFR Owner to ensure that this certification is included in the action memo to the RRO requesting approval to publish the rule in the Federal Register. USAID must publish its certification within the rule at the time of publication in the Federal Register, along with a statement providing the factual basis for the certification.

Under [E.O. 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. USAID must respond in the notice of final rulemaking to any written comments submitted by SBA’s Office of Advocacy on the proposed rule.

The IPO should consult [E.O. 13272](#) and the SBA 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.

156.3.4.2 “Collection of Information” Requirement

Effective Date: 06/17/2020

The [Paperwork Reduction Act, 44 U.S.C. 3501-3520](#) provides the statutory framework for the Federal Government’s collection, use, and dissemination of information. The objectives of the Paperwork Reduction Act (PRA) include the following:

- Minimize the paperwork and reporting burden on individuals, small entities, and others resulting from the collection of information by or for the Federal Government;
- Minimize the cost to the Federal Government for collecting and disseminating information; and
- Maximize the public benefit from and the utility of the information collected.

The PRA generally defines a “collection of information” as the obtaining or disclosure of facts or opinions by or for an agency from 10 or more non-Federal persons. The Act requires an agency to justify to OMB its proposed collection of information from the public by establishing the need and intended use of the information, estimating the burden that the collection will impose on respondents, and showing that the collection is the least burdensome way to gather the information. In addition, the information collected should not be duplicative of other Federal information collections.

An IPO requesting a regulatory change that includes a potential information collection requirement (ICR) should consult with M/MPBP/POL, M/MS/IRD, the CFR Owner, and GC to confirm whether provisions of the PRA apply to the rule. M/MPBP/POL, in coordination with M/MS/IRD and the CFR Owner, will consult with OMB/OIRA as necessary to make the final determination as to whether the rule has an ICR.

If the proposed rule has no ICR, the NPRM must state that the provisions of the PRA do not apply. If OMB/OIRA determines that the rule has a collection of information requirement, M/MPBP/POL must obtain permission from OMB/OIRA before the ICR is implemented and seek periodic extensions for existing regulations with ongoing collection of information requirements. The IPO must consult with the CFR Owner on such requirements.

If OMB/OIRA confirms that the rule has an ICR, the IPO should consult [ADS 156mac, Information Collection Requirements Related to Rulemaking](#), to ensure that the rule includes required notification to the public about the ICR to provide substantive public comment, and that the appropriate ICR documentation related to the rule is submitted to

M/MS/IRD at the appropriate timeline for OMB approval. The IPO should consider the impact that an ICR may have on the rulemaking process, such as the time required to obtain the data needed to inform the ICR documentation for OMB review and approval.

156.3.4.3 Unfunded Mandates

Effective Date: 06/17/2020

The [Unfunded Mandates Reform Act of 1995 \(P. L. 104-4\)](#) requires agencies to give special consideration to proposed rules containing Federal mandates on state, local, and tribal governments and the private sector without providing the funding appropriate to the costs imposed by the Federal mandates. 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 the CFR Owner and M/MPBP/POL, must prepare a budgetary impact statement and include it in the preamble to the proposed rule sent to OMB/OIRA.

156.3.4.4 Federalism Implications

Effective Date: 06/17/2020

Under [E.O. 13132](#), “Federalism” requires covered Federal agencies to “have an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.” Rules that have federalism implications are those that have “substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.”

E.O. 13132 prohibits Federal agencies from promulgating any rule with federalism implications unless they have consulted with state and local officials early in developing the proposed rule and have prepared a “federalism summary impact statement” in the preamble of the NPRM. The IPO must coordinate with the CFR Owner and M/MPBP/POL to prepare this statement, which must include a description of prior consultations with state and local officials, a summary of their concerns, the Agency’s position on the need to issue the rule, and a statement indicating how the officials’ concerns have been met.

156.3.4.5 Constitutionally-Protected Property Rights

Effective Date: 06/17/2020

The Federal Government could be required to pay just compensation to a property owner for any “taking” of private property resulting from a Federal regulation. [E.O. 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 the CFR Owner and M/MPBP/POL to prepare that statement, if required.

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

Effective Date: 06/17/2020

Under [E.O. 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 the CFR Owner and M/MPBP/POL to prepare the statement, if required.

156.3.4.7 Environmental Health and Safety Risks for Children

Effective Date: 06/17/2020

If a rule concerns an environmental health risk or safety risk that may disproportionately affect children, [E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks](#), requires agencies to provide OMB/OIRA with:

- An evaluation of the environmental or safety 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 the CFR Owner and M/MPBP/POL to prepare the documentation, if required.

156.3.4.8 Indian Tribal Governments

Effective Date: 06/17/2020

Under [E.O. 13175, Consultation and Coordination with Indian Tribal Governments](#), agencies are generally prohibited from promulgating any regulation not required by law that has tribal implications and imposes substantial direct costs on tribal governments unless necessary funds are provided or the Agency consults with tribal officials and provides a “tribal summary impact statement” describing those consultations. The IPO must coordinate with the CFR Owner and M/MPBP/POL to prepare the statement, if required.

156.3.5 Public Participation in Rulemaking

Effective Date: 06/17/2020

Pursuant to [E.O. 13563](#), USAID must promote public participation and an open exchange of information in rulemaking. The CFR Owner must provide the public with the option to submit comments in at least one of the following methods:

- Via the U.S. Postal Service;
- Via email to the CFR Owner; or

- Submitted online through the official U.S. Government website www.regulations.gov.

If possible, the CFR Owner should provide more than one method for the public to submit comments. The CFR Owner should encourage the public to submit comments electronically to the regulations.gov website to facilitate access to comments and to enhance the Agency's ability to manage comments for timely response. Submitting comments via regular mail should be discouraged due to potential delays from security screening.

Following are sample instructions to include within the "Supplementary Information" section of the proposed rule:

Instructions:

All comments must be in writing and submitted through one of the methods specified in the "Addresses" section above. All submissions must include the title of the action and RIN for this rulemaking. Please include your name, title, organization, postal address, telephone number, and email address in the text of the message.

Please note that USAID recommends sending all comments to the Federal eRulemaking Portal because security screening precautions have slowed the delivery and dependability of surface mail to USAID in Washington, DC.

All comments will be made available at www.regulations.gov for public review without change, including any personal information provided. We recommend that you do not submit information that you consider Confidential Business Information (CBI) or any information that is otherwise protected from disclosure by statute.

USAID will only address substantive comments on the rule. USAID may not consider comments that are insubstantial or outside the scope of the proposed rule.

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 by issue, in the event that multiple comments reflect a common idea, concern, or topic. The CFR Owner will receive public comments for 30 to 60 days after publication of the ANPRM or NPRM. The CFR Owner must post the comments in the Federal Docket Management System as outlined in **156.3.2.4**.

156.3.5.1 Federal Docket Management System

Effective Date: 06/17/2020

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 website 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” online 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 M/CIO and M/MPBP/POL. The CFR Owner must request access to the FDMS via www.fdms.gov. Once the request is made, it is sent to USAID’s FDMS Administrators to grant access to the FDMS system.

156.3.5.2 Limitations on Ex Parte Contact with the Public

Effective Date: 06/17/2020

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 and GC and managed by the CFR Owner.

USAID staff must not engage in individual and/or inappropriate contact with interested persons – through meetings, phone conversations, or email 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. The CFR Owner should obtain authorization from M/MPBP/POL and GC/EA to determine whether ex parte contact on a specific rulemaking proceeding is permissible.

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 Ongoing Responsibility Regarding Rules

Effective Date: 06/17/2020

[E.O. 13563](#) 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 CFR Owner must review all regulations within their authorities to determine whether they continue to serve the purpose for which they were originally issued or whether they should be modified or eliminated.

Under Section 610 of the [Regulatory Flexibility Act](#), USAID must review existing regulations that have or will have a significant economic impact on a substantial number of small entities within 10 years of their adoption as final rules. The purpose of the review is to determine whether such rules should be continued without change or should be amended or rescinded in order to minimize their 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 degree of complexity of the rule;
- The extent of overlap, duplication, or conflict with other Federal, state, or local regulation; and
- The length of time since the Agency has reviewed the rule, and/or the extent to which circumstances have changed which may affect regulated entities, such as changes in technology, economic circumstances, competitive forces, and the cumulative burden faced by regulated entities.

156.3.7 Semi-Annual Unified Agenda Report

Effective Date: 06/17/2020

Pursuant to [E.O. 12866](#), USAID must prepare a semi-annual regulatory Unified Agenda of rules that are under development. Twice a year, OMB/OIRA publishes regulatory and deregulatory actions under development throughout the Federal Government. USAID's latest Unified Agenda listing its rulemaking activities can be found [here](#).

To complete the Unified Agenda, M/MPBP/POL will contact each CFR Owner to obtain a description of the rulemaking activities each office plans to undertake within the next 12 months. The CFR Owner, in coordination with 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 rule; and
- The status of any such rules previously listed in the Agenda.

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

- A regulation identifier number (RIN);
- A brief summary;

- The legal authority for the action;
- The CFR citation;
- Any legal deadline; and
- The name and telephone number of a knowledgeable USAID point of contact.

If a new rule must be added to the Unified Agenda, the CFR Owner, in consultation with the IPO and GC, must provide the information requested in [ADS 156maa, New Rule Submission for Unified Agenda](#) to M/MPBP/POL for review. M/MPBP/POL will notify the CFR Owner each spring and fall to begin the process to complete the Unified Agenda with a timetable for review and completion. Each CFR Owner should adhere to the timetable to ensure timely submission of the report.

In select circumstances, a CFR Owner may seek to publish a rule in the Federal Register for notice and comment before it has been included in the Agency's published Unified Agenda (e.g., to comply with a statutory requirement, executive order, or other directive). In such instances, the CFR Owner should draft a letter to OMB/OIRA signed by the head of their B/IO that requests a waiver to publish the rule prior to its inclusion in the published Unified Agenda. M/MPBP/POL will submit the waiver request letter to OMB/OIRA on the B/IO's behalf. The CFR Owner must still comply with all internal Agency clearance requirements as outlined in **156.3.2.3** and with OMB/OIRA significance review requirements as outlined in **156.3.2.1**.

156.3.8 Monitoring of Policy Implementation

Effective Date: 06/17/2020

M/MPBP/POL will monitor implementation of the Agency rulemaking policy as follows:

- Coordinate with the CFR Owners to provide accurate, up-to-date information on new and existing Agency rules in the Unified Agenda, submitting the Unified Agenda to the RRO for approval no later than three weeks prior to OMB's bi-annual Unified Agenda deadlines; and
- The CFR Owner, in coordination with M/MPBP/POL and M/MS/IRD, publishes the NPRM in the Federal Register within 30 days of OMB/OIRA's completion of its significance review of the rule under [E.O. 12866](#).

156.4 MANDATORY REFERENCES

156.4.1 External Mandatory References

Effective Date: 06/17/2020

- a. [Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701 et seq.](#)

- b. [Congressional Review Act, P.L. 104-121](#)
- c. [E-Government Act of 2002](#)
- d. [E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights \(53 Fed. Reg. 8859, March 18, 1988\)](#)
- e. [E.O. 12866, Regulatory Planning and Review \(58 Fed. Reg. 51735, October 4, 1993\); amended by E.O. 13258 \(67 Fed. Reg. 9385, February 28, 2002\)](#)
- f. [E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations \(59 Fed. Reg. 7629, February 16, 1994\)](#)
- g. [E.O. 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 \(68 Fed. Reg. 19931, April 23, 2003\)](#)
- h. [E.O. 13132, Federalism \(64 Fed. Reg. 43255, August 10, 1999\)](#)
- i. [E.O. 13175, Consultation and Coordination with Indian Tribal Governments \(65 Fed. Reg. 67249, November 9, 2000\)](#)
- j. [E.O. 13272, Proper Consideration of Small Entities in Agency Rulemaking \(67 Fed. Reg. 53461, August 16, 2002\)](#)
- k. [E.O. 13563, Improving Regulations and Regulatory Review](#)
- l. [E.O. 13771, Reducing Regulation and Controlling Regulatory Costs](#)
- m. [E.O. 13777, Enforcing the Regulatory Reform Agenda](#)
- n. [FDMS Frequently Asked Questions](#)
- o. [Federal Register Document Drafting Handbook](#)
- p. [Memorandum M-17-21, Guidance Implementing EO 13771](#)
- q. [Memorandum M-19-14, Guidance on Compliance with the Congressional Review Act](#)
- r. [OMB Circular A-4, "Regulatory Analysis"](#)
- s. [Paperwork Reduction Act, 44 U.S.C. 3501-3520](#)

- t. [Plain Writing Act of 2010](#)
- u. [Regulatory Flexibility Act, 5 U.S.C. § 601 et seq.](#)
- v. [Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1501-1571](#)
- w. [The Office of Federal Procurement Policy Act, 41 U.S.C. 1707](#)

156.4.2 Internal Mandatory References

Effective Date: 06/17/2020

- a. [ADS 156maa, New Rule Submission for Unified Agenda](#)
- b. [ADS 156mab, USAID Rulemaking Timeline](#)
- c. [ADS 156mac, Information Collection Requirements Related to Rulemaking](#)
- d. [ADS 156mad, Business Process Mapping of Rulemaking at USAID](#)
- e. [ADS 516, Federal Register Notices](#)

156.4.3 Mandatory Forms

Effective Date: 06/17/2020

- a. [Submission of Federal Rules Under the Congressional Review Act Form](#)

156.5 ADDITIONAL HELP

Effective Date: 06/17/2020

- a. [Federal Register](#)
- b. [Government Printing Office Style Manual](#)
- c. [OMB OIRA: Req Map: Informal Rulemaking Flow Chart](#)
- d. [OMB OIRA: Reginfo.gov- Frequently Asked Questions](#)
- e. [OMB OIRA Regulatory Impact Analysis: Frequently Asked Questions \(FAQs\)](#)
- f. [SBA Office of Advocacy – A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act](#)
- g. [SBA Office of Advocacy – Condensed Guide to the Regulatory Flexibility Act](#)

156.6 DEFINITIONS
Effective Date: 06/17/2020

See the [ADS Glossary](#) for all ADS terms and definitions.

Advanced Notice of Proposed Rulemaking (ANPRM)

An information gathering document issued to the public prior to the development of a specific proposed rulemaking. (**Chapter 156**)

Code of Federal Regulations (CFR) Owner

The Bureau or Independent Office (B/IO) that advises and assists the Initiating Program Office (IPO) by determining the need for changes to the CFR that require rulemaking, establishing rulemaking requirements, and identifying any regulatory analysis required to support rulemaking. The CFR Owner develops the rule that impacts their regulation, ensuring that the rule complies with regulatory drafting requirements and fits within the structure and format of the regulation codified in the CFR. (**Chapter 156**)

Federal Docket Management System (FDMS)

An online regulatory system and a component of the federal eRulemaking 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)

The B/IO that provides subject matter expertise on regulatory matters that impact the IPO's programs. The IPO identifies new or revised technical requirements, requests changes to the CFR, and utilizes its technical expertise to develop the rule and supporting documentation for review during the rulemaking process (e.g., analysis of regulatory costs and impact on the public). The IPO serves as the Agency lead on drafting sections of the rule that require technical expertise or analysis to support the basis for the rule, responding to technical or subject matter queries raised during the rulemaking process, and updating supporting documentation on the rule based on input received during the rulemaking process. (**Chapter 156**)

Notice of Proposed Rulemaking (NPRM)

A notice of proposed rulemaking, or proposed rule, is the official document that announces or explains the Agency's plan to address a problem or accomplish a goal. (**Chapter 156**)

Regulatory Policy Officer

The Assistant Administrator, Bureau for Management (AA/M) serves as the Agency's Regulatory Policy Officer (RPO) and provides oversight for the rulemaking process. (**Chapter 156**)

Regulatory Reform Officer

The Deputy Administrator serves as USAID's Regulatory Reform Officer (RRO) and is responsible for overseeing implementation of regulatory reform initiatives and policies to ensure USAID effectively reduces regulatory burdens, consistent with applicable law. **(Chapter 156)**

Rule/Regulation

An agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency. A rule issued by an agency alters rights and interests of outside parties.

The terms "rule" and "regulation" are often used interchangeably in discussions of the Federal regulatory process. Both rules and regulations are subordinate to statutes, especially to the specific statutes 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)**

Rules Coordinator

A staff member of M/MPBP/POL, the Rules Coordinator (RC) acts as the liaison between the IPO and OMB/OIRA concerning USAID's rule development and review process. **(Chapter 156)**

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