



## 22 CFR Part 212

RIN 0412-AB00

Procedures for the review and clearance of USAID's Guidance Documents

**AGENCY:** U.S. Agency for International Development (USAID).

**ACTION:** Final rule.

**SUMMARY:** This final rule amends USAID's regulations to implement Executive Order (E.O.) 13891, *Promoting the Rule of Law Through Improved Agency Guidance Documents*. This rule sets forth processes and procedures for USAID to issue guidance documents as defined in the E.O. in a manner consistent with the requirements of Federal law applicable to all employees involved in inherently governmental deliberative decision-making on policy and employees involved in related administrative processes.

**DATES:** This final rule is effective January 5, 2021.

**FOR FURTHER INFORMATION CONTACT:** Tyrone K. Brown, Guidance Mailbox (202) 355-7450) [tybrown@usaid.gov](mailto:tybrown@usaid.gov).

### **SUPPLEMENTARY INFORMATION:**

#### **Background**

On October 9, 2019 (84 FR 55235), President Trump issued Executive Order (E.O.) 13891, *Promoting the Rule of Law Through Improved Agency Guidance Documents*. The E.O. asserts that, except as mandated by applicable law or incorporated into a binding contract or agreement, Federal Departments and Agencies should treat guidance documents as non-binding on outside entities both in law and practice. To further the principle that Federal guidance should be transparent and made readily available to the public, Section 3 of the E.O. requires that Departments and Agencies make guidance documents available on a single, searchable, indexed public website. Section 3 also requires that Departments and Agencies review their guidance documents and, consistent with applicable law, rescind those that should no longer be in effect.

Lastly, Section 4 requires that each Department and Agency put in place processes and procedures for issuing guidance documents as defined by the E.O.

In accordance with that direction, to codify our processes and procedures for guidance documents, the U.S. Agency for International Development (USAID) is amending our Automated Directives System (ADS) to update ADS Chapter 501, which governs the clearance process for reviewing and issuing Agency policy documents, to include guidance documents as defined by the E.O.. USAID's formal clearance process ensures that all guidance documents receive legal review and, when appropriate, review and approval from USAID's Regulatory Reform Officer, who is the Agency's Deputy Administrator.

Before the Agency issues guidance documents as defined by E.O. 13891, we must review them to ensure they are written in plain language and do not impose any substantive legal requirements above and beyond statute or regulation. If a guidance document purports to describe, approve, or recommend specific conduct not required by existing laws, statutes, and regulations, then it must include a clear and prominent statement that the contents of the guidance document do not have the force and effect of law and are not meant to bind the public in any way, and that the guidance document is intended only to provide clarity to the public regarding existing requirements under the law or internal Agency policies and procedures applicable to our staff.

According to E.O. 13891, guidance documents shall also be subject to notice-and-comment procedures. The E.O. mandates that Departments and Agencies shall publish a notice in the *Federal Register* to announce that a draft of the proposed guidance document is publicly available; shall post the draft guidance document on the guidance portal of the Department or Agency; shall invite public comment on the draft document for a minimum of 30 days; and shall prepare and post a public response to major concerns raised in the comments, as appropriate, on its guidance portal, when the Department or Agency finalizes and issues the guidance document. Consistent with E.O. 13891, USAID proposes procedures to allow the public to petition for the

modification or withdrawal of an active guidance document posted on the Agency's guidance portal. USAID's guidance portal will provide clear and specific instructions on how to request the modification or withdrawal of an active guidance document.

The Office of the General Counsel (GC) at USAID has determined that the Agency has no "guidance documents" as defined under E.O. 13891. USAID's internal guidance materials do not qualify as "guidance documents" under the E.O., nor do grant and contract solicitations and awards; *Country and Regional Development Cooperation Strategies*; Agency programmatic Policies and *Strategies*; and purely internal Agency policies not intended to have substantial effect on the behavior of regulated parties, such as Chapters of our ADS. The procedures contained in this final rule apply to all guidance documents, which USAID defines as any statement of Agency policy or interpretation that concerns a statute, regulation, or technical matter within the jurisdiction of the Agency that is intended to have general applicability and future effect on the behavior of regulated parties, but which is not intended to have the force or effect of law in its own right and is not otherwise required by statute to satisfy the rulemaking procedures of the [Administrative Procedure Act](#).

### **Notice and Comment Not Required**

This rule relates to internal Agency management. Therefore, pursuant to Section 553(a)(2) of Title 5 of the United States Code (U.S.C. ), notice of proposed rulemaking and opportunity to comment are not required.

### **Procedural Requirements**

The Office of Management and Budget (OMB) has determined that this regulatory action does not meet the criteria for significant regulatory action pursuant to E.O. 12866, Regulatory Planning and Review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in E.O. 13771.

The regulations added by this rule are intended to improve the internal management of USAID. As such, it is for the use of USAID personnel only and is not intended to, and does not,

create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its Departments and Agencies or other entities, its officers or employees, or any other person. Accordingly, we expect the economic impact of this rule, if any, to be minimal.

### **Regulatory Flexibility Act**

Because notice-and-comment rulemaking is not necessary for this rule, the provisions of the Regulatory Flexibility Act, Section 604 of Title 5 of the U.S.C. do not apply.

### **Paperwork Reduction Act**

This final rule imposes no new reporting or recordkeeping requirements that necessitate clearance by OMB.

### **List of Subjects in 22 CFR Part 212**

Administrative practice, Freedom of Information Act (FOIA) , Procedures

In consideration of the foregoing, and under the authority of E.O. 13891, the U.S. Agency for International Development (USAID) amends 22 CFR part 212 as follows:

1. The authority citation for part 22 continues to read as follows:

AUTHORITY: Pub. L. 114-185, 130 Stat. 538

2. Add subparts N and O, consisting of §212.25 through 212.40, to read as follows:

#### **Sec.**

#### **Subpart N-- Rulemaking**

**§212.25.** Responsibilities.

#### **Subpart O--Procedures for Guidance Documents**

**§212.26.** General.

**§212.27.** Review and clearance by the Office of the Bureau for Management.

**§212.28.** Requirements for clearance.

**§212.29.** Public access to effective guidance documents.

**§212.30.** Good-faith cost estimates.

**§212.31.** Approved procedures for guidance documents identified as “significant” or “otherwise of importance to the Agency’s interests.”

**§212.32.** Definitions of “significant guidance document” and guidance documents that are “otherwise of importance to the Agency’s interests.”

**§212.33.** Designation procedures.

**§212.34.** Notice-and-comment procedures.

**§212.35.** Petitions for guidance.

**§212.36.** Rescinded guidance.

**§212.37.** Exigent circumstances.

**§212.38.** Reports to Congress and the Government Accountability Office.

**§212.39.** No judicial review or enforceable rights.

**§212.40.** Use of guidance documents.

## **SUBPART N – Rulemaking**

### **§212.25. Responsibilities.**

(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 manages regulatory burdens, consistent with applicable law.

(b) The Assistant Administrator for Management serves as USAID’s Regulatory Policy Officer (RPO) and provides oversight for the Agency’s internal 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 Office of Management Policy, Budget, and Performance in the Bureau for Management (M) coordinates the rulemaking process and ensures the Agency’s rulemaking activities comply with all statutory and regulatory requirements.

(d) The Initiating Program Office (IPO) at USAID is the Bureau or Independent Office (B/IO) that provides subject-matter expertise on regulatory matters that affect the IPO’s programs.

(e) The Office of the General Counsel at USAID provides guidance on legal and procedural requirements during the Agency’s rulemaking process.

## **SUBPART O – Guidance Procedures**

### **§212.26. General.**

(a) This subpart governs all employees of the United States Agency for International Development (USAID) involved in any phase of issuing Agency guidance documents as defined by under E.O. 13891.

(b) This subpart applies to all guidance documents issued by all components of the Agency after January 5, 2021.

(c) For purposes of this subpart, the term “guidance document” includes any statement of Agency policy or interpretation that concerns a statute, regulation, or technical matter within the jurisdiction of the Agency that is intended to have general applicability and future effect, but is not intended to have the force or effect of law in its own right and is not otherwise required by statute to be implemented through the rulemaking procedures specified in 5 U.S.C. 553. The term is not confined to formal written documents; guidance may come in a variety of forms, including (but not limited to) letters, memoranda, circulars, bulletins, and advisories, and may include video, audio, and web-based formats. See OMB Bulletin 07-02, Agency Good Guidance Practices.

(d) This subpart does not apply to the following:

- (1) Rules exempt from rulemaking requirements under 5 U.S.C. 553(a);
- (2) Rules of Agency organization, procedure, or practice;
- (3) Decisions of Agency adjudications under 5 U.S.C. 554 or similar statutory provisions;
- (4) Internal executive management legal advice or legal advisory opinions addressed to executive officials;
- (5) Agency statements of specific applicability, including advisory or legal opinions directed to particular parties about circumstance-specific questions (*e.g.*, case or investigatory letters responding to complaints, warning letters), notices regarding particular locations or facilities (*e.g.*, guidance that pertains to the use, operation, or control of a U.S. Government facility or property), and correspondence with individual

persons or entities (e.g., Congressional correspondence), except documents ostensibly directed to a particular party but designed to guide the conduct of the broader regulated public;

(6) Legal briefs, other court filings, or positions taken in litigation or enforcement actions;

(7) Agency statements that do not set forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statute or regulation, including speeches and individual presentations, editorials, media interviews, press materials, or Congressional testimony that do not set forth for the first time a new regulatory policy;

(8) Guidance pertaining to military or foreign-affairs functions;

(9) Grant solicitations and awards;

(10) Contract solicitations and awards; or

(11) Purely internal Agency guidance policies, such as Chapters of the ADS directed solely to USAID's employees, or to other Federal Departments and Agencies not intended to have substantial future effect on the behavior of regulated parties; USAID's *Country/Regional Development Cooperation Strategies*; the Agency's programmatic Policies and *Strategies*; Acquisition and Assistance Policy Directives (AAPDs); Application Guidelines; COVID-19 Guidance; Food for Peace Information Bulletins (FFPIBs); Guidance and Tools for Global Food-Security Programs; Procurement Executive Bulletins (PEBs); Standard Provisions for the Protecting Life in Global Health Assistance (PLGHA) Policy; and documents in the USAID Policy Registry.

**§212.27. Review and clearance by the Office of Management Policy, Budget, and Performance in the Bureau for Management..**

All USAID guidance documents, as defined by E.O. 13891 and §212.26, require review and clearance in accordance with this subpart. The Bureau for Management (M Bureau) must review and clear any guidance a Bureau or Independent Office within USAID proposes to issue.

**§212.28. Requirements for clearance.**

USAID's review and clearance of guidance documents shall ensure that each one that a B/IO within the Agency proposes to issue satisfies the following requirements:

(a) The guidance document complies with all relevant statutes and regulations (including any statutory deadlines for the Agency's action);

(b) The guidance document identifies or includes the following:

(1) The term "guidance" or its functional equivalent;

(2) The issuing B/IO within the Agency;

(3) A unique identifier, including, at a minimum, the date of issuance and title of the document and a Regulation Identifier Number (RIN), if applicable;

(4) The activity or entities to which the guidance applies;

(5) Citations to applicable statutes and regulations;

(6) A statement that notes whether the guidance is intended to revise or replace any previously issued guidance and, if so, sufficient information to identify the previously issued guidance; and

(7) A short summary at the top of the document of the subject matter covered in the guidance document.

(c) The guidance document avoids using mandatory language, such as "shall," "must," "required," or "requirement," unless the language is describing an established statutory or regulatory requirement, or is addressed to USAID's staff and will not foreclose the Agency's consideration of positions advanced by affected private parties; and

(d) The guidance document is written in plain and understandable English. All guidance documents should include a clear and prominent statement to declare that the contents of the document do not have the force and effect of law and are not meant to bind the public in any way, and the document is intended only to provide clarity to the public regarding existing requirements under the law or USAID's policies.

**§212.29. Public access to effective guidance documents.**

Each B/IO within USAID responsible for issuing guidance documents shall do the following:

(a) Ensure all effective guidance documents, identified by a unique identifier that includes, at a minimum, the document's title and date of issuance or revision and its RIN, if applicable, are on USAID's guidance portal in a single, searchable, indexed database and are available to the public in accordance with 5 U.S.C. 552(a)(2);

(b) Note on USAID's guidance portal that guidance documents lack the force and effect of law, except as authorized by law and are not meant to bind the public in anyway;

(c) Maintain and advertise USAID's guidance portal as a means for the public to comment electronically on any guidance documents that are subject to the notice-and-comment procedures described in §212.34 and to submit requests electronically for the issuance, reconsideration, modification, or rescission of guidance documents in accordance with §212.26; and

(d) The Bureau for Management is the office designated to receive and address complaints from the public that USAID is not following the requirements of OMB's Good Guidance Bulletin, or is improperly treating a guidance document as a binding requirement.

**§212.30. Good-faith cost estimates.**

Even though not legally binding, some Agency guidance could result in a substantial economic impact. For example, the issuance of Agency guidance could induce private parties to alter their conduct to conform to recommended standards or practices, such that they could incur costs beyond the costs of complying with existing statutes and regulations. While it might be difficult to predict with precision the economic impact of voluntary guidance, to the extent practicable the proposing B/IO within USAID shall make a good-faith effort to estimate the likely economic cost impact of the guidance document to determine whether it might qualify as "significant."

When a B/IO is assessing or explaining whether it believes a guidance document is significant, it should, at a minimum, provide the same level of analysis that would be required for a determination under the Congressional Review Act (M-19-14), *Guidance on Compliance with*

*the Congressional Review Act*, that the guidance document is major. When USAID determines that a guidance document will be “economically significant,” the proposing B/IO should conduct and publish a regulatory-impact analysis of the sort that would accompany an economically significant rulemaking, to the extent reasonably possible (in conformance with E.O. 12866).

**§212.31. Approval procedures for guidance documents identified as “significant” or “otherwise of importance to the Agency’s interests.”**

(a) For guidance a USAID B/IO proposes to issue, if there is a reasonable possibility a guidance document could be as “significant” or “otherwise of importance to the Agency’s interests” within the meaning of §212.31, or if the B/IO is uncertain whether the guidance could qualify as such, the B/IO should email a copy of the proposed guidance document (or a summary of it) to the M Bureau for review and further direction before issuance.

(b) As with significant regulations, after appropriate internal consultation and review, the M Bureau will submit significant guidance documents that are otherwise of importance to the Agency’s interests to the Office of Information and Regulatory Affairs (OIRA) within OMB for review and designation.

(c) If OMB/OIRA determines a guidance document from a USAID B/IO not to be either significant or otherwise of importance to the Agency’s interests within the meaning of §212.31, the Bureau for Management may proceed with issuance. For each guidance document coordinated through the Office of the Administrator, the issuing B/IO should include a statement in the Action Memorandum to indicate that the OMB/OIRA has reviewed and cleared the guidance document in accordance with this process.

**§212.32. Definitions of “significant guidance document” and guidance documents that are “otherwise of importance to the Agency’s interests.”**

(a) The term “significant guidance document” means a guidance document USAID will disseminate to regulated entities or the general public and that might reasonably be anticipated:

(1) To lead to an annual effect on the U.S. economy of \$100 million or more, or adversely affect in a material way the U.S. economy, a sector of the U.S. economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) To create serious inconsistency or otherwise interfere with an action taken or planned by another Federal Department or Agency;

(3) To alter materially the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) To raise novel legal or policy issues that arise out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866, as further amended.

(b) The term "significant guidance document" does not include the categories of documents excluded by §212.26 or any other category of guidance documents exempted in writing by OMB/OIRA.

(c) OMB/OIRA must review significant and economically significant guidance documents under E.O. 12866 before issuance, and they must demonstrate compliance with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in E.O. 12866, E.O. 13563, E.O. 13609, E.O. 13771, and E.O. 13777.

(d) Even if not "significant," USAID will consider a guidance document of regulatory impact as "otherwise of importance to the Agency's interests" within the meaning of this paragraph if it might reasonably be anticipated:

(1) To relate to a major program, policy, or activity of the Agency or a high-profile issue that is pending for decision before the Agency;

(2) To involve one of the Administrator's top policy priorities;

(3) To garner significant press or Congressional attention; or

(4) To raise significant questions or concerns from constituencies of importance to the Agency, such as Committees of Congress, States or Indian tribes, the White House

or other Departments and Agencies of the Executive Branch, courts, consumer or public-interest groups, or leading representatives of industry.

(e) As noted in paragraphs (a) through (d) of this section, “guidance documents” for the purposes of this rule, including this subpart, do not include those documents identified in this subpart O.

### **§212.33. Designation procedures.**

(a) The Bureau for Management may request a B/IO within USAID to prepare a designation request for certain guidance documents. Designation requests must include the following information:

(1) A summary of the guidance document; and

(2) The B/IO’s recommended designation of “not significant,” “significant,” or “economically significant,” as well as a justification for that designation.

(b) Except as otherwise provided in paragraph (c) of this section, the Agency will seek significance determinations from OMB/OIRA for certain guidance documents, as appropriate, in the same manner as for rulemakings. Prior to publishing these guidance documents, after internal consultation and review, the Bureau for Management shall submit the document to OMB/OIRA for review under the provisions in Section 6 of E.O. 12866 to determine if it meets the definition of “significant” or “economically significant.”

(c) All “guidance documents” as with rulemakings, receive a significance determination from OMB/OIRA, unless explicitly exempt from E.O. 12866. Note that the only documents that do not receive designations are those that fall outside the definition of “guidance” or within a group categorically considered nonsignificant as agreed upon by OMB/OIRA in Memorandum M-20-02).

### **§212.34. Notice-and-comment procedures.**

(a) Except as provided in paragraph (b) of this section, all proposed USAID guidance documents determined to be a “significant guidance document” within the meaning of §212.31 shall be subject to the following notice-and-comment procedures:

- (1) The issuing B/IO within USAID shall publish a notice in the *Federal Register* to announce that a draft of the proposed guidance document is publicly available; post the draft guidance document on the Agency’s guidance portal; invite public comment on the draft document for a minimum of 30 days; and
- (2) Prepare and post a public response to major concerns raised in the comments, as appropriate, on USAID’s guidance portal, when the Agency finalizes and issues the guidance document.

(b) The requirements of paragraph (a) of this section will not apply to any significant guidance document or categories of significant guidance documents for which the Bureau for Management finds, in consultation with GC, the proposing B/IO, and USAID’s RRO, good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest (and incorporates the finding of good cause and a brief statement of reasons therefore in the guidance issued).

(c) Where appropriate, the Bureau for Management and the proposing B/IO may recommend to the RRO that a particular guidance document that is otherwise of importance to the Agency’s interests shall also be subject to the notice-and-comment procedures described in paragraph (a) of this section.

**§212.35. Petitions for guidance.**

Any person may petition the Agency to withdraw or modify a particular guidance document by using the procedures found in §212.26(c). USAID should respond to all requests in a timely manner, but no later than 90 days after receipt of the request.

**§212.36. Rescinded guidance.**

No B/IO within USAID may cite, use, or rely on guidance documents that are rescinded, except to establish historical facts.

**§212.37. Exigent circumstances.**

In emergency situations, or when a statutory deadline or court order requires the issuing B/IO within USAID to act more quickly than normal review procedures allow, the issuing B/IO shall coordinate with the Bureau for Management to notify OMB/OIRA as soon as possible and, to the extent practicable, shall comply with the requirements of this subpart at the earliest opportunity. Wherever practicable, the issuing B/IO should schedule its proceedings to permit sufficient time to comply with the procedures set forth in this subpart.

**§212.38. Reports to Congress and the Government Accountability Office.**

Unless otherwise determined in writing, it is the policy of USAID that upon issuing a guidance document determined to be “significant” within the meaning of §212.31 the issuing B/IO shall submit a report to Congress and the Government Accountability Office in accordance with the procedures described in 5 U.S.C. 801 (the Congressional Review Act [CRA]). Under the CRA, USAID must coordinate with OMB/OIRA regarding a major determination for all guidance documents, irrespective of whether the Agency otherwise would submit a rule for regulatory review (Memorandum-19-14).

**§212.39. No judicial review or enforceable rights.**

This subpart is intended to improve the internal management of USAID. As such, it is for USAID personnel only and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its Departments and Agencies or other entities, its officers or employees, or any other person.

**§212.40. Use of guidance documents.**

Guidance documents cannot create binding requirements that do not already exist by statute or regulation. Accordingly, non-compliance with guidance documents cannot be used as a basis for proving violations of applicable law. Guidance documents can do no more, with

respect to prohibition of conduct, than articulate USAID's understanding of how a statute or regulation applies to particular circumstances.

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