Guidelines for Complying with the Regulatory Flexibility Act



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Office of Strategic Management and Enterprise Integrity
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Introduction

Under Executive Order (E.O.) 13272, titled "Proper Consideration of Small Entities in Agency Rulemaking," agencies are required to establish policies and procedures consistent with the Regulatory Flexibility Act (RFA), to ensure that the potential impacts of agencies' draft rules on small businesses, small governmental jurisdictions, and small organizations are properly considered during the rulemaking process. A recent Government Accountability Office (GAO) audit **Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance** (GAO-25-106950) recommended: *The Administrator of SBA should develop and implement policies and procedures for complying with the Regulatory Flexibility Act.*[1]

The Small Business Administration (SBA or Agency) has developed this framework and guidelines for SBA program managers, economists, attorneys, and other staff who support Agency rulemaking. While it is not meant to be the only source of information on RFAs, it contains and summarizes key information from SBA's Office of Advocacy's guidance that will be used to guide and enhance evidence-based practices at the SBA.

The purpose of these procedures is to provide the SBA with guidance for meeting the requirements of the RFA and E.O. 13272. Both the RFA and E.O. 13272 require agencies to consider the potential impact of rules on small businesses, small governmental jurisdictions, and small organizations during the development of their rules. E.O. 13272 reinforces the intent of the RFA by requiring agencies to establish policies and procedures to promote compliance with the RFA. This document fulfills the requirement of E.O. 13272.

Compliance with the RFA and E.O. 13272

RFA Process Summary

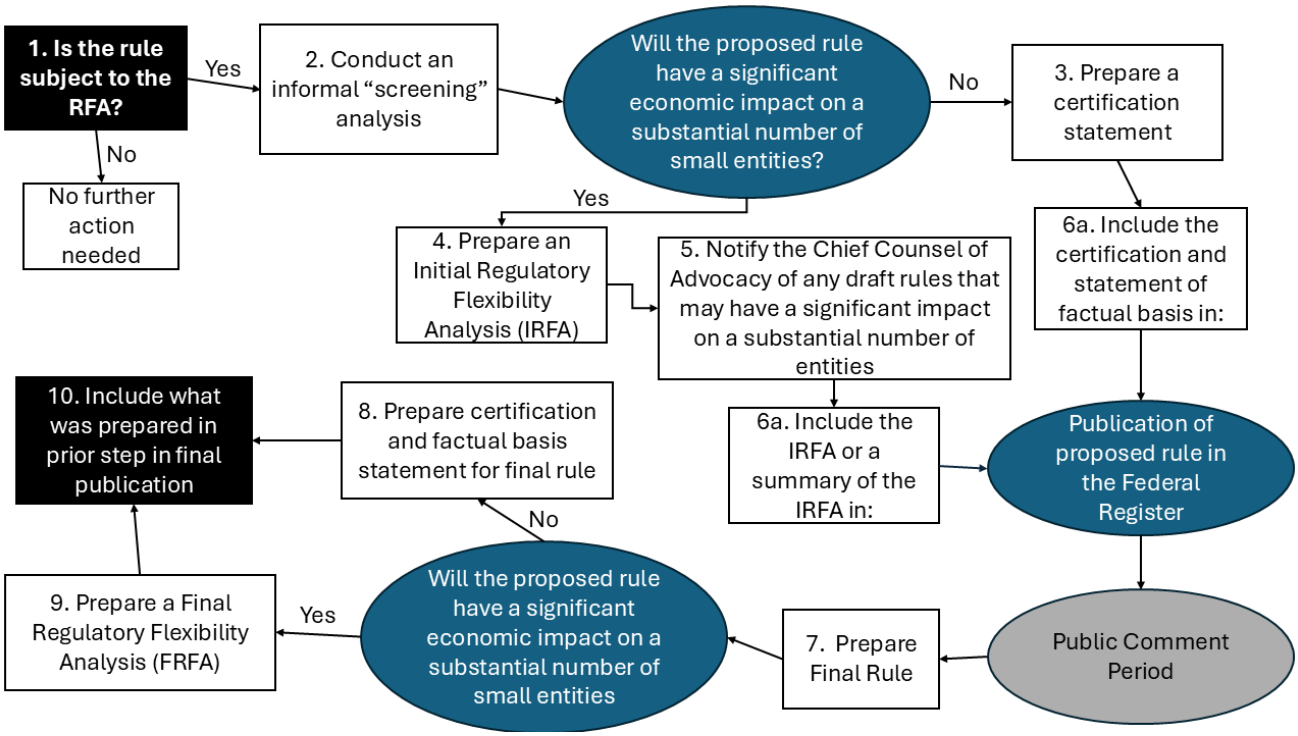
The SBA intends to take the following steps in connection with each rulemaking to comply with the RFA and E.O. 13272. Please note that not all these steps are required for each rule; some are required only for rules likely to have a significant economic impact on a substantial number of small entities, and others are required only for rules that do not have such an impact. A more detailed description of the requirements follows the list.

Please note that these steps, as summarized in Figure 1, are aligned with Office of Advocacy's guidance and are subject to change when the guidance is updated.[2]

Figure 1. Summary RFA Process

[1] Regulatory Flexibility Act: Improved Policies for Analysis and Training Could Enhance Compliance (GAO-25-106950, April 2025).

[2] A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act – Office of Advocacy



Step 1. Determine whether the rule is subject to the RFA. The RFA only applies to rules that undergo notice and comment. IFRs and DFRs are exempt from this requirement.

Step 2. Conduct an informal "screening" analysis – often referred to as a **Threshold Analysis** – to determine whether the proposed rule will have a significant economic impact on a substantial number of small entities. If the proposed rule **will not** have a significant economic impact on a substantial number of small entities, go to step 3. Otherwise, go to step 4.

Step 3. Prepare a certification and a statement of the factual basis supporting the certification (as part of the proposed rule) that the proposed rule will not have a significant economic impact on a substantial number of small entities. Skip steps 4 and 5; go to step 6.

Step 4. Prepare an Initial Regulatory Flexibility Analysis (IRFA).

Step 5. Notify the Chief Counsel for Advocacy of the Small Business Administration of any draft rules that may have a significant economic impact on a substantial number of small entities (i) when SBA submits the draft rule to OMB under Executive Order 12866, or (ii) if submission to OMB is not required, at a reasonable time prior to publication of the rule. This can be done through internal agency clearance.

Step 6. Include with the proposed rule published in the Federal Register either (a) the certification and statement of factual basis, or (b) the IRFA. Transmit a copy of such certification and statement of factual basis or IRFA to Advocacy.

Step 7. In preparing the final rule, consider and respond to comments by Advocacy. If it is determined that the final rule **will not** have a significant economic impact on a substantial number of small entities, go to step 8. Otherwise, skip step 8 and go to step 9.

Step 8. Prepare a certification statement and a statement of the factual basis supporting the certification that the final rule **will not** have a significant economic impact on a substantial number of small entities. Skip step 9; go to Step 10.

Step 9. Prepare a Final Regulatory Flexibility Analysis (FRFA).

Step 10. Include with the final rule published in the Federal Register either (a) the certification and statement of factual basis, or (b) the FRFA.

Detailed RFA Process and Guidance

The following discussion elaborates on what program offices must do under each of the above steps.

STEP 1. DETERMINE WHETHER THE RULE IS SUBJECT TO THE RFA

The RFA covers all rulemakings where SBA is required to publish a general notice of proposed rulemaking (NPRM). If the SBA office initiating the regulatory action is uncertain if the RFA applies, it should contact its Office of General Counsel.

STEP 2. CONDUCT A THRESHOLD ANALYSIS TO DETERMINE WHETHER OR NOT THE PROPOSED RULE WILL HAVE A SIGNIFICANT ECONOMIC IMPACT ON A SUBSTANTIAL NUMBER OF SMALL ENTITIES

To determine whether a rule is likely to have a significant economic impact on a substantial number of small entities, it is necessary to coordinate and conduct an informal screening analysis. The first step in the analysis is to identify what types of small entities would be subject to the rules' requirements - businesses, nonprofit organizations, pension plans, etc. To determine whether there is likely to be a significant economic impact on a substantial number of small entities, identify the actions a small entity will have to take to comply with the requirements of the rule. This step will help clarify the nature of the impacts (e.g., installation of new technology, revised recordkeeping system) and may help in determining whether the potential impacts are of sufficient magnitude and scope to warrant preparation of an IRFA. In addition, some agencies have developed their own criteria to make the determination of what represents a "significant impact." For example, an agency may decide to prepare an IRFA if the costs of a rule are expected to exceed 1 percent of revenue or 3 percent of profits for the small entities each year. In addition, if SBA has other reasons for believing that the rule may have a significant economic impact on small entities, an IRFA should be prepared for the rule. If the proposed rule will not have a significant economic impact on a substantial number of small entities, **go to step 3. Otherwise, skip step 3 and go to step 4.**

STEP 3. PREPARE A CERTIFICATION STATEMENT AND A STATEMENT OF THE FACTUAL BASIS SUPPORTING THE CERTIFICATION THAT THE PROPOSED RULE WILL NOT HAVE A SIGNIFICANT ECONOMIC IMPACT ON A SUBSTANTIAL NUMBER OF SMALL ENTITIES

If the rule will not have a significant economic impact on a substantial number of small entities, prepare a certification statement to that effect, along with an explanation of the factual basis for the certification. The certification, which is subject to judicial review, should clearly explain how SBA reached its decision and, where appropriate, describe or provide the information on which SBA relied to make the decision.

CHECKLIST 1. RFA Statutory Requirements in Certification Statements

Compliance with the following statutory requirements helps make clear to affected small entities

that the agency is certifying the proposed rule.

- ✓ Certification comes from the head of the agency.
- ✓ Certification states that the rule "will not have a significant impact on a substantial number of small entities."
- ✓ Certification includes a statement providing the factual basis for certifying the rule.

CHECKLIST 2. Key Elements Underlying the Factual Basis for Certifying

Advocacy describes key elements agencies should include in their certification analysis to obtain meaningful public comment and information on the rule's impact on small entities.[3] These include:

- ✓ A description and estimate of the number of small entities affected by the rule.
- ✓ A description and estimate of the economic impacts on small entities, including costs, benefits, and indirect impacts.
- ✓ Criteria for determining "significant economic impact" and "substantial number," such as percentage of revenue or percentage of small businesses affected.
- ✓ Why either the number of entities or the size of the impacts justifies the certification.

What is meant by "significant"?

The following factors need to be considered when making the determination of whether the rule is expected to have a "significant impact on a substantial number of small businesses":

- The size of the business.
- The size of the competitor's business.
- The comparative impact the regulation has on larger competitors.[4]

Please note that Advocacy's guide states that the term "significant" is neutral with respect to whether the impact is beneficial or harmful to small businesses and therefore agencies should consider both beneficial and adverse impacts in an analysis.[5] The terms "significant" and "substantial" have not been defined in statute. Generally, when more than 30% of small businesses experience an impact of greater than 3% of their revenue, the rule is considered to have a significant impact on a substantial number of entities.

Advocacy's guide states that although not required by statute, it is good public policy for agencies to consider, with a reasonable amount of effort, the effects of the rule on small entities that conduct business with entities directly regulated by the rule. OMB's Circular A-4 states that regulatory analysis should look beyond the direct costs and benefits of the rule and consider

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[3] *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (Aug. 31, 2017)

[4] For example, Advocacy's guidance notes that a regulation may have a significant impact solely because the disparity in impact on small entities may make it more difficult for them to compete in a particular sector of the economy relative to large businesses. Similarly, it states that a rule that has a significant economic impact on five small entities could be considered to impact a substantial number of small entities if there are only 20 in that particular sector.

[5] In its guide, Advocacy acknowledges that agencies have taken issue with this interpretation but maintains that it is possible to analyze beneficial impacts with minimal effort and without necessarily triggering the need for a full regulatory flexibility analysis. In addition, Advocacy's guide states that analyzing beneficial impacts lends credibility to the alternatives selected by the agency.

secondary costs and benefits. As part of these additional requirements, agencies need to disclose assumptions and describe data sources, as explained by the following check-list items:

- ✓ Explain why the number of small entities or the size of the economic impact justified the RFA certification.
- ✓ Disclose all other assumptions made in the analysis.
- ✓ Identify the data source(s) used to analyze economic impact.
- ✓ Identify the data source(s) used to determine the number of small entities affected by the rule.

Contact OSMEI for assistance with developing the economic analysis section.

An example of an adequate certification (From Advocacy's Compliance Guidance)

The following example of an adequate certification by the U.S. Small Business Administration is from the proposed rule on small business investment companies.

> When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA) requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis" which will "describe the impact of the **proposed** rule on small entities." (5 U.S.C. §. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the **proposed** rulemaking is not expected to have a significant economic impact on a substantial number of small entities.
>
> This **proposed** rule directly affects all SBICs, of which there are currently 432. SBA estimates that approximately 75 percent of these SBICs are small entities. Therefore, SBA has determined that this **proposed** rule will have an impact on a substantial number of small entities.
>
> However, SBA has determined that the impact on entities affected by the **proposed** rule will not be significant. The effect of the **proposed** rule will be to allow SBICs the flexibility to choose the optimal structure for their investments without having to notify or seek approval from SBA. SBA expects the impact of the **proposed** rule will be a reduction in the paperwork burden for SBICs. SBA asserts that the economic impact of the reduction in paperwork, if any, will be minimal and entirely beneficial to small SBICs. Accordingly, the Administrator of the SBA hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. SBA invites comment from members of the public who believe there will be a significant impact either on SBICs, or on companies that receive funding from SBICs.

After preparing the certification statement and statement of factual basis, skip steps 4 and 5; go to step 6.

STEP 4. PREPARE AN INITIAL REGULATORY FLEXIBILITY ANALYSIS

If the rule may have a significant economic impact on a substantial number of small entities, prepare an IRFA for the rule. In accordance with the RFA, the IRFA must:

- describe the reasons why action by SBA is being considered;
- succinctly state the objectives of, and legal basis for, the proposed rule;
- describe and, where feasible, estimate the number of small entities to which the proposed rule will apply;
- describe the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
- identify, to the extent practicable, all relevant Federal rules that may duplicate, overlap or conflict with the proposed rule; and
- describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes and that minimize any significant economic impact of the proposed rule on small entities.

Consistent with the stated objectives of applicable statutes, the analysis must discuss significant alternatives such as: (1) establishing differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) clarifying, consolidating, or simplifying compliance and reporting requirements under the rule for such small entities; (3) using performance rather than design standards; and (4) exempting small entities from coverage of the rule, or any part thereof.

CHECKLIST 3. Required Elements for Initial Regulatory Flexibility Analysis (IRFA)

- ✓ Description of need for the rule.
- ✓ Statement of proposed rule's objectives.
- ✓ Statement of proposed rule's legal basis.
- ✓ Description of affected small entities.
- ✓ Estimate of number of affected small entities.
- ✓ Description of the reporting, recordkeeping, and other compliance requirements.
- ✓ Description of necessary professional skills for preparation of the report or record.
- ✓ Identification, to the extent practicable, of federal rules that may duplicate, overlap, or conflict with the proposed rule.
- ✓ Description of alternatives to the proposed rule.

CHECKLIST 4. Additional Requirements for Key Elements of IRFAs

When writing IRFAs, the following additional requirements – related to compliance costs, indirect costs/benefits, documentation, and transparency – need to be incorporated into analysis:

- ✓ Include a quantitative estimate of the compliance costs for small entities. Examples include capital costs for equipment and hiring employees dedicated to compliance with the regulatory requirements.[6]
- ✓ Where feasible, the analysis should quantify the economic effects.[7]
- ✓ As previously stated, Advocacy's guidance recommends that agencies consider indirect and beneficial impacts on small entities, and OMB's guidance states that regulatory analysis should consider secondary costs and benefits.
- ✓ Provides data sources for estimating the number of affected entities.
- ✓ It needs to be "generally easy to obtain information from SBA analyses" such as making sure the analysis is contained in the RFA section of the rule notice.[8]

STEP 5. NOTIFY ADVOCACY OF ANY DRAFT RULES THAT MAY HAVE A SIGNIFICANT ECONOMIC IMPACT ON A SUBSTANTIAL NUMBER OF SMALL ENTITIES (I) WHEN SBA SUBMITS THE DRAFT RULE TO OMB UNDER EXECUTIVE ORDER 12866, OR (II) IF SUBMISSION TO OMB IS NOT REQUIRED, AT A REASONABLE TIME PRIOR TO PUBLICATION OF THE RULE

If a draft rule may have a significant economic impact on a substantial number of small entities, E.O. 13272 requires notice to Advocacy of the draft rule. This can be done through internal SBA clearance. If the rule will be a "significant regulatory action" under E.O. 12866, it must be submitted to OMB for review.

STEP 6. INCLUDE WITH THE PROPOSED RULE PUBLISHED IN THE FEDERAL REGISTER EITHER THE CERTIFICATION AND STATEMENT OF FACTUAL BASIS, OR THE IRFA. TRANSMIT A COPY OF THE CERTIFICATION AND STATEMENT OF FACTUAL BASIS OR THE IRFA TO ADVOCACY.

When preparing the proposed rule for publication in the Federal Register, include in the document either the certification and statement of factual basis, or the IRFA. If the IRFA is lengthy and incorporated into the Regulatory Impact Analysis, summarize it in the Federal Register document. Make the IRFA available for review in the public docket for the regulatory action on regulations.gov.

STEP 7. IN PREPARING THE FINAL RULE, CONSIDER AND RESPOND TO COMMENTS BY ADVOCACY

During preparation of the final rule, in accordance with E.O. 13272, "give every appropriate consideration" to comments provided by Advocacy, and respond in the final rule preamble to any written comments submitted by Advocacy on the proposed rule. (A response to Advocacy's comments is not needed in the final rule if head of SBA certifies that inclusion of a response does not serve the public interest.) If SBA has determined that final rule will not have a significant economic impact on a substantial number of small entities, **go to step 8. Otherwise, skip step 8**

[6] More examples are available in Advocacy's guide: *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (Aug. 31, 2017)
[7] *Circular A-4* (Sept. 17, 2003) and GAO-23-105460.
[8] GAO RFA Statement of Facts pg. 13

and go to step 9.

STEP 8. PREPARE A CERTIFICATION STATEMENT AND A STATEMENT OF THE FACTUAL BASIS SUPPORTING THE CERTIFICATION THAT THE FINAL RULE WILL NOT HAVE A SIGNIFICANT ECONOMIC IMPACT ON A SUBSTANTIAL NUMBER OF SMALL ENTITIES

If SBA has determined that the final rule will not have a significant economic impact on a substantial number of small entities, prepare a certification statement to that effect, along with the factual basis for the certification. The certification is subject to judicial review, so explain clearly how the decision was reached and, where appropriate, describe or provide the information on which SBA relied to make the decision. Address any public comments received about certification of the rule explaining why the agency is choosing to certify the rule.

Ensure that the certification statement and statement of the factual basis supporting the certification contain all RFA statutory requirements as well as all key elements underlying the factual basis for certifying listed under Step 3 (above). Skip step 9; go to step 10.

STEP 9. PREPARE A FINAL REGULATORY FLEXIBILITY ANALYSIS (FRFA)

If the final rule may have a significant economic impact on a substantial number of small entities, prepare a FRFA for the rule. In accordance with the RFA, the FRFA must:

(1) succinctly state the need for, and objectives of, the rule;
(2) summarize the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, the assessment of the agency of such issues, and describe any changes made in the proposed rule as a result of such comments;
(3) respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and include a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.
(4) describe and estimate the number of small entities to which the rule will apply or explain why no such estimate is available;
(5) describe the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
(6) describe the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

CHECKLIST 5. Required Elements for Final Regulatory Flexibility Analysis (FRFA)

- ✓ Description of need for the rule.
- ✓ Statement of rule's objectives.

- ✓ Description of issues raised in public comments (or stating that no comments were received if that was the case).
- ✓ Response to any comments filed by SBA's Office of Advocacy (or stating that no comments were received if that was the case).
- ✓ Description of affected small entities.
- ✓ Estimate of number of affected small entities.
- ✓ Description of the reporting, recordkeeping, and other compliance requirements.
- ✓ Description of necessary professional skills for preparation of the report or record.
- ✓ Description of steps to minimize impact on small entities.
- ✓ Description of reasons for selecting alternative adopted in final rule.

CHECKLIST 6. Additional Requirements for Key Elements of FRFAs

When writing FRFAs, the following additional requirements – related to compliance costs, indirect costs/benefits, documentation, and transparency – need to be incorporated into analysis:

- ✓ Include a quantitative estimate of the compliance costs for small entities. Examples include capital costs for equipment and hiring employees dedicated to compliance with the regulatory requirements.[9]
- ✓ Where feasible, the analysis should quantify the economic effects.[10]
- ✓ As previously stated, Advocacy's guidance recommends that agencies consider indirect and beneficial impacts on small entities, and OMB's guidance states that regulatory analysis should consider secondary costs and benefits.
- ✓ Provides data sources for estimating the number of affected entities.
- ✓ It needs to be "generally easy to obtain information from SBA analyses" such as making sure the analysis is contained in the RFA section of the rule notice.[11]

STEP 10. INCLUDE IN THE FINAL RULE PUBLISHED IN THE FEDERAL REGISTER EITHER THE CERTIFICATION AND STATEMENT OF FACTUAL BASIS, OR THE FRFA

When preparing the final rule for publication in the Federal Register, include in the document either the certification and statement of factual basis (see steps 3 and 8), or the FRFA. If the FRFA is lengthy and incorporated into the Regulatory Impact Analysis as discussed above, summarize it in the Federal Register document. Make a copy of the FRFA available for review in the public docket for the regulatory action on regulations.gov.

Participation of Small Entities in Rulemaking

If a rule will have a significant economic impact on a substantial number of small entities, assure that small entities have an opportunity to participate in the rulemaking through techniques such as the following: (1) stating in an advance notice of proposed rulemaking, if issued, that the proposed rule may have a significant economic effect on a substantial number of small entities;

[9] More examples are available in Advocacy's guide: *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (Aug. 31, 2017)
[10] *Circular A-4* (Sept. 17, 2003) and GAO-23-105460.
[11] GAO RFA Statement of Facts, p. 13

(2) publishing the NPRM in publications likely to be obtained by small entities; (3) directly notifying interested small entities; (3) conducting open conferences or public hearings concerning the rule for small entities; (4) using computer networks to solicit and receive comments; and (5) adopting or modifying agency procedural rules to reduce the cost and complexity of participation in the rulemaking for small entities.

SBA personnel involved in rulemaking must be cognizant of the special considerations involved regarding contacts with persons outside of the Executive Branch of the Federal Government who are interested in a rulemaking. SBA personnel involved in a rulemaking should engage in such open contact with the public as will be helpful in the resolution of questions of substance and justification. This open contact can include interacting with small entities early in the rulemaking process to ensure that the eventual final rule will meet its objectives while minimizing adverse effects on small entities. Early and continued interaction with small entities can help identify and resolve important issues and obtain information useful to the development of the rule. The Chief Counsel for Advocacy can serve as a resource for agencies to facilitate this interaction between SBA and small entities.

Reservation of Authority

The statements in this document are intended solely as guidance. This document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. SBA may decide to follow the guidance provided in this document, or to act at variance with the guidance, based on its analysis of the specific facts presented. This guidance may be revised without public notice to reflect changes in SBA's approach to implementing the Regulatory Flexibility Act or to clarify and update text.