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Department of the Interior

Departmental Manual

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Series: Administrative Procedure

Part 318: Federal Register Documents

Chapter 3: Record of Compliance and Other Required Documentation

Originating Office: Executive Secretariat and Office of Regulatory Affairs

318 DM 3

3.1 What is the purpose of this chapter? This chapter tells you what to include in the Record of Compliance (ROC). Appendix 1 contains the ROC format and instructions. Appendix 2 describes in detail additional requirements of laws, Executive Orders, and the Departmental Manual that you may have to satisfy depending upon determinations that you make in the ROC, and Appendix 3 provides guidance for meeting the requirements of those laws and Executive Orders.

3.2 What does the ROC do? The laws and Executive Orders listed in section 3.4 impose various requirements on rulemaking documents. The ROC:

A. Documents your compliance with these requirements; and

B. Explains the basis for each of the determinations that you are required to make.

3.3 Why is the ROC necessary? The ROC serves as proof that we've met all legal requirements, thus decreasing the chance that the rule will be litigated. It is also a record of why and how we developed the rule. This will be useful when the rule is revised in the future.

3.4 What does the ROC contain? The ROC must contain the basis for the determinations listed in the table below. For more information on these determinations and related requirements, see Appendix 2 and 3 to this chapter.

The provisions of...	require you to determine if your rule...
E.O. 12866 (Regulatory Planning and Review)	meets one of four criteria for significance
5 U.S.C. 601 et seq. (Regulatory Flexibility Act)	has a significant economic effect on a substantial number of small entities.
5 U.S.C. 801 et seq. (Small Business Regulatory Enforcement Fairness Act)	determine whether rule meets one of three criteria that would make it a major rule
2 U.S.C. 1501 et seq. (Unfunded Mandates Reform Act)	imposes a cost of \$100 million or more annually on State, local, or tribal governments, or affects small governments.
E.O. 12630 (Governmental Actions and Interference with Constitutionally Protected Property Rights)	affects property rights protected by the Constitution or causes a compensable taking.
E.O. 12612 (Federalism)	affects the relationship between State and Federal governments
E.O. 12988 (Civil Justice Reform)	places an undue burden on judicial system
44 U.S.C. 3501 et seq. (Paperwork Reduction Act)	collects information from the public
516 DM (NEPA)	has a significant effect on the environment
512 DM 21 (Indian trust resources)	affects Indian trust resources

3.5 When do I prepare a ROC? You should prepare a ROC as soon as you are able to address the requirements listed in section 3.4. It is possible that this may not occur until you actually draft the NPRM. You must distribute the ROC before you publish your proposed rule.

3.6 Is there a required format for the ROC? Yes. Follow the format in Appendix 1 to this chapter.

3.7 What standards must the ROC meet?

A. For each of the statutes and executive orders listed in section 3.4, the ROC must:

(1) Certify that you made the required determination;

(2) Summarize the rationale for the certification; and

(3) Cite any analyses you made or other documentation upon which you based the certification. You must send to us with the ROC copies of any additional analyses upon which you based the ROC.

B. You must support each conclusion about effects and the magnitude of those effects (such as "not significant" or "substantial"). We will return to you for further work any determination based on an unsupported conclusion.

C. The ROC may be subject to judicial review if anyone challenges the determinations or certifications in it.

3.8 May I address the requirements of more than one law or Executive Order in a single analysis? Yes. We encourage you to do this.

3.9 What is the development, review, and distribution process for the ROC? In preparing your ROC, follow the requirements in the table below.

Stage	What you must do	When you should do it
development	work with the Office of Policy Analysis (PPA) to reduce possibility of required economic and cost-benefit analyses being held up during review (see Appendix 3 to Chapter 3)	early in development process
review	send ROC to PPA and ORA for review within 10 days; rectify any problems identified in the review	early in the rulemaking process at the same time as you send the rule for review
signature	have all officials listed on the ROC sign	after PPA/ORR review
distribution	distribute ROC to all recipients shown in ROC instructions	after signature

3.10 May I use e-mail to distribute the ROC? Yes. We encourage you to circulate the ROC electronically both for PPA/ORR review and after signature. After the ROC is signed, you should:

- A. Retain the original signed copy in your files;
- B. Enter the dates of the signatures and the words "signed by [enter name of signer]" in the appropriate parts of the electronic copy; and
- C. Send the electronic copy to your regulatory contact, who will e-mail it to recipients identified in ROC instructions.

Appendix 1 to Chapter 3

United States Department of the Interior
Record of Compliance for a Rulemaking Document

Title of rule: _____ RIN: _____

Sponsoring bureau/office: _____

Contact name/phone number: _____

The Record of Compliance (ROC) certifies that this rulemaking action complies with the various statutory, Executive Order, and Department Manual requirements applicable to rulemaking. Some of the statutory requirements are judicially reviewable. Accordingly, the ROC also provides a brief though convincing rationale for the various certifications with citations to any underlying analyses, copies of which must be attached.

A. Need for this regulation.

1. Why we are publishing this rule. *(Explain why the regulation is needed or what problem it will solve. Some examples might be a specific legislative requirement, program deficiencies identified as a result of an audit, remediation of a chronic abuse or problem, etc.)*

2. Why alternative approaches are not feasible. *(Explain why you must publish a rule to fill the need you describe in item A1. Describe what alternatives to rulemaking you considered and why each of them was not feasible.)*

3. Authority under which this rule will be published. *(Describe the legal authority under which this rule will be published.)*

B. Determinations and Certifications.

1. Regulatory Planning and Review. In accordance with the criteria in Executive Order 12866, this rule *[is/is not]* a significant regulatory action. OMB makes the final determination under

Executive Order 12866.

a. This rule *[will/will not]* have an annual economic effect of \$100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. A cost-benefit and economic analysis *[has been completed and is attached/is not required]*. *(Give the basis for the determination.)*

b. This rule *[will/will not]* create inconsistencies with other agencies' actions. *(Give the basis for the determination.)*

c. This rule *[will/will not]* materially affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients. *(Give the basis for the determination.)*

d. This rule *[will/will not]* raise novel legal or policy issues. *(Give the basis for the determination.)*

2. Regulatory Flexibility Act. I certify that this rule *[will/will not]* have a significant economic effect on a substantial number of small entities as defined under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). An *[initial/final]* Regulatory Flexibility Analysis *[is attached and identifies steps taken to minimize significant economic impacts on small entities/is not required]*. Accordingly, a Small Entity Compliance Guide *[has been published/will be published/ is not required]*. *(Give the basis for the determination here. Explain what steps you took to minimize significant impacts. Summarize factual basis for certification. Cite specific parts of the Regulatory Flexibility Analysis, if you prepared one.)*

3. Small Business Regulatory Enforcement Fairness Act. This rule *[is/is not]* a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule:

a. *[Has/Does not have]* an annual effect on the economy of \$100 million or more. *(Give the basis for the determination here and attach any analyses that support your statements.)*

b. *[Represents/Will not cause]* a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. *(Give the basis for the determination here and attach any analyses that support your statements.)*

c. *[Has/Does not have]* significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. *(Give the basis for the determination here and attach any analyses that support your statements.)*

4. Unfunded Mandates Reform Act. In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

a. This rule *[will/will not]* "significantly or uniquely" affect small governments. A Small Government Agency Plan *[is required and a copy is attached/is not required]*. *(Give the basis for the determination here.)*

b. This rule *[will/will not]* produce a Federal mandate of \$100 million or greater in any year, i.e., it *[is/is not]* a "significant regulatory action" under the Unfunded Mandates Reform Act.

Add the following only if the proposed regulation will produce a Federal mandate of \$100 million or more:

(1) The analysis prepared for Executive Order 12866 will *[meet the requirements of the Unfunded Mandates Reform Act/not be sufficient and we have prepared and attached a separate analysis]*.

(2) Several regulatory alternatives *[were prepared and are attached/were not prepared]* and the least burdensome option *[was/was not]* selected. *(Summarize why the alternative selected was the least burdensome. If you did not select the least burdensome alternative, explain why you did not.)*

(3) The consultation process for state, local, and tribal government input *[was/was not]* implemented. *(Give the basis for the determination here. Attach the analyses that support your statements.)*

5. Takings. In accordance with Executive Order 12630, the rule *[has/does not have]* significant takings implications. A takings implication assessment *[has been prepared and is attached/is not required]*. *(Give the basis for the determination here. Cite specific parts of supporting analysis, if any.)*

6. Federalism. In accordance with Executive Order 12612, the rule *[has/does not have]* significant Federalism effects. A Federalism assessment *[is required and is attached/is not required]*. *(Give the basis for the determination here.)*

7. Civil Justice Reform. In accordance with Executive Order 12988, the Office of the Solicitor has determined that the rule *[does/does not]* unduly burden the judicial system and *[does not meet/meets]* the requirements of sections 3(a) and 3(b)(2) of the Order. *(Give the basis for the determination here. Attach supporting documentation, if any.)*

8. Paperwork Reduction Act. This regulation *[does/does not]* require an information collection under the Paperwork Reduction Act. The information collection *[is/is not]* covered by an existing OMB approval. An OMB form 83-I *[has/has not]* been prepared and *[has/has not]* been approved by the Office of Policy Analysis. *(Give the basis for the determinations here. If the information collection already has OMB approval, explain this and give the OMB approval number and the expiration date.)*

9. National Environmental Policy Act. We have analyzed this rule in accordance with the criteria of the National Environmental Policy Act and 516 DM. This rule *[constitutes/does not constitute]* a major Federal action significantly affecting the quality of the human environment. An environmental *[impact statement/assessment]* is *[attached/not required]*. *(Give the basis for the determination here. When applicable, state where to obtain copies of environmental impact statements or assessments.)*

10. Government-to-Government Relationship with Tribes. In accordance with the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951) and [512 DM 2](#) *(one or the other of the following)*:

We have evaluated potential effects on Federally recognized Indian tribes and have determined that there are no potential effects. *(Give the basis for the determination here.)*

OR

We have identified potential effects on Indian trust resources and they *[are/are not]* addressed in this rule. *(Give the basis for the determination here.)* Accordingly:

- a. We *[have/have not yet]* consulted with the affected tribe(s).

- b. We *[have/have not yet]* treated and consulted with tribes on a government-to-government basis and the consultations have been open and candid so that the affected tribe(s) could fully evaluate the potential impact of the rule on trust resources.

- c. We *[have fully considered tribal views/will consider tribal views in the final rule]*.

- d. We *[have/have not yet]* consulted with the appropriate bureaus and offices of the Department about the potential effects of this rule on Indian tribes. *(Identify the bureaus that you consulted.)*

C. Approvals.

I have made each of the certifications/determinations specified above based upon the material in this record of compliance or documents indicated in each section above. I have ensured that this document will be distributed in accordance with Part D, below.

(Signature and title of Official)

Date

Concur:

(Signature and title of head of Bureau or Office or other approving official)

Date

(Signature and title of program Assistant Secretary or other approving official)

Date

D. Distribution.

Copies of this document must be distributed to:

- Office of Regulatory Affairs (ORA)
- Office of Policy Analysis (PPA)
- Office of Small and Disadvantaged Business Utilization (OSDBU)
- Chief Counsel for Advocacy, Small Business Administration (SBA)

Instructions for Preparing the Record of Compliance (ROC)

The sample ROC in the first part of this appendix is a template that you can fill in with the appropriate phrases. In the template, wherever you see italicized material in brackets, you should choose one of the phrases to insert into your ROC; enter the chosen phrase in a normal typeface and delete the phrase not chosen. Where there is italicized material in parentheses you should provide additional text as appropriate. Where separate analyses are necessary, try to combine all your analytical work into one document.

If you determine that the provisions of a particular Executive Order or law do not apply, you must include in the ROC an explanation of the basis for your determination. We will return to you for further work any ROC that does not contain the required explanations. To avoid delays in publishing your rule, you should contact PPA for advice and consultations regarding the preparation of any analyses that would undergird the ROC.

The item numbers in these instructions correspond to the item numbers in the template. When you have completed the ROC, you must distribute it as shown in the template and these instructions. We encourage you to prepare and send your ROC electronically. Call your bureau regulatory contact to request an electronic copy of the template.

A. Need for this regulation.

1. You must give a convincing explanation of why this rule is needed, what the consequences of not publishing a regulation would be, and under what authority the rule is being published.
2. Explain which alternatives to rulemaking you considered and why they were not feasible.
3. Describe the legal authority for publishing the rule.

B. Determinations and Certifications. (See Appendix 2 to this chapter for details.)

1. Executive Order 12866, "Regulatory Planning and Review," requires you to prepare an impact analysis if your rule is significant. To be significant, your rule must meet one of the criteria in the sample ROC. Although OMB makes the final determination of whether a rule is significant under E.O. 12866, you must include in the ROC the basis for your determination. For each of the criteria listed, explain the basis of your determination of why or why not the criterion applies.

2. The Regulatory Flexibility Act, as amended, (5 U.S.C. 601 etseq.) requires you to either:

a. Certify that the rule will not have a significant economic effect on a substantial number of small entities [*Note: Indian tribes are not considered to be small entities for purposes of this Act*];
or

b. Prepare a small entity regulatory flexibility analysis and minimize the economic effects on small entities consistent with the stated objectives of law.

3. The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 etseq.) requires the items listed below.

a. Implementation of a Small Government Agency Plan for consultation if the rule will have a significant or unique impact on small governments; this includes any governmental jurisdiction with a population of less than 50,000 persons. A more elaborate analysis and the implementation of a consultation plan are required if the regulatory action is likely to result in expenditures greater than \$100 million per year by State, local governments, or by the private sector.

b. Input from other levels of government into the development of the rule and a plan to alert small governments of regulatory requirements which might significantly or uniquely affect them -- including making provision for their input and subsequently informing and educating them.

c. For "significant" regulations, consideration of a reasonable number of regulatory alternatives.

d. Selection of the least burdensome option unless it is inconsistent with the law, or an explanation

of why another option was selected;

4. If your rule is likely to impose an annual cost of \$100 million or more on State, local, or tribal governments, it is a "significant regulatory action." For assistance in determining whether the action would be significant and what actions you should undertake in that case, see Appendix 3 to this chapter.

5. Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," requires you to prepare a takings implication assessment for any rule that will affect property rights protected by the Constitution or that poses a risk of being a compensable taking.

6. Executive Order 12612, "Federalism," October 26, 1987, requires you to prepare a Federalism assessment for any rule that will have a significant effect on states' abilities to make their own decisions;

7. Executive Order 12988, "Civil Justice Reform," February 5, 1996, provides principles to promulgate regulations which do not unduly burden the judicial system.

8. The Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) establishes a process to reduce the information burden the Federal government places on the public when there is an information collection requirement associated with a rule. See 381 DM 11 and 12 and instructions issued by the Office of Policy Analysis.

9. The National Environmental Policy Act of 1969 as amended (42 U.S.C. 4321 - 4347) requires you to determine whether an environmental impact statement is necessary. See 516 DM for guidance.

10. The President's memorandum of April 29, 1994, and [512 DM 2](#) require you to make the determinations in this section. If Indian trust resources are not affected, briefly state why not. If trust resources are affected, summarize the effects; list the names of the tribes affected, list the names of the tribes consulted on a government-to-government basis and briefly summarize the results of the consultations(s); list the names of the Departmental organizations that you consulted in regard to the effects on tribes.

C. Approvals.

You must obtain the approvals shown in the template before distributing the ROC. If you distribute the ROC electronically, you should insert the name and title of the signing official and the date in each of the lines in this part to indicate that the ROC has the required approvals.

D. Distribution.

You must distribute the ROC to the reviewing offices shown on the template, preferably by e-mail. Here are the addresses to use:

Reviewer	E-mail address	Mailing address
ORA	exsec@ios.doi.gov	MS 7229, MIB
PPA	indur_goklany@ios.doi.gov	MS 4426, MIB
OSDBU	ralph_rausch@ios.doi.gov	MS 5524, MIB
SBA	jennifer.smith@sba.gov	Chief Counsel for Advocacy
		Attention: Regulatory Flexibility
		Small Business Administration
		Room 1010
		409 Third Street SW
		Washington, DC 20416

Appendix 2 to Chapter 3

Detailed information on requirements of Executive Orders, legislation, and the DM relating to rules

1. Executive Order 12866.

A. When is a rule significant under E.O. 12866? A rule may be significant under E.O. 12866 if it:

(1) Has an annual effect on the economy of \$100 million or more, or adversely affects in a material way the economy (or a sector of it), productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency;

(3) Materially alters the budgetary effects of entitlements, grants, user fees, or loan programs or the rights and obligations of their recipients; or

(4) Raises novel legal or policy issues.

B. Who determines whether a rule is significant? OMB makes the final determination on whether a rule is significant under E.O. 12866.

C. What must I do if a rule is significant? If your rule is significant under E.O. 12866 you must send it to OMB for review before it can be published. You must also send to OMB the additional information specified in Appendix 3 to this chapter.

2. Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act (SBREFA).

A. What additional documentation must I prepare if my rule has a significant impact on a substantial number of small entities? If your rule meets the criteria in Appendix 3 to this chapter, you will have to prepare:

(1) initial and final regulatory flexibility analyses (the final regulatory flexibility analysis must specify steps taken to minimize the impact consistent with applicable statutes); and

(2) a small entity compliance guide to assist small entities in complying with the rule.

B. When is a rule major under 5 U.S.C. 804? Under 5 U.S.C. 804(2) (known as the Small Business Regulatory Enforcement Fairness Act or SBREFA) a rule is major if OMB finds that it results in:

(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 the ability of U.S.-based enterprises to compete with foreign-based enterprises.

C. What must I do if a rule is major under 5 U.S.C. 804? You must send it to OMB for review before it can be published. You must also send OMB the additional information specified in section 2.A. above.

3. Unfunded Mandates Reform Act.

A. What must I do to comply with the Unfunded Mandates Reform Act?

(1) If your rule imposes on industry or state or local governments costs exceeding \$100 million, you must prepare an additional analysis that meets the requirements in Appendix 3 to this Chapter.

(2) If your rule "significantly or uniquely" affects small governments, you must implement a Small Government Agency Plan for consultation and input from affected small governments. Your NPRM must describe the plan and how it will be implemented.

4. Executive Order 12630.

A. When must I prepare a Takings Implication Assessment? You must prepare a Takings Implication Assessment (TIA) if your rule affects property rights protected by the Fifth Amendment or involves a compensable "taking." See Appendix 3 to this chapter for further guidance.

5. Executive Order 12612, "Federalism."

A. When do I need to prepare a Federalism Assessment?

(1) You need to prepare a Federalism Assessment if your rule:

(a) Relates to the structure and role of the States; and

(b) Will have direct, substantial, and significant effects on States.

(2) If your rule meets the criteria in paragraph A, you must prepare an assessment, even if the action is required by law or the Department otherwise has no discretion.

B. What must a Federalism Assessment contain?

Your assessment should state :

(1) the likely effects of your rule on States;

(2) possible alternatives to publishing the rule, and

(3) the rationale for the conclusion you reach.

6. Executive Order 12988.

What does Executive Order 12988 require? Among other things, this Executive Order requires that your rule:

- (1) Contain no drafting errors or ambiguity and be written to minimize litigation;
- (2) Provide clear standards;
- (3) Simplify procedures and reduce burden;
- (4) Be clearly written;
- (5) Specify **in clear language** the rule's:
 - (a) preemptive effect;
 - (b) retroactive effect (if any); and
 - (c) effect on existing law or regulations.

7. Paperwork Reduction Act.

A. What must I do if my rule collects information from the public? You must obtain OMB approval before you collect information from the public. If your rule requires the public to submit information, see 381 DM 11 and 12, Attachment 2 ("Collections of Information from the Public: Interim Guidelines") of the Interim Guidelines issued by the Office of Policy Analysis (dated March 20, 1997), and consult with your bureau information collection officer.

8. National Environmental Policy Act (NEPA).

A. What does NEPA require? The National Environmental Policy Act of 1969 as amended (42 U.S.C. 4321 - 4347) requires you to prepare an environmental impact statement if your rule will affect the environment. See 516 DM for relevant criteria and guidance.

9. 512 DM 21 - Indian Trust Resources.

A. What must I do to fulfil Departmental responsibilities for Indian trust resources?

(1) If your rule affects tribal trust resources, trust assets, or health and safety, you must consult with the affected tribes on a government-to-government basis. List the names of the tribes that you consult and summarize the results of the consultations. Cite any study reports or other materials that you produce.

(2) If Indian trust resources are not affected, state this.

Appendix 3 to Chapter 3

INTERIM GUIDELINES

Analytical and Consultation Requirements

Under the

Unfunded Mandates Reform Act (UMRA),

the Regulatory Flexibility (RF) Act Amendments,

and E.O. 12866

Office of Policy Analysis

Department of the Interior

March 20, 1997

Preface

Over the past two years, Congress has enacted legislation with new requirements for consultation and analyses that must be undertaken prior to promulgating rules and regulations. These include the Unfunded Mandates Reform Act of 1995, and the Small Business Enforcement Fairness Act which amended the Regulatory Flexibility Act. These laws add new layers to pre-existing procedural and analytical requirements. The Office of Policy Analysis has prepared guidelines with a view to consolidating and integrating these new requirements with existing mandates and with Executive Order 12866 on Regulatory Planning and Review. The aim is to simplify the Department's implementation of, and compliance with, the overlapping and complex web of analytical requirements. The use of these guidelines is not mandatory.

These guidelines specify what needs to be done to comply with these statutes and the Executive Order but not how to do it precisely. The emphasis here is on meeting the various analytical requirements with one set of analyses. However, the guidelines do not provide a step-by-step approach to meeting those requirements because the details and circumstances surrounding each rulemaking are too diverse and varied for a cookie-cutter approach.

These guidelines will be augmented and supplemented with new material as we gain greater experience regarding compliance with the various mandates and with the required cost-benefit analyses. To facilitate this, these documents will be accessible on the Internet through the Natural Resource Library Virtual Reading Room (under "Information from the Department of the

Interior.") at <http://www.ios.doi.gov/nrl/Virtual.html#VirtualRR>. In addition, a page has been established on the Internet devoted to "Frequently Asked Questions" which will be updated regularly.

Finally, note that nothing in these guidelines shall affect any otherwise available judicial review of agency action. These guidelines are intended only to improve the internal management of the Department and do not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the Department, its agencies or instrumentalities, its officers or employees, or any other person.

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Overview of the Significant Requirements of the Unfunded Mandates Reform Act (UMRA), Regulatory Flexibility (RF) Act, as Amended, and E.O. 12866

Analytical and Procedural Requirements for a Typical Interior Rulemaking Under UMRA, RFA, and E.O. 12866.

Attachment A: Detailed Requirements of the Unfunded Mandates Reform Act

Attachment B: Detailed Requirements of the Regulatory Flexibility Act

Attachment C: Detailed Requirements of Executive Order 12866

Attachment D: Detailed Guidance on the Conduct of Regulatory Cost-Benefit Analysis to Meet These Requirements

Attachment E: Cost-Benefit Analysis Checklist

Attachment F: References and Selected Data Sources

Frequently Asked Questions

Determining Analytical and Consultation Requirements Under the Unfunded Mandates Reform Act (UMRA), Regulatory Flexibility Act (RFA) Amendments, and E.O. 12866

This section provides a step-by-step approach to determine whether a particular rulemaking action trips one or more of the numerous triggers specified in these three sets of mandates and, if it does, the major analytical--and associated consultation-- requirements associated with the tripped trigger(s). There is substantial overlap between the various analytical requirements even if they are brought into effect by different triggers. Moreover, all these analytical requirements require some kind of qualitative and quantitative cost-benefit or economic analysis.

Step 1: Do a "threshold analysis." This should include a preliminary qualitative and quantitative cost-benefit analysis. The threshold analysis would help meet Sec. 201, UMRA's broad--and undefined-- requirement for an assessment of effects on state, local and tribal governments and the private sector. It will also help answer the following series of questions which further define the consultation and analytical requirements that should be undertaken during the rulemaking, as well as the decision rules that ought to be applied in the selection of options:

- A) Will the regulation "significantly or uniquely" affect small governments? [*UMRA*]

- B) Will it have a "significant impact on a substantial number of small entities?" [*RF Act*]

- C) Is it a "significant regulatory action", under E.O. 12866?

- D) Will it produce a Federal mandate > \$100 million in any year, i.e., is it a "significant regulatory action" under UMRA?

NOTE: Because a single rulemaking may elicit an affirmative response to more than one of the above questions, analytical and consultation requirements should be combined wherever possible. For example, if the answers to B) and C) are "yes" [but not to A) and D)], then a single combined analysis could meet the analytical requirements for both the RF Act and E.O. 12866 provided its scope is sufficiently broad.

Step 2A: If the answer to A) is "yes", the agency needs to implement a Small Government Agency Plan for rules "significantly or uniquely" affecting small governments (Sec. 203, UMRA). This should, wherever applicable, also be used to obtain input from affected tribes in order to comply with the various Executive and Secretarial Orders on environmental justice and trust responsibilities.

Step 2B: If the answer to B) is "yes," then the requirements are:

- Analysis. Do at least a Final Regulatory Flexibility (RF) Analysis. An Initial RF Analysis is also recommended.

- Decision Rule. The Final RF Analysis should also describe steps taken to minimize effects on small entities consistent with the objective of the law, and reasons for selecting/rejecting options.

- Consultation. Special requirements pertain to affected small entities, e.g., publication in more user friendly venues, open conferences or public hearings, and adoption/modification of procedural rules to reduce cost and complexity of participation.

- Other. Publish a Small Entity Compliance Guide once the rule is final.

Alternatively, the agency head needs to certify that the answer to B) is "no".

Step 2C: The answer to C) is yes if the regulation will have:

- An annual economic impact of \$100 million,

- An adverse effect on the economy, environment, public health, safety, other units of government, or sectors of the economy,

- A serious inconsistency with other federal actions,
- Novel legal or policy implications, OR
- Material effects on budgets or rights and obligations of recipients of entitlements, fees, grants or loans.

If answer to C) is "yes," then the requirements are:

- Analysis. Qualitative/quantitative cost-benefit and economic analysis [*same as for Step 2D*].
- Decision Rule. Selection of the most economically efficient approach considering equity and feasibility, consistent with the regulation's objectives and with the law (or there is a good explanation in the Final notice).

Step 2D: If answer to D) is "yes," then the requirements are:

- Analysis. Qualitative/quantitative cost-benefit and economic analysis.
- Decision Rule. Selection of the "least costly, least burdensome and most cost-effective alternatives" unless inconsistent with law (or there is a good explanation in the Final notice).
- Consultation. If the Federal intergovernmental mandate > \$100 million, implementation of a process for input from state, local and tribal governments (SLTGs). (Sec. 204, UMRA).

Certain meetings between SLTGs and agencies are exempted from Federal Advisory Committee Act (FACA) requirements. If this process is triggered then Step 2A is almost certainly applicable; thus, the two sets of consultations should be undertaken simultaneously.

NOTE: If answer to D) is "yes", the answer will generally also be "yes" to C), but not necessarily *vice versa*.

Overview of the Significant Requirements of the Unfunded Mandates Reform Act (UMRA),

Regulatory Flexibility (RF) Act, as Amended, and E.O. 12866

*This table assumes that, in the interest of good government, whether or not they are explicitly required, each notice will: (i) identify the need for the specific action and the objectives and legal basis for the rulemaking, (ii) be subject to public comment and the final notice will summarize, evaluate and respond to those comments, and (iii) provide a defensible justification for the option(s) selected in the final notice, with such justifications being crucial if a "decision rule" is specified below. **Note: the requirements are not mutually exclusive, the analytical requirements overlap, and can be fulfilled simultaneously with a unified analysis.***

	Threshold Analysis	Small Govt. Agency Plan	Regulatory Flexibility (RF) Analysis		Significant under E.O. 12866	Significant Federal Mandate
			Initial	Final		
<i>Legal requirement</i>	201, UMRA	203, UMRA	5 U.S.C. 603	5 U.S.C. 604	E.O. 12866	202, UMRA
<i>Threshold</i>	None. Almost all should undertake. Should include a preliminary cost/benefit analysis.	Significant or unique impact on small govts.	Significant economic impact on a substantial number of small entities.		> \$100 million, novel policy, significant sectoral impact, conflicting regs., OR material budgetary impacts.	Intergovt. or private sector mandate >\$100 million
<i>Special Consultation Requirements</i>	.	With affected small govts. 203.	With affected small entities.		.	With state, local and tribal govts (SLTGs), including FACA waiver. 204.
<i>Analysis of Effects</i>	Enough detail to	Not explicit,	Sufficient detail to check whether above		Qualitative/quantitative cost-benefit analysis	

Content and detail of analysis	check if thresholds are crossed.	but see previous column.	threshold is crossed and--if it is--address how "decision rule" is met. See below.	Level of detail dep-endent on magnitude & type of effects, & analytical complexity.	Analyze methods by--and extent to--which Fed. govt. pays for additional costs to SLTGs.
<i>Small Entities Affected</i>	.	.	Which? How many? What types?	Same as RF Analysis.	Implicitly included.
<i>Reports, record-keeping and compliance requirements</i>	.	.	Describe. Which types of entities affected? What skills are needed to comply?	Included in costs.	Implicitly included.
<i>Duplicative, overlapping and conflicting rules</i>	.	.	Describe	Implicitly included, see below.	Serves as a trigger for applicability. Implicitly included--see "decision rule."
<i>Selection of Alternatives</i>	.	.	Should minimize sign. econ. impacts on...small entities.	Reasonable number.	Reasonable number.
<i>Decision Rule</i>	.	.	Minimize sign. economic impacts on...small entities consistent with stated objectives of statute.	Economic efficiency considering equity, and feasibility, unless inconsistent with law.	Least costly, least burdensome, most cost-effective, unless inconsistent with law. 205.
<i>Special Requirement</i>	.	.	.	Small Entity Compliance Guide.	Explicitly address whether mandate is necessary.
<i>Exemption</i>	No	If threshold is not crossed.	Certification by agency head showing that threshold is not crossed.	If threshold is not crossed.	If threshold is not crossed; also categorical exclusions likely (see Attachment

A).

Analytical and Procedural Requirements for a Typical Interior Rulemaking under UMRA, RFA and E.O. 12866

The majority of Interior rulemakings will not, in all likelihood, trigger the thresholds for "significant regulatory actions." Therefore, most rulemaking will be subject to fewer requirements than if they crossed those thresholds. The **typical** rulemaking for the Department of the Interior will need to fulfill the following analytical and procedural requirements to comply with the Unfunded Mandates Reform Act, the Regulatory Flexibility Act (as amended) and E.O. 12866:

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- Threshold analysis, to determine whether the regulation:
 - will have a significant or unique effect on small governments (UMRA). [Many rules may trigger the "unique" requirement.]
 - will have a significant impact on a substantial number of small entities (RFA). [The chances are reasonably high that the answer to this will be "yes".]
 - is "significant" under E.O. 12866. [Most will probably not trigger the \$100 million threshold, but some may get snagged under the "novel, legal or policy issues" requirement, especially as interpreted by OMB.]

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- Small Government Agency Plan--a consultation plan--will need to be implemented [if the "unique" requirement under UMRA is triggered]. This procedure should also be used to obtain input from affected tribes under the various Executive and Secretarial Orders on environmental justice and trust responsibilities.

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- Certification that the rule will not have a significant impact on a substantial number of small entities with backup documentation.

In the absence of such a Certification, a Final Regulatory Flexibility Analysis will be required. [This is reasonably likely because many rules will have a "significant impact on a substantial number of small entities."] This should also address what actions were taken to minimize impacts on small entities consistent with the law's objectives and the reasons for selecting/rejecting options. An Initial Regulatory Flexibility Analysis is highly recommended. In addition, there should be:

- Enhanced consultation with or participation of affected small entities.

- A small entity compliance guide once the rule is final.

Attachment A

UNFUNDED MANDATES REFORM ACT OF 1995 (2 U.S.C. 1501 et seq.)

Applicability

All regulations except those

- Enforcing constitutional rights;

- Enforcing statutory rights barring discrimination based upon race, color, religion, national origin, age, handicap or disability;

- Requiring compliance with various fiscal procedures regarding Federal grants, moneys or property;

- Providing for emergency assistance;

- Necessary for national security;

- Relating to Title II of the Social Security Act;

- Relating to Presidentially or Congressionally designated "emergency legislation."

"Significant" regulations will need greater efforts.

Summary

Requires agencies to:

-- Assess the effects of their regulations on state, local and tribal governments (SLTGs) and the private sector (Sec. 201).

-- Undertake additional analyses if a regulation imposes an aggregate expenditure of at least \$100 million on SLTGs or the private sector, including analysis of costs and benefits (quantitative and qualitative), compliance costs, effects on the economy, methods to reduce costs on SLTGs (Sec. 202). It also requires agencies to select the least burdensome option that meets the rule's objectives or to explain why that option was not selected (Sec. 205).

-- Develop a plan to provide small SLTGs with notice (Sec. 203 (a) (1)), opportunity for "meaningful" consultation (Sec. 203 (a) (2)), and information, advice and education on compliance (Sec. 203 (a) (3)) if a regulatory requirement should significantly or uniquely affect a small government. "Significantly or uniquely" is not defined.

-- Develop an effective process to permit elected officials of SLTGs to provide meaningful and timely input while developing regulatory proposals containing "significant" intergovernmental mandates (Section 204). Section 204 also exempts certain meetings between SLTGs and Federal officials from FACA requirements.

Definitions

A Significant regulatory action is implicitly one that is likely to result in a Federal mandate that may cause state, local and tribal governments (SLTG), in the aggregate, or the private sector to spend more than \$100 million in any one year (inflation adjusted).

Federal mandate is a Federal intergovernmental mandate or a Federal private sector mandate.

Federal intergovernmental (or private sector) mandate is:

-- A legal, statutory or regulatory provision which would impose an enforceable duty on state, local or tribal governments. However, it does not include anything required as a condition of Federal assistance or if the duty arises from participation in a voluntary Federal

program.

-- Also created by reducing Federal appropriations or assistance going to SLTGs (or the private sector) for compliance with a duty, unless such duty is relaxed.

Small government means a governmental jurisdiction with a population less than 50,000 and any tribal government. This would include special governmental "districts" and authorities such as those for irrigation, soil conservation, schools, and ports subject to direct election of board members, and all Indian tribes.

Assessment of Effects

Each agency shall assess the effects of regulatory actions (unless excluded or otherwise prohibited by law) on SLTGs and the private sector. NOTE: there is no qualification on this requirement based on significance. [Sec. 201].

Judicial Review: Not subject to judicial review.

Written Statements for Significant Regulatory Actions [Sec. 202 and OMB guidelines]

When: Before final rule promulgation

What: A written statement containing:

(1) Legal basis for the rule.

(2) Qualitative and quantitative cost-benefit analysis including:

- costs and benefits to SLTGs;

 - costs and benefits to the private sector;

 - effects on health, safety and the natural environment;

 - an analysis of the extent to which Federal government may directly or indirectly pay (or be paying) for costs borne by SLTGs;

 - the extent to which Federal resources are available to carry out the Federal intergovernmental mandate.
- (3) Cost estimates, if accurate estimates are reasonably feasible, of
- compliance costs of the Federal mandates;

 - disproportionate budgetary effects on regions or segments of SLTG, communities or the private sector.
- (4) Estimates of the effects on the national economy including effects on productivity, economic growth, jobs, full employment and international competitiveness, if reasonably feasible and relevant.
- (5) Description of prior consultation with elected (*and other*) representatives of affected SLTGs.
- (6) Summary of comments and concerns of SLTGs.
- (7) Agencies' evaluation of above comments and concerns, *and position regarding the need for the mandate.*

Where: A summary of the written statement (above) shall be included in the proposal or final rule, i.e., in the Federal Register.

Copies: 2 to OMB.

Judicial Review: [Sec. 401 (a)]

-- Court may compel agency to write this statement but failure to do so "shall not be used for staying, enjoining, invalidating or otherwise affecting" the regulations.

-- Information generated in this statement may be considered as part of the record if judicial review is undertaken under another law.

Selection of Least Costly, Least Burdensome, and Most Cost Effective Regulation [Sec. 205]

Additional requirements for significant regulatory actions:

-- Identify and consider a reasonable number of regulatory alternatives.

-- Select the one that is least costly, most cost-effective or least burdensome for SLTs and the private sector, as applicable, if it contains a Federal intergovernmental and/or private sector mandate, unless it is inconsistent with law.

-- Alternatively, agency head shall publish why that was not done along with final rules.

Judicial Review: Not reviewable. [Sec. 401 (b)]

Small Government Agency Plan [Sec. 203]

When: Prior to any rulemaking "significantly or uniquely " affecting small governments.

NOTE: "significantly or uniquely" is not defined.

What: A plan to:

- (1) provide notice to any affected small governments;
- (2) enable their officials to provide meaningful and timely input in the development of proposals containing significant intergovernmental mandates;
- (3) inform, educate and advise small governments on compliance with the rules.

Judicial Review: Same as for the Written Statement.

Note: OMB's guidelines for Sec. 204 (below) asked agencies to describe these plans by January 15, 1996.

State, Local and Tribal Governmental Input [Sec. 204]

What: Each agency shall develop an effective process allowing elected officers of SLTGs (or their designees) to provide meaningful and timely input for developing regulatory proposals containing significant Federal intergovernmental mandates.

FACA shall not apply to meetings exclusively, between elected SLT and Federal government officials (or their designees) if such meetings are limited to exchange of views, information or advice related to managing or implementing any program with explicitly or implicitly shared responsibility or administration.

OMB Guidelines: Issued in the Federal Register, September 29, 1995, pursuant to Sec. 204 (c), recommend that agencies:

- Develop an intergovernmental consultation process;

- Consult early;

- Consult with heads of governments, program and financial officers, elected officials and Washington representatives;

- Consult on costs, benefits, risks, alternative and flexible methods of compliance, potential duplication;

- Inform SLTGs of their (expected) up-front and recurring direct costs.

Judicial Review: Not reviewable. [Sec. 401 (b)]

Annual Agency and OMB Reports

OMB shall detail agencies' compliance with these requirements in a report to Congress each year. Accordingly, agencies should provide OMB with their own reports by each January 15.

Attachment B

REGULATORY FLEXIBILITY ACT, 5 U.S.C. CHAPTER 6, AS AMENDED

Applicability

The Regulatory Flexibility Act, as amended, applies to any rule affecting "small entities".

Summary of Requirements

-- Proposed rule should be accompanied by an Initial Regulatory Flexibility Analysis (RFA), and a final rule should be accompanied by a Final RFA unless agency head (a) certifies that the rule will not have "a significant economic impact on a substantial number of small entities," and (b) provides the factual basis for such certification.

-- The Final RFA allows an agency to take steps to shape rules so as to minimize impacts on small entities as long as the rules are "consistent with the stated objectives of applicable statutes".

-- Either the RFAs or their summaries should be published in the Federal Register. RFAs should be made available to the public. In addition, if a rule will have "a significant economic impact on a substantial number of small entities", additional special measures shall be taken to ensure that such entities have an opportunity to participate in the rulemaking.

-- If there is a final RFA, small entity compliance guide(s) written in plain language should also be published.

-- Initial and final RFAs (or certification) will be part of any report provided to the Comptroller General (and made available to each House of Congress) prior to any rule taking effect.

-- Judicial review of agency compliance has been extended to many new, as well as old, requirements.

Definitions

Small entity is a small business, small organization or a small governmental jurisdiction.

Small business, defined in 13 CFR part 121 for several types of industry and business, is generally one that has relatively low receipts or employment. For example, the upper limits are \$500,000 for grazing and many kinds of agricultural crop production; \$3 million for fishing, hunting and trapping, and 500 employees for mining and logging. A small business must be independently owned and operated and should not be dominant in its field. For rules promulgated under SMCRA, a "small business" should not have annual surface and underground coal production in excess of 100,000 tons.

Small organization is any non-profit enterprise which is independently owned and operated, and is not dominant in its field.

Small governmental jurisdiction is the government of any city, county, town, township, village, school district or special district with a population less than 50,000. It would, for example, include many irrigation districts; however, it is not clear whether tribal governments are included within this definition.

Note that for circumstances unique to a particular rule, if you wish to use a different definition than those provided by 13 CFR part 121, you must follow procedures in that part and must confer with ORA before embarking on that course of action.

Exemption from Initial and Final RFA [Sec. 605 (b)-new]

(1) The agency head must certify that the rule will not have a "significant economic impact on a substantial number of small entities."

(2) The agency head must provide the factual basis for the above claim. NOTE: SBA notes that this will require a "threshold analysis."

(3) Publish (1) and (2) in the FR at the same time as the initial and final RFAs, as applicable.

(4) Provide (1) and (2) to the Chief Counsel for Advocacy, Small Business Administration.

Judicial Review: Compliance is judicially reviewable [Sec. 611-new].

Initial Regulatory Flexibility Analysis (RFA) [Sec. 603-old]

When: At the same time as the proposal is published in the Federal Register.

Where: Initial RFA should be made available for public comment. In addition, either a summary or the full Initial RFA should be published in the Federal Register.

What: The Initial RFA should:

(1) Describe need for action

(2) Describe objectives and legal bases of proposed rules (succinctly).

(3) Describe small entities potentially affected. Where feasible, provide number of potentially affected small entities.

- (4) Describe projected reporting, recording keeping and other compliance requirements.
- (5) Estimate classes of small entities subject to above requirements under (4).
- (6) Describe types of professional skills necessary to prepare reports or records under (4).
- (7) Identify, to the extent practicable, all relevant Federal rules that may duplicate, overlap or conflict with proposed rule.
- (8) Describe significant alternatives to proposed rule which:
 - i) accomplish the objectives of the rule [see (1) and (2)], and
 - ii) minimize significant economic impacts on small entities.

Alternatives may, if consistent with the objectives, discuss differential treatment of small entities in matters regarding applicability of rules, compliance, record keeping requirements and schedules, and use of performance rather than design standards.

Note: Descriptions may be in quantitative or qualitative terms [Sec. 607-old].

Copy: Chief Counsel for Advocacy, Small Business Administration.

Waiver: These requirements may be waived or delayed if agency head certifies there is an emergency which makes timely compliance impracticable. [Sec. 608(a)-old]

Judicial Review: Compliance with these requirements for an Initial RFA are not judicially reviewable.

Final Regulatory Flexibility Analysis (RFA) [Sec. 604-new]

When: Simultaneously with the publication of the final rule, unless delayed due to a certified emergency (see below).

Where: Either a summary or the full Final RFA should be published in the Federal Register.

What: The Final RFA should:

- (1) Describe need for action succinctly.
- (2) Describe objectives and legal basis of proposed rules succinctly.
- (3) Describe small entities potentially affected, and provide number of potentially affected small entities. Alternatively, provide an explanation why no estimate is available.
- (4) Describe projected reporting, recording keeping and other compliance requirements.
- (5) Estimate classes of small entities subject to an above requirement under (4).
- (6) Describe types of professional skills necessary to prepare reports or records under (4).
- (7) Describe:
 - i) significant issues raised by public comments in response to the Initial RFA,
 - ii) agency's assessment of these issues,

iii) changes made as a result of (i) and (ii).

(8) Describe steps taken to minimize significant economic impact on small entities consistent with the stated objectives of applicable statutes.

(9) State factual, policy and legal reasons for selecting the option(s) in the final notice and rejecting others.

Note: Descriptions may be in quantitative or qualitative terms [Sec. 607-old].

Waiver: Unless exempted altogether (see below)--delay, yes; waiver, no. This may be delayed for up to 180 days, in cases of a certified emergency making timely compliance impracticable. If a final RFA is not prepared within 180 days, the rule shall lapse. It may not be repromulgated unless the Final RFA is completed. [Sec. 608(b)-old].

Judicial Review: Compliance with the requirements for a Final RFA is judicially reviewable if an affected small entity files for review within (generally) one year after publication of the Final RFA. [611--new]

Additional Procedural Requirements if an Initial or Final RFA is Needed

If a rule will have "a significant economic impact on a substantial number of small entities", additional special measures shall be taken to ensure that such entities have an opportunity to participate in the rulemaking. Such special measures may consist of:

(1) a specific statement in an ANPRM stating that it will have "a significant economic impact..."

(2) publication in more user-friendly venues

(3) direct notification

(4) open conferences or public hearings

(5) adoption/modification of agency procedural rules to reduce cost or complexity of participation

Judicial Review: Reviewable only in conjunction with requirements for a Final RFA.
[611-new]

Small Entity Compliance Guides [Sec. 212, Small Business Regulatory Enforcement Fairness Act of 1996-new]

What: If there is a Final RFA, then agency should prepare and make available a Small Entity Compliance Guide to explain the rule and its requirements in plain language. Guides may be prepared and distributed in cooperation with small entity associations.

When: Not Stated

Where: "Agencies shall cooperate [to make Guides available] through comprehensive sources of information." Note, a multi-agency clearinghouse, NTIS or GPO should meet that requirement.

Judicial Review: While the Guides are not judicially reviewable, they may be considered in establishing any fines, penalties or damages. [What if there is no guide? Presumably, it will allow a small entity's lawyer to use that as an argument, at least in setting penalties.]

Semiannual Regulatory Flexibility Agenda [Sec. 602-old]

When: April and October of each year.

What: Publish its Regulatory Flexibility Agenda in the Federal Register briefly describing:

- (1) Subject area of any proposed or final rulemaking likely to have a "significant economic impact on a substantial number of small entities".
- (2) The nature of each rulemaking including its objectives and legal bases.
- (3) Approximate schedule for completing action on any rule for which a notice of proposed rulemaking has been issued.

Copies for Comments to:

- (1) Chief Counsel for Advocacy, Small Business Administration.
- (2) Publications likely to be obtained by affected small entities.

Judicial Review: Not reviewable.

Periodic Review Plan

Applicability: Rules having a significant economic impact on a substantial number of small entities.

What: Each agency should have already had (as of 1981) a plan to periodically review:

-- All new rules since September 19, 1980, within 10 years of promulgation.

-- All existing rules as of September 19, 1980, before September 19, 1990. However, five one-year extensions were allowed if agency head certified that such a review was not feasible.

Moreover, each year the agency shall publish a Federal Register notice listing--and briefly describing--all such reviews slated over the following twelve months. The description should include the need and the legal basis for the rule, and invite public comment.

Why: The review would/should determine whether the rule should be continued, modified or rescinded, in order to minimize any significant economic impact on a substantial number of small entities. The review should consider:

- (1) Consistency with the stated objective of the applicable statute.
- (2) Need for rule.
- (3) Nature of complaints and comments.
- (4) Complexity of rule.
- (5) Extent of overlap, duplication or conflict with other Federal rules and, to the extent feasible, state and other governmental rules.
- (6) Length of time since rule was last reviewed.
- (7) Changes in technology, economic conditions and other factors since last reviewed.

Judicial Review: Compliance with these requirements are judicially reviewable. [Sec. 611-new]

Miscellaneous

An agency may produce a single RFA for several "closely related rules" or meet the above requirements in conjunction with any other efforts that have to be undertaken in any case.

Attachment C

EXECUTIVE ORDER 12866: REGULATORY PLANNING AND REVIEW

Applicability

E.O. 12866 applies to all regulations as defined below.

(E.O. 12866 addresses many aspects of the Federal rule-making process. However, only those aspects that apply to the analysis of specific rules are summarized in this attachment.)

Summary of Major Requirements

E.O. 12866 specifies broad guidelines for all regulations. To the extent permitted by law, these guidelines require agencies to:

-- Identify and assess the problem to be addressed by regulation;

- Avoid regulations that are inconsistent, incompatible, or duplicative with other regulations;
- Identify and assess alternatives to, and alternative forms of, regulation;
- Design regulations to achieve regulatory objectives in the most cost-effective manner;
- Assess and minimize regulatory impacts on state, local, and tribal governments;
- Based upon the best reasonably obtainable information, assess all costs and benefits of regulatory alternatives, and select regulatory alternatives based upon a reasoned determination that the benefits of regulation justify its costs;
- Draft regulations to be simple and easy to understand.

Significant regulatory actions have additional requirements for review by OMB and the public.

Definitions

A regulation or rule is an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy, or to describe the procedure or practice requirements of an agency. Exceptions to this definition include:

- Regulations issued according to "formal rule-making" provisions (5 U.S.C. 556, 557); and
- Regulations or rules that are limited to agency organization, management, or personnel matters.

A regulatory action is any substantive action that promulgates or is expected to lead to the promulgation of a final regulation or rule.

A significant regulatory action is any regulatory action that will likely:

- Have an annual effect on the economy of \$100 million or more, or adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- Create a serious inconsistency or interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles established by E.O. 12866.

Regulatory actions can be designated as significant by either the promulgating agency or OMB.

Major Requirements for all Rules

E.O. 12866 specifies broad guidelines for all regulations. To the extent permitted by law, these guidelines require agencies to:

- Identify and assess the problem to be addressed by regulation;
- Assess whether existing regulations have contributed to the problem;

- Avoid regulations that are inconsistent, incompatible, or duplicative with other regulations;
- Identify and assess alternatives to regulation;
- Identify and assess alternative forms of regulation;
- Design regulations to achieve regulatory objectives in the most cost-effective manner;
- Assess and minimize regulatory impacts on state, local, and tribal governments;
- Assess and, to the extent possible, quantify all costs and benefits of regulatory alternatives;
- Select regulatory alternatives based upon a reasoned determination that the benefits of regulation justify its costs;
- Base decisions on the best reasonably obtainable information; and
- Draft regulations to be simple and easy to understand.

Review of Significant Regulatory Actions

For any significant regulatory action, agencies are required to provide OMB with:

- A detailed description of the need for regulation and an explanation of how the planned regulation will address that need;

- An assessment of the anticipated costs and benefits of the planned regulation; and

- An assessment of the costs and benefits of reasonably feasible alternatives to the planned regulation, and an explanation of why the planned regulation is preferable to those alternatives.

After a regulatory action has been published in the Federal Register, agencies must make available to the public the information provided to OMB (above).

Attachment D

REGULATORY COST-BENEFIT ANALYSIS:

DEPARTMENTAL GUIDANCE

Regulatory cost-benefit analyses are intended to inform decision-makers about the potential consequences of proposed actions. Such analyses should provide sufficient information to *reasonably* determine 1) whether regulatory action is needed, 2) whether the benefits of regulatory action can justify its costs, and 3) whether a particular regulatory action will maximize net-benefits within statutory and judicial constraints. This information can help define regulatory objectives and identify the most efficient way to achieve them.

The goal of cost-benefit analysis is to determine the net-benefits of a proposed action in order to evaluate its desirability with respect to other alternatives. In general, net-benefits are determined by characterizing individual impacts as costs or benefits, assigning a relative weight or value to each, and then calculating the balance of the benefits in excess of costs. This type of analysis is not a substitute for common sense, but rather a systematic framework for organizing thoughts, estimating impacts, and evaluating alternative actions.

Regulatory cost-benefit analyses should not be complicated or costly in most situations. Order-of-magnitude estimates will often suffice to indicate whether the benefits of regulatory action will justify its costs and whether net-benefits are maximized within statutory and judicial constraints. Such estimates can often rely on existing studies in the economics literature. In some situations, detailed economic studies may need to be conducted to evaluate complicated regulatory actions with large economic impacts. In any case, the level of analytic effort should be scaled to the task at hand.

This document provides guidance to bureaus and offices on how regulatory cost-benefit analyses should be prepared. (This guidance is intended only to improve the internal management of the U.S. Department of the Interior and does not create any right or benefit, substantive or procedural, enforceable by any party in any administrative or judicial action.) There is no standard blueprint for preparing cost-benefit analyses since different regulatory actions may require different analytic emphases. Rather, analytic principles are provided to allow bureaus and offices maximum flexibility in the preparation of credible cost-benefit analyses. The main body of this document is divided into four sections that discuss the scope of analysis, principles of analysis, elements of analysis, and non-market valuation. Two appendices are also included that provide a checklist for analysts and a list of references and selected data sources.

Scope of Analysis

This guidance applies to all regulatory cost-benefit analysis, regardless of the particular mandate requiring its use. Three separate mandates establish the requirement for, and scope of, regulatory cost-benefit analysis. These are Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995. These are briefly discussed below.

Executive Order 12866 (58 FR 51735) establishes the general scope of regulatory cost-benefit analysis by setting standards for regulatory planning and review. These standards require agencies to determine whether a compelling public need exists for regulatory action, consider a range of possible alternatives to serve that need, and choose the alternative that maximizes social net-benefits within statutory and judicial constraints.

Toward this end, agencies are required to assess the costs and benefits of regulatory actions and, for significant regulatory actions, submit a detailed report of their assessments to the Office of Management and Budget (OMB) for review. (Significant regulatory actions are defined in section 3(f) of Executive Order 12866 and, for purposes of economic analysis, generally include actions that have an annual economic impact of \$100 million or more, or that adversely affect the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.) Agencies must assess a wide range of impacts including economic, environmental, public health and safety, and distributive impacts. Costs and benefits are to be quantified when feasible, or qualitatively described when quantification is not feasible. OMB has issued general guidance on how these requirements may be satisfied (Office of Management and Budget January 11, 1996).

Two recent statutes expand the scope of regulatory cost-benefit analysis established by Executive Order 12866. The Regulatory Flexibility Act (P.L. 96-354), which was amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires agencies to assess the impacts of regulatory actions on small businesses and other small entities. Agencies must prepare a regulatory flexibility analysis if a significant impact on a substantial number of small entities is anticipated. See the Office of Policy Analysis guidance on this statute (Attachment B) for specific requirements.

The second statute, Unfunded Mandates Reform Act of 1995 (P.L. 104-4), requires agencies to assess the impacts of regulatory actions on state, local, and tribal governments, as well as on the private sector. This act also requires agencies to consider a reasonable range of regulatory alternatives and to select the most cost-effective alternative or justify why the most cost-effective alternative was not selected. See the Office of Policy Analysis guidance on this statute (Attachment A) for specific requirements.

Principles of Analysis

The mandates for regulatory analysis discussed above do not bind agencies to a strict cost-benefit test. Promulgating agencies are not necessarily required to abandon regulatory approaches that yield negative balances in a simple comparison of costs and benefits. Indeed, a simple comparison of costs and benefits is often frustrated by significant impacts that resist monetization. Rather, agencies are required to structure their considerations in an explicit cost-benefit framework in order to systematically examine all relevant factors.

Non-monetized impacts are qualitatively described and presented on a par with monetized costs and benefits. Agency decisions must then be justified in the context of all available information. Statutory and judicial mandates obviously trump the results of a cost-benefit analysis.

The following additional principles, adopted in part from Arrow et al. (1996), should guide bureaus and offices in the preparation of cost-benefit analyses.

-- Identify the baseline then estimate *incremental* costs and benefits using a practical array of alternatives.

-- Explicitly identify uncertainties by presenting the possible range of costs and benefits along with their best estimates.

-- Present qualitative descriptions of significant impacts that resist monetization on a par with monetary estimates of costs and benefits.

-- Identify distributional impacts, including impacts on state, local, and tribal governments, and on small entities.

-- Explicitly identify all assumptions and justify deviations from commonly accepted practice.

-- Provide transparent descriptions for non-technical readers.

-- Subject cost-benefit analyses to external review.

-- Scale analytic efforts appropriately with the likely significance of regulatory impacts and the range of regulatory discretion provided by statute or judicial mandate.

The last principle regarding scaling deserves some elaboration. Regulatory actions will not always warrant the cost of conducting detailed economic studies. In most situations, credible analyses can be prepared using values obtained from existing studies in the

economics literature or other reliable sources. Alternatively, detailed economic studies may be conducted for some components of an analysis while existing values from the economics literature are used for other components. The scale of analytic effort that is appropriate for any particular analysis generally depends on the likely significance of regulatory impacts. More thorough analysis is warranted as the magnitude, breadth, and complexity of the anticipated impacts increase. The appropriate scale of analytic effort also depends on the range of regulatory discretion provided by statute or judicial mandate. Less extensive efforts are warranted as available options become limited.

Bureaus and offices should prepare a preliminary cost-benefit analysis that relies solely on existing economic values and other readily available data to guide their decisions as to the appropriate scale of analytic effort. This preliminary cost-benefit analysis should be prepared as part of the threshold analysis conducted to determine analytic requirements under Executive Order 12866 and other mandates. See the Office of Policy Analysis guidance on threshold analyses for specific requirements. A preliminary cost-benefit analysis can identify impacts that may warrant a more elaborate economic treatment.

Economists in the Office of Policy Analysis are available to assist in the preparation of cost-benefit analyses. Bureaus and offices are encouraged to consult with the Office of Policy Analysis early-on in the rulemaking process. Early consultation can reduce the cost of producing credible analyses by identifying opportunities to rely on existing economic studies.

Elements of Analysis

OMB's guidance on Executive Order 12866 requires that cost-benefit analyses of significant regulatory actions contain three elements. These are a statement of need for the proposed action, an examination of alternative approaches, and an analysis of costs and benefits. These elements are designed to organize the analysis and selection of regulatory alternatives.

Statement of Need for the Proposed Action

The statement of need should establish the justification for considering regulatory action. Justifications include the existence of a significant market failure or other compelling public need such as improving governmental processes and addressing distributional concerns. Moreover, regulatory actions are often mandated by statute or judicial ruling. Justifications should be clearly stated in order to identify regulatory objectives by suggesting desirable outcomes.

For example, consider a market failure related to hazardous waste disposal. A market failure occurs when resources are not allocated in a manner that maximizes their total value. For instance, markets fail when one party's actions impose uncompensated impacts on others. (This type of market failure is called an externality. Other types of market failure include natural monopoly, market power, and inadequate or asymmetric information.) When hazardous wastes are released into the environment, the public often bears uncompensated costs in the form of higher water treatment costs, adverse health effects, fish consumption advisories, and degraded wildlife habitat. The total value of the environmental resources and other resources involved in the production of hazardous wastes could be increased if polluters were required to pay the full cost of their waste disposal.

The justification for regulatory action in this example is that existing market mechanisms fail to maximize the total value of scarce resources. The regulatory objective then is to ameliorate the market failure by reducing the uncompensated effects of hazardous waste disposal. When developing the justification for regulatory action, means other than Federal regulation should also be considered. These include judicial actions, legislative proposals, Federal actions other than regulation, and proposals for governmental actions at the state, local, or tribal level.

Examination of Alternative Approaches

Alternative approaches to achieving the regulatory objectives identified in the statement of need should be examined in a screening analysis. The purpose of this analysis is to identify a practical array of alternatives for inclusion in a detailed cost-benefit analysis. The following categories should be examined.

-- Performance-oriented standards (as opposed to design-oriented standards)

- Customized requirements for different resource user groups, economic sectors, income groups, etc.

- Alternative compliance standards (more or less stringent)

- Alternative compliance dates

- Alternative monitoring and enforcement procedures

- Measures that improve the availability of information

- Market-oriented approaches

The level of effort that is appropriate for the screening analysis will generally be less than that required for the detailed cost-benefit analysis.

Analysis of Costs and Benefits

Each regulatory alternative that is identified in the screening analysis is first analyzed separately. The results of the different analyses are then compared and considered in the selection of the preferred alternative. Each analysis should identify all methodologies, data, and assumptions with sufficient detail to permit independent verification and replication. The following considerations apply to the analysis of each alternative.

The analytic baseline should be established before any costs or benefits are defined. The baseline is the state of the world that would exist without the proposed action. All costs and benefits that are included in the analysis should be incremental with respect to this baseline. Future impacts that would occur with or without the proposed action, as well as past impacts that have already occurred, should not be included in the analysis.

Such an incremental approach avoids double-counting by recognizing only net-costs and net-benefits. For example, the net-costs of a water quality regulation include the additional resources required to comply with new reporting requirements plus forgone producer profit. Forgone gross revenue is not an appropriate cost measure since the producer saves the cost of any input not used as a result of the regulation. Similarly, the net-benefits of the water quality regulation include increases in consumer surplus that result from improved water quality. Consumer surplus is the difference between the maximum amount a consumer is willing to pay and what the consumer actually pays. Hence, consumer surplus reflects a net-benefit.

Future costs and benefits should be discounted to reflect time preference considerations. A dollar received today is valued more than a guarantee today of a dollar to be received in the future. This is because the future payment implies forgone consumption or investment opportunities today. A range of discount rates should be used, including the 7 percent rate specified in OMB Circular A-94 and other rates that may be better suited to the proposed action. For example, when discounting values that are attributable to natural resources, the current economics literature (e.g., Freeman 1993) and recent Federal rule-makings (61 FR 453 and 61 FR 20584) support the use of a 3 percent discount rate.

The analysis should explicitly recognize that many costs and benefits are uncertain. Uncertainty should be considered either by specifying a probability distribution over a set of outcomes or, absent such detailed information, by specifying a likely range of key parameter values in a sensitivity analysis. Costs and benefits should be expressed in terms of their certainty equivalents when the necessary information is available (outcome probabilities and risk premiums). Absent such information, the influence of risk and risk attitudes on individuals' valuations should be qualitatively discussed.

The analysis will often involve impacts that resist estimation in monetary terms. The presentation of monetary costs and benefits is preferred when acceptable estimates are available. However, some regulatory impacts are cost-prohibitive to quantify and value in monetary terms. For example, it may not be feasible to monetize at a reasonable cost the beneficial impacts of aquatic habitat improvements that result from a water quality regulation. The likely significance of such regulatory impacts will generally determine the feasible limits of valuation. Impacts that cannot be monetized at a reasonable cost should be otherwise quantified using objective physical measures. In the water quality example, it would be appropriate to quantify benefits in terms of acres of habitat improvement and numeric increases in biotic populations and diversity.

The analysis should account for the incremental costs of regulatory enforcement. In addition to the costs of compliance incurred by regulated entities, regulating agencies will likely incur significant monitoring and enforcement costs. Furthermore, it is unlikely that any foreseeable level of regulatory enforcement will yield perfect compliance. Therefore, enforcement cost estimates should be based on a reasonable assessment of regulatory compliance.

The costs and benefits of regulatory actions may be unevenly distributed over different resource user groups, economic sectors, income groups, and even generations. When significant, such differential impacts should be quantified to describe their likely magnitude and incidence on various groups. There are no generally accepted standards for preferring one distribution of net-benefits over another. Therefore, the analysis should describe distributional impacts without judging their fairness.

It is important to include only "real" costs and benefits in the overall calculation of net-benefits. Real costs and benefits accrue to society in the aggregate, regardless of their incidence on particular groups or sectors. Distributional impacts should nevertheless be described and quantified as additional information. Some regulatory impacts on state, local, and tribal governments, and small entities may not constitute real costs or benefits. If not, such costs and benefits should be described and quantified as distributional impacts.

The selection of the preferred alternative will likely involve the simultaneous consideration of different criteria such as equity, political feasibility, and economic efficiency. With respect to the later, the criterion when all significant costs and benefits are monetized should be maximum net present value. This criterion recommends the alternative that yields the greatest total discounted benefits in excess of total discounted costs.

When all significant costs and benefits are not monetized, the economic efficiency criterion should be maximum cost-effectiveness. When applying this criterion, a break-even value for impacts that are not monetized can be identified by comparing monetized benefits with monetized costs. For example, suppose that the beneficial impacts of aquatic habitat improvement cannot be monetized at a reasonable cost. Further suppose that a comparison of monetized impacts for a particular regulatory alternative indicates that total monetized costs exceeds total monetized benefits by \$10 million. Then the habitat improvement benefits must equal \$10 million for the regulatory alternative to just break-even (i.e., to achieve zero overall net-benefits). The regulatory alternative with the smallest break-even benefit will have the best chance of achieving a positive overall net-benefit. Hence, the maximum cost-effectiveness criterion recommends the alternative that yields the smallest break-even benefit.

Non-Market Valuation

Market transactions provide a rich source of information for cost and benefit estimation *if the good or service affected by the regulatory action is traded in a market.*

Unfortunately for purposes of quantitative analysis, many regulatory impacts are not reflected in market transactions. Environmental, historic, and cultural amenities are not often allocated in a market. Therefore, "non-market" approaches to valuation may be used to estimate the costs and benefits of regulatory actions affecting these amenities.

Non-market valuation methodologies rely on the measurement of "services" provided by environmental, historic, or cultural resources. Such resources can be thought of as capital assets that provide a flow of valuable services through time. A national park may provide camping, hiking, fishing, and historic appreciation services through time. A forest may provide carbon dioxide removal, oxygen production, and timber growth services through time. While a market for such assets may not exist, the price that could be commanded if a market did exist can be related to the flow of services provided through time. This relationship rests on the assumption that no buyer would rationally pay more for an asset than the net return that could be obtained from its use.

Therefore, the basis of non-market valuation in a regulatory cost-benefit analysis is the change in the value of service flows that results from a regulatory action. A number of economic methodologies are available to value non-market resources. These include travel cost models, random utility models, contingent valuation, and hedonic pricing. There are a number of excellent references that describe these methodologies in detail (Freeman 1993; Kopp and Smith 1993).

The appropriate methodology depends on the nature of the affected service flow. In this regard, services can be characterized on a descriptive spectrum from "pure private" to "pure public." Pure private services are exchanged in markets. Hence, traded quantities and prices can be directly observed. An example of a pure private service on public land is mineral production. Consumption of a pure private service by one precludes consumption by others. Access to these services can be controlled. The appropriate valuation methodology for pure private services is the usual market supply and demand estimation.

Pure public services are not exchanged in markets. An example of a pure public service on public land is existence value, the appreciation of the mere knowledge that a resource such as the Grand Canyon is protected in a given condition. Quantities and prices cannot be directly observed. Moreover, the measure of service use is often difficult to define and may vary between individuals. Consumption of a pure public service does not preclude consumption by others. Access cannot be controlled. Appropriate valuation methodologies for pure public services include contingent valuation and, in some situations, hedonic pricing.

Quasi-public services are between the polar extremes of pure private and pure public services. These services are often not exchanged in markets, but could be. An example of a quasi-public service on public land is wildlife watching. Quantities may be directly observed, but price must often be inferred, usually from closely associated behavior. Up to a point, consumption by one does not affect consumption by others. Beyond that point, congestion diminishes consumption by all. Access can be controlled, but often is not. Appropriate valuation methodologies for quasi-public services include travel cost models, random utility models, contingent valuation, and hedonic pricing.

A rich literature exists on the valuation of non-market resources (e.g., Bergstrom and Cordell 1991; Walsh, Johnson, and McKean 1992). Analysts should consult this literature to determine if an existing study can be used to evaluate such regulatory impacts.

Conclusion

This document has presented the departmental guidance for preparing regulatory cost-benefit analyses. Analytic principles were stressed rather than a cookbook approach since different regulatory actions may require different analytic emphases. The goal of this guidance was to provide bureaus and offices maximum flexibility in the preparation of credible cost-benefit analyses.

One key principle is that the level of analytic effort should be scaled to the task at hand. The appropriate scale of analytic effort will be determined by the likely significance of regulatory impacts and the range of regulatory discretion provided by statute or judicial mandate. Regulatory cost-benefit analyses should not be complicated or costly in most situations.

Another key principle is that bureaus and offices are not bound by a strict test that rejects regulatory approaches that yield negative balances in a simple comparison of costs and benefits. Rather, agencies should employ cost-benefit analysis as a framework to systematically examine all relevant factors. Non-monetized impacts should be qualitatively described and presented on a par with monetized costs and benefits. Agency decisions must then be justified in the context of all available information.

Finally, bureaus and offices are encouraged to contact the Office of Policy Analysis for assistance in preparing regulatory cost-benefit analyses. Early consultation, in particular, is encouraged to reduce the cost of producing credible analyses.

Attachment E

COST-BENEFIT ANALYSIS CHECKLIST

STATEMENT OF NEED FOR THE PROPOSED ACTION

-- Does the analysis contain a discussion of the particular market failure, or other public need, that the proposed action is intended to address?

-- Are alternatives to Federal regulation considered (e.g., judicial action or legislative proposal)?

EXAMINATION OF ALTERNATIVE APPROACHES

-- Are alternative approaches to achieving regulatory objectives examined in a screening analysis (e.g., performance-oriented standards and alternative compliance standards)?

ANALYSIS OF COSTS AND BENEFITS

-- Are all methodologies, data, and assumptions clearly identified?

-- Has an analytic baseline been established?

-- Are all costs and benefits incremental with respect to the baseline?

-- Would the analysis be substantially improved if additional information could be collected at a reasonable cost?

-- Are future costs and benefits discounted at an appropriate rate of discount?

-- Does the analysis explicitly address uncertainty (e.g., sensitivity analysis)?

-- Are objective physical measures used to quantify impacts that cannot be monetized?

-- Does the analysis provide qualitative descriptions of impacts that cannot be quantified?

-- Does the analysis account for the costs of regulatory enforcement using a reasonable assessment of compliance?

-- Are distributional impacts identified and quantitatively described, including impacts on state and local governments, and small entities?

- Does the analysis include only real costs in the overall calculation of net-benefits?

 - Has the appropriate economic efficiency criterion been used (maximum net present value or maximum cost-effectiveness)?

 - Has the analysis been externally reviewed?
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Attachment F

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