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FEDERAL REGISTER NOTICES AND RULES

I. Purpose

This Management Directive (MD) establishes the Department of Homeland Security (DHS) policy for issuing Federal Register Notices and Rules.

II. Scope

This directive applies to all DHS organizational elements.

This directive applies to the following types of rulemaking documents:

- A. Any advance notice of proposed rulemaking, notice of proposed rulemaking (proposed rule), temporary or interim rule, final rule, or DHS Decision published in the Federal Register;
- B. Any other publicly issued document of general applicability and future effect designed to implement, interpret, or prescribe law or policy, or describing the procedure or practice requirements of an office or directorate, unless otherwise excluded under Paragraph IV.B;
- C. Any document that withdraws or substantively amends a previously issued regulation;
- D. Any document published in the Notice section of the Federal Register, other than a notice involving a test procedure pursuant to § 101.9 of the Customs regulations, that:
 - 1. Requires or authorizes any action on the part of any person to participate in a program, avoid a penalty, or obtain a benefit.
 - 2. Contains a reporting or recordkeeping requirement.
 - 3. Establishes or revises policy.
 - 4. Could limit the policymaking discretion of States. or
 - 5. Could infringe upon a constitutionally protected property right.

6. Any other document or category of documents to the extent determined by a policy official, the General Counsel, or the Under Secretary for Management.

This directive does not apply to the following documents, whether or not they pertain to a rulemaking or fit the definition of a regulation:

- A. Documents making non-substantive technical corrections to a previously issued regulation.
- B. Other documents specifically designated by the Under Secretary for Management in consultation with the General Counsel.
- C. Other documents specifically exempted by the Office of Management and Budget (note: this provides for routine and frequent field regs).
- D. Administrative rulings, protest review decisions, legal determinations and decisions or other similar legal documents issued pursuant to the Customs regulations and operational directives and instructions.

III. Authorities

This directive is governed by numerous Executive Orders, Public Laws and national policy, such as:

- A. "Administrative Procedure Act," 5 U.S.C. 553.
- B. "Regulatory Flexibility Act," 5 U.S.C. 601 et seq.
- C. "Paperwork Reduction Act of 1995," 44 U.S.C. 3501 et seq., as amended.
- D. Congressional Review of Agency Rulemaking Act, 5 U.S.C. § 808.
- E. Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121).
- F. Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538).
- G. National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4347).
- H. E.O. 12866, "Regulatory Planning and Review," dated September 30, 1993 (58 FR 51735 (October 4, 1993)), as amended by E.O. 13258, dated February 26, 2002 (67 FR 9385 (February 28, 2002)).
- I. E.O. 13132, "Federalism," dated October 26, 1987 (52 FR 41685).

- J. E.O. 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights," dated March 15, 1988 (53 FR 8859).
- K. Executive Order 12988, Civil Justice Reform.
- L. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks.
- M. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments.
- N. Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use.
- O. Presidential Directive on Plain Language (June 1, 1998).
- P. 5 CFR 1320, "Controlling Paperwork Burdens on the Public," revised August 29, 1995 (60 FR 44978).

IV. Definitions

- A. **Designated DHS official:** includes senior DHS officials as designated by the Secretary, Deputy Secretary or Under Secretaries.
- B. **Policy Official:** includes the Under Secretaries and Designated DHS officials.
- C. **Significant Regulatory Action:** includes, but is not limited to, an economically significant action as defined in EO 12866.

V. Responsibilities

- A. **Under Secretary for Management:** shall be responsible for the following tasks relating to the preparation and review of Federal Register Notices and Regulations:
 - 1. Provide technical advice and assistance for Federal Register format to DHS officials responsible for drafting the documents.
 - 2. Review draft documents for clarity and consistency.
 - 3. Maintain document control.
 - 4. Coordinate internal clearance and approval process, including establishing review timelines, through electronic means.

5. Make all approved documents accessible via electronic means.
6. Ensure adequate resources are provided to support the regulatory development process and the timely publication of rulemaking documents.
7. Coordinate submission and clearance of information collection requests with CIO/agency paperwork clearance officers.
8. Submit a budget line-item request to cover Federal Register expenses.
9. Coordinate preparation of the semi-annual Regulatory Agenda, and in consultation with the General Counsel, the Regulatory Plan.

B. **General Counsel:** shall be responsible for the following tasks relating to the preparation and review of Federal Register Notices and Regulations:

1. Review draft documents to ensure legality and compliance with DHS policies, Executive Orders, and other national policies.
2. Coordinate documents with appropriate Associate General Counsels, legal advisors, regional counsels and other DHS attorneys.
3. Coordinate documents with the Office of Management and Budget for clearance.
4. Provide regulatory drafting assistance as needed by DHS policy officials and components.

C. **All Policy Officials:** shall be responsible for the following tasks relating to the preparation and review of Federal Register Notices and Regulations that pertain to their area of responsibility:

1. Submit draft documents in the prescribed format, including any necessary white papers or supporting documentation, to the Under Secretary for Management. Once submitted, the Under Secretary for Management will begin the clearance and approval process as noted above.
2. Review all draft documents submitted by other Under Secretaries and/or DHS officials to ensure clarity and consistency across DHS areas of responsibility.

VI. Policy & Procedures

A. **Preparation and Review of Federal Register Notices and Regulations:**

The designated policy official shall submit draft documents to the Under Secretary for Management for tracking and processing. Enclosure (1) prescribes the format for all DHS Federal Register Notices. The Under Secretary for Management shall ensure that appropriate Regulatory Identification Numbers (RIN's) and any other necessary tracking numbers are assigned and manage the review and approval process within DHS.

B. **Opportunity for Public Participation:** Consistent with applicable law and the circumstances of a regulatory action, each directorate and office shall give the public an early and meaningful opportunity to participate in the regulatory process.

1. Special Requirements.

a. Directorates and offices should allow at least 60 days for public comment on proposed, temporary or interim regulations that are economically significant (see Part I), are likely to have a significant economic impact on a substantial number of small entities (see Part II), or contain a requirement for the collection of information (see Part III), unless circumstances make a shorter comment period necessary.

b. For regulations to be issued without opportunity for notice and public comment, refer to Part VI.

2. **Preliminary Public Involvement.** No DHS official should consult with selected members of the public interested in a rulemaking prior to consultation with the General Counsel. *Ex parte* communication following publication of a proposed rule is strongly discouraged and may require notice in the docket and mention in the final rule.

3. **Congressional Comments.** Directorates and offices shall promptly provide the DHS General Counsel with a copy of any written comment from a member of Congress or Senator that criticizes or opposes a proposed regulation. If a Directorate, office, or component agency prepares a substantive response to any such comment, a copy of the response also shall be coordinated with DHS General Counsel.

C. **Departmental Review of Regulations:**

1. **Document Identification.**

a. The Under Secretary for Management shall ensure that a unique identifier is assigned to each departmental regulation drafted under this directive. The identifying number shall ordinarily be the Regulatory Identification Number (RIN). If a DHS constituent organizational element requires an identifying number other than the RIN an appropriate unique identifier shall be assigned by a designated regulations official within that organizational element. The same RIN shall be assigned to all rulemaking stages of the regulation (e.g., a proposed regulation and subsequent final regulation must be assigned the same identifier).

b. The identifier shall be displayed on the regulation and on all memoranda and related documents (e.g., transmittals to the Office of Management and Budget (OMB) and correspondence referenced in paragraph VI.B.2.) submitted to the Department with respect to such regulation. Inquiries concerning the status of review should be directed to the DHS General Counsel and reference the unique identifier.

2. Review Required. No directorate or office may publish or otherwise issue a significant regulatory action, subject to this Directive, as determined by DHS and OMB, until Departmental review and OMB review have been completed.

3. Departmental Review Procedures.

a. Regulations Issued by, or Subject to Review or Approval of, a DHS Policy Official.

(1) Regulations issued by, or subject to review or approval of, a DHS policy official shall be reviewed by appropriate counsel, signed by the DHS policy official, and transmitted to the Under Secretary for Management and the General Counsel. Review shall be requested by a memorandum from the DHS policy official (or from an office or directorate official through the policy official) to the Under Secretary for Management. The memorandum shall, at a minimum, fully, clearly, and succinctly:

- (a) describe the regulation;
- (b) explain the reason it is being issued;
- (c) assess the potential costs and benefits of the regulatory action;

- (d) assess the costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation and provide an explanation why the planned regulatory action is preferable to the identified potential alternatives;
- (e) indicate whether any political or media interest has been expressed in the subject matter of the regulation; and
- (f) describe the nature of correspondence received urging or opposing issuance of the regulation.
- (g) Each transmittal shall include the materials and documentation described in Enclosure 1.

Other Regulations. Regulations not issued by, or subject to review or approval of, a DHS policy official shall be reviewed by appropriate counsel, signed by the appropriate office or directorate official, and transmitted to the DHS General Counsel.

4. Special Procedures.

- a. Paperwork Reduction Act. If a regulation is subject to review by OMB pursuant to the Paperwork Reduction Act (see Part III), the regulation and all required documentation shall be reviewed by the reports management office of the component or directorate. An electronic copy shall be transmitted to the Office of Administration for review in coordination with the DHS General Counsel.
- b. E.O. 12866. The originating office should provide the notice of planned regulatory action required by E.O. 12866 to the DHS General Counsel. If a regulation is subject to review by OMB pursuant to E.O. 12866 (see Part I), the originating office shall provide an electronic copy of the regulation and all required documentation directly to the DHS General Counsel.

5. SEMIANNUAL AGENDAS AND REGULATORY PROGRAMS. Pursuant to the Regulatory Flexibility Act and E.O. 12866, Section 4(b), the Department of Homeland Security will publish in the Federal Register a combined semiannual Regulatory Agenda during April and October of each year. Pursuant to E.O. 12866, Section 4(c), the Department of Homeland Security annually will prepare a regulatory program. Directorates and offices will prepare and transmit the semiannual agendas and regulatory programs as directed by the DHS General Counsel.

D. **Questions or Concerns Regarding the Process:** Any questions or concerns regarding this directive should be addressed to the Office of the Under Secretary for Management.

ATTACHMENTS

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PART I

REGULATORY PLANNING AND REVIEW (E.O. 12866)

1. Non-applicability. The provisions of this Part, other than paragraph 3, do not apply to:

- a. Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557.
- b. Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services.
- c. Regulations or rules that are limited to agency organization, management, or personnel matters.
- d. Regulatory actions issued under emergency procedures or under or a short-term deadline imposed by statute or judicial order, to the extent provided in Part VI.
- e. Regulations making non-substantive technical corrections to previously published regulations.

2. Significant Regulatory Actions.

a. Definition. OMB will designate all rules as either significant or non-significant for the purposes of its review. Any rule designated significant by OMB shall also be deemed significant for the purposes of review within DHS. However, on occasion, a rule judged non-significant by OMB, may nevertheless be treated as significant within DHS. For OMB's purposes, a "significant" regulatory action means any regulatory action that is:

- (1) Likely to result in a rule that may have an annual effect on the economy of \$100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.
- (2) Create a serious inconsistency or otherwise 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.
- (3) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

b. Except as provided in paragraph 2, a regulation shall be deemed an economically significant regulatory action, and shall require a Regulatory Impact Analysis, if the appropriate directorate head or policy official, the General Counsel or the Under Secretary for Management determines it is likely to have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

c. A regulation that is deemed significant and subject to E.O. 12866, review but not economically significant, does not require a Regulatory Impact Analysis, although OMB encourages such an analysis.

3. Regulatory Impact Analyses.

a. Preliminary Regulatory Impact Analysis (PRIA). In the case of a notice of proposed rulemaking determined to be a significant regulatory action, the originating directorate or office shall prepare a PRIA prior to, or at the time of, the actual drafting of the notice of proposed rulemaking. If appropriate, such analysis may be combined with an Initial Regulatory Flexibility Analysis if such analysis is required by Part II. The PRIA shall accompany the notice of proposed rulemaking through all review levels and shall comply with the requirements of E.O. 12866, Section 6(a)(3)(C).

b. Final Regulatory Impact Analysis (FRIA). In the case of a final or temporary or interim regulation determined to be a significant regulatory action, the originating directorate or office shall prepare a FRIA using the same criteria as with the PRIA. Such analysis may be combined with a Final Regulatory Flexibility Analysis if such analysis is required by Part II. The FRIA shall accompany the final regulation through all review levels.

c. Availability. If the PRIA or FRIA is not published with the regulation, the directorate or office shall include in the preamble of, or as an appendix to, the regulation:

(1) A brief summary of the analysis.

(2) A statement advising the public how copies of the analysis may be obtained.

d. Content. RIA must be consistent with the requirements of E.O. 12866 and the Office of Management and Budget guidance. RIA shall include a description of:

(1) The problem or need for regulatory action.

- (2) The market failure that created this problem or need.
- (3) Alternatives.
- (4) Quantified and monetized costs and benefits to the extent possible.

4. Federal Register Statements. Regulatory actions published in the Federal Register shall include in the preamble a statement substantially similar to one of the following, as appropriate:

- a. "This document is not subject to the requirements of E.O. 12866. [Brief explanation of basis for determination]."
- b. "The Office of Management and Budget (OMB) has determined that this document is not a significant regulatory action as defined in E.O. 12866 and a regulatory impact analysis is not required. [Brief explanation of basis for determination]."
- c. "The Office of Management and Budget (OMB) has determined that this document is an economically significant regulation as defined in E.O. 12866. Accordingly, a [preliminary/final] regulatory impact analysis has been prepared." In addition, the bureau or directorate shall include a brief statement that the regulation is within the authority delegated by law and consistent with congressional intent.
- d. "The Office of Management and Budget (OMB) has determined that this document is a significant regulation, but not economically significant, as defined in E.O. 12866. Accordingly, OMB has reviewed and approved this regulation."

5. Required Submissions to OMB.

- a. General. Except with respect to regulations described in paragraph 1, all significant regulations or rules, required transmittal forms, and applicable regulatory impact analyses shall be submitted to OMB, through the DHS General Counsel, for review pursuant to E.O. 12866.
- b. Designation of Significant Regulations or Rules. Consistent with E.O. 12866, Section 6(a)(3)(A), each office or directorate shall, through the DHS General Counsel, submit lists of planned regulations, indicating those which the office or directorate believes are significant regulations under E.O. 12866.
- c. OMB Review. The standard OMB review period for regulations submitted for review under E.O. 12866 is:

(1) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulations actions prior to a notice of proposed rulemaking, ten working days.

(2) For all other regulatory actions, 90 calendar days.

d. All directorates and offices planning to publish a rulemaking document within a 60-day period must submit a list of those regulations to the Under Secretary of Management not later than the 15th day of the month prior to the 60-day period. The General Counsel, in consultation with the Under Secretary for Management will review the lists and forward the lists to the respective OMB desk officer for approval. Non-significant rules may be selected from these lists for Departmental review per this Directive. The lists must be formatted as follows:

(1) New significant rules.

(2) Significant rules that have been previously reviewed by OMB.

(3) New Non-significant rules.

(4) Non-significant rules that have been previously reviewed by OMB.

The Under Secretary of Management will circulate the list within DHS and all DHS directorates and components for coordination. OMB concurrence on non-significant rules on the list will be authority to publish the rulemaking document in the Federal Register. Significant rulemakings must still follow the formal review procedures set forth in this MD. Offices and directorates are advised to incorporate review periods into publication schedules and that OMB may extend the review period for any regulation.

e. Coordination with E.O. 12630. Refer to Part V, paragraphs 2.b. and 2.d., for required submissions concerning E.O. 12630.

PART II

REGULATORY FLEXIBILITY ACT

1. All Regulations.

a. In General.—The Regulatory Flexibility Act (RFA) applies to all regulations except as provided in subsection (b). The Regulatory Flexibility Act directs each bureau or office that is required by 5 U.S.C. 553 or any other law to publish a notice of proposed rulemaking to consider the impact of the regulation on small entities as defined in the RFA (5 U.S.C. 601(6)).

b. Non-applicability.—Except as may be otherwise required by law, the provisions of this Part (other than sections 201(c)(2) and 201(c)(3)) do not apply to—

(1) Anprms, provided that they do not contain proposed regulatory text.

(2) Except as provided in section 202(a), regulations not required to be issued with notice and opportunity for public comment pursuant to 5 U.S.C. 553, or any other law, even if a NPRM is published at the discretion of an office or bureau.

(3) Final regulations where the prior NPRM was published before January 1, 1982.

(4) Regulations of particular applicability relating to rates, wages, corporate or financial structures, or reorganization thereof, prices, facilities, appliances, services, or allowances therefore, or to valuations, costs or accounting, or practices related to such rates, wages, structures, prices, appliances, services or allowances.

(5) To the extent provided in Part 9, regulations that will have a significant economic impact on a substantial number of small entities that are issued in response to an emergency situation or a short-term deadline imposed by statute or judicial order.

c. Certification or Statement of Non-applicability.—

(1) In General.—

(a) The RFA provides that an agency may exempt a regulation from the requirement to prepare regulatory flexibility analyses upon certification that the regulation will not have a significant economic impact on a substantial number of small entities. In other instances the Act may not apply to a regulation.

(b) Notwithstanding a certification that a NPRM will not have a significant economic impact on a substantial number of small entities, if a bureau or office, at any time prior to issuing a final regulation, finds that the regulation is likely to have such an impact, the bureau or office shall notify the Associate General Counsel. Offices and bureaus are advised that preparation of an analysis for the final rule may be required.

(2) Required Federal Register Certification or Statement.—Offices and bureaus shall include in the preamble to each ANPRM that contains proposed regulatory text, NPRM, temporary (interim), and final regulation, a statement as follows:

(a) Regulations Subject to the Act and Not Having a Significant Economic Impact on a Substantial Number of Small Entities.—In the case of a regulation subject to the RFA that—

i. Will not have a significant economic impact on a substantial number of small entities.

ii. Implements a statute or other legal authority that imposes a significant economic impact on a substantial number of small entities, to the extent such impact flows directly from such statute or authority, a certification substantially similar to the following:

"It is hereby certified that this regulation will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required." This statement must be followed by a brief explanation of the basis for the certification.

(b) Regulations Not Subject to the Act.—In the case of a regulation not subject to the RFA, a statement explaining why the Act does not apply.

(c) Regulations Subject to the Act and Having a Significant Economic Impact on a Substantial Number of Small Entities.—In the case of regulations subject to the analysis requirements of the RFA, refer to subsections (d)(2) or (e)(2) (statement concerning public availability of analyses). Refer to Part 9, section 904, if the regulation is being issued in response to an emergency situation or a statutory or judicial deadline.

d. Initial Regulatory Flexibility Analysis (IRFA).—

(1) Content.—In the case of a NPRM that is likely to have a significant economic impact on a substantial number of small entities, the initiating office or bureau shall prepare an IRFA. The analysis shall be approved by the head of the office or bureau and accompany the regulation through all review levels. The analysis shall contain:

- (a) A description of the reasons why action by the agency is being considered.
- (b) A succinct statement of the objectives of, and the legal basis for, the proposed rule.
- (c) A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply.
- (d) A description of 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 such requirements and the type of professional skills necessary for preparation of the report or record.
- (e) An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap or conflict with the proposed rule.
- (f) A description of 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, including a discussion of significant alternatives such as—
 - i. The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities.
 - ii. The clarification, consolidation or simplification of compliance and reporting requirements for small entities.
 - iii. If applicable, the use of performance standards rather than design standards.
 - iv. The exemption from the rule, or any part of the rule, for small entities.

(2) Public Availability.—The originating office or bureau shall make copies of the IRFA available to the public and shall include in the preamble to the NPRM—

(a) Summary of the analysis and a statement describing how copies of the analysis may be obtained.

(b) The text of the complete analysis.

(3) Public Participation.—When an office or bureau publishes in the *Federal Register* a proposed rule for which it has prepared an IRFA, the office or bureau shall take steps to offer affected small entities additional opportunities to participate in the rulemaking through the reasonable use of techniques such as:

(a) Publishing the NPRM in publications likely to be read by affected small entities.

(b) Directly notifying interested small entities of the rulemaking.

(c) Holding open conferences or public hearings for affected small entities.

(d) Posting the NPRM on the Internet and receiving public comments by electronic mail.

(4) Transmittal to Small Business Administration.—A copy of each IRFA shall be transmitted by the Associate General Counsel to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

e. Final Regulatory Flexibility Analysis (FRFA).—

(1) Content.—In the case of a final regulation for which an IRFA was prepared or for which a FRFA is otherwise required, the originating office or bureau shall prepare a FRFA. The analysis shall be approved by the head of the office or bureau and shall accompany the regulation through all review levels. The analysis shall contain:

(a) A succinct statement of the need for and the objectives of the rule.

(b) A summary of the significant issues raised by the public comments in response to the IRFA, a summary of the assessment of the office or bureau of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

(c) A description of and an estimate of the number of small entities to which the proposed rule will apply, or an explanation of why no such estimate is available.

(d) A description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to such requirements and the type of professional skills necessary for preparation of the report or record.

(e) A description of the steps the office or bureau has taken to minimize the significant economic impact of the rule 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, and why each of the other significant alternatives to the rule considered by the agency that affects the impact on small entities was rejected.

(2) Public Availability.—The originating office or bureau shall make copies of the final analysis available to the public and shall include in the preamble to the final regulation—

(a) Summary of the analysis and a statement describing how copies of the analysis may be obtained. or

(b) The text of the complete analysis.

2. Periodic Review of Rules.

a. In General.—Not later than 10 years after the effective date of a final rule that was determined to have a significant economic impact on a substantial number of small entities, and not later than every 10 years thereafter, the issuing office or bureau shall complete a review of the rule to assess its impact on small entities and determine whether the rule should be continued without change, amended or rescinded. In making such a determination the office or bureau shall consider—

(1) The continued need for the rule.

(2) The comments filed by the public pursuant to the notice required by subsection (b)(1) and other comments or complaints received from the public concerning the rule.

(3) The complexity of the rule.

(4) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules and, to the extent feasible, with State or local government rules.

(5) The length of time since the rule was previously reviewed pursuant to this subsection or the degree to which technology, economic conditions or other factors have changed in the area affected by the rule.

b. Federal Register Publications.—

(1) At least 9 months before the date a review required by subsection (a) must be completed, the issuing office or bureau shall publish a notice in the *Federal Register* soliciting comments on the continued need for the rule, its impact on small entities and whether the rule should be continued, amended or rescinded.

(2) Not later than that date a review required by subsection (a) must be completed, the issuing office or bureau shall publish in the *Federal Register*—

(a) A notice of its determination to continue the rule without change, together with an explanation of that determination. or

(b) A proposed or final rule to amend or rescind the rule.

The notices required by paragraphs (1) and (2)(a) shall be forwarded to the Associate General Counsel for review and approval prior to publication.

3. Small Business Compliance Guides.

a. In General.—For each final rule (or group of final rules) that was determined to have a significant economic impact on a substantial number of small entities, the issuing office or bureau shall publish one or more guides to assist small entities in complying with the rule. These publications shall be designated "small entity compliance guides."

b. Contents.—Each small entity compliance guide shall—

(1) Explain the actions a small entity is required to take to comply with the rule (or group of rules).

(2) Be written in a manner likely to be understood by affected small entities, taking into account the subject matter of the rule and the language of applicable statutes.

4. Judicial Review.

a. In General.—Offices and bureaus are advised that section 242 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) amended RFA section 611 to provide for judicial review of agency compliance with the RFA provisions governing—

- (1) Certifications that a proposed or final rule does not have a significant economic impact on a substantial number of small entities.
- (2) The content of a final regulatory flexibility analysis, including whether quantification of the effects on small business is practicable or reliable.
- (3) Determinations to waive or delay completion of an initial regulatory flexibility analysis, or to delay completion of a final analysis.
- (4) The periodic review of rules determined to have a significant economic impact on a substantial number of small entities.
- (5) Office or bureau efforts to solicit public comments on a proposed rule that will have a significant economic impact on a substantial number of small entities from affected small entities by means other than publishing the proposed rule in the *Federal Register* for comment.

b. Remedies.—If a court finds that an office or bureau did not comply with the RFA, remedies available include remanding the rule to the agency and suspending enforcement of the rule with respect to small entities.

PART III

PAPERWORK REDUCTION ACT AND RULEMAKING

1. Notices of Proposed Rulemaking and Subsequent Final Regulations. Any notice of proposed rulemaking that contains a reporting or recordkeeping requirement, and any final regulation issued pursuant to such notice of proposed rulemaking, is subject to 44 U.S.C. 3507(d) and to such related rules, regulations and procedures as may be promulgated by OMB (see 5 CFR 1320.8, 1320.9, 1320.11, and 1320.12).
2. All Other Documents. Any document (including non-regulatory documents) not described in paragraph 1. that contains a reporting or recordkeeping requirement is subject to clearance by OMB prior to publication pursuant to 44 U.S.C. 3507 and to such related rules, regulations and procedures as may be promulgated by the OMB (see generally 5 CFR 1320.8, 1320.9 and 1320.10). Offices and directorates are advised to ensure that required submissions to OMB are made at least 30 days prior to date of anticipated publication or issuance.
3. Definitions. For purposes of this Part:
 - a. Collection of Information.—The term "collection of information" means a reporting, recordkeeping or disclosure requirement, whether compliance therewith is mandatory or voluntary.
 - b. Reporting Requirement.—The term "reporting requirement" means a requirement that persons provide information to an entity of the Federal Government. A form codified in a regulation constitutes a reporting requirement.
 - c. Recordkeeping Requirement.—The term "recordkeeping requirement" means a requirement that persons maintain specified records, whether or not an entity of the Federal Government actually seeks access to the records or whether the records are ultimately provided to an entity of the Federal Government.
 - d. Disclosure Requirement.—The term "disclosure requirement" means a requirement that a person disclose information to another person, or to the public at large, and includes a requirement that information be disclosed on a label. A disclosure form codified in a regulation constitutes a disclosure requirement.
4. Non-applicability. This Part does not apply to:
 - a. Regulations that do not contain a reporting or recordkeeping requirement.

- b. Regulations that contain a reporting or recordkeeping requirement, if:
 - (1) Such information is required only of agencies, instrumentalities or employees of the United States and is not collected for general statistical purposes.
 - (2) The requirement in the regulation is not self-executing (i.e., the regulation does not specify the information to be reported or maintained and instead requires the submission on a form, or pursuant to instructions not codified in the regulation).
 - c. Regulations that contain a reporting or recordkeeping requirement for a purpose specifically described in 44 U.S.C. 3518(c)(1).
 - d. Collections of information specifically designated in 5 CFR 1320.3(h).
5. Required Submissions to OMB.
- a. Except as provided in paragraph 4, originating offices and directorates shall prepare required submissions to OMB for regulations and other reporting or recordkeeping requirements that contain a collection of information as directed by the Office of the Under Secretary for Management. Such submissions shall be reviewed and approved by the appropriate directorate or office reports management officer and forwarded to the DHS Office of the Under Secretary for Management for coordination with the General Counsel.
 - b. OMB Review.
 - (1) Notices of Proposed Rulemaking. Prepublication approval by OMB is not required. Submissions must be made to OMB not later than the date of publication in the Federal Register. The OMB review period is 60 days from the date the regulation is published, during which time OMB shall notify the Department of its decision to approve, to instruct the Department to make a substantive or material change to, or to disapprove, the collection of information.
 - (2) Final and Temporary or Interim Regulations Issued Subsequent to a Notice of Proposed Rulemaking. Prepublication review and approval by OMB is required only if any reporting or recordkeeping requirement contained in the temporary or final regulation:
 - (a) Was not contained in the prior notice of proposed rulemaking.
 - (b) Is materially different from that contained in the prior notice of proposed rulemaking.

(c) Was commented upon by OMB in connection with its review of the prior notice of proposed rulemaking (Offices and directorates shall consult with DHS General Counsel in such circumstances).

The OMB review period is 60 days. Offices and directorates are advised to incorporate this review period into publication schedules. If the required submission cannot be made to OMB at least 30 days prior to anticipated publication, offices and directorates shall consult with DHS General Counsel.

(3) Temporary or Interim and Final Regulations Issued Without a Prior Notice of Proposed Rulemaking. Prepublication approval by OMB is required. The OMB review period is 60 days. Offices and directorates are advised to incorporate this review period into publication schedules and that OMB may extend the review period for an additional 30 days. If the required submission cannot be made to OMB at least 30 days prior to anticipated publication, offices and bureaus shall consult with DHS General Counsel.

6. Federal Register Statements.

a. Notices of Proposed Rulemaking. The preamble to a notice of proposed rulemaking that contains a reporting or recordkeeping requirement shall include, at a minimum, a statement substantially similar to the following and containing all the information elements specified:

PAPERWORK REDUCTION ACT

The collection[s] of information contained in this notice of proposed rulemaking has/have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3507(d)). Comments on the collection[s] of information should be sent to the Office of Management and Budget, Paperwork Reduction Project (XXXX-YYYY*), Washington, D.C., 20503, with copies to the [name of office or directorate] at the address previously specified.

* XXXX = Agency Code; YYYY = OMB Control Number, if known

The collection[s] of information in this proposed regulation [is/are] in section[s] [list CFR section(s) containing the collections of information]. This information is required by [name of office or directorate] to [brief description of purpose of reporting/recordkeeping requirement]. This information will be used to [brief description of how collected information will be used]. The likely [respondents and/or record keepers] are [use one or more of the following terms, as appropriate: individuals or households, State or local governments, Federal agencies or employees, non-profit institutions, and/or small businesses or organizations].

Estimated total annual reporting and/or recordkeeping burden: _____hours.

[Estimated average annual burden hours per respondent and/or record keeper: _____hours/minutes] OR [The estimated annual burden per respondent/record keeper varies from _____to _____hours/minutes, depending on individual circumstances, with an estimated average of _____hours/minutes].

Estimated number of respondents and/or record keepers: _____.

Estimated annual frequency of responses: _____. [For reporting requirements only]

b. Final Regulations Issued Pursuant to a Notice of Proposed Rulemaking.

(1) General. A final regulation that is issued pursuant to a notice of proposed rulemaking and that contains a reporting or recordkeeping requirement shall, at a minimum, include in the preamble a statement substantially similar to one of the following, as appropriate, and containing all the information elements specified:

PAPERWORK REDUCTION ACT

The collection[s] of information contained in this final regulation has/have been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3504(h)) under control number XXXX-YYYY*. [The estimated average burden associated with the collection[s] of information in this final rule is _____hours/minutes per respondent or record keeper] OR [The estimated annual burden per respondent/record keeper varies from _____to _____hours/minutes, depending on individual circumstances, with an estimated average of _____hours/minutes].

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to [name and address of office/directorate reports management office] and to the Office of Management and Budget, Paperwork Reduction Project (XXXX-YYYY*), Washington, D.C. 20503.

* Insert 8-digit OMB Control Number.

PAPERWORK REDUCTION ACT

The collection of information requirements contained in this final regulation have been submitted to the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3 504(h)). [The estimated average burden associated with the collection[s] of information in this final rule is _____ hours/minutes per respondent or record keeper] OR The estimated cost burden (non-labor expenses) for recordkeeping and/or reporting this information varies from _____ to _____. Final action by OMB with respect to these requirements is pending. The [name of office or directorate] will publish notification of OMB's final action in the Federal Register.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to [name and address of directorate/office **reports management office**] and to the Office of Management and Budget, Paperwork Reduction Project (XXXX-YYYY*), Washington, D.C. 20503.

*XXXX = Agency Code, YYYY = OMB Control Number, if known.

Note: In addition, the effective date provision of the final rule shall specify that the collection of information shall not become effective until further notification is published in the Federal Register.

(2) Special Requirements.

(a) In the case of a final rule, to be issued pursuant to a prior notice of proposed rulemaking, that contains a reporting or recordkeeping requirement, the office or directorate shall include in the preamble an explanation of how any reporting or recordkeeping requirements contained in the final regulation respond to the comments, if any, filed by OMB or the public, or an explanation of why it rejected those comments.

(b) If the final regulation rejects comments filed by OMB, the originating bureau or office shall consult with DHS General Counsel.

(c) Final Regulations Issued Pursuant to a Prior Temporary or Interim Regulation. A final regulation that is issued pursuant to a temporary or interim regulation and that contains a reporting or recordkeeping requirement shall, at a minimum, include in the preamble a statement substantially similar to one of the following, as appropriate, and containing all the information elements specified:

PAPERWORK REDUCTION ACT

The collection[s] of information contained in this final regulation has/have been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control number XXXX-YYYY*. [The estimated average burden associated with the collection[s] of information in this final rule is _____hours/minutes per respondent or record keeper] OR [The estimated annual burden per respondent/record keeper varies from _____to _____hours/minutes, depending on individual circumstances, with an estimated average of _____hours/minutes].

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to [name and address of office/directorate **reports management office**] and to the Office of Management and Budget, Paperwork Reduction Project (XXXX-YYYY*), Washington, D.C. 20503.

* Insert 8-digit OMB Control Number.

(d) Temporary or Interim and Final Regulations Issued Without a Prior Notice of Proposed Rulemaking. A temporary or interim or final regulation that is issued without a prior notice of proposed rulemaking and that contains a reporting or recordkeeping requirement shall, at a minimum, include in the preamble one of the following statements, as appropriate, and containing all the information elements specified:

(3) Regulations Not Issued With a Separate and Contemporaneous Cross-Reference Notice of Proposed Rulemaking.

PAPERWORK REDUCTION ACT

This regulation is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection[s] of information contained in this regulations [has/have] been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under control number XXXX-YYYY*. Comments concerning the collection[s] of information and the accuracy of estimated average annual burden, and suggestions for reducing this burden should be directed to the Office of Management and Budget, Paperwork Reduction Project (XXXX-YYYY*), Washington, D.C., 20503, with copies to the [name and address of office/directorate **reports management office**]. Any such comments should be submitted not later than [60 days from publication].

* Insert 8-digit OMB Control Number.

The collection[s] of information in this regulation [is/are] in section[s] [list CFR section(s) containing the collections of information]. This information is required by [name of office or directorate] to [brief description of purpose of reporting/recordkeeping requirement]. This information will be used to [brief description of how collected information will be used]. The likely [respondents and/or record keepers] are [use one or more of the following terms, as appropriate: individuals or households, State or local governments, Federal agencies or employees, non-profit institutions, and/or small businesses or organizations].

Estimated total annual reporting and/or recordkeeping burden: _____hours.

[Estimated average annual burden hours per respondent and/or record keeper: _____hours/minutes] OR [The estimated annual burden per respondent/record keeper varies from _____to _____hours/minutes, depending on individual circumstances, with an estimated average of _____hours/minutes].

Estimated number of respondents and/or record keepers: _____.

Estimated annual frequency of responses: _____. [For reporting requirements only]

(4) Regulations Issued With A Separate and Contemporaneous Notice of Proposed Rulemaking.

PAPERWORK REDUCTION ACT

This regulation is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection[s] of information contained in this regulation [has/have] been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under control number XXXX-YYYY*. [The estimated average annual burden associated with the collection[s] of information in this regulation is _____hours/ minutes per respondent or record keeper] OR [The estimated annual burden per respondent/record keeper varies from _____to _____hours/minutes, depending on individual circumstances, with an estimated average of _____hours/minutes.]

For further information concerning this collection of information, and where to submit comments on the collection[s] of information and the accuracy of the estimated burden, and suggestions for reducing this burden, refer to the preamble to the cross-reference notice of proposed rulemaking published elsewhere in this issue of the Federal Register.

* Insert 8-digit OMB Control Number.

7. Control Numbers. Directorates and offices shall ensure that control numbers assigned by the Office of Management and Budget to reporting and recordkeeping requirements contained in any final or temporary or interim regulation are published in the Federal Register, and the Code of Federal Regulations if such regulation will be codified therein.

8. Review of Previously Approved Regulations. Directorates and offices shall submit regulations previously approved by OMB under 44 U.S.C. 3504(h) of the Paperwork Reduction Act of 1980 or 3507(d) of the Paperwork Reduction Act of 1995 in accordance with procedures prescribed by the Under Secretary for Management.

PART IV

FEDERALISM (E.O. 13132)

1. Introduction. Offices and directorates shall review proposed regulatory actions to ensure that they are consistent with the principles of E.O. 13132.
2. Federalism Assessment.
 - a. General. A Federalism Assessment shall be prepared with respect to any regulatory action that raises significant federalism implications, or when otherwise directed by the General Counsel. In any case where a Federalism Assessment is required, such assessment shall be approved by the office or directorate head and shall accompany the regulation through all review levels. Directorates and offices are advised that all Federalism Assessments will be provided to the OMB in conjunction with any submission that otherwise is required to be made pursuant to E.O. 12866.
 - b. Content. Each Federalism Assessment shall:
 - (1) Contain a certification of the General Counsel that the regulation has been assessed in light of the principles, criteria, and requirements stated in sections 2 through 4 of E.O. 12612.
 - (2) Identify any provision or element of the regulatory policy that is inconsistent with the principles, criteria, or requirements stated in sections 2 through 4 of E.O. 12612.
 - (3) Identify the extent to which the regulatory policy imposes additional costs or burdens on the States, including the likely source of funding for the States and the ability of the States to fulfill the purposes of the regulatory policy.
 - (4) Identify the extent to which the policy would affect the State's ability to discharge traditional State governmental functions, or other aspects of State sovereignty.
3. Federal Register Statement. A directorate head, policy official, or the General Counsel may determine that a regulatory policy raises federalism concerns that should be addressed in the preamble to an advance notice of proposed rulemaking, a notice of proposed rulemaking, or other document for which public comments are solicited. Whenever an office or a directorate publishes in the Federal Register a regulation, it shall include in the preamble a statement substantially similar to one of the following, as appropriate:

- a. "This document is not subject to the requirements of E.O. 13132. [Brief explanation of basis for determination]."
- b. "This document is subject to the requirements of E.O. 13132. "[Statement is followed by appropriate discussion to satisfy E.O. 13132]

PART V

GOVERNMENTAL ACTIONS AND INTERFERENCE WITH CONSTITUTIONALLY PROTECTED PROPERTY RIGHTS (E.O. 12630)

1. Applicability.
 - a. Except as provided in paragraph 1.b, this Part applies to any regulation that affects or may affect the use or value of private property.
 - b. This Part does not apply to regulations:
 - (1) That do not affect the use or value of private property.
 - (2) That reduce federal restrictions on the use or value of private property.
 - (3) Concerning property held in trust by the United States or held with respect to treaty negotiations with foreign countries.
 - (4) Concerning agency plans and studies.
 - (5) Concerning military property.
 - (6) Exercising the power of eminent domain.
 - (7) Issued pursuant to 5 U.S.C. 553(a)(1) with respect to a military or foreign affairs function of the United States.
 - (8) Issued in furtherance of pending or imminent litigation, whether judicial or administrative.
 - (9) Issued by the Office of the Inspector General and bureau offices performing functions similar to those prescribed by the Inspector General Act of 1978, as amended.
 - (10) Concerning activities specifically identified in supplemental guidelines as may be issued by the Attorney General.
2. Identification of Takings: Required Documentation.
 - a. General. Offices and directorates shall review proposed regulatory actions to ensure that they are consistent with the principles of E.O. 12630 and implementing Guidelines issued by the Attorney General. General Counsel shall be consulted in any case where an office or directorate believes that a regulatory action may raise takings implications.

b. Takings Implication Assessment. Except with respect to regulatory actions for the protection of public health and safety (see paragraph 2.c.) where a proposed regulatory action affects or may affect the use or value of private property under prevailing case law or guidelines promulgated by the Attorney General, the initiating office or directorate shall prepare a Takings Implications Assessment (TIA). Each TIA shall be approved by the office or directorate head, accompany the regulation through all review stages, and include the following information:

- (1) An assessment of the likelihood that the regulation may effect a taking for which compensation is due in light of the principles referenced in E.O. 12630, applicable guidelines promulgated by the Attorney General, and applicable case law.
- (2) An identification and discussion of alternatives, if any, to the regulation, that would achieve the desired result in a manner that would reduce intrusion on the use or value of private property.
- (3) To the extent it is determined that the regulation effects or may effect a taking for which compensation is due, an estimate, based on available data, of the potential financial exposure to the Government should a court find the regulation to be a taking.

Offices and directorates are advised that these documents will be provided to OMB upon request if the regulation is subject to E.O. 12866.

c. Regulations for the Protection of Public Health and Safety. If a regulation would regulate private property for the protection of public health or safety (see Part VI if the regulatory action responds to an emergency situation), the originating office or directorate shall prepare a document, that shall be approved by the office or directorate head and shall accompany the regulation through all review levels, that:

- (1) Identifies clearly, with as much specificity as possible, the public health or safety risk created by the private property use that is the subject of the regulatory action.
- (2) Establishes that such proposed action substantially advances the purpose of protecting public health and safety against the specifically identified risk.
- (3) Establishes to the extent possible that the restrictions imposed on the private property are not disproportionate to the extent to which the use contributes to the overall risk.

(4) Estimates, to the extent possible, the potential cost to the government in the event that a court later determines that the action constituted a taking.

Offices and directorates are advised that these documents will be provided to OMB upon request if the regulation is subject to E.O. 12866.

d. Coordination With E.O. 12866.

(1) Submission Required. If a regulation is subject to OMB review pursuant to E.O. 12866 (see Part I) and the regulation (a) is a significant regulatory action, or (b) poses a substantial risk that a taking of private property may result or insufficient information as to facts or law exists to enable an accurate assessment of substantial risk, the originating directorate or office shall prepare a submission for OMB, that shall be approved by the office or directorate head and accompany the regulation through all review levels.

(2) Content. Any required submission shall summarize any identified takings implications of the regulation and address the merits of the regulation in light of those implications.

PART VI

EMERGENCY RULES ISSUED WITHOUT PRIOR NOTICE AND PUBLIC PROCEDURE UNDER AN EXEMPTION TO 5 U.S.C. 553

1. General. If a directorate or office determines, because of an emergency situation, or statutory or judicial deadline, to issue any regulation that is subject to E.O. 12866, an analysis requirement of the Regulatory Flexibility Act, the Paperwork Reduction Act, a Federalism Assessment, or a Takings Impact Analysis, the directorate or office shall immediately consult with General Counsel. No directorate or office shall issue any such regulation or rule without review by the General Counsel and the Under Secretary for Management in accordance with this Directive.
2. Special Requirements for Regulations Not Issued for Public Comment or to Become Effective in Less than 30 Days from Publication. The preamble to a regulation that is issued without opportunity for notice and public comment, or is effective less than 30 days from the date of publication, shall contain a specific statement explaining, and a citation to the provisions of 5 U.S.C. 553 that authorize, such action.
3. Effect on E.O. 12866 Review. When a regulation would otherwise be subject to review by OMB under E.O. 12866, the following procedures apply and General Counsel should be consulted immediately:
 - a. Emergencies. When an emergency situation requires that a rule be issued without prior review by OMB under E.O. 12866, the initiating directorate or office shall include in the preamble a statement of the reasons why in light of the pending emergency it is impracticable for the directorate or office to comply with the review provisions of E.O. 12866. If the regulation is economically significant and a Regulatory Impact Analysis normally would be required pursuant to Part I, the directorate or office shall prepare an analysis as directed by General Counsel.
 - b. Statutory or Judicial Deadlines. When a regulation that responds to a statutory or judicial deadline is published in the Federal Register or otherwise issued without prior review by OMB under E.O. 12866, the directorate or office shall include in the preamble a statement of the reasons why it is impracticable for the directorate or office to comply with the review provisions of E.O. 12866. In the case of a significant regulatory action, directorates and offices are advised that the preparation of a Regulatory Impact Analysis may be required by OMB.

4. Effect on Regulatory Flexibility Analyses.

a. Initial Regulatory Flexibility Analysis (IRFA). When a notice of proposed rulemaking responds to an emergency situation or statutory or judicial deadline, and if such notice otherwise would be subject to the analysis requirements of Part II, the directorate or office head, with the concurrence of the appropriate policy official and General Counsel, may determine that the preparation of an IRFA is impracticable. In such case the transmittal memorandum to the Under Secretary for Management shall explain why preparation of the analysis is impractical. The directorate or office shall publish in the preamble to the notice of proposed rulemaking a finding and explanation that the notice is being issued in response to an emergency or statutory or judicial deadline and that compliance with the requirements of the Regulatory Flexibility Act concerning preparation of an IRFA is impracticable.

b. Final Regulatory Flexibility Analysis (FRFA).

(1) When a final or temporary or interim regulation responds to an emergency situation or statutory or judicial deadline, and if such regulation otherwise would be subject to the analysis requirements of Part II, the directorate or office head may, with the concurrence of the appropriate policy official and General Counsel, delay preparation of the FRFA. In such case the transmittal memorandum to the Under Secretary for Management shall explain the need to delay preparation of the analysis.

(2) The originating directorate or office may delay publication of the final analysis for a period of not more than 180 days after the date of publication of the regulation in the Federal Register. Upon publication of the regulation in the Federal Register, the directorate or office shall include a statement that the regulation is being issued in response to an emergency, or statutory or judicial deadline, which makes timely compliance with the requirement of a FRFA impracticable.

(3) The directorate or office shall prepare and transmit a FRFA to General Counsel not later than 150 days after publication of the regulation. Directorates and offices are advised that the Regulatory Flexibility Act provides that failure to publish the FRFA (or advise the public how copies may be obtained) within 180 days after publication of the regulation will cause the regulation to lapse and have no effect (5 U.S.C. 608(b)).

5. Effect on Paperwork Reduction Act Review.

- a. Notices of Proposed Rulemaking. Notices of proposed rulemaking that respond to an emergency or a statutory or judicial deadline that contain a reporting or recordkeeping requirement remain subject to the submission requirements of 44 U.S.C. 3507(d) and applicable regulations promulgated by OMB (see Part III).
 - b. Final or Temporary or Interim Regulations. Final or temporary or interim regulations that respond to emergency situations or to statutory or judicial deadlines and contain a reporting or recordkeeping requirement generally are subject to review by OMB prior to issuance pursuant to 44 U.S.C. 3507 and applicable regulations promulgated by OMB (see Part III). Directorates and offices proposing issuance of such regulations or rules should promptly consult with General Counsel. Directorates and offices proposing issuance of such notices of proposed rulemaking, as well as such final or temporary or interim regulations, should take note of the “Emergency Processing” provisions in 5 CFR 1320.13.
6. Effect on Federalism Assessment. Where a Federalism Assessment (see Part IV) is required for any regulation that responds to an emergency situation or statutory or judicial deadline, and such regulation would otherwise be subject to review by OMB pursuant to E.O. 12866 (see Part I), the procedures of paragraph 3 apply. Offices and directorates shall promptly consult with General Counsel if the regulation is not otherwise subject to review by OMB pursuant to E.O. 12866.
7. Effect on Takings Analysis Where Regulatory Action is Taken for the Protection of Public Health or Safety. In any instance in which there is an immediate threat to health and safety that constitutes an emergency requiring immediate response, the Takings Analysis required by Part V may be performed upon completion of the emergency action.

FORMAT FOR REGULATORY REVIEW SUBMISSIONS

1. General. Directorates and offices shall obtain from the Under Secretary for Management a unique identifier for each regulation that shall be displayed on the regulation, transmittal memorandum, and any other submissions or documents prepared with respect to such regulation.

2. Folders. Each transmittal must be in a folder, with the Clearance Sheet prescribed by the Under Secretary for Management on the outside cover.

a. The RIGHT side of the folder must contain ONLY the following materials in the order stated below:

- (1) Original transmittal memorandum from the policy official to the Under Secretary for Management (or from a directorate or office head through the policy official to the Under Secretary for Management).
- (2) One copy of the regulation.
- (3) One copy of the Regulatory Impact Analysis (if applicable and not contained in the regulatory document in full).
- (4) One copy of the Regulatory Flexibility Analysis (if applicable and not contained in the regulatory document in full).
- (5) One copy of the Federalism Assessment (if applicable).
- (6) One copy of the Takings Impact Analysis and/or OMB submission (if applicable).
- (7) Background information (optional).

b. The LEFT side of the folder must contain ONLY the following materials in the order stated:

- (1) Five copies of the transmittal memorandum to the Under Secretary for Management (with no attachments).
- (2) A completed "Regulatory Profile," (Enclosure 1) for each regulation in the folder, with the following attachments:
 - (a) Documents Subject to OMB Review under E.O. 12866: One copy of the SF-83 (parts I and II completed).

ENCLOSURE 1

Note: Separately provide General Counsel with four SF-83's (parts I and II completed), each attached to a copy of the regulation and, unless contained in the regulation in full, any required Regulatory Impact Analysis, Regulatory Flexibility Analysis, Federalism Assessment, and Takings Impact Submission (not Takings Assessment) attached.

(b) Regulations Subject to the Paperwork Reduction Act. One copy of the SF-83 (parts I and III completed).

(c) Regulations Subject to Regulatory Flexibility Act Analysis Requirements.

i. If the analysis is contained in full in the regulation, provide one additional copy of the regulation.

ii. If the analysis is not contained in full in the regulation, provide one additional copy of the regulation and the analysis.

(3) Two copies of the transmittal memorandum, each with copy of the regulation and, unless contained in the regulatory document in full, any required Regulatory Impact Analysis, Regulatory Flexibility Analysis, Federalism Assessment, and Takings Impact Analysis and/or Submission attached.

REGULATORY PROFILE

Office/Directorate and Unique
Identifying Number

1. Type of Document

_____ Proposed Regulation/NPRM

_____ Final Regulation Without Prior NPRM

_____ Final Regulation With Prior NPRM

_____ Temporary or Interim Regulation

_____ Advance Notice of Proposed
Rulemaking

_____ Other

2. If a FINAL RULE or TEMPORARY OR INTERIM RULE, is the effective date less
than 30 days from date of publication? _____ Yes _____ No

3. Is issuance of the document subject to a statutory or judicial deadline, or does
the document respond to an emergency situation? _____ No _____ Yes

4.

a. Is the document subject to review by OMB under Executive Order 12866?

_____ Yes (attach SF-83 and answer b. below) _____ No

b. If "Yes" to a., is the document an Economically Significant Rule?

_____ Yes _____ No

c. If "Yes" to b., has a PRIA or FRIA been prepared? _____ Yes _____ No

5.

a. Does the document limit or preempt the policymaking discretion of the
States?

_____ No _____ Yes (answer b. below)

b. If "yes" to a., has a Federalism Assessment been prepared?

_____ Yes _____ No

ENCLOSURE 2

6.

a. Does or could the document affect constitutionally protected property rights?

____ No ____ Yes (answer b. below)

b. If "Yes" to a., has a Takings Assessment/OMB Submission been prepared?

____ Yes ____ No

7.

a. Is the document likely to have a significant economic impact on a substantial number of small businesses or other small entities? ____ No ____ Yes (answer b. below)

b. If "Yes" to a., has a Regulatory Flexibility Analysis been prepared?

____ Yes ____ No

8. If a ANPRM, NPRM or FINAL/TEMPORARY/INTERIM REGULATION WITHOUT PRIOR NPRM, does the document contain a reporting or recordkeeping requirement subject to the Paperwork Reduction Act? ____ No ____ Yes (attach SF-83)

9. If a FINAL/TEMPORARY/INTERIM REGULATION WITH PRIOR NPRM and the document contains a reporting or recordkeeping requirement:

a. Was the NPRM submitted to OMB under the Paperwork Reduction Act?

____ Yes (answer b. below) ____ No (submission now required; attach SF-83)

b. If "Yes" to a., did OMB approve the information collection in the NPRM?

____ Yes (OMB # _____; answer c. below) ____ No (answer d. below)

c. If "Yes" to b., is the collection of information materially different from that contained in the NPRM?

____ No ____ Yes

d. If "No" to b.:

____ The regulation has been modified to address OMB's objections.

____ The regulation retains the disapproved collection