



U. S. Department of
Transportation

RULEMAKING REQUIREMENTS

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N.B.: This document provides references to DOT guidance manuals but not to less formal guidance documents, such as Assistant General Counsel memoranda or email.

STATUTES

I. Administrative Procedure Act (APA); Informal Rulemaking ([5 U.S.C. §553](#)).

- A. Coverage. The APA's informal rulemaking requirements apply to all rules unless excepted or a specific statute provides otherwise. "Rule" includes such terms as "regulation" and "amendment."
- B. Definition of "Rule". There are basically three types. The legal distinctions are not always clear, and an agency statement can contain more than one kind of rule. The categories are:
 - 1. Legislative/substantive rules. These are rules issued under statutory authority. They implement the statute. They have the force and effect of law (i.e., they are binding on the agency, the public, and the courts).
 - 2. Non-legislative rules.
 - a. Interpretative (or interpretive) rules. These tell the public what the agency thinks the statutes and rules it administers mean.
 - b. General statements of policy. These tell the public prospectively how the agency plans to exercise a discretionary power.
 - 3. Management and procedural rules. There are two subcategories:
 - a. Management or personnel. These are rules that involve the running or supervising of the agency's business. They concern the agency and do not affect the public.
 - b. Organization, procedure, or practice. These are rules that describe the agency's structure and functions and the way in which its determinations are made.
- C. Rule of Particular Applicability. The law is not clear on this subject, and deletion of the term from the APA would probably not have a significant effect. The term was intended to cover rulemakings on such things as the setting of future rates.
- D. Exceptions. Rulemakings involving military or foreign affairs functions, or matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts, are not covered.
- E. Requirements.
 - 1. Notice of proposed rulemaking (NPRM). An NPRM must be issued before any final action can be taken.

- a. Publication. The NPRM must be published in the *Federal Register*, unless there is special service on all persons subject to the regulation or such persons have actual notice.
 - b. Contents. It must provide the legal authority for the proposed rule and either its terms or substance or a description of the subjects and issues involved.
 - (1) Preamble. Any material other than actual rule language is referred to as the “preamble.”
 - (2) Scope of the Notice. An agency cannot issue a final rule unless it is within the “scope of the notice”; i.e., a final rule cannot adopt a provision if the NPRM did not clearly provide notice to the public that the agency was considering adopting it.
 - c. Exceptions. Unless notice or hearing is required by statute, it is not required under the APA for interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or when the agency states in the final rule that it has good cause, and provides reasons therefore, that notice and public procedure are “impracticable, unnecessary, or contrary to the public interest.”
 - d. Public Comment. The agency must invite interested persons to comment on the proposed rule and may provide an opportunity for oral presentations. Among other things, public hearings or meetings make it easier for some people to comment on the rulemaking, offer an opportunity for the agency to ask questions of a commenter, and can make it easier for commenters to hear opposing viewpoints.
 - e. “Informal” vs. “Formal” Rulemaking. The process of “notice and comment” rulemaking is referred to as “informal rulemaking” (subject to section 553 of the APA). When rules are statutorily required “to be made on the record after opportunity for an agency hearing,” the trial-type or adversary process is referred to as “formal rulemaking” (subject to sections [556](#) and [557](#) of the APA); with the exception of limited proceedings such as ratemaking, formal rulemaking is rarely used.
2. Final Rule.
- a. Basis and Purpose. After consideration of the public comment, the agency may issue a final rule, which must include a concise general statement of its basis and purpose.

b. Publication/Availability (5 U.S.C. §552).

- (1) Procedural rules and substantive rules, policy statements and interpretations of general applicability. Agencies must publish these rules in the *Federal Register*. A person may not “be required to resort to or be adversely affected by,” a rule that an agency is required to publish if it is not published, unless the “person has actual and timely notice” (e.g., personal service) of the rule.
- (2) Interpretations and policy statements of general applicability not published in the Register. Agencies must make these documents available for public inspection and copying.
- (3) Interpretations, policy statements, and staff manuals or instructions. If these documents are not published or actual and timely notice is not provided and they affect a member of the public, they must be electronically available before the agency can rely on them, use them, or cite them as precedent.
- (4) Rules of Particular Applicability. There are no publication requirements for rules of particular applicability.

c. Effective Date. Final rules shall not be made effective in less than thirty days after publication or service except for:

- (1) Substantive rules, which grant or recognize an exemption or relieves a restriction.
- (2) Interpretative rules and statements or policy.
- (3) Good cause. As otherwise provided by the agency for good cause found and published with the rule.

3. Petitions. The public has the right to petition for the issuance, amendment, or repeal of a rule.

4. Exemptions and Waivers. Courts have made it clear that the public has a right to petition for exemption from a rule. Such exemptions are generally granted only for unique circumstances not considered during the rulemaking. In addition, a statute may specifically provide an agency with authority to exempt individuals from particular rules and may even provide the conditions for such an exemption. Some use the term “waiver” interchangeably with “exemption.” DOT tries to maintain a distinction by generally using “waiver” to refer to a specific provision in a rule that permits an individual to be exempted from complying with the general rule if specified conditions are met.

- F. Additional Steps. Agencies can supplement but not waive the requirements of the APA. Examples of extra steps DOT uses are:
1. ANPRM. Agencies issue advance notices of proposed rulemaking when, e.g., they know there is a problem but do not have sufficient information to know the appropriate solution to propose.
 2. SNPRM. Agencies issue supplemental notices of proposed rulemaking after they have issued an NPRM when, e.g., they wish to obtain public comment on new factual information or alternative proposals before issuing a final rule.
 3. IFR. Agencies issue interim final rules when they have met the requirements for issuing a final rule but, e.g., wish to obtain public comment on the provisions of that final rule and indicate that, after reviewing the comments, they may modify the interim final rule and issue a “final” final rule. (It is not a substitute for an otherwise required NPRM.)
- G. Direct Final Rulemaking.
1. Purpose. This is a process used to expedite the issuance of rules for which the agency expects no adverse comment.
 2. Process. Generally, the agency publishes the rule in the *Federal Register* with a statement that, unless adverse comment is received within a certain time period, the rule will become effective on a specified date. If the agency receives no public comment, it publishes a notice to that effect in the *Register*. If adverse comment is received, the rule is withdrawn and the agency may republish it as an NPRM.
 3. Authority. The agency authority for this process is that notice and comment rulemaking would be “unnecessary” under the APA “good cause” exception, but it still provides an expedited process for public comment.
 4. Procedural Rules. DOT agencies that use this process first issue procedural rules describing the process and the matters for which it will be used.
- H. Dockets.
1. Documents. DOT agencies place each rulemaking or support document (e.g., proposed and final rule, economic or environmental analyses) and all public comments received in a public docket. They may also place other documents (e.g., technical studies) in the docket. Generally, they do not place internal correspondence with other executive branch agencies in the docket.

2. Related Requirements. E-Government Act (Pub. L. No. 107-347 (2002)) and Privacy Act (5 U.S.C. §552a).

- I. Judicial Review (5 U.S.C. §§701-706). If challenged in court under the APA, an agency rulemaking action is subject to standards whereby it can be held unlawful and set aside if it is found to be “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;” unconstitutional; or in violation of statute or a procedural law. The court can also “compel agency action unlawfully withheld or unreasonably delayed.”
- J. Negotiated Rulemaking Act (5 U.S.C. §§561-570a). Agencies can convene advisory committees made up of representatives of interests affected by the issues involved to negotiate an NPRM and a final rule. This act amended the APA to provide agencies the clear authority to employ this process.

II. Regulatory Flexibility Act (5 U.S.C. §§601-612).

- A. Impacts. Agencies must consider the impact of their rulemakings on “small entities” (small businesses, small organizations and local governments).
- B. Regulatory Flexibility Analyses (RFA). When an agency is required by 5 U.S.C. §553 to publish an NPRM, an RFA is required for both the notice and the final rule if the rulemaking could “have a significant economic impact on a substantial number of small entities.”
- C. Contents of RFA. Among other things, the agency must estimate the number of small entities to which the rule will apply or explain why an estimate is not available; describe the skills necessary to prepare required reports; explain what it has done to minimize the significant burdens for small entities; and explain why it chose the alternative it did, as well as explaining why it rejected other alternatives that would have minimized burdens for small entities.
- D. Certification in Lieu of RFA. If an RFA is not required, the agency must certify in the rulemaking document that the rulemaking will not “have a significant economic impact on a substantial number of small entities.” They agency must provide a factual basis for any certification, not just the reasons.
- E. Agenda. An agenda of rulemakings having significant economic impacts on a substantial number of small entities must be published semi-annually.
- F. Reviews. Existing regulations must be reviewed periodically to determine whether changes can be made to lessen or eliminate their impact on small entities.
- G. Judicial Review. Judicial review of agency compliance with most of the Act is permitted.

- H. **Executive Order 13272, Proper Consideration of Small Entities in Agency Rulemaking (2002).** This executive order requires the following:
1. **SBA’s Office of Advocacy Review.** Agencies must “notify” the Small Business Administration’s Office of the Chief Counsel for Advocacy (Advocacy) of draft rules that may have a significant economic impact on a substantial number of small entities when the draft rule is submitted to the Office of Management and Budget’s (OMB’s) Office of Information and Regulatory Affairs (OIRA) under [E.O. 12866](#) or, if submission to OIRA is not required, “at a reasonable time prior to publication of the rule.” Advocacy is authorized to submit comments on the draft rule.
 2. **Consideration of Advocacy Comments.** Agencies must give “every appropriate consideration” to any Advocacy comments on a draft rule. If consistent with legal requirements, agencies must include in final rule preambles their response to any written Advocacy comments on the proposed rule, unless the agency head certifies that the public interest is not served by such action.
 3. **Agency Procedures.** Agencies must issue procedures ensuring that the potential impact of their draft rules are “properly considered.”
- I. **Advocacy Guidance.** See [“A Guide for Government Agencies – How to Comply with the Regulatory Flexibility Act” \(2003\).](#)
- J. **DOT Guidance.** See “Department of Transportation Policies and Procedures for Implementing Executive Order 13272, ‘Proper Consideration of Small Entities in Agency Rulemaking’” (February 2003). See, also, DOT “Guidance Manual on the Small Business Regulatory Enforcement Fairness Act of 1996” (1996).

III. **Small Business Regulatory Enforcement Fairness Act (Pub. L. No. 104-121 (1996), Subtitles A-D)**

- A. **Compliance Guides (5 U.S.C. §601 note)**
1. **Guides.** Agencies must prepare and publish one or more guides explaining the actions a small entity is required to take to comply with “each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis” (FRFA) under the Regulatory Flexibility Act ([5 U.S.C. §604](#)).
 2. **Evidence.** Although the substance of the guide is not subject to judicial review, its contents “may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages” in any

civil or administrative action against a small entity.

B. Informal Guidance (5 U.S.C. §601 note)

1. Program. Agencies are required to have a program for answering small entity inquiries “concerning information on, and advice about, compliance with” statutes and regulations within the agency’s jurisdiction, “interpreting and applying the law to specific sets of facts supplied by the small entity.”
2. Evidence. This guidance “may be considered as evidence of the reasonableness or appropriateness of any proposed fines, penalties or damages sought against” a small entity in any civil or administrative action.

C. SBA Enforcement Ombudsman (15 U.S.C. §657)

1. Ombudsman. The Administrator of the Small Business Administration (SBA) is required to designate a Small Business and Agriculture Regulatory Enforcement Ombudsman (Ombudsman).
2. Annual Report. The Ombudsman is required to report annually to Congress and the affected agencies on the enforcement activities of agency personnel, including a rating of the agency’s responsiveness to small businesses, “based on substantiated comments received from small business concerns and the” Regional Small Business Regulatory Fairness Boards (Boards). The Ombudsman must provide agencies an opportunity to comment on draft reports and must include in the report a section with agency comments that are not addressed in revisions to the draft.

D. Regional Small Business Regulatory Fairness Boards (15 U.S.C. §657).

1. Boards. The SBA Administrator is required to establish Boards in each SBA regional office; they consist of five members from small business concerns.
2. Reports to Ombudsman. The Boards provide the Ombudsman with advice on small business concerns about agency enforcement activity; reports “on substantiated instances” of excessive agency enforcement actions against small business concerns, including their findings or recommendations on agency enforcement policy or practice; and comments on the Ombudsman’s annual report.

E. Rights of Small Entities in Enforcement Actions (5 U.S.C. §601 note)

1. Reduction or Waiver of Penalties. Each agency that regulates small entities must have a policy or program “to provide for the reduction, and under appropriate circumstances for the waiver, of civil penalties for violations of

a statutory or regulatory requirement by a small entity.”

2. Considerations, Conditions, or Exclusions. “Under appropriate circumstances, an agency may consider ability to pay in determining penalty assessments on small entities.” Subject to other statutes, the agency policy or program must have conditions or exclusions.
 3. Presidential Directive. See [Presidential memorandum of March 4, 1995](#), concerning fines on small businesses.
- F. Other Requirements. Other provisions of the Act applicable to rulemaking are covered in this document under the Regulatory Flexibility Act or the Congressional Review of Agency Rulemaking statute.
- G. DOT Guidance. See DOT “Guidance Manual on the Small Business Regulatory Enforcement Fairness Act of 1996” (1996).

IV. **Congressional Review of Agency Rulemaking ([5 U.S.C. §§801-808](#))**

- A. Submission of Rules. The statute requires the submission of all final rules (and supporting documents) to Congress and the Comptroller General before the rules can take effect.
- B. Rule. A “rule” is as defined in [5 U.S.C. §551](#), with very few, limited exceptions.
- C. Effective Date.
1. Non-Major Rule. Non-major rules can take effect “as otherwise provided by law” after submission to Congress.”
 2. Major Rule.
 - a. General. A major rule (one that the Office of Management and Budget (OMB) finds is a costly rule, generally over \$100 million per year) cannot take effect for at least 60 days after it is submitted to Congress; there are complex provisions involved that could prevent major rules from becoming effective through the end of a Congress, if a joint resolution is introduced.
 - b. Good Cause. A major rule can take effect earlier if the agency, for good cause, finds “that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.”
 - c. Presidential Determination. The President may determine that a rule should take effect regardless of the statute if it is necessary for:

- (1) Imminent threat to health or safety or other emergency.
 - (2) Enforcement of criminal laws.
 - (3) National security.
- d. Submission Date. A major rule submitted within 60 session/legislative days before Congress adjourns a session is treated as having been submitted on the 15th session/legislative day of the next session; under these circumstances, the rule can “take effect as otherwise provided by law including” 5U.S.C.§801.
- D. Congressional Disapproval Procedures. Congress can always overturn a rule by enactment of legislation, but this statute contains procedures for expedited review and disapproval. Under this statute, Congress can only disapprove the rule; it cannot change it. If a rule is overturned under these procedures, it is “treated as though ... [it] had never taken effect.”
- E. Substantially the Same. If the rule is disapproved, the agency can not adopt a “substantially the same” rule, unless authorized by a new statute
- F. Judicial Review. “No determination, finding, action or omission” under the statute is subject to judicial review. No court (or agency) may infer any intent from Congressional action or inaction.
- G. OMB Guidance. See [OMB memorandum of March 30, 1999](#), on “Guidance for Implementing the Congressional Review Act. ”
- V. The Unfunded Mandates Reform Act; Title II – Regulatory Accountability and Reform (2 U.S.C. §§1532-1538)**
- A. Effects Assessments. Agencies are required to assess the effects of Federal regulatory actions on state, local and tribal governments and on private industry, except to the extent the regulations incorporate requirements specifically set forth in law.
- B. Written Statements.
- 1. Requirement. Unless otherwise prohibited by law, agencies must prepare a written statement prior to issuing NPRMs and final rules (for which a “general notice of proposed rulemaking was published”) that include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” (see

[DOT Guidance on “Threshold of Significant Regulatory Actions Under the Unfunded Mandates Reform Act of 1995” \(2008\)](#)). The statement may be included as part of another analysis.

2. Contents. Each written statement must include, among other things, an analysis of the costs and benefits and a description of prior consultations with and input from State, local, or tribal governments.
 3. Federal Mandates. These are rules that impose an enforceable duty, except a:
 - a. Condition of Federal assistance.
 - b. Duty arising from participation in a voluntary Federal program (with certain exceptions).
- C. Regulatory Alternatives. Where a written statement is required, the agency must “identify and consider a reasonable number of regulatory alternatives, and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objective of the rule” or explain why it could not.
- D. Preamble Summary. Each agency must include a summary of any required statement in the NPRM’s or the final rule’s preamble.
- E. Report to Congress. OMB must annually report to Congress on agency compliance with the Act, including a certification, with a written explanation, of agency compliance with the least burdensome option requirement.
- F. Small Government Agency Plans. Before imposing regulatory requirements that may “significantly or uniquely” affect small governments, agencies must develop a plan to
1. Notify affected small governments of the requirements;
 2. Allow meaningful and timely input by them into the development of the rule; and
 3. Inform, educate, and advise the affected entities of the requirements.
- G. State, Local, and Tribal Government Input.
1. Process. Agencies are required to develop an effective process for meaningful and timely input from State, local and tribal governments in the development of rules with significant intergovernmental mandates.

2. FACA Exemption. Agency meetings with State, local or tribal elected officers (or their authorized designees) solely to exchange views, information, or advice relating to the management or implementation of Federal programs that share intergovernmental responsibilities or administration are exempt from the Federal Advisory Committee Act.
- H. Judicial Review. An agency action can be challenged for failure to prepare a written statement or a small government agency plan. Preparation can be compelled, but inadequacy or failure to prepare cannot be used to stay, enjoin, invalidate or otherwise affect the rule.
- I. Executive Order 12875, “Enhancing the Intergovernmental Partnership” (1993). This executive order also contains requirements concerning unfunded mandates.
- J. OMB Guidance. See OMB memorandum of September 21, 1995, on “Guidelines and Instructions for Implementing Section 204, ‘State, Local, and Tribal Government Input,’ of Title II of Public Law 104-4.”

VI. Paperwork Reduction Act (44 U.S.C. §§3501-3520).

- A. Burdens. The Act requires that agencies consider the impact of paperwork and other information collection burdens imposed on the public.
- B. Coverage. It applies to all agency actions, not just rulemakings. It was amended (in 1995) to include “disclosure to third parties or the public.”
- C. Reduction. It mandates specific reductions in the amount of paperwork requirements imposed by agencies.
- D. OMB Approval. It requires specific approval by OMB of any new requirements for collection of information imposed on ten or more persons by an agency; without such approval, the agency lacks the authority to enforce any such requirement.
- E. Enforcement. Agencies must inform respondents that a response is not required unless the collection of information displays a valid OMB control number.
- F. Information Collection Budget (ICB). Annually, each agency must submit an ICB for OMB approval. The ICB covers existing requirements, new proposals, and planned reductions.
- G. OMB Regulations. See 5 C.F.R. Part 1320, “Controlling Paperwork Burdens on the Public,” for supplemental requirements.

- H. Electronic Information. The **Government Paperwork Elimination Act (44 U.S.C. §3504 note)** requires that, by October 21, 2003, agencies allow “electronic maintenance, submission, or disclosure of information, when practicable as a substitute for paper” and “for the use and acceptance of electronic signatures, when practicable.”
- I. Electronic Signature. The **Electronic Signature in Global and National Commerce Act (15 U.S.C. §§7001-7031)** establishes the legal equivalence, in private commerce, between legally-required written and electronic documents and “pen-and-ink” and electronic signatures. To the extent Federal law or regulation requires the retention of a document or information, this Act allows electronic retention; agencies are permitted to require paper records in certain circumstances.
- J. OMB Guidance. See [OMB/OIRA memorandum of May 22, 1995](#), on “Preparing to Implement S.244, the ‘Paperwork Reduction Act of 1995’”; [OMB memorandum of April 25, 2000](#), on “OMB Procedures and Guidance on Implementing the Government Paperwork Elimination Act”; [OMB/OIRA memorandum of July 25, 2000](#), on “Achieving Electronic Government: Instruction for Plans to Implement the Government Paperwork Elimination Act”; and [OMB memorandum of September 25, 2000](#), on “OMB Guidance on Implementing the Electronic Signatures in Global and National Commerce Act.”

VII. Privacy Act (5 U.S.C. §552a) and Related Requirements.

- A. Nondisclosure. Agencies must not disclose any record that is contained in “a group of records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual” to any person or another agency, except as authorized in writing by the individual, unless disclosure would meet specified conditions, including a routine use described in the system of records.
- B. Privacy Impact Assessments.
 - 1. **FY 2005 Omnibus Appropriations Act, Pub. L. No. 108-447, division H, § 522.** Specified agencies, including DOT, must evaluate “regulatory proposals involving collection, use, and disclosure of personal information by the Federal Government” and conduct a privacy assessment of their proposed rules “on the privacy of information in an identifiable form, including the type of personally identifiable information collected and the number of people affected.”
 - 2. Other requirements. See, also, [E-Government Act](#).
 - 3. DOT Guidance. See the DOT website “[Privacy Impact Assessments](#)” and the DOT document “[Privacy Impact Assessment Information Gathering](#).”

VIII. Quality, Objectivity, Utility, and Integrity of Information (Treasury and General Government Appropriations Act for FY 2000, [Pub. L. No.106-554; § 515](#)).

- A. Agency-Disseminated Information. OMB must provide “guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of” the Paperwork Reduction Act.
- B. Agency Guidelines. Agencies must issue guidelines implementing OMB’s guidelines and establishing administrative mechanisms that allow affected persons to seek and obtain correction of the agency information.
- C. OMB Guidelines. See OMB “**Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies**,” [67 Fed. Reg. 8452](#) (February 22, 2002). Agencies must have processes for substantiating the quality of the information they have disseminated through documentation or other means appropriate to the information.
- D. DOT Guidelines. See “[The Department of Transportation’s Information Dissemination Quality Guidelines](#),” (2002).
- E. Peer Review. See OMB’s “[Final Information Quality Bulletin for Peer Review](#),” (2004).
- F. Risk Analysis. See OMB’s and the Office of Science and Technology Policy’s Memorandum of September 19, 2007, on “Updated Principles for Risk Analysis” ([M-07-24](#)).

IX. Small Business Paperwork Relief Act of 2002 ([44 U.S.C. § 101 note](#))

- A. One Point of Contact. Each agency (pursuant to [44 U.S. C. § 3502](#), this means the Department of Transportation) must establish one “point of contact ... to act as a liaison between the agency and small business concerns” with respect to information collections and the control of paperwork.

- B. Burden Reduction. Each agency must “make efforts to further reduce the information collection burden for small business concerns with fewer than 25 employees.”

X. Federal Advisory Committee Act (FACA) ([5 U.S.C. App. II](#)).

- A. Requirements. Generally, if any agency meets with more than one person (not officers or employees of the federal government) for the purpose of receiving group/consensus advice, rather than individual views, that group must be chartered as a federal advisory committee and must meet certain requirements -- such as keeping its meetings open to the public, taking minutes, and having a membership “fairly balanced” among the various views.
- B. Rulemaking Implications. FACA becomes a factor in rulemaking when a decisionmaker seeks advice from specific members of the public on how to handle a particular rulemaking. Often, to get such advice, the decision maker must charter an advisory committee under FACA.
- C. [Executive Order 12838, “Termination and Elimination of Federal Advisory Committees” \(1993\)](#). This executive order directs agencies, among other things, to limit new advisory committees to those required by statute or needed because of “compelling considerations.” By OMB memorandum (April 8, 1996; M-9621), negotiated rulemaking advisory committees are exempted from the OMB ceiling on the number of committees allowed in DOT.
- D. GSA Regulations. See [41 C.F.R. Part 101-6, Subpart 101-6.10](#), “Federal Advisory Committee Management” for supplemental requirements.
- E. DOT Order. See [DOT Order 1120.3B \(1993\)](#), “Committee Management Policy and Procedures,” for supplemental requirements.

XI. National Environmental Policy Act (NEPA) ([42 U.S.C. §§4321-4347](#)) and other Environmental Requirements.

- A. General. NEPA, numerous other statutes, regulations (see, e.g., Council of Environmental Quality Regulations at [40 C.F.R. 1500-1508](#) and FHWA/FTA regulations at [23 C.F.R. Part 771](#)), executive orders, and a [DOT Order \(5610.1c\)](#) impose requirements for considering the environmental impacts of agency decisions.

- B. Environmental Impact Statement (EIS). NEPA requires that an EIS be prepared for “major federal actions significantly affecting the quality of the human environment.” The agency is required to obtain public comment on a draft EIS before issuing a final EIS.
- C. Environmental Assessment (EA). If an action may or may not have a significant impact, an environmental assessment must be prepared. If, as a result of this study, a Finding Of No Significant Impact (FONSI) is made, no further action is necessary. If it will have a significant effect, then the assessment is used to develop an EIS. There is no statutory requirement to obtain public comment on an EA, but it is DOT policy or, in some cases, required by agency regulations. ([See 23 C.F.R. 771.119\(f\)](#))
- D. Categorical Exclusions. Agencies can categorically identify actions (e.g., establishment or modification of terminal control areas) that do not normally have a significant impact on the environment. In the rare instances when an action normally classified as categorically excluded could have a significant impact, the agency would have to do EA or even an EIS. Unless a major federal action is categorically excluded, an agency must prepare an EA or EIS.
- E. Rules. Rulemaking is a “major” federal action. Agencies must complete the NEPA documentation before issuing the final rule. Under agency regulations, rulemaking may be categorically excluded (see, e.g., [23 C.F.R. 771.117\(c\)\(20\)](#)), so little NEPA documentation is required.
- F. Effects. Beneficial as well as detrimental effects are covered.
- G. Consultation/Coordination/Public Participation. The various requirements imposed on agencies include obligations to consult or coordinate with various other federal agencies and to provide special opportunities for public comment. Issuance of rulemaking documents may have to be delayed pending completion of the review/comment period.
- H. Other Requirements. There are many additional environmental requirements, including some that have substantive effects (e.g., those applying to wetlands).

XII. Trade Agreements Act ([19 U.S.C. §§2531-2533](#)).

- A. Obstacles to Foreign Commerce. This statute prohibits agencies from setting standards that create “unnecessary obstacles to the foreign commerce” of the U.S. The statute is primarily concerned with “products.” Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles.
- B. Performance Criteria. The statute requires the use of performance rather than design standards, where appropriate.

- C. International Standards. In developing U.S. standards, it also requires the consideration of international standards and, where appropriate, that they be the basis for the U.S. standards.
- D. Agreement on Technical Barriers to Trade. Article 2 of this international agreement imposes similar requirements, including requiring members to use international standards “as the basis for technical regulations,” unless they would be “ineffective or inappropriate.”

XIII. National Technology Transfer and Advancement Act, Section 12(d) ([15 U.S.C. §272 Note](#)).

- A. Utilization of Consensus Technical Standards by Federal Agencies. Agencies are required to “use technical standards that are developed or adopted by voluntary consensus standards bodies” to carry out policy objectives determined by the agencies, unless they are “inconsistent with applicable law or otherwise impractical.”
- B. Consultation and Participation. Agencies are required to consult with and -- if compatible with agency missions, authority, priorities and resources -- participate with voluntary, private sector, consensus standards bodies.
- C. OMB Circular. See [OMB Circular A-119 Revised](#), “Federal Participation in the Development of and Use of Voluntary Consensus Standards and in Conformity Assessment Activities” (1998), for supplemental information.

XIV. Assessment of Federal Regulations and Policies on Families (Omnibus Appropriations Act FY 99, [Pub. L. No. 105-277 \(1998\); §654](#)).

- A. Family Policymaking Assessment. Agencies are required to assess policies and regulations that may affect family well-being before “implementing” them. Several factors are listed for consideration in the assessment .
- B. Written Certification. Agency heads are required to submit a written certification to OMB and Congress that the assessment has been done.
- C. Rationale. Agency heads are also required to provide an “adequate rationale” for implementing actions that may negatively affect family well-being.
- D. OMB Responsibilities. OMB is required to ensure that policies and regulations are implemented consistent with these requirements. It also must compile, index, and submit annually to Congress the written certifications it receives.

- E. Assessments Requested by Member of Congress. Agencies are required to conduct assessments in accordance with this section's criteria when requested by a Member of Congress.
- F. Judicial Review. This section is not intended to create any right or benefit enforceable against the U.S.

XV. E-Government Act ([Pub. L. No. 107-347 \(2002\)](#)).

- A. Public Information. To the extent practicable, agencies must provide a website that includes all "information about that agency" required to be published in the *Federal Register* under [5 U.S. C. §552\(a\) \(1\) and \(2\)](#). (N.B.: §552(a)(2) does not require publication of any documents.)
- B. Electronic Submission. To the extent practicable, agencies must accept electronically those submissions made under [5 U.S.C. §553\(c\)](#).
- C. Electronic Dockets. To the extent practicable, agencies must have an internet-accessible rulemaking docket that includes all public comments and other materials that by agency rule or practice are included in the agency docket.
- D. Privacy Impact Assessments. Agencies must assess privacy impacts before collecting information that will be collected, maintained, or disseminated using information technology and that "includes any information in an identifiable form permitting the physical or online contacting of a specific individual, if identical questions have been posed to, or identical reporting requirements imposed on, 10 or more persons, other than" Federal agencies or employees.

XVI. Agency Authorizing Statutes.

- A. Authorizing Language. An agency cannot issue a regulation unless it has statutory authority to do so. The language in DOT statutes varies:
 1. Specific. The authority may be specific (e.g., it may require the installation of emergency locator transmitters in aircraft).
 2. General. The authority may be very general (e.g., simply requiring an agency to set "minimum," "reasonable," "minimum and reasonable," or "minimum or reasonable" standards).
 3. Factors to Consider. Some statutes also require that the agency specifically consider certain factors, such as the efficient utilization of navigable airspace, in imposing a requirement.

- B. Conflicts. Some of DOT's statutory requirements may result in rules that affect another statutory requirement implemented by the same DOT agency (e.g., a NHTSA safety equipment requirement may add weight that will affect the ability to comply with a NHTSA fuel economy requirement). Some may affect rules of other agencies within DOT (e.g., a NHTSA child seat standard may conflict with an FAA standard barring use of the seat in an aircraft.) Such conflicts are handled through agency or OST oversight. Some requirements may affect those of another, non-DOT agency (e.g., an FAA requirement for a windshear detection device may emit noise and conflict with an EPA "pollution" standard). These are generally handled through memoranda of understanding between agencies, agency coordination efforts, or OMB oversight.
- C. Procedural Requirements. The statutes may also impose other procedural (e.g., public hearings) or review (e.g., the Department is required to allow Department of Energy review of automobile fuel economy standards and to provide any response in the preamble if changes are not made) requirements upon the Department.

EXECUTIVE ORDERS

- I. Executive Order 12866: Regulatory Planning and Review ([E.O. 12866](#))¹ (1993) (as amended by [E.O.'s 13258](#) (2002) and [13422](#) (2007)).**
- A. Regulatory Philosophy and Principles. The executive order sets forth regulatory philosophy and principles to which each agency should adhere. They include requirements to regulate in the “most cost-effective manner,” to make “a reasoned determination that the benefits of the intended regulation justify its costs,” and to develop regulations that “impose the least burden on society.”
- B. Unified Regulatory Agenda and Regulatory Plan. Each agency is required to prepare a (semiannual) Agenda of all regulations under development or review; as part of the October Agenda, the agency prepares a Plan of its most important significant regulatory actions..
- C. Review of Existing Regulations. Agencies are required to submit to the Office of Management and Budget’s (OMB) Office of Information and Regulatory Affairs (OIRA) a program for periodic review of existing significant regulations to determine whether to modify or eliminate them. Rules to be reviewed must be included in the agency’s Plan. Agencies must also identify legislatively mandated regulations that are unnecessary or outdated.
- D. Public Participation. Before issuing an NPRM, agencies should seek involvement of those intended to benefit or be burdened. Agencies should provide a meaningful opportunity to comment, including a 60-day comment period in most cases. Where appropriate, agencies must use consensual mechanisms.
- E. OIRA Review.
1. Coverage. Agencies must submit all significant rulemakings, and guidance documents requested by OIRA, to OIRA for review before issuance. There are rigid time frames for completion of such review for rulemakings but not for guidance documents.
 2. Definitions. As used in the executive order, a rule is limited to legislative rules, rules that “the agency intends to have the force and effect of law. Guidance documents are defined as interpretations or policy statements (including policy on a “technical issue”).
 3. Changes During OIRA Review. Agencies must identify for the public substantive changes made to the rulemaking documents after submission to OIRA, specifically identifying those “made at the suggestion or

¹ This is an unofficial version of E.O. 12866 with the amendments made by E.O.’s 13258 and 13422. Other links in this document to E.O. 12866 are the unamended version, unless indicated.

recommendation of OIRA.”

F. Regulatory Analysis.

1. Assessment. Agencies are required to prepare an assessment, including analyses, of benefits and costs, quantified to the extent feasible, of the anticipated action and “potentially effective and reasonably feasible alternatives,” including an explanation of why the planned action is preferable.
2. OMB Guidance. See [OMB Circular No. A-4, “Regulatory Analysis”](#) (2003).

G. Risk Analysis.

1. Assessment. Agencies are required to “consider, to the extent reasonable, the degree and nature of the risks posed” and “how the agency action will reduce risks to public health, safety, or the environment.”
2. OMB/OSTP Guidance. See OMB’s and the Office of Science and Technology Policy’s Memorandum of September 19, 2007, on “Updated Principles for Risk Analysis” ([M-07-24](#)).

H. Disclosure of OIRA Contacts. Procedures are established for disclosure of OIRA communications with people outside of the executive branch.

I. Resolution of Conflicts. Disagreements among agencies or with OMB that cannot be resolved by OIRA shall be resolved by the President.

J. OMB Guidance. See OMB/OIRA [memoranda of October 12, 1993](#), containing supplemental information, and [August 3, 1994](#), containing additional DOT exemptions. See, also, a [memorandum of September 20, 2001](#), from the OIRA Administrator describing how OIRA carries out its regulatory review and summarizing the principles and the procedures it uses.

K. White House and OMB Directives. See [Presidential Chief of Staff memoranda of January 20, 2001](#), on “Regulatory Review Plan” (rules must be approved by an appointee of President Bush), and February 5, 2001, on “Administration Coordination and Clearance Processes” and OMB [memorandum of January 26, 2001](#), on “Effective Regulatory Review.”

L. Guidance Documents. See OMB’s “**Final Bulletin for Agency’s Good Guidance Practices**” ([M-07-07](#); 2007) and OMB’s “Implementation of Executive Order 13422 (amending Executive Order 12866) and the OMB Bulletin on Good Guidance Practices” ([M-07-13](#); 2007).

II. Executive Order 13132: Federalism (1999).

- A. Principles and Criteria. This E.O. sets forth principles and criteria that agencies must adhere to in policymaking that has federalism implications. These include taking action only when a problem is of “national significance” and providing “the maximum administrative discretion possible” where States administer Federal statutes and regulations.
- B. Federalism Implications. The E.O. covers policies with federalism implications. This means “regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”
- C. Preemption.
1. Statutory Construction. Agencies shall construe statutes to preempt State law only where there is express preemption or “clear evidence” Congress intended preemption, or State action “conflicts with” Federal action. If the statute does not preempt, agencies shall construe it to authorize preemption only when State action “directly conflicts” with Federal action or there is “clear evidence” Congress intended to give authority.
 2. Minimum Necessary. Agencies must restrict regulatory preemption to the minimum necessary to achieve the statutory objectives.
 3. Consultation and Participation. Agencies must consult, to the extent practicable, with State and local officials when possible conflicts are identified and provide them opportunities for “appropriate participation” in rulemakings.
- D. Consultation.
1. Process. Agencies must have an “accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.”
 2. Federalism Official. Agencies must designate an official principally responsible for implementing the E.O.
 3. Compliance Costs and Preemption. To the extent practicable and permitted by law, agencies shall not issue rules with federalism implications that (1)

impose “substantial direct compliance costs on State and local governments,” if not required by statute, unless they comply with a or b, below, or (2) preempt State law, unless they comply with b, below:

- a. Funds Provided. The Federal government must provide money for the direct compliance costs of State and local governments.
- b. Federalism Summary Impact Statement.
 - (1) Consultation. Agencies must consult with State and local officials “early in the process of developing the proposed regulation.”
 - (2) Preamble. In a separately identified portion of the rule’s preamble, agencies must provide a federalism summary impact statement describing (a) the prior consultations with State and local officials, (b) the nature of the officials’ concerns and the agencies’ justification for the rule, and (c) the extent to which the concerns have been met.
 - (3) Written Communications. Agencies must make available to OMB State and local officials’ written communications.
- E. Waivers. As appropriate, practicable, and permitted by law, agencies must streamline the processes for waivers of statutes and rules for State and local governments, consider increasing opportunities for using “flexible policy approaches,” and make decisions on waivers within 120 days.
- F. OMB Review. Agencies submitting to OMB under [E.O. 12866](#) final rules with federalism implications must include a certification from their Federalism Official that this E.O.’s requirements were “met in a meaningful and timely manner.”
- G. OMB Guidance. See [OMB memorandum of October 28, 1999](#), on “Guidance for Implementing E. O. 13132.”
- H. DOT Guidance. See DOT Guidance on “Federalism” (1988).

III. [Executive Order 13175](#): Consultation and Coordination with Indian Tribal Governments (2000).

- A. Principles and Criteria. This E.O. sets forth principles and criteria that agencies must adhere to in policymaking that has tribal implications. These include respecting Indian tribal self-government and sovereignty, consulting with tribal officials on the need for Federal standards, and providing “the maximum

administrative discretion possible” where Indian tribal governments administer Federal statutes and regulations.

- B. Tribal Implications. The E.O. covers policies with tribal implications. This means “regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.”
- C. Consultation.
1. Process. Agencies must have an “accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.”
 2. Tribal Consultation and Coordination Official. Agencies must designate an official principally responsible for implementing the E.O.
 3. Compliance Costs and Preemption. To the extent practicable and permitted by law, agencies shall not issue rules with tribal implications that (1) impose “substantial direct compliance costs on Indian tribal governments,” if not required by statute, unless they comply with a or b, below, or (2) preempt tribal law, unless they comply with b, below:
 - a. Funds Provided. The Federal government must provide money for the direct compliance costs of the Indian tribal governments.
 - b. Tribal Summary Impact Statement.
 - (1) Consultation. Agencies must consult with tribal officials “early in the process of developing the proposed regulation.”
 - (2) Preamble. In a separately identified portion of the rule’s preamble, agencies must provide a tribal summary impact statement describing (a) the prior consultations with tribal officials, (b) the nature of the officials’ concerns and the agencies’ justification for the rule, and (c) the extent to which the concerns have been met.
 - (3) Written Communications. Agencies must make available to OMB tribal officials’ written communications.
 4. Consensual Mechanisms. Agencies must use consensual mechanisms, including negotiated rulemaking, where appropriate, for developing

regulations on issues relating to tribal self-government, tribal trust resources, or Indian tribal treaty and other rights.

- D. Waivers. As appropriate, practicable, and permitted by law, agencies must streamline the processes for waivers of statutes and rules for Indian tribes, consider increasing opportunities for using “flexible policy approaches,” and make decisions on waivers within 120 days.
- E. OMB Review. Agencies submitting to OMB under [E.O. 12866](#) final rules with tribal implications must include a certification from their Tribal Consultation and Coordination Official that this E.O.’s requirements were “met in a meaningful and timely manner.”
- F. OMB Guidance. See [OMB memorandum of January 11, 2001](#), on “Guidance for Implementing E. O. 13175, ‘Consultation and Coordination with Indian Tribal Governments.’”
- G. [Presidential Memorandum: Government-to-Government Relations with Native American Tribal Governments \(April 29, 1994\)](#). This memorandum requires each agency to apply the requirements of [E.O. 12875](#), “Enhancing the Intergovernmental Partnership” (1993) to design solutions and tailor its programs, “in appropriate circumstances, to address specific or unique needs of tribal communities.” [E.O. 13132](#) revoked E.O. 12875.

IV. [Executive Order 12988](#): Civil Justice Reform (1996).

- A. Regulatory Requirements. Within budgetary constraints and executive branch coordination requirements, agencies must review existing and new regulations to ensure they comply with specific requirements (e.g., “eliminate drafting errors and ambiguity” and “provide a clear legal standard for affected conduct rather than a general standard”) to improve regulatory drafting in order to reduce needless litigation.
- B. Specific Issues for Review. In conducting the reviews, agencies must “make every reasonable effort to ensure that the rule meets specific objectives (e.g., specifies in clear language the preemptive or retroactive effect, if any).
- C. Determination of Compliance. Agencies must determine that the rule meets the applicable standards or that it is unreasonable to meet one or more of those standards. (Agencies are not required to submit a certification of compliance to OMB as was required under the 1991 executive order.)
- D. DOT Guidance. See DOT Guidance (1992) on prior E.O. (12778).

V. **Executive Order 12630: Governmental Actions and Interference with Constitutionally Protected Property Rights (1988).**

- A. General Principles. Each agency “shall be guided by” the principles set forth in the E.O. when “formulating or implementing policies that have takings implications.”
- B. Safety. These principles include the point that “the mere assertion of a ... safety purpose is insufficient to avoid a taking.” They should be undertaken only for “real and substantial threats,” be designed to significantly advance safety, “and be no greater than is necessary.”
- C. Criteria. To the extent permitted by law, agencies are required to comply with a set of criteria before undertaking covered actions that include an assessment identifying the risk, establishing that safety is substantially advanced and that restrictions are not disproportionate to the overall risk, and estimating the cost to the government if the action is found to be a taking. In the event of an emergency, the analysis can be done later.
- D. Policies That Have Taking Implications. These include proposed and final rules that if implemented “could effect a taking” (e.g., licenses, permits, or other conditions or limitations on private property use).
- E. Ensuring Compliance. OMB and the Department of Justice are responsible for ensuring compliance with the E.O.

VI. **Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (1994).**

- A. Strategies. Each agency is required to develop a strategy that “identifies and addresses disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations” and identify, among other things, rules that should be revised to meet the objectives of the Order.
- B. Conduct. Each agency must ensure that its programs, policies, and activities that substantially affect human health or the environment” do not exclude persons (including populations) from participating in or getting the benefits of, or subject them to discrimination under, such programs, policies, and activities.
- C. Documents and Hearings. An agency’s public documents, notices, and hearings relating to human health and the environment must be “concise, understandable, and readily accessible.”

- D. **Presidential Memorandum: Environmental Justice (February 11, 1994)**. This memorandum underscores certain provisions of existing law that can help ensure that communities have a safe and healthful environment.
- E. **DOT Environmental Justice Strategy (1995; 60 Fed. Reg. 33896)**. This document contains the Department's commitment to certain principles of environmental justice and identifies the actions the Department will take to implement the E.O.
- F. **DOT Order to Address Environmental Justice in Minority Populations and Low-Income Populations (1997; 62 Fed. Reg. 18377)**. This order sets forth the process that DOT and its operating administrations will use to integrate the goals of the E.O. into their operations.

VII. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks (1997).

- A. **Policy**. With respect to its rules, "to the extent permitted by law and appropriate, and consistent with the agency's mission," each agency must "address disproportionate risks to children that result from environmental health risks or safety risks."
- B. **Analysis**. For any substantive rulemaking action that "is likely to result in" an economically significant rule that concerns "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," the agency must provide OMB/OIRA:
 1. **Evaluation**: "an evaluation of the environmental health or safety effects [attributable to products or substances that the child is likely to come in contact with or ingest] of the planned regulation on children."
 2. **Alternatives**: "an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency."

VIII. Executive Order 12889: Implementation of the North American Free Trade Agreement (1993).

- A. **Notice**. Agencies subject to the APA must provide at least a 75-day comment period for "any proposed Federal technical regulation or any Federal sanitary or phytosanitary measure of general application."
- B. **Exceptions**.

1. NAFTA Implementation. Regulations ensuring that the NAFTA Implementation Act is appropriately implemented on the date NAFTA enters into force (pursuant to [19 U.S.C. §3314\(a\)](#)).
2. Perishable Goods. Technical regulations relating to perishable goods.
3. Urgent Safety or Protection Rules. Technical regulations addressing an “urgent problem” relating to safety or to protection of human, animal, or plant life or health; the environment; or consumers.
4. Urgent Sanitary or Phytosanitary Protection. Regulations addressing an “urgent problem” relating to sanitary or phytosanitary protection.

C. Definitions.

1. Technical Regulations. These are defined in the Trade Agreements Act at [19 U.S.C. §2576 b\(7\)](#) [Essentially, a legislative rule].
2. Sanitary or Phytosanitary Measures. These are defined at [19 U.S.C. §2575 b\(7\)](#).

IX. [Executive Order 13211](#): Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (2001).

- A. Statement of Energy Effects. Agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law.
- B. Contents of Statement. Agencies must provide a detailed statement of “any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)” for the action and reasonable alternatives and their effects.
- C. Publication. Agencies must publish the Statement or a summary in the related NPRM and final rule.
- D. Significant Energy Action. A “significant energy action” is one that is “significant” under [E.O. 12866](#) and is likely to have a significant adverse energy effect, or is designated by the OMB.
- E. OMB Guidance. See [OMB memorandum of July 13, 2001](#), on “Guidance for Implementing E.O. 13211.”

X. Other Executive Orders.

There are other executive orders that impose a variety of procedural and substantive requirements (e.g., the department's implementation of certain statutes concerning transportation of the handicapped must be cleared with the Department of Justice) on some of DOT's rulemakings.

PRESIDENTIAL DIRECTIVES AND RELATED ACTIONS

I. Presidential Memoranda or Directives.

Presidents periodically require particular action in the rulemaking area through memoranda or other steps. For example, by a [memorandum dated March 4, 1995](#), the President directed agencies, among other things, as follows:

- A. Results Not Process. Agencies must take steps to focus regulatory programs on results not process.
- B. Negotiated Rulemaking. Agencies must "expand substantially" their use of negotiated rulemaking.
- C. Small Business Fines. Agencies are given the authority to waive fines imposed on small businesses that have acted in good faith (so that they can use the money to fix the problem) or to waive fines for first-time violations by small businesses when the firms move quickly and sincerely to correct the problem.

II. Plain Language (1998).

- A. [Presidential Directive \(June 1, 1998\)](#). Agencies must use plain language in proposed and final rulemaking (and other) documents. To the extent agencies have the opportunity and resources, they should consider rewriting existing rules in plain language.
- B. Vice-Presidential Memorandum/Guidance (July 28, 1998). Agencies must designate a senior official responsible for implementing plain language and prepare a plain language action plan. The Vice President also provided guidance on writing in plain language.
- C. DOT Guidance. ["Plain Language Resource Page"](#). This page has links to the above referenced documents and other information about plain language.
- CI.

OMB BULLETINS AND OTHER DIRECTIVES

- I. [OMB Circular No. A-4](#), “Regulatory Analysis” (2003)
- A. General. This circular provides guidance on the development of regulatory analyses and on the regulatory accounting statements for each major final rule required under the Regulatory Right-to-Know Act.
- B. Benefit-Cost Analysis (BCA) and Cost-Effectiveness Analysis (CEA).
1. Major Health and Safety Rulemakings. A BCA and CEA are necessary.
 2. Other Major Rulemakings. A BCA is necessary; a CEA should also be provided, if some primary benefits cannot be monetized.
 3. Qualitative Discussion. If quantification cannot be produced, qualitative discussion should be presented.
- C. Discount rate. Agencies should use a discount rate of 7 percent as a base case under [OMB Circular A-94](#) but should provide estimates of net benefits using both 3 percent and 7 percent.
- D. Uncertainties. Agencies should provide a formal quantitative analysis of the relevant uncertainties about benefits and costs for rules involving annual effects of \$1 billion or more, using appropriate statistical techniques to determine a probability distribution of relevant outcomes.
- E. Sensitivity Analysis. Agencies should examine how results vary with plausible changes in assumptions, data, and alternative analytical approaches.
- F. DOT Guidance.
1. Value of Statistical Life and Injuries. See DOT guidance on [“Treatment of the Value of Statistical Life and Injuries in Preparing Economic Evaluations” \(2008\)](#). This document sets the value for a statistical life (adjusted annually) and injuries in the economic analyses used for determining benefits for DOT rulemaking actions. It also requires an analysis of the costs and benefits of each major subcomponent of a rule.
 2. Value of Travel Time. See [“Departmental Guidance for the Valuation of Travel Time in Economic Analysis” \(1997\)](#) and [“Revised Departmental Guidance-Valuation of Travel Time in Economic Analysis \(2003\)”](#). This document contains procedures and empirical

estimates for calculating the value of time saved or lost by users of the transportation system.

3. Unfunded Mandates Reform Act. See DOT guidance on [“Threshold of Significant Regulatory Actions Under the Unfunded Mandates Reform Act of 1995”](#) (2008).

II. Final Information Quality Bulletin for Peer Review (2004):

A. Review.

1. Influential Scientific Information. To the extent permitted by law, each agency must conduct a peer review of all influential scientific information that the agency intends to disseminate. This is information that could have “a clear and substantial impact on important public policies or private sector decisions.”
2. Highly Influential Scientific Information. Additional requirements apply to highly influential scientific information, that which could have an impact exceeding \$500 million in any year or is “novel, controversial, or precedent-setting or has significant interagency interest.”

B. Dissemination. Dissemination is an “agency initiated or sponsored distribution of information to the public.” Among other things, it does not include distributions for peer review under the Bulletin when the distribution has a disclaimer.

C. Peer Review Mechanism.

1. Influential Scientific Information. The choice of the peer review mechanism for influential scientific information is based on the novelty and complexity of the information, the importance of the information to the decision, the extent of prior peer review, and the expected benefits and costs of the review and transparency factors. The options range from the use of agency personnel who have not participated in the development of the product being reviewed to independent third parties.
2. Highly Influential Scientific Information. Additional requirements are imposed on the mechanism used for peer review of highly influential scientific information. Employees of DOT can only be used under exceptional circumstances, when approved by the Secretary or Deputy Secretary and when employed by a DOT agency different from the one disseminating the information. Whenever feasible and appropriate, the agency must provide an opportunity for public comment during the peer review, including a public meeting with the peer reviewers.

- D. Timing.
1. General. Although the Bulletin does not require a peer review to be conducted at a specific time during the rulemaking process, it does state that “it is most useful to consult with peers early in the process of producing information.”
 2. Critical Information. It also notes that, when the information “is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options.”
 3. Public Participation. Agencies may decide that peer review should precede an opportunity for public comment, but there are situations where “public participation in peer review is an important aspect of obtaining a high-quality product.”
- E. Reports and Agency Responses.
1. Influential Scientific Information. The peer reviewers must prepare a report, which must be posted on the agency’s website along with related materials, discussed in the preamble to any related rulemaking, and included in the administrative record.
 2. Highly Influential Scientific Information. Additional requirements are imposed on the reports for this information and the agency must prepare a written response to the report explaining any agreements or disagreements, the actions the agency is undertaking in response, and the reason the agency believes those actions satisfy the “key” concerns in the report. The agency response must be posted on its website along with related material.
- F. Planning. Each agency must post on its website, and update at least every six months, an agenda of its peer review plans, setting out what will be reviewed and how, including opportunities for public participation.
- G. Exemptions. The exemptions include the following:
1. Negotiations involving treaties where there is a need for “secrecy or promptness.”
 2. Individual agency adjudication or permit proceedings “unless the peer review is practical and appropriate and ... the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings.”

3. Regulatory impact analyses or regulatory flexibility analyses subject to [E.O. 12866](#), “except for underlying data and analytical models used.”
 4. Information disseminated in connection with routine rules “that materially alter entitlements, user fees, or loan programs, or the rights and obligations of recipients thereof.”
- H. DOT Guidance. See DOT “Guidelines for Implementing the Office of Management and Budget’s ‘Final Information Quality Bulletin for Peer Review.’” (2005).

III. **Final Bulletin for Agency’s Good Guidance Practices** [\(M-07-07; 2007\)](#)

- A. General. This bulletin establishes requirements for the development, issuance, and use of significant guidance documents by agencies.
- B. Coverage. The bulletin applies to significant guidance documents (which includes the subset of economically significant guidance documents). It is important to review the specific definitions, but briefly, as used in the bulletin:
1. *Agency* means the Department level at DOT.
 2. *Guidance document* --
 - a. Means a generally applicable interpretation of, or a policy statement on, a statutory or regulatory issue or a policy statement on a technical issue.
 - b. To be covered, it must be “prepared by the agency and distributed to the public or regulated entities”
 - c. If it responds to an individual person or entity, it is not covered unless it is intended to have a precedential effect (e.g., if it is posted on the internet).
 - d. The definition is not limited to written materials.
 3. *Significant and economically significant guidance document* have essentially the same meaning as legislative rules under [E.O. 12866](#), except that a legislative rule is one that “is likely to result in a rule that may” have the effect described, whereas guidance “may reasonably be anticipated to” have that effect.
- C. Approval Procedures. Each agency must have written procedures for the approval by “appropriate senior agency officials” of significant guidance documents.

- D. Standard Elements. Agencies must provide specified, standard elements in each significant guidance document.
- E. Public Access for Significant Guidance Documents.
1. Access. Each agency must have a website providing the public with specified information about significant guidance documents.
 2. Feedback.
 - a. Comments and Requests. Each agency must provide a process for the public to submit electronic comments on – and electronic requests for issuance, reconsideration, modification, or rescission of – significant guidance documents. Agencies are not required to respond to the comments.
 - b. Complaints. Each agency must designate an office(s) to receive and address public complaints that it is not complying with the OMB bulletin or is improperly treating a significant guidance bulletin as a binding requirement.
- F. Notice and Public Comment for Economically Significant Guidance Documents
1. Public Comment on Draft: For economically significant guidance documents, each agency must invite public comment on a draft before issuing the guidance. The agency must respond to the public comments.
 2. Exemptions: In consultation with OIRA, the agency head may identify particular documents or categories for which these requirements are not “feasible or appropriate.”
- G. Emergencies: For emergencies or legal deadlines that would not allow normal review procedures, each agency must notify OIRA as soon as possible and comply with the bulletin to the extent practicable.
- H. OMB Review.
1. Notice. Pursuant to [E.O. 13422](#) amendments to [E.O. 12866](#), each agency must “take such steps as are necessary ... to ensure” that it provides OIRA with advance notification of any significant guidance documents.
 2. Review. Upon the request of OIRA, each agency must provide OIRA any draft guidance document it requests to review.

- I. DOT Guidance. See DOT “Guidance on Guidance” (2007).
- J. DOT Website. See DOT’s website implementing the requirements of the OMB Bulletin and providing other information at regs.dot.gov.

IV. Updated Principles for Risk Analysis ([M-07-24](#); 2007)

- A. General. This memorandum is intended to “reinforce generally-accepted principles for risk analysis upon which a wide consensus now exists,” to “assist and guide agencies.”
- B. General Principles. Risk analysis is a tool that must adapt to scientific advances and be consistent with statutes and administration priorities. Agencies must consider risks to the extent reasonable and should distinguish between the risk assessment and risk management (which may change behavior in ways that alter risks). The depth of the analysis should be “commensurate with the nature and significance of the decision.”
- C. Principles for Risk Assessment. Agencies should use the “best reasonably attainable scientific information; characterizations of risks should be qualitative and quantitative and “broad enough to inform the range of policies to reduce risks”; judgments should be explicit and their influence articulated; “all appropriate hazards” should be included, with attention given to “subpopulations that may be particularly susceptible to such risks and/or may be more highly exposed”; the use of peer review should be maximized; and agencies should use consistent approaches in evaluating risks.
- D. Principles for Risk Management. Agencies should analyze the distribution of risks and the costs and benefits of risk management strategies; and the alternative selected should provide the “greatest net improvement in total societal welfare” when accounting for a “broad range of relevant social and economic considerations.”
- E. Principles for Risk Communication. Agencies should have an “open, two-way exchange between professionals (including policy makers and “experts”) and the public; goals should be clear, and risk assessments and risk management decisions “communicated accurately and objectively in a meaningful manner”; the basis for significant assumptions, data, models, and inferences should be explained; the sources, extent and magnitude of significant uncertainties should be described; “appropriate risk comparisons” should be made, considering such factors as public attitudes toward voluntary and involuntary risk; and the public should be provide timely public access to relevant supporting documents and a reasonable opportunity to comment.
- F. Principles for Priority Setting Using Risk Analysis. Agencies should compare risks and group them in categories of concern (e.g., high, moderate, and low);

set priorities for risk management to achieve the “greatest net improvement in societal welfare” first; inform priority-setting by consideration of views from a broad range of individuals, with consensus views being reflected where possible; and coordinate risk reduction efforts with other agencies, where feasible and appropriate.

DOT ORDERS

I. DOT Order 2100.5: Regulatory Policies and Procedures (1979).

- A. Coverage. This order applies to all DOT rulemakings, including those that establish conditions for financial assistance, but excludes formal rulemakings and those related to military or foreign affairs functions, agency management or personnel, and Federal procurement. Special provisions are also made for “emergency” rulemakings.
- B. Objectives. It sets forth objectives for DOT rulemaking (e.g., necessity, clarity).
- C. Regulations Council. It establishes a Department Regulations Council, chaired by the Deputy Secretary, vice-chaired by the General Counsel, and made up of the heads of OST offices and the operating administrations. The Council can review and make recommendations concerning regulatory review programs (see paragraph G), significant rulemakings (see paragraph E), and the Regulatory Policies and Procedures. It can also set up task forces or require studies if necessary.
- D. Initiating Office Responsibilities. It establishes responsibilities for the offices initiating regulations to do such things as coordinate their proposals with other operating administrations within the Department.
- E. Significant Rulemaking Review. It requires the submission of all significant rulemakings to the Office of the Secretary for approval by the Secretary. (A significant rulemaking is essentially one that is costly or controversial.)
- F. Economic Analyses. It requires an economic analysis for all proposed (including ANPRMs) and final rulemaking actions, not just for major/economically significant (very costly) rulemakings. Where the impact is so minimal that a full analysis is not warranted, a statement to that effect and the basis for it is included in the rulemaking document.
- G. Reviews. It requires the periodic review of existing regulations to determine whether they should be revised or revoked.
- H. Public Participation. It sets forth some specific procedures to ensure a full opportunity for public participation; for example, it provides for a comment period of at least 45 days on nonsignificant regulations and 60 days on significant regulations, unless the rulemaking document states the reasons for a shorter time

period. It also requires that, to the maximum extent possible, even when not mandated, opportunity for the public to comment on proposed rules should be provided, if it could be expected to result in useful information.

- I. Agenda. It requires the development and issuance of a semi-annual regulations Agenda. (This is incorporated into the [E.O. 12866](#) Agenda.)
- J. DOT Guidance.
 - 1. Economic Analysis. See DOT “Guidance for Regulatory Evaluations: A Handbook for DOT Benefit-Cost Analysis” (April 1982, revised April 1984). Note that, although this document has not been updated to reflect more recent OMB documents and DOT changes to values, it does contain helpful information.
 - 2. Values Used in Economic Analysis. See DOT guidance described under OMB Circular No. A-4:
 - a. [Value of Statistical Life and Injuries](#).
 - b. [Value of Time](#).
 - c. [Unfunded Mandates Reform Act](#).

II. **DOT Order 2100.2: Public Contacts in Rulemaking (1970) and Other Guidance**

The order and other guidance discourage oral communications from the time a notice of proposed rulemaking is issued until the end of the comment period and strongly discourage them between that time and the time the final decision is issued. If such contacts occur, they must be summarized in writing and placed in the public rulemaking docket. If contacts occur after the close of the comment period, they must be carefully reviewed to determine whether reopening of the comment period will be required. (If a contact occurs before the issuance of the NPRM, it may be summarized in the preamble to the NPRM.)

AGENCY RULEMAKING PROCEDURES

Some of the DOT operating administrations and OST have published regulations setting forth their specific procedures for implementing the APA. For example, they may provide an address for filing petitions for rulemaking and indicate how long the agency generally takes to review such petitions, or they may indicate that late-filed comments may be considered if they do not delay the issuance of a final rule.