U.S. Department of Transportation

RULEMAKING REQUIREMENTS

March 2020

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This document is a summary of the requirements imposed on DOT as it implements its responsibilities for rulemaking. This document was originally prepared for the DOT professionals who are involved in the rulemaking process and is not intended to have a substantial future effect on the behavior of regulated parties.

STATUTES

I. Administrative Procedure Act (APA).

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 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. Nonlegislative Rules.

   a. Interpretive Rules or Guidance. These tell the public what the agency thinks the statutes and the rules it administers mean. Interpretive rules are not binding.

   b. General Statements of Policy. These tell the public prospectively how the agency plans to exercise a discretionary power.

3. Management and Procedural Rules.

   a. Management or Personnel. These 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 describe the agency's structure and functions and the way in which its determinations are made.

C. 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.

D. Formal Rulemaking. 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 under the APA is rarely used.

E. Informal Rulemaking. The process of "notice and comment" rulemaking is referred to as "informal rulemaking" (subject to section 553 of the APA).

1. Notice of Proposed Rulemaking (NPRM). Subject to certain exceptions identified below, general notice of proposed rulemaking must be issued before any final action can be taken. This document is called a notice of proposed rulemaking, or NPRM.

   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.

      (1) The NPRM must include the following:

         (A) a statement of the time, place, and nature of the proceedings (for informal rulemaking, this includes the time period and procedure for submitting comments);

         (B) the legal authority for the proposed rule; and

         (C) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

      (2) 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.

      (3) Rule Text. Agencies may include the text of the proposed rule in the NPRM; however, unless specifically required by statute, this is not mandatory.

      (4) Preamble. Any material other than actual rule language is referred to as the preamble.

   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.

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. Timing. Unless otherwise set by statute, there is no time limit within which an agency must publish a final rule after publishing an NPRM.

c. 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 *Federal 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.

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

(1) Substantive rules that grant or recognize an exemption or relieve a restriction.

(2) Interpretative rules and statements of policy.

(3) Good Cause. As otherwise provided by the agency for good cause found and published with the rule.

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

G. 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."

H. Additional Steps. Agencies can supplement but not waive the requirements of the APA. Examples of extra steps DOT uses are:

1. Advance Notice of Proposed Rulemaking (ANPRM). Agencies issue ANPRMs when, *e.g.*, they know there is a problem but do not have sufficient information to know the appropriate solution to propose. In addition, DOT generally publishes an ANPRM when a rule is expected to be economically significant or a high-impact rule. See *Administrative Rulemaking, Guidance, and Enforcement Procedures*, 84 FR 71714 (Dec. 27, 2019).

2. Supplemental Notice of Proposed Rulemaking (SNPRM). Agencies issue SNPRMs 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. Interim Final Rule (IFR). Agencies issue IFRs in limited circumstances without first issuing an NPRM 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.)

I. 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, it will become effective on a specified date. If the agency receives no public comment, it publishes a notice to that effect in the *Federal Register*. If the agency receives adverse comment, 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.

J. 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.

K. 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 the APA requires an agency 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. The 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 (E.O.) requires the following:

1. SBA's Office of Advocacy Review. Agencies must notify the Office of the Chief Counsel for Advocacy (Advocacy) of the Small Business Administration (SBA) 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 Information and Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB) 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.

4. DOT Guidance. See the DOT website "Rulemaking Requirements Concerning Small Entities."

I. Flexibility and Job Creation. See Presidential Memorandum of January 18, 2011, on "Regulatory Flexibility, Small Business, and Job Creation." This memorandum directs agencies, "when initiating rulemaking that will have a significant economic impact on a substantial number of small entities, to give serious consideration to whether and how it is appropriate, consistent with law and regulatory objectives, to reduce regulatory burdens on small businesses, through increased flexibility."

1. Possible Forms of Flexibility.
   a. Extended compliance dates.
   b. Performance standards.
   c. Simplification of reporting and compliance.
   d. Different requirements for small businesses.
   e. Partial or total exemptions.

2. Justification. When not providing such flexibility for other than legal limitations, an agency should explicitly justify its decisions in the proposed or final rule.

J. Advocacy Guidance. See "A Guide for Government Agencies – How to Comply with the Regulatory Flexibility Act" (2017).

K. DOT Guidance. See the DOT website "Rulemaking Requirements Concerning Small Entities." See "Department of Transportation Policies and Procedures for Implementing Executive Order 13272, 'Proper Consideration of Small Entities in Agency Rulemaking'" (February 2003).

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 SBA Administrator 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.

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 the DOT website "Rulemaking Requirements Concerning Small Entities."

H. SBA Guidance. See Small Business Compliance Points of Contact: Department of Transportation.

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 must take effect as otherwise provided by law after submission to Congress.

2. Major Rule.

   a. General. A major rule (one that 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" 5 U.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 cannot adopt a rule that is substantially the same, 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." See also OMB memorandum of April 11, 2019, on "Guidance on Compliance with 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 latest DOT Guidance on "Threshold of Significant Regulatory Actions Under the Unfunded Mandates Reform Act of 1995"; see description of OMB Circular No. A-4.) 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. OMB Guidance. See OMB memorandum of September 25, 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 memorandum of April 25, 2000, on "OMB Procedures and Guidance on Implementing the Government Paperwork Elimination Act"; OMB memorandum of September 25, 2000, on "OMB Guidance on Implementing the Electronic Signatures in Global and National Commerce Act"; OMB/OIRA memorandum of April 7, 2010, on "Information Collection under the Paperwork Reduction Act" implementing the Presidential Memorandum of January 21, 2009, on "Transparency and Open Government"; and OMB/OIRA memorandum of April 7, 2010, on "Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction 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. OMB Memorandum. See OMB memorandum of February 11, 2005 (M-05-08) from Deputy Director for Management on "Designation of Senior Agency Officials for Privacy." It discusses senior officials' role in development and evaluation of regulatory proposals with privacy issues, the need to evaluate the proposal's impact, and the need to consider alternatives.

3. DOT Guidance. See the DOT website "DOT Privacy Policy."

4. DOT PIA Documents. See the DOT website "Privacy Impact Assessments."

C. System of Records Notices.

1. DOT SORN Documents. See the DOT website "Privacy Act System of Records Notices."

D. DOT Order. See DOT Order 1351.18 (2014), "Departmental Privacy Risk Management Policy," for supplemental requirements.

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 FR 8452 (Feb. 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," (2019).

E. Peer Review. See OMB's "Final Information Quality Bulletin for Peer Review," (2004).

F. Risk Analysis. See OMB 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.

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.

C. SBA Compliance Assistance with Federal Agencies. See "Small Business Compliance Points of Contact: Department of Transportation."

D. Small Business Paperwork Relief Task Force. See "Report of the Small Business Paperwork Relief Act Task Force" (2004).

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 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 decision maker 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.

D. Executive Order 13875, "Evaluating and Improving the Utility of Federal Advisory Committees," (2019). This executive order directs review of current advisory

committees, limits creating new advisory committees, and provides reporting requirements and an exemption for merit review panels.

E. GSA Regulations. See 41 C.F.R. Part 101-6, Subpart 101-6.10, "Federal Advisory Committee Management" for supplemental requirements.

F. GSA Guidance. See "Presidential Advisory Commission on Election Integrity Briefing: Federal Advisory Committee Act; Presidential Records Act" (2017).

G. 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 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 United States. 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 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.

E. OMB/USTR Memorandum. See OIRA Administrator/Deputy United States Trade Representative memorandum of May 19, 2011 (M-11-23), reminding agencies of their obligations under Act.

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 United States.

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 (a)(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.

E. OMB Memorandum. See OMB memorandum (M-03-22) on the privacy impact assessments required under the statute.

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 related to use 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 wind shear detection device may emit noise and conflict with an EPA standard). These are generally handled through memoranda of understanding between agencies, agency coordination efforts, or OMB oversight.

Procedural Requirements. The statutes may also impose on DOT other procedural (*e.g.*, public hearings) or review (*e.g.*, DOT 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.

EXECUTIVE ORDERS

I. Executive Order 12866: Regulatory Planning and Review (1993).

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 Agenda of Regulatory and Deregulatory Actions and Regulatory Plan. Each agency is required to prepare a (semiannual) Agenda of all regulatory action under development or review; as part of the Fall Agenda, the agency prepares a Plan of its most important significant regulatory actions.

C. Review of Existing Regulations. Agencies are required to submit to 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 to OIRA for review before issuance. There are rigid time frames for completion of such review.

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.

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 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); see Agency Checklist: Regulatory Impact Analysis (2010).

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 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. There are procedures for disclosure of OIRA communications with people outside of the executive branch.

I. Resolution of Conflicts. The President resolves disagreements among agencies or with OMB that cannot be resolved by OIRA.

J. OMB Guidance.

1. OIRA Review. See OIRA Administrator memorandum of September 20, 2001, describing how OIRA carries out its regulatory review and summarizing the principles and the procedures it uses.

2. Electronic Dockets. See OIRA Administrator memorandum of May 28, 2010, on "Increasing Openness in the Rulemaking Process – Improving Electronic Dockets." This memorandum requires that agencies compile and maintain comprehensive electronic regulatory dockets.

3. RINs. See OIRA Administrator memorandum of April 7, 2010, on "Increasing Openness in the Rulemaking Process – Use of the Regulation Identifier Number (RIN)." This memorandum requires that agencies use RINs on all documents related to a particular rulemaking.

K. White House and OMB Directives.

1. This Presidential Memorandum of March 4, 1995, builds on the regulatory philosophy of E.O. 12866 and directs 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.

2. At the beginning of each administration, White House and OMB Directives explain the processes for handling rules during the transition from the previous administration. See, *e.g.*, Presidential Memorandum of January 20, 2017, "Regulatory Freeze Pending Review," and OMB memorandum of January 24, 2017 (M-17-16), "Implementation of Regulatory Freeze."

L. Guidance Documents. See OMB's "Final Bulletin for Agency's Good Guidance Practices" (M-07-07; 2007) and the OMB Bulletin on Good Guidance Practices" (M-07-13; 2007). See also, OMB Director's memorandum of March 4, 2009 (M-09-13) on the effect of E.O. 13497's rescission of E.O. 13422 on OIRA review of guidance.

M. International Agreements.

1. OIRA. Pursuant to 22 C.F.R. 181.4(e)(2), agencies are required to consult with OIRA in a timely manner before entering into an international agreement that could reasonably be expected to require (for its implementation) the issuance of a significant regulatory action, as defined in E.O. 12866.

2. USTR. 19 U.S.C. § 2541 gives USTR responsibility for establishing mutual agreements for standards-related activities and requires USTR to consult with any agency having expertise in the subject.

II. Executive Order 13563: Improving Regulation and Regulatory Review (2011).

A. General Principles. This E.O. supplements and reaffirms E.O. 12866, stressing that, to the extent permitted by law, an agency rulemaking action must be based on benefits that justify its costs, impose the least burden, consider cumulative burdens, maximize benefits, use performance objectives, and assess available alternatives.

B. Public Participation.

1. Meaningful Participation. Agencies must provide a meaningful opportunity for public comment (generally 60 days) through the Internet, with timely and easy access to all pertinent documents. Prior to issuing NPRMs, agencies should seek the views of those likely to be affected, where feasible and appropriate. See OIRA Administrator memorandum of March 20, 2012, on "Cumulative Effects of Regulations."

2. Use of the Internet. See OIRA Administrator memorandum of April 7, 2010, on "Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act."

C. Integration and Innovation. Each Agency must promote coordination, simplification, and harmonization across agencies to reduce redundant, inconsistent, or overlapping rules. They shall also seek to achieve goals designed to promote innovation.

D. Flexible Approaches. Agencies must consider approaches that reduce burdens and maintain flexibility and freedom of choice.

E. Science.

1. Objectivity. Agencies must ensure the objectivity of any scientific and technological information and processes supporting their rulemaking.

2. Related Documents.

a. "Scientific Integrity." See Presidential Memorandum of March 9, 2009, and Director of OSTP memorandum of December 17, 2010.

b. "Principles for Regulation and Oversight of Emerging Technologies." See Director of OSTP, et al. memorandum of March 11, 2011.

c. "Implementation of Departmental Scientific Integrity Policy." See DOT memorandum of April 10, 2012.

F. Retrospective Analysis.

1. Retrospective Review. Agencies must consider how best to promote retrospective analysis of rules. They must have a plan to periodically review their existing significant regulations to make them more effective or less burdensome. See OIRA Administrator memorandum of June 14, 2011 (M-11-19), on "Final Plans for Retrospective Analysis of Existing Rules."

2. Related Documents.

a. Paperwork and Reporting. See OIRA Administrator memorandum of February 23, 2011, on "Minimizing Paperwork and Reporting Burdens; Data Call for the 2011 Information Collection Budget." This memorandum asks agencies to produce one or more burden reduction initiatives that will have significant progress in the next year with particular focus on relief for small businesses or recipients of Federal benefits. The memorandum offers a variety of approaches that could help.

b. State, Local, and Tribal Governments. See Presidential Memorandum of February 28, 2011, on "Administrative Flexibility, Lower Costs, and Better Results for State, Local, and Tribal Governments." Agencies must work closely with State, local, and tribal governments to identify regulatory and other barriers in Federally funded programs that prevent efficient and effective use of the funds. By August 28, 2011, agencies are to identify requirements that can be streamlined, reduced, or eliminated.

G. OMB Guidance.

1. General. See OIRA Administrator memorandum of February 2, 2011 (M-11-10), on "Executive Order 13563, 'Improving Regulation and Regulatory Review.'"

2. Guidance. See OIRA Administrator memorandum of January 4, 2012, on "Clarifying Regulatory Requirements: Executive Summaries."

III. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs (2017).

A. Regulatory Cap. Each agency, when publicly proposing a new regulation, must identify at least two existing regulations for elimination. Any new incremental costs associated with new regulations must, to the extent permitted by law, be offset by the elimination of the existing costs associated with the two prior regulations that were identified.

B. Regulatory Cost Budget. During the Presidential budget process, the OMB Director must identify to each agency a total amount of incremental costs that will be allowed for the agency in issuing new regulations and repealing existing regulations for the next fiscal year. The total incremental cost allowance may allow an increase or require a reduction in total regulatory cost.

C. Annual Regulatory Cost Submissions. Each agency, when submitting its Regulatory Plan required by E.O. 12866, is required to provide its best approximation of the costs and cost savings associated with each new regulation or repealed regulation.

D. Approval of Regulations. Agencies are only permitted to issue regulations that were included in the most recent version or update of the published Unified Agenda of Regulatory and Deregulatory Actions, unless the issuance of a regulation was approved in advance in writing by the OMB Director. The Unified Agenda includes all regulations approved by the Director.

E. OMB Guidance. See OIRA Administrator memorandum of April 5, 2017 (M-17-21), on "Guidance Implementing Executive Order 13771, Titled 'Reducing Regulation and Controlling Regulatory Costs.'" See also OIRA Administrator memorandum of February

22, 2018, on "Compliance with Section 3(c) of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs."

IV. Executive Order 13777: Enforcing the Regulatory Reform Agenda (2017).

A. Regulatory Reform Officers. Each agency is required to designate an official as its Regulatory Reform Officer (RRO). Each RRO is responsible for overseeing the implementation of E.O. 13771 (regarding the number and cost of regulations), E.O. 12866 (regarding regulatory planning and review), section 6 of E.O. 13563 (regarding retrospective review), and other regulatory reforms.

B. Regulatory Reform Task Force. Each agency must establish a Regulatory Reform Task Force (RRTF), chaired by its RRO. Each RRTF is responsible for identifying existing regulations of an agency for repeal, replacement, or modification.

C. Performance Indicators. Each agency must incorporate indicators in its annual performance plan that track the agency's progress toward implementing regulatory reform initiatives, as well as the agency's progress in identifying regulations for repeal, replacement, or modification.

D. OMB Guidance. See OIRA Administrator memorandum of April 28, 2017 (M-17-23), on "Guidance on Regulatory Reform Accountability under Executive Order 13777, titled 'Enforcing the Regulatory Reform Agenda.'"

E. Current Waivers. See "List of Agencies with Current Waivers under Executive Order 13777," (2018).

V. Executive Order 13891: Promoting the Rule of Law Through Improved Agency Guidance Documents (2019).

A. Policy. This E.O. directs agencies to treat guidance documents as non-binding both in law and in practice, except as incorporated into a contract, take public input into account when appropriate in formulating guidance documents, and make guidance documents readily available to the public.

B. Transparency. This E.O. directs agencies to have a single, searchable, indexed database on their websites that contain or link to all guidance documents from that agency. It also requires the website to state that guidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract.

C. Procedures for Issuing Guidance. The E.O. directs agencies to promulgate processes and procedures for issuing guidance. Those processes and procedures must include: a requirement that each guidance document clearly state that it does not bind the public, except as authorized by law or as incorporated into a contract, and procedures for the public to petition for withdrawal or modification of a particular guidance document. Guidance designated significant by OIRA must include the following unless exigency,

safety, health, or other compelling cause warrants an exemption: a 30-day notice and comment period, except where impracticable, unnecessary, or contrary to the public interest; approval on a non-delegable basis by the agency head or by an agency component head appointed by the President, before issuance; OIRA review; and compliance with applicable requirements for regulations and rules in E.O.s 12866, 13563, 13609, 13771, and 13777.

1. DOT Implementation. See *Administrative Rulemaking, Guidance, and Enforcement Procedures*, 84 FR 71714 (Dec. 27, 2019).

D. Exempt. The following actions are exempt from this E.O.: any action that pertains to foreign or military affairs, or to a national security or homeland security function of the United States; to any action related to a criminal investigation or prosecution, or any civil enforcement action or related investigation by the Department of Justice; to any investigation of misconduct by an agency employee or any disciplinary, corrective, or employment action taken against an agency employee; any document exempt from disclosure under the Freedom of Information Act; and under any circumstances that would harm national security.

E. OMB Guidance. Guidance Implementing Executive Order 13891, Titled "Promoting the Rule of Law Through Improved Agency Guidance Documents."

VI. 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 State and local officials' written communications available to OMB.

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. Preemption. See Presidential Memorandum of May 20, 2009, on "Preemption." Pursuant to this memorandum, agencies should:

1. Not include statements in regulatory preambles that they intend to preempt State law through regulation, unless such preemption is also included in the codified regulation.

2. Not include preemption provisions in codified regulations unless justified under legal principles governing preemption, including Executive Order 13132.

H. OMB Guidance. See OMB memorandum of October 28, 1999, on "Guidance for Implementing E.O. 13132."

I. DOT Guidance. See DOT Guidance on "Federalism" (1999).

VII. 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 tribal officials' written communications available to OMB.

4. Consensus Mechanisms. Agencies must use consensus 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. Presidential Memoranda:

1. Government-to-Government Relations with Native American Tribal Governments. This memorandum of April 29, 1994, requires each agency to design solutions and tailor its programs, in appropriate circumstances, to address specific or unique needs of tribal communities and to remove procedural impediments to working directly and effectively with tribal governments.

2. Tribal Consultation. This memorandum of November 5, 2009 requires each agency to submit to OMB a detailed plan to implement the policies and directives of E.O. 13175, after consultation with Indian tribes and tribal officials. Each agency must also submit to OMB annual progress reports and any updates to the plan.

G. OMB Guidance. See OMB memorandum of January 11, 2001, on "Guidance for Implementing E.O. 13175, "Consultation and Coordination with Indian Tribal Governments'" and OIRA memorandum of July 30, 2010, on "Guidance for Implementing E.O. 13175, "Consultation and Coordination with Indian Tribal Governments."

H. DOT Plan. See DOT Tribal Consultation Plan (February 3, 2010).

I. Alaska Native Corporations. Pursuant to Pub. L. No. 108-199, as amended by Pub. L. No. 108-447, agencies are required to "consult with Alaska Native corporations on the same basis as Indian tribes under" E.O. 13175.

VIII. 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 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 either 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.)

IX. 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.

X. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (1994), amended by E.O. 12498, (1995).

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. See Presidential Memorandum of February 11, 1994, on "Environmental Justice" underscoring certain provisions of existing law that can help ensure communities have a safe and healthful environment.

E. DOT Environmental Justice Strategy (2016). 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 Updated Environmental Justice Order 5610.2(a). 77 FR 27534 (May 10, 2012). 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.

G. MOU on Environmental Justice and E.O. 12898. This document is an interagency Memorandum of Understanding to implement E.O. 12898.

XI. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks (1997), amended by E.O. 13229 (2001); E.O. 13296 (2003).

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."

XII. 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. § 2576b(7) [Essentially, a legislative rule].

2. Sanitary or Phytosanitary Measures. These are defined at 19 U.S.C. § 2575b(7).

XIII. 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 OMB.

E. OMB Guidance. See OMB memorandum of July 13, 2001, on "Guidance for Implementing E.O. 13211."

XIV. Other Executive Orders.

There are other executive orders that impose a variety of procedural and substantive requirements on some of DOT's rulemakings.

PRESIDENTIAL DIRECTIVES AND RELATED ACTIONS

I. 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. Guidance to Accompany the Presidential Directive (July 1998). This document directed Agencies to designate a senior official responsible for implementing plain language and prepare a plain language action plan. It also provided guidance on writing in plain language.

C. DOT Guidance. See the DOT website "Plain Language" circulated with Secretarial memorandum on "Plain Language" dated April 5, 1999.

D. Plain Writing Act (2010). This statute, which is intended to promote clear government communication, does not apply to regulations. However, E.O.s 12866, 13563, and 12988 do impose requirements for plain language. The statute does cover documents that explain to the public how to comply with a requirement that the Federal Government administers or enforces. See Administrator of OIRA memorandum of April 13, 2011 (M-11-15), on "Final Guidance on Implementing the Plain Writing Act of 2010." The memorandum notes that guidance and rulemaking preambles are covered by the Act.

II. Transparency and Open Government

A. Presidential Memorandum (January 21, 2009). This memorandum requires agencies to harness new technologies to put information online, offer Americans increased opportunities to participate in policymaking, and use innovative tools, methods, and systems to cooperate with other government agencies and the public. It also requires agencies to solicit public feedback on how they can improve in these areas.

B. Disclosure and Simplification. See OMB Director memorandum of December 8, 2009, on "Open Government Directive" and OIRA Administrator memorandum of June 18, 2010, on "Disclosure and Simplification as Regulatory Tools." The latter memorandum provides principles designed to assist agencies in their efforts to issue information disclosure to achieve their regulatory objectives.

C. RINs. See OIRA Administrator memorandum of April 7, 2010, on "Increasing Openness in the Rulemaking Process – Use of Regulation Identifier Number (RIN)." To help the public more easily find documents related to a rulemaking in its various stages, agencies should use RINs on all relevant documents throughout the lifecycle of a rulemaking. This includes NPRMs, final rules, and (to the extent they are associated with a rulemaking), notices, guidance, environmental impact statements, regulatory impact analyses, information collections, and supporting materials, as well as the metadata/text in the *Federal Register* and Regulations.gov.

D. Electronic Dockets. See OIRA Administrator memorandum of May 28, 2010, on "Increasing Openness in the Rulemaking Process – Improving Electronic Dockets."

1. Comprehensive Dockets. Agencies must compile and maintain comprehensive electronic regulatory dockets that include supporting materials, such as notices, significant guidance, environmental impact statements, regulatory impact analyses, and information collections, which should be available during the notice and comment process.

2. Machine Readable. Documents in the docket should be in a format that enables full-text searches.

3. Timely Postings. Public comments are expected to be posted to the docket in a timely manner.

4. Compliance with Law. Agencies must ensure that they comply with all applicable laws and policies, including those on national security, information security, confidentiality, privacy, and intellectual property.

5. Taxonomy. Agencies must use a common taxonomy for documents, sub-documents, and non-rulemaking document types.

E. Regulatory Compliance. A Presidential Memorandum of January 11, 2011, on "Regulatory Compliance" requires greater disclosure of agency regulatory compliance information.

1. Accessible, Downloadable, and Searchable Information. Agencies with broad regulatory compliance and administrative enforcement responsibilities must make information about their regulatory compliance and enforcement activities easily accessible, downloadable, and searchable on-line.

2. Cross-Agency Comparisons and Sharing of Information. The Federal Chief Information Officer and the Chief Technology Officer must make compliance/enforcement information available in ways that facilitate cross-agency comparisons and share such information across the government, to promote flexibility and coordinated enforcement.

F. Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act. See OIRA Administrator memorandum of April 7, 2010, on this subject. It clarifies the application of the Paperwork Reduction Act to agency use of social media and web-based interactive technologies. Although certain uses of these tools are excluded from coverage under the Act, agencies need to carefully review the constraints discussed in this memorandum.

G. Export and Trade Promotion, Public Participation, and Rulemaking. See OIRA Administrator/Deputy United States Trade Representative memorandum of May 19, 2011 (M-11-23), on this subject. It highlights the importance of regulatory transparency and openness in promoting international trade and describes existing agency obligations that can help reduce trade barriers.

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. OMB Guidance.

1. Checklist. See "Agency Checklist: Regulatory Impact Analysis." It provides a checklist for compliance with E.O. 12866 and OMB Circular A-4.

2. Frequently Asked Questions. See "Regulatory Impact Analysis: Frequently Asked Questions (FAQs)." It provides the answers.

3. International Effects. See OIRA Administrator/Deputy United States Trade Representative memorandum of May 19, 2011 (M-11-23), on "Export and Trade Promotion, Public Participation, and Rulemaking."

G. DOT Guidance.

1. Value of Statistical Life and Injuries. See "Guidance on Treatment of the Economic Value of a Statistical Life (VSL) in U.S. Department of Transportation Analyses – 2016 Adjustment." 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.

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" (2016). These documents contain 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 "Threshold of Significant Regulatory Actions Under the Unfunded Mandates Reform Act of 1995."

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 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 be used only 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 it 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.

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.

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 either 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. *See also* E.O. 13891 (requiring agencies to have a single, searchable, indexed database on their websites that contain or link to all guidance documents from that agency).

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.

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. This

memorandum builds upon OIRA Administrator memorandum of January 12, 1995, on "Principles for Risk Analysis."

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 provided 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.

G. DOT Order. See DOT Order 1351.18 (2014), "Departmental Privacy Risk Management Policy," for supplemental requirements.

V. Disclosure and Simplification as Regulatory Tools (2010).

A. General. This OIRA Administrator memorandum sets forth principles to help agencies in their use of summary and full disclosure of information and simplification to achieve regulatory objectives.

B. Disclosure.

1. Summary Disclosure. This is the best method to inform the public at the point of decision. Agency summary disclosures should explicitly identify their goals; generally, be simple and specific; be fair and accurate and in plain language; be properly placed and timed (*e.g.*, in a prominent location at place and time of purchase); use meaningful ratings or scales; if feasible, be tested in advance and monitored over time to determine their effects; and if feasible, analyzed to determine their costs and benefits.

2. Full Disclosure. This is the best method for all public access to a broad range of information, allowing them to analyze and disseminate it in creative ways. A full disclosure should be as accessible as possible (usually via the Internet); as useable as possible (usually in a format (*e.g.*, XML) not requiring specialized software); periodically assessed to determine whether as accurate and useful as possible; and if feasible, analyzed for costs and benefits.

3. Smart Disclosure. This is the best method for making information machine readable and in standardized formats, and thus, available, accessible, and usable. See OMB memorandum of September 8, 2011, on "Informing Consumers through Smart Disclosure."

C. Simplification. Simplification of choices and use of default rules can improve outcomes. In choosing an approach, to the extent permitted, agencies should consider: the appropriateness of using default rules (*e.g.*, automatic enrollment) in lieu of, or as a supplement to, a mandate or ban; effects of the default rules and choose the rule most beneficial to the relevant population; active choosing as an alternative to a specified default rule, especially for diverse and appropriately informed groups; and how to eliminate unnecessary complexity and simplify choices.

D. Presidential Memorandum (January 21, 2009). This memorandum requires agencies to harness new technologies to put information online, offer Americans increased opportunities to participate in policymaking, and use innovative tools, methods, and systems to cooperate with other government agencies and the public. It also requires agencies to solicit public feedback on how they can improve in these areas.

E. Disclosure and Simplification. See OMB Director memorandum of December 8, 2009, on "Open Government Directive" and OIRA Administrator memorandum of June 18, 2010, on "Disclosure and Simplification as Regulatory Tools." The latter memorandum provides principles designed to assist agencies in their efforts to issue information disclosure to achieve their regulatory objectives.

DOT REGULATIONS, ORDERS, MEMORANDA, AND PROCEDURES

I. Administrative Rulemaking, Guidance, and Enforcement Procedures, 84 FR 71714 (Dec. 27, 2019).

A. Policies and Procedures for Rulemaking.

1. Coverage. This rule applies to all DOT rulemakings, but excludes those related to military or foreign affairs functions, agency management or personnel, and Federal procurement.

2. Policies. The rule codifies several policies governing DOT regulations. For example, it states that there should be no more regulations than necessary; that regulations should specify performance objectives rather than specific conduct, when possible; that regulations should be narrowly tailored to address specific market failures or statutory mandates; and that rules that are expected to impose greater economic costs should be accompanied by additional procedural protections and avenues for public participation.

3. Responsibilities. The rule describes the responsibilities of individuals involved in the rulemaking process in the Office of the Secretary (OST) and operating administrations (OAs). It requires each OA and OST component responsible for rulemaking to designate a Regulatory Quality Officer, responsible for reviewing all rulemaking documents for plain language, technical soundness, and general quality.

4. Regulatory Reform Task Force. The rule describes the composition and functions of the Regulatory Reform Task Force (RRTF), which, among other things, is responsible for reviewing each request for new rulemaking actions.

5. Initiating Office Responsibilities. The rule requires that any operating administration or rulemaking component of the Office of the Secretary that seeks to develop a rulemaking must submit a Rulemaking Initiation Request to the RRTF.

6. General Rulemaking Procedures. The rule sets requirements for the process by which DOT rulemakings are developed and promulgated. The following are some of the most significant topics covered:

a. Departmental Review. The rule requires all rulemakings to be reviewed and cleared by the Office of the Secretary, with certain exceptions (such as FAA emergency rules). It also describes procedures for review and clearance.

b. Review of Existing Regulations. The rule describes and sets requirements for the process by which departmental regulations are reviewed on a 10-year cycle.

c. Supporting Economic Analysis. The rule requires rulemakings to include assessments of potential costs and benefits or a reasoned determination that a formal analysis is not warranted. Rulemakings must also include a reasoned determination that the benefits of a regulatory action outweigh the costs or an explanation of why a less costly alternative is not an option.

7. Notices of Proposed Rulemakings (NPRMs). The rule sets minimum requirements for the contents of NPRMs.

8. Final Rules. The rule sets minimum requirements for the contents of final rules, such as a requirement that a final rule contain an explanation of any changes from the rule as proposed in the NPRM and a justification of why the changes were needed or appropriate.

9. Interim Final Rules (IFRs) and Direct Final Rules (DFRs). The rule states that IFRs and DFRs are not favored, as issuing rulemakings without notice and comment should be the exception.

10. Public Comment. The rule requires a comment period of at least 30 days for nonsignificant rules and at least 45 days for significant rules.

11. Negotiated Rulemakings. The rule states that DOT encourages the use of negotiated rulemaking when appropriate, in order to promote consensus, enable DOT to receive data efficiently, simplify implementation, reduce the likelihood or scope of a litigation challenge, and result in a more effective or durable final rule.

12. Special Procedures for Economically Significant Rules.

a. Definitions. The rule defines “economically significant rule” as a significant rule likely to impose a total annual cost to the U.S. economy of $100 million or more, or a net loss of at least 75,000 full-time jobs in the United States over five years. It defines a “high-impact rule” as a significant rule likely to impose a total annual cost to the U.S. economy of $500 million or more, or a net loss of at least 250,000 full-time jobs in the United States over five years.

b. Additional Requirements. The rule creates additional requirements for economically significant and high-impact rules. The following are some of the most significant requirements included:

(1) Comment Period. The rule requires a comment period of at least 60 days for economically significant rules and at least 90 days for high-impact rules.

(2) Objectives and Metrics. The rule requires economically significant and high-impact rules to include a discussion of their objectives and the metrics by which the OA or OST component will measure progress toward those objectives.

(3) Formal Hearings. The rule describes procedures for formal hearings, which may be held concerning a rulemaking. The rule requires a proposing OA or OST component to hold a formal hearing for a high-impact rule if a party petitions for one and makes certain plausible showings regarding the need for a formal hearing. It allows the proposing OA or OST component to deny a petition for a formal hearing in the case of economically significant rules, under certain circumstances.

(4) Review Period. Economically significant and high-impact rules must be reviewed every 5 years for regulatory impact.

13. Public Contacts.

a. In General. The rule allows contacts between DOT personnel and interested members of the public at any stage of the rulemaking process, subject to certain guidelines provided the substance of material information submitted by the public is adequately disclosed, and subject to other guidelines as well.

b. Reopening the Comment Period. The rule describes circumstances in which the comment period on a rulemaking should be reopened, such as when DOT receives a large number of requests for meetings, or when it learns of significant new information.

14. See also DOT Order 2100.6: Policies and Procedures for Rulemakings (2018).

B. Policies and Procedures for Guidance.

1. Definition. The rule defines "guidance document" as any statement of agency policy or agency interpretation which is intended to have general applicability and future effect but which is not intended to have the force or effect of law and does not fall under APA section 553 or section 556.

2. Review and Clearance. The rule sets requirement for internal review and clearance of guidance.

3. Requirements. The rule specifies several requirements that a guidance document must meet in order to be issued. For example, the document must contain the term "guidance" or its functional equivalent; it must avoid using mandatory language such as "shall" or "require" unless it is describing an established requirement; and it must state clearly and prominently that the document is not legally binding in its own right and that conformity with the document is voluntary only.

4. Public Access. The rule requires each OA and OST component responsible for issuing guidance documents to maintain an electronic list of all guidance documents, ensure that such documents are accessible to the public in electronic form, maintain a means for the public to comment on guidance documents electronically, and designate an office to receive public complaints regarding the use of guidance documents.

5. Cost Estimates. The rule states that if an OA and OST component responsible for issuing guidance documents has reason to believe that the issuance of guidance may result in substantial costs or cost savings, then it should make a good faith effort to estimate the likely economic cost impact of the guidance document.

6. Significant Guidance Documents.

    a. Definition. A "significant guidance document" is one that may reasonably be anticipated to lead to annual costs in the United States of $100 million or more; adversely affect in a material way the U.S. economy or an important sector thereof; create serious inconsistency or interfere with the actions of another Federal agency; alter materially the budgetary impact of Federal programs; or raise novel legal and policy issues. Even if not significant, a guidance document can be "otherwise of importance to the Department's interests."

    b. Additional Requirements. The memo creates additional requirements for guidance documents that are "significant" or "otherwise of importance to the Department's interests." For instance, both of these categories of documents must be approved by the Secretary, and significant guidance documents must undergo informal notice-and-comment procedures. However, several categories of guidance are generally exempt from these requirements, such as safety advisories.

7. See also DOT Memo on "Review and Clearance of Guidance Documents" (2018).

C. Policies and Procedures for Enforcement.

1. Applicability. The rule applies to all enforcement actions taken by DOT operating administrations and offices of the Office of the Secretary with enforcement authority.

2. Policy. The rule requires that a regulated party be afforded appropriate due process in all enforcement actions. DOT enforcement processes must have (i) a clear legal foundation founded on a grant of statutory authority, (ii) fairness and lack of bias, (iii) no unfair surprise, and (iv) a well-documented and clear decision.

3. See also DOT Memo on "Procedural Requirements for DOT Enforcement Actions" (2019).

II. Other Agency Rulemaking Provisions.

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.

III. Dockets.

A. Documents. DOT agencies place each rulemaking and supporting document (*e.g.*, proposed and final rule, economic or environmental analyses and information collection materials) and all public comments received, including late-filed comments and any other relevant information received, in a public docket located at Regulations.gov. 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, but they do place information in the docket noting any changes made to draft rulemaking documents during interagency review under E.O. 12866.

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

C. OIRA Memorandum. See OIRA Administrator memorandum of May 28, 2010, on "Increasing Openness in the Rulemaking Process – Improving Electronic Dockets."