



**U.S. Department
of Transportation**

Office of the Secretary
of Transportation

SUBJECT: POLICIES AND
PROCEDURES FOR
RULEMAKINGS

DOT ORDER

DOT Order 2100.6

December 20, 2018

1. PURPOSE

This Order sets forth updated policies and procedures governing the development and issuance of regulations by the Department of Transportation (the Department or DOT). This Order is intended to ensure that DOT, including each of its operating administrations (OAs) and all components of the Office of the Secretary of Transportation (OST) with rulemaking authority, adheres to (i) all statutory requirements applicable to DOT rulemakings, including the rulemaking provisions of the Administrative Procedure Act, referenced below; (ii) Executive Order 12866, as referenced below, and any amendment thereto; (iii) all applicable Office of Management and Budget (OMB) directives for rulemaking; (iv) the Department's Strategic Plan; and (v) best practices for rulemaking, including best practices for economic analyses and for appropriate outreach to interested parties throughout the rulemaking process. This Order shall be interpreted and applied to promote and to be consistent with the safe operation of the transportation systems and transportation activities over which DOT is granted regulatory authority.

2. APPLICABILITY

- a. This Order governs all DOT employees and contractors involved with all phases of rulemaking at DOT.
- b. Unless otherwise required by statute, this Order applies to all DOT regulations, which shall include all rules of general applicability promulgated by any components of the Department that affect the rights or obligations of persons outside the Department, including substantive rules, rules of interpretation, and rules prescribing agency procedures and practice requirements applicable to outside parties. This Order applies to all regulatory actions intended to lead to the promulgation of a rule and any other generally applicable agency directives, circulars, or pronouncements concerning matters within the jurisdiction of an OA or component of OST that are intended to have the force or effect of law or that are required by statute to satisfy the rulemaking procedures specified in section 553 or section 556 of title 5, United States Code.
- c. This Order does not apply to:
 - (1) Any rulemaking in which a notice of proposed rulemaking was issued before the effective date of this Order and which was still in progress on that date;

- (2) Regulations issued with respect to a military or foreign affairs function of the United States;
- (3) Rules addressed solely to internal agency management or personnel matters;
- (4) Regulations related to Federal Government procurement; or
- (5) Guidance documents, which are not intended to, and do not in fact, have the force or effect of law for parties outside the Department.

3. CANCELLATIONS

The following DOT orders are hereby canceled and superseded by this Order:

- a. DOT 2100.2: Policies for Public Contacts in Rule Making.
- b. DOT 2100.5: Policies and procedures for simplification, analysis, and review of regulations.

4. EFFECTIVE DATE

This Order shall be effective upon issuance.

5. REFERENCES

- a. Administrative Procedure Act (APA), 5 U.S.C. 552(a)(1), 553, 556, and 557, which prescribes general procedural requirements of law applicable to all Federal agencies regarding the formulation and issuance of regulations.
- b. Executive Order 12866, "Regulatory Planning and Review" (Oct. 4, 1993), which sets forth a regulatory philosophy and principles to which all Federal agencies should adhere, including requirements to regulate in the "most cost-effective manner," to make "a reasoned determination that the benefits of the intended regulations justify its costs," and to develop regulations that "impose the least burden on society."
- c. Executive Order 13771, "Reducing Regulation and Controlling Regulatory Costs" (Jan. 30, 2017), which directed agencies to identify at least two existing regulatory burdens to be revoked for each new significant regulation to be imposed. In addition, agencies must create a regulatory budget that offsets the incremental costs of any new regulations by eliminating costs associated with existing regulations.
- d. Executive Order 13777, "Enforcing the Regulatory Reform Agenda" (Feb. 24, 2017), which directed agencies to designate a Regulatory Reform Officer, to establish a Regulatory Reform Task Force with the Regulatory Reform Officer as the chair, and to evaluate existing regulations and make recommendations for their repeal, replacement, or modification.

6. POLICIES

The following policies govern the development and issuance of regulations at DOT:

- a. There should be no more regulations than necessary. In considering whether to propose a new regulation, policy makers should consider whether the specific problem to be addressed requires agency action, whether existing rules (including standards incorporated by reference) have created or contributed to the problem and should be revised or eliminated, and whether any other reasonable alternatives exist that obviate the need for a new regulation.
- b. All regulations must be supported by statutory authority and consistent with the Constitution.
- c. Where they rest on scientific, technical, economic, or other specialized factual information, regulations should be supported by the best available evidence and data.
- d. Regulations should be written in plain English, should be straightforward, and should be clear.
- e. Regulations should be technologically neutral, and, to the extent feasible, they should specify performance objectives, rather than prescribing specific conduct that regulated entities must adopt.
- f. Regulations should be designed to minimize burdens and reduce barriers to market entry whenever possible, consistent with the effective promotion of safety. Where they impose burdens, regulations should be narrowly tailored to address identified market failures or specific statutory mandates.
- g. Unless required by law or compelling safety need, regulations should not be issued unless their benefits are expected to exceed their costs. For each new significant regulation issued, agencies must identify at least two existing regulatory burdens to be revoked.
- h. Once issued, regulations and other agency actions should be reviewed periodically and revised to ensure that they continue to meet the needs they were designed to address and remain cost-effective and cost-justified.
- i. Full public participation should be encouraged in rulemaking actions, primarily through written comment and engagement in public meetings. Public participation in the rulemaking process should be conducted and documented, as appropriate, to ensure that the public is given adequate knowledge of substantive information relied upon in the rulemaking process.
- j. The process for issuing a rule should be sensitive to the economic impact of the rule; thus, the promulgation of rules that are expected to impose greater economic costs should be accompanied by additional procedural protections and avenues for public participation.

7. RESPONSIBILITIES

- a. The Secretary of Transportation supervises the overall planning, direction, and control of the Department's Regulatory Agenda; approves regulatory documents for issuance and submission to OMB under Executive Order 12866; identifies an approximate regulatory budget for each fiscal year as required by Executive Order 13771; establishes the Department's Regulatory Reform Task Force (RRTF); and designates the members of the RRTF and the Department's Regulatory Reform Officer (RRO) in accordance with Executive Order 13777.
- b. The Deputy Secretary of Transportation assists the Secretary in overseeing overall planning, direction, and control of the Department's Regulatory Agenda and approves the initiation of regulatory action, as defined in Executive Order 12866, by the OAs and components of OST. The Secretary has designated the Deputy Secretary to serve as the Chair of the Leadership Council of the RRTF and as the Department's RRO.
- c. The General Counsel of DOT is the chief legal officer of the Department with final authority on all questions of law for all components of DOT; serves on the Leadership Council of the RRTF; and serves as the Department's Regulatory Policy Officer pursuant to section 6(a)(2) of Executive Order 12866.
- d. The RRO of DOT is delegated authority by the Secretary to oversee the implementation of the Department's regulatory reform initiatives and policies to ensure the effective implementation of regulatory reforms, consistent with Executive Order 13777 and applicable law.
- e. DOT's non-career Deputy General Counsel is a member of the RRTF as designated by the Secretary and serves as the Chair of the RRTF Working Group.
- f. DOT's Assistant General Counsel for Regulation supervises the Office of Regulation (C-50) within the Office of the General Counsel (OGC); oversees the process for DOT rulemakings; provides legal advice on compliance with all APA and other administrative law requirements and with executive orders, OMB directives, and other regulatory procedures; circulates regulatory documents for departmental review and seeks concurrence from reviewing officials; submits regulatory documents to the Secretary for approval before issuance or submission to OMB; coordinates with the Office of Information and Regulatory Affairs (OIRA) within OMB on the designation and review of regulatory documents and the preparation of the Unified Agenda of Regulatory and Deregulatory Actions; publishes the monthly Internet report on significant rulemakings; and serves as a member of the RRTF Working Group.
- g. Pursuant to delegations from the Secretary under 49 CFR Part 1, OA Administrators and Secretarial officers exercise the Secretary's rulemaking authority under 49 U.S.C. 322(a), and they have responsibility for ensuring that the regulatory data included in the Regulatory Management System (RMS) for their OAs and OST components is accurate and is updated at least once a month.

- h. OA Chief Counsels supervise the legal staffs of the OAs; interpret and provide guidance on all statutes, regulations, executive orders, and other legal requirements governing the operation and authorities of their respective OAs; and review all rulemaking documents for legal sufficiency.
- i. Each OA or OST component responsible for rulemaking will have a Regulatory Quality Officer, designated by the Administrator or Secretarial office head, who will have responsibility for reviewing all rulemaking documents for plain language, technical soundness, and general quality.

8. REGULATORY REFORM TASK FORCE

- a. Purpose. The Regulatory Reform Task Force (RRTF) evaluates proposed and existing regulations and makes recommendations to the Secretary regarding their promulgation, repeal, replacement, or modification, consistent with applicable law and Executive Orders 13777, 13771, and 12866.
- b. Structure. The RRTF comprises a Leadership Council and a Working Group.
 - (1) The Working Group coordinates with leadership in the Secretarial offices and OAs, reviews and develops recommendations for regulatory and deregulatory action, and presents recommendations to the Leadership Council.
 - (2) The Leadership Council reviews the Working Group's recommendations and advises the Secretary.
- c. Membership.
 - (1) The Leadership Council comprises the following:
 - (a) The Regulatory Reform Officer (RRO), who serves as Chair;
 - (b) The Department's Regulatory Policy Officer, designated under section 6(a)(2) of Executive Order 12866;
 - (c) A representative from the Office of the Under Secretary of Transportation for Policy;
 - (d) At least three additional senior agency officials as determined by the Secretary.
 - (2) The Working Group comprises the following:
 - (a) At least one senior agency official from the Office of the General Counsel, including at a minimum the Assistant General Counsel for Regulation, as determined by the RRO;

- (b) At least one senior agency official from the Office of the Under Secretary of Transportation for Policy, as determined by the RRO;
 - (c) Other senior agency officials from the Office of the Secretary, as determined by the RRO.
- d. Functions and responsibilities. In addition to the functions and responsibilities enumerated in Executive Order 13777, the RRTF performs the following duties:
 - (1) Reviews each request for a new rulemaking action initiated by an OA or OST component; and
 - (2) Considers each regulation and regulatory policy question (which may include proposed guidance documents) referred to it and makes a recommendation to the Secretary for its disposition.
- e. Support. The Office of Regulation within the Office of the General Counsel (C-50) provides support to the RRTF.
- f. Meetings. The Leadership Council meets approximately monthly and will hold specially scheduled meetings when necessary to address particular regulatory matters. The Working Group meets approximately monthly with each OA and each component of OST with regulatory authority, and the Working Group may establish sub-committees, as appropriate, to focus on specific regulatory matters.
- g. Agenda. The Office of Regulation prepares an agenda for each meeting and distributes it to the members in advance of the meeting, together with any documents to be discussed at the meeting. The OA or OST component responsible for matters on the agenda will be invited to attend to respond to questions.
- h. Minutes. The Office of Regulation prepares summary minutes following each meeting and distributes them to the meeting's attendees.

9. INITIATING A RULEMAKING

- a. Before an OA or component of OST may proceed to develop a regulation, the Administrator of the OA or the Secretarial officer who heads the OST component must consider the regulatory philosophy and principles of regulation identified in section 1 of Executive Order 12866 and the policies set forth in section 6 of this Order. If the OA Administrator or OST component head determines that rulemaking is warranted consistent with those policies and principles, the Administrator or component head may prepare a Rulemaking Initiation Request.
- b. The Rulemaking Initiation Request should specifically state or describe:
 - (1) A proposed title for the rulemaking;

- (2) The need for the regulation, including a description of the market failure or statutory mandate necessitating the rulemaking;
 - (3) The legal authority for the rulemaking;
 - (4) Whether the rulemaking is expected to be regulatory or deregulatory;
 - (5) Whether the rulemaking is expected to be significant or nonsignificant, as defined by Executive Order 12866;
 - (6) Whether the final rule in question is expected to be an economically significant rule or high-impact rule, as defined in section 12 of this Order;
 - (7) A description of the economic impact associated with the rulemaking, including whether the rulemaking is likely to impose quantifiable costs or cost-savings;
 - (8) The tentative target dates for completing each stage of the rulemaking; and
 - (9) Whether there is a statutory or judicial deadline, or some other urgency, associated with the rulemaking.
- c. The OA or OST component submits the Rulemaking Initiation Request to the Office of Regulation, together with any other documents that may assist in the RRTF's consideration of the request.
 - d. The Office of Regulation includes the Rulemaking Initiation Request on the agenda for consideration at the OA's or OST component's next Working Group meeting.
 - e. If the Working Group recommends the approval of the Rulemaking Initiation Request, then the Request is referred to the Leadership Council for consideration. In lieu of consideration at a Leadership Council meeting, the Working Group, at its discretion, may submit a memorandum to the RRO seeking approval of the Rulemaking Initiation Request.
 - f. The OA or OST component may assign a Regulatory Information Number (RIN) to the rulemaking only upon the Leadership Council's (or RRO's) approval of the Rulemaking Initiation Request.
 - g. The process for initiating a rulemaking as described herein may be waived or modified for any rule with the approval of the RRO. Unless otherwise determined by the RRO, the Administrator of the Federal Aviation Administration (FAA) may promulgate an emergency rule under section 106(f)(3)(B)(ii) or section 46105(c) of title 49, United States Code, without first submitting a Rulemaking Initiation Request.
 - h. Rulemaking Initiation Requests will be considered on a rolling basis; however, the Office of Regulation will establish deadlines for submission of Rulemaking Initiation Requests so that new rulemakings may be included in the Unified Agenda of Regulatory and Deregulatory Actions.

10. UNIFIED AGENDA OF REGULATORY AND DEREGULATORY ACTIONS

- a. The Unified Agenda of Regulatory and Deregulatory Actions (Unified Agenda) provides uniform reporting of data on regulatory and deregulatory activities under development throughout the Federal Government, covering approximately 60 departments, agencies, and commissions. DOT's faithful participation in the Unified Agenda demonstrates the Department's ongoing commitment to fundamental regulatory reform and to reducing unnecessary regulatory burdens on the American people.
- b. Fall editions of the Unified Agenda include the Regulatory Plan, which presents the Department's statement of regulatory priorities for the coming year. Fall editions also include the outcome and status of the Department's reviews of existing regulations, conducted in accordance with section 11(d) of this Order.
- c. The OAs and components of OST with rulemaking authority must:
 - (1) Carefully consider the principles contained in Executive Orders 13771, 13777, and 12866 in the preparation of all submissions for the Unified Agenda;
 - (2) Ensure that all data pertaining to the OA's or OST component's regulatory and deregulatory actions are accurately reflected in the Department's Unified Agenda submission; and
 - (3) Timely submit all data to OGC's Office of Regulation (C-50) in accordance with the deadlines and procedures communicated by that office.
- d. Unless required to address a safety emergency or otherwise required by law, approved by the RRTF (or RRO), or approved by the Director of OMB (as appropriate), no regulation may be issued by an OA or component of OST if it was not included on the most recent version or update of the published Unified Agenda. Furthermore, no significant regulatory action may take effect until it has appeared in either the Unified Agenda or the monthly Internet report of significant rulemakings for at least 6 months prior to its issuance, unless good cause exists for an earlier effective date or the action is otherwise approved by the RRTF (or RRO).

11. GENERAL RULEMAKING PROCEDURES

- a. Definitions.
 - (1) "Significant rulemaking" means a regulatory action designated by OIRA under Executive Order 12866 as likely to result in a rule that may:
 - (a) Have an annual effect on the U.S. economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

- (b) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
 - (c) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
 - (d) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.
- (2) "Nonsignificant rulemaking" means a regulatory action not designated significant by OIRA.
- b. Departmental review process.
- (1) OST review and clearance.
 - (a) Except as provided herein or as otherwise provided in writing by OGC, all departmental rulemakings are to be reviewed and cleared by the Office of the Secretary.
 - (b) The FAA Administrator may promulgate emergency rules pursuant to sections 106(f)(3)(B)(ii) and 46105(c) of title 49, United States Code, without prior approval from OST; provided that, to the maximum extent practicable and consistent with law, the FAA Administrator will give OST advance notice of such emergency rules and will allow OST to review the rules in accordance with the provisions of this Order at the earliest opportunity after they are promulgated.
 - (2) Leadership within the proposing OA or component of OST shall:
 - (a) Ensure that the OA's or OST component's Regulatory Quality Officer reviews all rulemaking documents for plain language, technical soundness, and general quality;
 - (b) Ensure that the OA's Office of Chief Counsel (or for OST rules, the Office within OGC responsible for providing programmatic advice) reviews all rulemaking documents for legal support and legal sufficiency; and
 - (c) Approve the submission of all rulemaking documents, including any accompanying analyses (e.g., regulatory impact analysis), to the Office of Regulation through the Regulatory Management System (RMS) for OST review and clearance.
 - (3) To effectuate departmental review under this Order, the following Secretarial offices ordinarily review and approve DOT rulemakings: the Office of the Under Secretary for Policy, the Office of Public Affairs, the Office of Budget and Programs and Chief Financial Officer, OGC, and the Office of Governmental Affairs. OGC's Office of Regulation may also require review and clearance by

other Secretarial offices and OAs depending on the nature of the particular rulemaking document.

- (4) Reviewing offices should provide comments or otherwise concur on rulemaking documents within 7 calendar days, unless exceptional circumstances apply that require expedited review.
- (5) The Office of Regulation (C-50) provides a pass back of comments to the proposing OA or OST component for resolution. Comments should be resolved and a revised draft submitted to the Office of Regulation by the OA or OST component within 14 calendar days.
- (6) The Office of Regulation prepares a rulemaking package for the General Counsel to request the Secretary's approval for the rulemaking to be submitted to the OMB for review (for significant rulemakings) or to the *Federal Register* for publication (for nonsignificant rulemakings). These rulemaking packages are submitted through the General Counsel to the Office of the Executive Secretariat.
- (7) The Office of Regulation notifies the proposing OA or OST component when the Secretary approves or disapproves the submission of the rulemaking to OMB or to the *Federal Register*.
- (8) The Office of Regulation is responsible for coordination with OIRA staff on the designation of all rulemaking documents, submission and clearance of all significant rulemaking documents, and all discussions or meetings with OMB concerning these documents. OAs and OST components should not schedule their own meetings with OIRA without Office of Regulation involvement. Each OA or OST component should coordinate with the Office of Regulation before holding any discussions with OIRA concerning regulatory policy or agreements to modify regulatory documents.

c. Petitions for rulemaking.

- (1) Any person may petition an OA or OST component with rulemaking authority to issue, amend, or repeal a rule, or for a permanent or temporary exemption from any rule.
- (2) Petitions for rulemaking are processed in accordance with 49 CFR Part 5 or other OA regulations or procedures.
- (3) When an OA or OST component receives a petition for rulemaking, the petition should be filed with the Docket Clerk in a timely manner. If a petition for rulemaking is filed directly with the Docket Clerk, the Docket Clerk will submit the petition in a timely manner to the OA or component of OST with regulatory responsibility over the matter described in the petition.

- d. Review of existing regulations.
 - (1) All departmental regulations are on a 10-year review cycle, as described in Appendix D of the Unified Agenda of Regulatory and Deregulatory Actions.
 - (2) The OA or OST component that issued the regulation will review it for the following:
 - (a) Continued cost justification: Whether the regulation requires adjustment due to changed market conditions or is no longer cost-efficient or cost-justified in accordance with section 6(h) of this Order;
 - (b) Regulatory flexibility: Whether the regulation has a significant economic impact on a substantial number of small entities and, thus, requires review under section 610 of the Regulatory Flexibility Act;
 - (c) General updates: Whether the regulation may require technical corrections, updates (e.g., updated versions of voluntary consensus standards), revisions, or repeal;
 - (d) Plain language: Whether the regulation requires revisions for plain language; and
 - (e) Other considerations as required by relevant executive orders and laws.
 - (3) The results of each OA's or OST component's review will be reported annually in Appendix D of the Unified Agenda of Regulatory and Deregulatory Actions.
- e. Supporting economic analysis.
 - (1) Rulemakings shall include, at a minimum:
 - (a) An assessment of the potential costs and benefits of the regulatory action (which may entail a regulatory impact analysis, or RIA) or a reasoned determination that the expected impact is so minimal or the safety need so significant and urgent that a formal analysis of costs and benefits is not warranted; and
 - (b) If the regulatory action is expected to impose costs, either a reasoned determination that the benefits outweigh the costs or, if the particular rulemaking is mandated by statute or compelling safety need notwithstanding a negative cost-benefit assessment, a detailed discussion of the rationale supporting the specific regulatory action proposed and an explanation of why a less costly alternative is not an option.
 - (2) To the extent practicable, economic assessments shall quantify the foreseeable annual economic costs and cost savings within the United States that would likely result from issuance of the proposed rule and shall be conducted in accordance

with the requirements of section 6(a)(B) & (C) of Executive Order 12866 and OMB Circular A-4, as specified by OIRA in consultation with OGC's Office of Regulation. If the proposing OA or OST component has estimated that the proposed rule will likely impose economic costs on persons outside the United States, such costs should be reported separately.

- (3) Deregulatory rulemakings (including nonsignificant rulemakings) shall be evaluated for quantifiable cost savings. If it is determined that quantification of cost savings is not possible or appropriate, then the proposing OA or OST component shall provide a detailed justification for the lack of quantification upon submission of the rulemaking to the Office of Regulation. Other nonsignificant rulemakings shall include, at a minimum, the economic cost-benefit analysis described in paragraph (1) of this subsection.
- f. Regulatory flexibility analysis. All rulemakings subject to the requirements of sections 603-604 of title 5, United States Code (sections 603-604 of the Regulatory Flexibility Act), and any amendment thereto, shall include a detailed statement setting forth the required analysis regarding the potential impact of the rule on small business entities.
 - g. Advance notices of proposed rulemaking. Whenever the OA or OST component responsible for a proposed rulemaking is required to publish an advance notice of proposed rulemaking (ANPRM) in the *Federal Register*, or whenever the RRTF determines it appropriate to publish an ANPRM, the ANPRM shall:
 - (1) Include a written statement identifying, at a minimum—
 - (a) The nature and significance of the problem the OA or OST component may address with a rule;
 - (b) The legal authority under which a rule may be proposed; and
 - (c) Any preliminary information available to the OA or OST component that may support one or another potential approach to addressing the identified problem;
 - (2) Solicit written data, analysis, views, and recommendations from interested persons concerning the information and issues addressed in the ANPRM; and
 - (3) Provide for a reasonably sufficient period for public comment.
 - h. Notices of proposed rulemaking.
 - (1) When required. Before determining to propose a rule, and following completion of the ANPRM process under subsection g, if applicable, the responsible OA or OST component shall consult with the RRTF concerning the need for the potential rule. If the RRTF thereafter determines it appropriate to propose a rule, the proposing OA or OST component shall publish a notice of proposed rulemaking (NPRM) in the *Federal Register*, unless a controlling statute provides

otherwise or unless the RRTF (in consultation with OIRA, as appropriate) determines that an NPRM is not necessary under established exceptions.

- (2) Contents. The NPRM shall include, at a minimum—
- (a) A statement of the time and place for submission of public comments and the time, place, and nature of related public rulemaking proceedings, if any;
 - (b) Reference to the legal authority under which the rule is proposed;
 - (c) The terms of the proposed rule;
 - (d) A description of information known to the proposing OA or OST component on the subject and issues of the proposed rule, including but not limited to—
 - (i) A summary of material information known to the OA or OST component concerning the proposed rule and the considerations specified in section 9(a) of this Order;
 - (ii) A summary of any preliminary risk assessment or regulatory impact analysis performed by the OA or OST component; and
 - (iii) Information specifically identifying all material data, studies, models, available voluntary consensus standards and conformity assessment requirements, and other evidence or information considered or used by the OA or OST component in connection with its determination to propose the rule;
 - (e) A reasoned preliminary analysis of the need for the proposed rule based on the information described in the preamble to the NPRM, and an additional statement of whether a rule is required by statute;
 - (f) A reasoned preliminary analysis indicating that the expected economic benefits of the proposed rule will meet the relevant statutory objectives and will outweigh the estimated costs of the proposed rule in accordance with any applicable statutory requirements;
 - (g) If the rulemaking is significant, a summary discussion of (i) the alternatives to the proposed rule considered by the OA or OST component, (ii) the relative costs and benefits of those alternatives, (iii) whether the alternatives would meet relevant statutory objectives, and (iv) why the OA or OST component chose not to propose or pursue the alternatives;
 - (h) A statement of whether existing rules have created or contributed to the problem the OA or OST component seeks to address with the proposed rule, and, if so, whether or not the OA or OST component proposes to amend or rescind any such rules and why; and

- (i) All other statements and analyses required by law, including, without limitation, the Regulatory Flexibility Act or any amendment thereto.
- (3) Information access and quality.
- (a) To inform public comment when the NPRM is published, the proposing OA or OST component shall place in the docket for the proposed rule and make accessible to the public, including by electronic means, all material information relied upon by the OA or OST component in considering the proposed rule, unless the information is exempt from disclosure under section 552(b) of title 5, United States Code. Material provided electronically should be made available in accordance with the requirements of section 794d of title 29, United States Code (section 508 of the Rehabilitation Act of 1973, as amended).
 - (b) If the proposed rule rests upon scientific, technical, or economic information, the proposing OA or OST component shall base the proposal on the best and most relevant scientific, technical, and economic information reasonably available to the Department and shall identify the sources and availability of such information in the NPRM.
 - (c) A single copy of any relevant copyrighted material (including consensus standards and other relevant scientific or technical information) should be placed in the docket for public review if such material was relied on as a basis for the rulemaking.
- i. Public comment.
- (1) Following publication of an NPRM, the Department will provide interested persons a fair and sufficient opportunity to participate in the rulemaking through submission of written data, analysis, views, and recommendations.
 - (2) The Department, in coordination with OIRA for significant rulemakings, will ensure that the public is given an adequate period for comment, taking into account the scope and nature of the issues and considerations involved in the proposed regulatory action.
 - (3) Generally, absent special considerations, the comment period for nonsignificant DOT rules should be at least 30 days, and the comment period for significant DOT rules should be at least 45 days.
- j. Exemptions from notice and comment.
- (1) Except when prior notice and an opportunity for public comment are required by statute or determined by the Secretary to be advisable for policy or programmatic reasons, the responsible OA or OST component may, subject to the approval of the RRTF (in consultation with OIRA, as appropriate), publish certain final rules in the *Federal Register* without prior notice and comment. These may include:

- (a) Rules of interpretation and rules addressing only DOT organization, procedure, or practice, provided such rules do not alter substantive obligations for parties outside the Department;
 - (b) Rules for which notice and comment is unnecessary to inform the rulemaking, such as rules correcting de minimis technical or clerical errors or rules addressing other minor and insubstantial matters, provided the reasons to forgo public comment are explained in the preamble to the final rule; and
 - (c) Rules that require finalization without delay, such as rules to address an urgent safety or national security need, and other rules for which it would be impracticable or contrary to public policy to accommodate a period of public comment, provided the responsible OA or OST component makes findings that good cause exists to forgo public comment and explains those findings in the preamble to the final rule.
- (2) Except when required by statute, issuing substantive DOT rules without completing notice and comment, including as interim final rules (IFRs) and direct final rules (DFRs), must be the exception. IFRs and DFRs are not favored. In most cases where an OA or OST component has issued an IFR, the RRTF will expect the OA or OST component to proceed at the earliest opportunity to replace the IFR with a final rule.
- k. Final rules. The responsible OA or OST component shall adopt a final rule only after consultation with the RRTF. The final rule, which shall include the text of the rule as adopted along with a supporting preamble, shall be published in the *Federal Register* and shall satisfy the following requirements:
- (1) The preamble to the final rule shall include—
 - (a) A concise, general statement of the rule's basis and purpose, including clear reference to the legal authority supporting the rule;
 - (b) A reasoned, concluding determination by the adopting OA or OST component regarding each of the considerations required to be addressed in an NPRM under subsection h(2)(e)-(i) of this section;
 - (c) A response to each significant issue raised in the comments to the proposed rule;
 - (d) If the final rule has changed in significant respects from the rule as proposed in the NPRM, an explanation of the changes and the reasons why the changes are needed or are more appropriate to advance the objectives identified in the rulemaking; and
 - (e) A reasoned, final determination that the information upon which the OA or OST component bases the rule complies with the Information Quality Act,

section 515 of Pub. L. No. 106-554—Appendix C, 114 Stat. 2763A–153-54 (2001), or any subsequent amendment thereto.

- (2) If the rule rests on scientific, technical, economic, or other specialized factual information, the OA or OST component shall base the final rule on the best and most relevant evidence and data known to the Department and shall ensure that such information is clearly identified in the preamble to the final rule and is available to the public in the rulemaking record, subject to reasonable protections for information exempt from disclosure under section 552(b) of title 5, United States Code. If the OA or OST component intends to support the final rule with specialized factual information identified after the close of the comment period, the OA or OST component shall allow an additional opportunity for public comment on such information.
 - (3) All final rules issued by the Department (a) shall be written in plain and understandable English; (b) shall be based on a reasonable and well-founded interpretation of relevant statutory text and shall not depend upon a strained or unduly broad reading of statutory authority; and (c) shall not be inconsistent or incompatible with, or unnecessarily duplicative of, other Federal regulations.
- l.* Reports to Congress. For each final rule adopted by DOT, the responsible OA or OST component shall submit the reports to Congress and comply with the procedures specified by section 801 of title 5, United States Code (the Congressional Review Act), or any subsequent amendment thereto.
- m.* Negotiated rulemakings.
- (1) In appropriate cases, DOT encourages OAs and OST components to consider using a negotiated rulemaking process to supplement APA procedures for informal rulemaking. By bringing representatives of affected constituencies together in a committee process to participate in the collaborative development of a proposed rule, negotiated rulemaking can promote consensus, enable DOT to receive relevant data more efficiently, simplify implementation of the final rule and reduce the likelihood or scope of a litigation challenge, and result in a more effective and durable final rule. DOT negotiated rulemakings are to be conducted in accordance with the Negotiated Rulemaking Act, 5 U.S.C. 561-571, and the Federal Advisory Committee Act, 5 U.S.C. App. 2, as applicable.
 - (2) Before initiating a negotiated rulemaking process, the OA or OST component should (a) assess whether using negotiated rulemaking procedures for the proposed rule in question is in the public interest, in accordance with section 563(a) of title 5, United States Code, and present these findings to the RRTF; (b) consult with the Office of Regulation on the appropriateness of negotiated rulemaking and the procedures therefor; and (c) receive the approval of the RRTF for the use of negotiated rulemaking.

- (3) Unless otherwise approved by the General Counsel, all DOT negotiated rule-makings should involve the assistance of a convener and a facilitator, as provided in the Negotiated Rulemaking Act. A convener is a person who impartially assists the agency in determining whether establishment of a negotiated rulemaking committee is feasible and appropriate in a particular rulemaking. A facilitator is a person who impartially aids in the discussions and negotiations among members of a negotiated rulemaking committee to develop a proposed rule. The same person may serve as both convener and facilitator.
- (4) All charters, membership, *Federal Register* notices, and operating procedures (or bylaws) for negotiated rulemaking committees must be approved by OGC.

12. SPECIAL PROCEDURES FOR ECONOMICALLY SIGNIFICANT RULES AND HIGH-IMPACT RULES

a. Definitions

- (1) “Economically significant rule” means a significant rule likely to impose (i) a total annual cost on the U.S. economy (without regard to estimated benefits) of \$100 million or more, or (ii) a total net loss of at least 75,000 full-time jobs in the U.S. over the five years following the effective date of the rule (not counting any jobs relating to new regulatory compliance).
- (2) “High-impact rule” means a significant rule likely to impose (i) a total annual cost on the U.S. economy (without regard to estimated benefits) of \$500 million or more, or (ii) a total net loss of at least 250,000 full-time jobs in the U.S. over the five years following the effective date of the rule (not counting any jobs relating to new regulatory compliance).

b. ANPRM required. Unless directed otherwise by the RRTF or otherwise required by law, in the case of a rulemaking for an economically significant rule or a high-impact rule, the proposing OA or OST component shall publish an ANPRM in the *Federal Register*.

c. Additional requirements for NPRM.

- (1) In addition to the requirements set forth in section 11(h) of this Order, an NPRM for an economically significant rule or a high-impact rule shall include a discussion explaining an achievable objective for the rule and the metrics by which the OA or OST component will measure progress toward that objective.
- (2) Absent unusual circumstances and unless approved by the RRTF (in consultation with OIRA, as appropriate), the comment period for an economically significant rule shall be at least 60 days and for a high-impact rule at least 90 days. If a rule is determined to be an economically significant rule or high-impact rule after the publication of the NPRM, the responsible OA or OST component shall publish a notice in the *Federal Register* informing the public of the change in classification and shall extend or reopen the comment period by not less than 30 days and allow

further public comment as appropriate, including comment on the change in classification.

d. Procedures for formal hearings.

- (1) Petitions for hearings. Following publication of an NPRM for an economically significant rule or a high-impact rule, and before the close of the comment period, any interested party may file in the rulemaking docket a petition asking the proposing OA or OST component to hold a formal hearing on the proposed rule in accordance with this subsection.
- (2) Mandatory hearing for high-impact rule. In the case of a proposed high-impact rule, the responsible OA or OST component shall grant the petition for a formal hearing if the petition makes a plausible prima facie showing that—
 - (a) The proposed rule depends on conclusions concerning one or more specific scientific, technical, economic, or other complex factual issues that are genuinely in dispute or that may not satisfy the requirements of the Information Quality Act;
 - (b) The ordinary public comment process is unlikely to provide the OA or OST component an adequate examination of the issues to permit a fully informed judgment on the dispute; and
 - (c) The resolution of the disputed factual issues would likely have a material effect on the costs and benefits of the proposed rule or on whether the proposed rule would achieve the statutory purpose.
- (3) Authority to deny hearing for economically significant rule. In the case of a proposed economically significant rule, the responsible OA or OST component may deny a petition for a formal hearing that includes the showing described in paragraph (2) but only if the OA or OST component reasonably determines that—
 - (a) The requested hearing would not advance the consideration of the proposed rule and the OA's or OST component's ability to make the rulemaking determinations required under this Order; or
 - (b) The hearing would unreasonably delay completion of the rulemaking in light of a compelling safety need or an express statutory mandate for prompt regulatory action.
- (4) Denial of petition. If the OA or OST component denies a petition for a formal hearing under this subsection in whole or in part, the OA or OST component shall include a detailed explanation of the factual basis for the denial in the rulemaking record, including findings on each of the relevant factors identified in paragraph (2) or (3) above. The denial of a good faith petition for a formal hearing under this subsection shall be disfavored.

- (5) Notice and scope of hearing. If the OA or OST component grants a petition for a formal hearing under this subsection, the OA or OST component shall publish a notice of the hearing in the *Federal Register* not less than 45 days before the date of the hearing. The notice shall specify the proposed rule at issue and the specific factual issues to be considered in the hearing. The scope of the hearing shall be limited to the factual issues specified in the notice.
- (6) Hearing process.
 - (a) A formal hearing for purposes of this subsection shall be conducted using procedures borrowed from sections 556 and 557 of title 5, United States Code, or similar procedures as approved by the Secretary, and interested parties shall have a reasonable opportunity to participate in the hearing through the presentation of testimony and written submissions.
 - (b) The OA or OST component shall arrange for an administrative judge or other neutral administrative hearing officer to preside over the hearing and shall provide a reasonable opportunity for cross-examination of witnesses at the hearing.
 - (c) After the formal hearing and before the record of the hearing is closed, the presiding hearing officer shall render a report containing findings and conclusions addressing the disputed issues of fact identified in the hearing notice and specifically advising on the accuracy and sufficiency of the factual information in the record relating to those disputed issues on which the OA or OST component proposes to base the rule.
 - (d) Interested parties who have participated in the hearing shall be given an opportunity to file statements of agreement or objection in response to the hearing officer's report, and the complete record of the proceeding shall be made part of the rulemaking record.
- (7) Actions following hearing.
 - (a) Following completion of the formal hearing process, the responsible OA or OST component shall consider the record of the hearing and, subject to the approval of the RRTF (in consultation with OIRA, as appropriate), shall make a reasoned determination whether (i) to terminate the rulemaking, (ii) to proceed with the rulemaking as proposed, or (iii) to modify the proposed rule.
 - (b) If the decision is made to terminate the rulemaking, the OA or OST component shall publish a notice in the *Federal Register* announcing the decision and explaining the reasons therefor.
 - (c) If the decision is made to finalize the proposed rule without material modifications, the OA or OST component shall explain the reasons for its

decision and its responses to the hearing record in the preamble to the final rule, in accordance with subsection e below.

- (d) If the decision is made to modify the proposed rule in material respects, the OA or OST component shall, subject to the approval of the RRTF (in consultation with OIRA, as appropriate), publish a new or supplemental NPRM in the *Federal Register* explaining the OA's or OST component's responses to and analysis of the hearing record, setting forth the modifications to the proposed rule, and providing an additional reasonable opportunity for public comment on the proposed modified rule.
 - (8) Relationship to interagency process. The formal hearing procedures under this subsection shall not impede or interfere with OIRA's interagency review process for the proposed rulemaking.
- e. Additional requirements for final rules.
- (1) In addition to the requirements set forth in section 11(k) of this Order, the preamble to a final economically significant rule or a final high-impact rule shall include—
 - (a) A discussion explaining the OA's or OST component's reasoned final determination that the rule as adopted is necessary to achieve the objective identified in the NPRM in light of the full administrative record and does not deviate from the metrics previously identified by the OA or OST component for measuring progress toward that objective; and
 - (b) In accordance with subsection d(7)(c) of this section, the OA's or OST component's responses to and analysis of the record of any formal hearing held under subsection d.
 - (2) Absent exceptional circumstances and unless approved by the RRTF or Secretary (in consultation with OIRA, as appropriate), the OA or OST component shall adopt as a final economically significant rule or final high-impact rule the least costly regulatory alternative that achieves the relevant objectives.
- f. Additional requirements for retrospective reviews. For each economically significant rule or high-impact rule, the responsible OA or OST component shall publish a regulatory impact report in the *Federal Register* every 5 years after the effective date of the rule while the rule remains in effect. The regulatory impact report shall include, at a minimum—
- (1) An assessment of the impacts, including any costs, of the rule on regulated entities;
 - (2) A determination about how the actual costs and benefits of the rule have varied from those anticipated at the time the rule was issued; and

- (3) An assessment of the effectiveness and benefits of the rule in producing the regulatory objectives it was adopted to achieve.
- g. Waiver and Modification. The procedures required by section 12 of this Order may be waived or modified as necessary with the approval of the RRO or the Secretary.

13. PUBLIC CONTACTS IN INFORMAL RULEMAKING

- a. Agency contacts with the public during informal rulemakings conducted in accordance with section 553 of title 5, United States Code.
 - (1) DOT personnel may have meetings or other contacts with interested members of the public concerning an informal rulemaking at any stage of the rulemaking process, provided the substance of material information submitted by the public that DOT relies on in proposing or finalizing the rule is adequately disclosed and described in the public rulemaking docket such that all interested parties have notice of the information and an opportunity to comment on its accuracy and relevance.
 - (2) After the issuance of the NPRM and pending completion of the final rule, DOT personnel should avoid giving persons outside the Executive Branch information regarding the rulemaking that is not available generally to the public.
 - (3) If DOT receives an unusually large number of requests for meetings with interested members of the public during the comment period for a proposed rule or after the close of the comment period, the issuing OA or component of OST should consider whether there is a need to extend or reopen the comment period, to allow for submission of a second round of “reply comments,” or to hold a public meeting on the proposed rule.
 - (4) If the issuing OA or OST component meets with interested persons on the rulemaking after the close of the comment period, it should be open to giving other interested persons a similar opportunity to meet.
 - (5) If DOT learns of significant new information, such as new studies or data, after the close of the comment period that the issuing OA or OST component wishes to rely upon in finalizing the rule, the OA or OST component should reopen the comment period to give the public an opportunity to comment on the new information. If the new information is likely to result in a change to the rule that is not within the scope of the NPRM, the OA or OST component should consider issuing a Supplemental NPRM to ensure that the final rule represents a logical outgrowth of DOT’s proposal.
- b. Contacts during OIRA review.
 - (1) Executive Orders 12866 and 13563 lay out the procedures for review of significant regulations by OIRA, which include a process for members of the public to request meetings with OIRA regarding rules under OIRA review. Per

Executive Order 12866, OIRA invites the Department to attend these meetings. The Office of Regulation will forward these invitations to the appropriate regulatory contact in the OA or component of OST responsible for issuing the regulation.

- (2) If the issuing OA or OST component wishes to attend the OIRA-sponsored meeting or if its participation is determined to be necessary by the Office of Regulation, the regulatory contact should identify to the Office of Regulation up to two persons from the OA or OST component who will attend the meeting along with a representative from the Office of Regulation. Attendance at these meetings can be by phone or in person. These OIRA meetings are generally listening sessions for DOT.
- (3) The attending DOT personnel should refrain from debating particular points regarding the rulemaking and should avoid disclosing the contents of a document or proposed regulatory action that has not yet been disclosed to the public, but may answer questions of fact regarding a public document.
- (4) Following the OIRA meeting, the attendee(s) from the issuing OA or OST component will draft a summary report of the meeting and submit it to the Office of Regulation for review. After the report is reviewed and finalized in coordination with the Office of Regulation, the responsible OA or OST component will place the final report in the rulemaking docket.

14. POLICY UPDATES AND REVISIONS

This Order shall be reviewed from time to time to reflect improvements in the rulemaking process or changes in Administration policy. If Congress revises applicable laws or if the Executive Branch issues new Executive Orders, Presidential memoranda, guidance, or implementing instructions governing Federal agency rulemaking, such changes shall be considered incorporated by reference in this Order.

15. DISCLAIMER

This Order is intended to improve the internal management of the Department. It is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its agencies or other entities, officers or employees, or any other person. In addition, this Order shall not be construed to create any right to judicial review involving the compliance or noncompliance with this Order by the Department, its OAs or OST components, its officers or employees, or any other person.

16. DISTRIBUTION

This Order is distributed to all Secretarial office heads and OA Administrators and will be available to the Department electronically and posted to a public Web site.

17. CONTACT

If you have specific questions related to this Order, please contact the Office of Regulation in OGC.

FOR THE SECRETARY OF TRANSPORTATION:

/s/ Steven G. Bradbury
General Counsel and Regulatory Policy Officer
U.S. Department of Transportation



