

submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

■ 2. Add § 100.35T08–0192 to read as follows:

§ 100.35T08–0192 Special Local Regulation; Ohio River, Louisville, KY.

(a) *Regulated area.* All navigable waters of the Ohio River from mile marker (MM) 597.0 to MM 607.0 in Louisville, KY.

(b) *Enforcement period.* This section will be enforced from 11 a.m. to 6 p.m. on August 14, 2020, from 12 p.m. to 11:59 p.m. on August 15, 2020, and from 12 a.m. to 2 a.m. on August 16, 2020. The Captain of the Port Sector Ohio Valley (COTP) or a designated representative will inform the public through broadcast notice to mariners of the enforcement period for the special local regulation.

(c) *Special local regulations.*

(1) In accordance with the general regulations in § 100 of this part, entry into this area is prohibited unless authorized by the COTP or a designated representative.

(2) Recreational vessels may be permitted to transit the regulated area, but are restricted to the Indiana side of the navigation channel. There shall be no anchoring or loitering in the navigation channel. There is a no-entry zone starting at Ohio River MM 602.7 through MM 607.0. Recreational vessels transiting into and away from this area are restricted to the slowest safe speed creating minimum wake.

(3) The COTP may terminate the event or the operation of any vessel at any

time it is deemed necessary for the protection of life or property.

(4) All other persons or vessels desiring entry into or passage through the area must request permission from the COTP or a designated representative. U.S. Coast Guard Sector Ohio Valley may be contacted on VHF Channel 13 or 16, or at 1–800–253–7465.

Dated: April 23, 2020.

A.M. Beach,

Captain, U.S. Coast Guard, Captain of the Port Sector Ohio Valley.

[FR Doc. 2020–10633 Filed 5–21–20; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 2

[EPA–HQ–OA–2020–0128, FRL–010007–83–OP]

RIN 2010–AA13

EPA Guidance; Administrative Procedures for Issuance and Public Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: These proposed regulations would, if finalized, establish the procedures and requirements for how the U.S. Environmental Protection Agency (EPA) will manage the issuance of guidance documents subject to the requirements of the Executive order entitled “Promoting the Rule of Law Through Improved Agency Guidance Documents.” These regulations establish general requirements and procedures for certain guidance documents issued by the EPA and incorporates additional requirements for guidance documents determined to be significant guidance under the Executive order. These regulations also provide procedures for the public to petition for the modification or withdrawal of active guidance documents under the Executive order. These regulations are intended to increase the transparency of EPA's guidance practices and improve the process used to manage EPA guidance documents.

DATES: Comments must be received on or before June 22, 2020.

ADDRESSES: Send comments, identified by Docket ID No. EPA–HQ–OA–2020–0128, by any of the following methods:

• **Federal eRulemaking Portal:** <https://www.regulations.gov/> (our

preferred method). Follow the online instructions for submitting comments.

• **Email:** docket_oms@epa.gov. Include Docket ID No. EPA–HQ–OA–2020–0128 in the subject line of the message.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via https://www.regulations.gov or email, as there is a temporary suspension of mail delivery to EPA, and no hand deliveries are currently accepted. For further information on EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OA–2020–0128, at https://www.regulations.gov (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include

discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

B. Does this action apply to me?

This is a rule of Agency procedure and practice. The provisions only apply to the EPA and do not regulate any external entities.

C. What action is the Agency taking?

This action solicits comment from the public on a proposed regulation establishing procedures that the EPA intends to use to issue guidance documents that are subject to the requirements of Executive Order (E.O.) 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents” (84 FR 55237, October 15, 2019), which directs Federal agencies to develop regulations to set forth processes and procedures for issuing guidance documents. The Administrator has sole and unreviewable discretion to deviate from this procedure.

D. What is the Agency’s authority for taking this action?

The EPA is authorized to promulgate this rule under its housekeeping authority. The Federal Housekeeping Statute provides that “[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.” 5 U.S.C. 301. The EPA gained housekeeping authority through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970), which “convey[s] to the [EPA] Administrator all of the housekeeping authority available to other department heads under section 301” and demonstrates that “Congress has vested the Administrator with the authority to run EPA, to exercise its functions, and to issue regulations incidental to the performance of those functions.”¹

The Agency considers this action a rule of agency organization, procedure,

or practice that lacks the force and effect of law. The EPA determined, as a matter of good government, to seek comment from the public. The Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(A), provides that an agency may issue interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice without providing notice and an opportunity for public comment.

II. Background

The EPA uses an open and fair regulatory process, including notice and an opportunity for comment, when imposing new obligations on the public, consistent with applicable law and following appropriate procedures. The EPA considers and responds to applicable comments before publishing final regulations in the **Federal Register**. Legally binding requirements are imposed on the public only through statutes and implementing regulations and on parties on a case-by-case basis through adjudications. Exceptions may exist when legally binding requirements are authorized by law through other means or when they are incorporated into a contract.

The EPA may issue non-binding guidance using a variety of methods to clarify existing obligations and provide information to help regulated entities comply with requirements. Guidance documents come in a variety of formats, including interpretive memoranda, policy statements, manuals, bulletins, advisories, and more. Any document that satisfies the definition of “guidance document” above would qualify, regardless of name or format.

Such guidance is not subject to APA notice-and-comment requirements. As such, EPA guidance documents are legally non-binding. The EPA does, however, often work with stakeholders to develop guidance documents, provide opportunities for public review and comment on the draft guidance document, and announces the availability of final guidance documents. Nevertheless, members of the public have noted that it is often difficult to identify all guidance documents that the EPA uses and relies upon. This regulation will improve the ability of members of the public to more easily identify all the guidance documents that the EPA uses and relies upon, resolving any concerns over the difficulty assessing the final and effective guidance of the Agency.

Well-designed guidance documents can serve many important functions in regulatory programs. The EPA may provide guidance to interpret existing law or to clarify how it intends to

implement a legal requirement. Additionally, EPA may generate guidance that sets forth a policy on a statutory, regulatory, or technical issue. Guidance documents, when used properly, can also help increase efficiency, and improve the public’s understanding of the EPA’s policies. Over reliance on guidance, to the exclusion of rulemaking, however, decreases the transparency of Agency implementation of legal requirements and can lead to inequitable outcomes.

On October 9, 2019, the President signed E.O. 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents.” E.O. 13891 directs Federal agencies to finalize regulations that “set forth processes and procedures for issuing guidance documents.”² E.O. 13891 notes that “Americans deserve an open and fair regulatory process that imposes new obligations on the public only when consistent with applicable law and after an agency follows appropriate procedures.”³ A central principle of E.O. 13891 is that guidance documents should clarify existing obligations only; they should not be a vehicle for implementing new, binding requirements on the public. E.O. 13891 recognizes that these documents, when designated as significant guidance documents, could benefit from public input prior to issuance. On October 31, 2019, the White House Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) issued a memorandum to Federal agencies outlining how to implement, E.O. 13891.⁴

Consistent with E.O. 13891 and OMB’s implementing memorandum, this action proposes the EPA’s procedures for developing and issuing guidance documents and to establish a petition process for public requests to modify or withdraw an active guidance document. The purpose is to ensure that the EPA’s guidance documents are:

- Developed with appropriate review;
- Accessible and transparent to the public; and,
- Provided for public participation in the development of significant guidance documents.

Implementing these procedures will lead to enhanced transparency and help to ensure that guidance documents are not improperly treated as legally binding requirements by the EPA or by

² See section 4(a) of Executive Order 13891 (October 15, 2019; 84 FR 55237).

³ See section 1 of Executive Order 13891 (84 FR 55235).

⁴ Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M–20–02).

¹ Authority of EPA to Hold Employees Liable for Negligent Loss, Damage, or Destruction of Government Personal Property, 32 O.L.C. 79, 2008 WL 4422366 at *4 (May 28, 2008) (“OLC Opinion”)

the regulated community. Moreover, the proposed regulation includes a definition of “guidance document” to provide greater clarity to the public regarding the scope of the proposed regulation.

Specifically, consistent with the E.O., this regulation provides that the EPA will use an online portal to clearly identify EPA guidance documents for the public and proposes to establish: Definitions of “guidance document” and “significant guidance document,” standard elements for such guidance documents and significant guidance documents, procedures for the EPA to enable the public to comment on proposed significant guidance documents, and procedures for the public to request that an active guidance document be modified or withdrawn. The EPA intends that this regulation be interpreted and implemented in a manner that, consistent with the goals of improving the Agency’s accountability and the transparency of the EPA’s guidance documents, provides appropriate flexibility for the EPA to take those actions necessary to accomplish its mission.

III. Guidance Document Procedures

This rule proposes to establish the EPA’s internal policies and procedures for the issuance of future guidance documents pursuant to the directives included in E.O. 13891 as well as codify the requirement that the Agency maintain an internet portal with all active and effective guidance of the Agency. The procedures contained in this proposed rule would apply to guidance documents issued by the EPA that are subject to the requirements of E.O. 13891 but not excluded under Section 4(b) of the E.O., as described in Unit III.A below. Section 4(b) of the E.O. directs the Administrator of OIRA to issue memoranda establishing exceptions from the E.O. for categories of guidance documents, as appropriate. Categorical exceptions may include documents that generally are only routine or ministerial, or that are otherwise of limited importance to the public. The EPA is proposing that the procedures established in this rule would not apply to guidance documents excepted from the requirements of E.O. 13891 under Section 4(b) of the E.O.

A. Definition of Guidance Document and Significant Guidance Document (Proposed 40 CFR 2.503)

Consistent with the definitions in E.O. 13891 and OMB’s implementing memorandum, the EPA is proposing the following definitions of the terms

“guidance document” and “significant guidance document.”

1. *Guidance Document.* For the purposes of this rule, “guidance document” would mean an Agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation. The definition is subject to the following exclusions:

- Rules promulgated pursuant to notice and comment under 5 U.S.C. 553, or similar statutory provisions;
- Rules exempt from rulemaking requirements under section 5 U.S.C. 553(a);⁵
- Rules of Agency organization, procedure, or practice;
- Decisions of Agency adjudications under 5 U.S.C. 554, or similar statutory provisions;
- Internal guidance directed to the EPA or its components or other agencies that is not intended to have substantial future effect on the behavior of regulated parties;
- Agency statements of specific, rather than general, applicability. The definition of “guidance document” would not apply to advisory or legal opinions directed to particular parties about circumstance-specific questions; notices regarding particular locations or facilities; and correspondence with individual persons or entities about particular matters, including congressional correspondence or notices of violation;
- Agency statements that do not set forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statute or regulation. This would exclude from the definition of “guidance document” Agency statements that merely communicate news updates about the Agency, such as most speeches and press releases as well as Agency statements of general applicability concerning participation in the EPA’s voluntary programs;
- Internal executive branch legal advice or legal opinions addressed to executive branch officials or courts, including legal opinions by the Office of General Counsel;
- Legal briefs and other court filings, because these are intended to persuade a court rather than affect the conduct of regulated parties;
- Grant solicitations and awards; or
- Contract solicitations and awards.

⁵ 5 U.S.C. 553(a) applies, except to the extent that there is involved: (1) A military or foreign affairs function of the United States; or (2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

2. *Significant Guidance Document.*

For the purposes of this rule, “significant guidance document” would mean a guidance document determined to be significant pursuant to E.O. 12866 and E.O. 13891.

Section 2(c) of E.O. 13891 defines “significant guidance document” to mean a guidance document that may reasonably be anticipated to: (i) Lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or, (iv) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles of E.O. 12866.⁶

B. Inventory of Active Guidance Documents (Proposed 40 CFR 2.504)

Section 3(a) of E.O. 13891 directs agencies to establish and maintain a website guidance portal that contains or links to guidance documents that are “active”, i.e., those guidance documents under this rule that the EPA expects to cite, use, or rely upon. The EPA Guidance Portal was made publicly available on February 28, 2020 (<https://www.EPA.gov/guidance>).⁷ The E.O. requires that all active guidance documents issued by an agency be included on the agency’s guidance portal and that any guidance document excluded from the portal does not represent the final guidance of the agency and will have no effect.

The EPA is providing here a description of the information that is currently available on the EPA Guidance Portal. The EPA Guidance Portal following information for each guidance document:

- A concise name for the guidance document;
- The date on which the guidance document was issued;
- The date on which the guidance document was posted to the Guidance Portal;
- An EPA unique identifier;
- A hyperlink to the guidance document and any supporting or ancillary documents;

⁶ See section 2(c) of Executive Order 13891 (84 FR 55236).

⁷ “Notice of Public Guidance Portal,” (85 FR 11986, February 28, 2020).

- The general topic, program, and/or statute addressed by the guidance document; and

- A brief summary of the guidance document's content.

In addition to the information associated with each guidance document, the EPA Guidance Portal includes a clearly visible note expressing that (a) guidance documents lack the force and effect of law, unless authorized by statute or incorporated into a contract; and (b) the Agency may not cite, use, or rely on any guidance document as defined in this rule, that is not posted on the EPA Guidance Portal, except to establish historical facts. The EPA Guidance Portal will also include a link to these EPA procedural regulations for guidance documents once issued as final regulations, as well as to any future proposed or final amendments.⁸

C. General Requirements and Procedures for Issuance of All Guidance Documents (Proposed 40 CFR 2.505)

Consistent with E.O. 13891, the EPA proposes to require certain standard elements for all guidance documents issued after this rule is finalized. Specifically, the EPA is proposing to require that each guidance document would satisfy the following:⁹

- Include the term “guidance;”
- Identify the office issuing the document;
 - Provide the title of the guidance;
 - Provide the unique document identification number;
 - Include the date of issuance;
 - When practicable, identify the general activities to which and the persons to whom the document applies;
 - Include the citation to the statutory provision (including the U.S.C. citation) or regulation (in CFR format) to which the guidance document applies or which it interprets;
 - Note if the guidance document is a revision to a previously issued guidance document and, if so, identify the guidance document that it modifies or replaces;
 - Include a short summary of the subject matter covered in the guidance document at the beginning of the document; and
 - Include a disclaimer stating that the contents of the guidance document do not have the force and effect of law and that the Agency does not intend to bind the public in any way and intends only

to provide clarity to the public regarding existing requirements under the law or Agency policies. If the guidance document is binding because it is authorized by law or because the guidance is incorporated into a contract, the EPA will make that clear in the document.¹⁰

Consistent with the requirements of E.O. 13891 and OMB's implementing memorandum, each new guidance document will be posted in the EPA Guidance Portal upon issuance.¹¹ When a new guidance document has been issued, or an active guidance document has been modified, or an active guidance document has been withdrawn, the EPA proposes to inform the public via the EPA Guidance Portal or other Agency website. The EPA solicits comment on the most effective means to inform the public that a new guidance document has been issued, an active guidance document has been modified, or an active guidance document has been withdrawn. Note that specific procedures for announcing new, modified, or withdrawn significant guidance documents are discussed in Unit III.D. of this document.

Given their legally nonbinding nature, guidance documents will avoid including mandatory language such as “shall,” “must,” “required” or “requirement,” unless these words are used to describe a statutory or regulatory requirement, or the language is addressed to EPA staff and will not foreclose consideration by the EPA of positions advanced by affected private parties. For example, a guidance document may explain how the EPA believes a statute or regulation applies to certain regulated entities or activities. As a practical matter, the EPA also may describe laws of nature, scientific principles, and technical requirements in mandatory terms so long as it is clear that the guidance document itself does not impose legally enforceable rights or obligations.¹²

Before issuing a new guidance document covered by this rule that is developed by an EPA Regional Office, the EPA is proposing that the EPA Regional Office must receive concurrence from the corresponding Presidentially-appointed EPA official (i.e., the relevant Assistant Administrator or an official who is

serving in the acting capacity) at EPA headquarters who is responsible for administering the national program to which the guidance document pertains.

The EPA will seek significance determinations from OIRA for certain guidance documents, as appropriate, in the same manner as for rulemakings.

D. Requirements for Issuance of Significant Guidance Documents (Proposed 40 CFR 2.506)

In addition to all the requirements described in Unit III.C., and consistent with the requirements of E.O. 13891, the EPA is proposing specific requirements for significant guidance documents.

The EPA does not intend to supersede non-conflicting internal policy and procedures that the EPA established for significant guidance documents in 2007 as part of its implementation of the OMB Bulletin for Agency Good Guidance Practices.¹³ Specifically, the EPA is proposing the following additional requirements for significant guidance documents.

1. Notice and Public Comment Opportunities. This proposed rule would establish a public review and comment opportunity for all significant guidance documents, whether that document is new or a modification or withdrawal of an active guidance document. The EPA is proposing to generally require the EPA to publish a Notice in the **Federal Register** to announce the availability of a new draft significant guidance document and provide a 30-day public comment opportunity prior to issuing the final significant guidance document. It also proposes to require the EPA to similarly publish a Notice in the **Federal Register** announcing the proposed modification or withdrawal of an active significant guidance document and provide a 30-day public comment opportunity before finalizing the modification or withdrawal of such a document. In addition to the published announcement of the availability of the draft significant guidance document, the draft significant guidance document itself (including a link to any supporting documents) would be posted on the EPA's website concurrently and labeled appropriately.¹⁴ To ensure comments will be received and responded to by the EPA, public comments on draft significant guidance documents and draft modifications or withdrawals of

⁸ See Q12 in Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019 (M-20-02).

⁹ See Q22 in Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M-20-02).

¹⁰ See Q20 in Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M-20-02).

¹¹ See section 3(b) of Executive Order 13891 (84 FR 55236). See Q9–Q12 in Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M-20-02).

¹² Final Bulletin for Agency Good Guidance Practices (72 FR 3432, 3436).

¹³ Final Bulletin for Agency Good Guidance Practices (72 FR 3432).

¹⁴ See section 4(a)(iii)(A) of Executive Order 13891 (84 FR 55237), and Q23 in Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M-20-02).

significant active guidance documents should be submitted using the methods specified in the Notice in the **Federal Register** announcing the availability of the draft significant guidance document or its withdrawal.

All comments received on a draft significant guidance document, or draft modification or withdrawal of an active significant guidance document, would be made available to the public either through the Federal eRulemaking Portal (*i.e.*, <https://www.regulations.gov/>) or on the EPA website.

2. Finalizing significant guidance documents. The EPA is proposing to publish a Notice in the **Federal Register** announcing when the issuance of a new or modified active significant guidance document or withdrawal of an active significant guidance document is finalized.

The proposed regulations would also require the EPA, when issuing a final new significant guidance document or a final modification or withdrawal of an active significant guidance document, to respond to major public comments and identify in the required Notice in the **Federal Register** how the public may access the comments received and the Agency's response.

The EPA solicits comment on whether the issuance of a modification to an active significant guidance document or the withdrawal of an active significant guidance document should be announced via the **Federal Register** and subject to a 30-day public comment period, or if other means of public engagement, such as the EPA's Guidance Portal or other Agency website, could be used to announce such actions.

3. Procedural exceptions. The EPA proposes limited exceptions to the significant guidance document notice and comment process. The EPA would not seek or respond to public comment before it implements a significant guidance document (or any other category of guidance document) if exigent circumstances, as determined by the Administrator, (*e.g.*, a public health, safety, environment or other emergency) make it impracticable to delay issuance of the guidance document, or there is a statutory or judicial requirement that compels the EPA to immediately issue the document.¹⁵ Further, the EPA would not seek or respond to public comment when it finds good cause that notice and public comment is impracticable, unnecessary, or contrary to public interest. The EPA would present the

good cause finding in the guidance document or notice of availability in the **Federal Register**.

4. Required approval. The EPA Administrator or other Presidentially-appointed EPA official, or an official who is serving in an acting capacity of either of the foregoing, would approve each significant guidance document before it is issued and posted on the EPA Guidance Portal.¹⁶

5. Compliance with other applicable requirements. Section 5 of E.O. 13891 specifies that significant guidance documents must demonstrate compliance with the requirements of E.O. 12866, "Regulatory Planning and Review;" E.O. 13563, "Improving Regulation and Regulatory Review;" and E.O. 13609, "Promoting International Regulatory Cooperation," consistent with the requirements of section 4 of E.O. 13891. E.O. 13891 directs that significant guidance documents must comply with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in these executive orders.

Accordingly, the EPA would comply with the requirements of Executive Orders 12866, 13563, 13609, and 13891 when issuing significant guidance documents. For example, the EPA would assess the potential impacts of the significant guidance document if those effects may reasonably be anticipated to lead to an annual effect on the economy of \$100 million.¹⁷ The analysis (Regulatory Impact Analysis (RIA) or Economic Analysis (EA)) would focus on how that economically significant guidance document affects the incentives of regulated parties and would conform to OMB Circular A-4 on Regulatory Analysis and EPA Guidelines for Preparing Economic Analyses.¹⁸ The EPA has not historically issued economically significant guidance documents (*i.e.*, those that lead to an annual effect on the economy of \$100 million or more).

E. Procedures for Public To Petition for Modification or Withdrawal (Proposed 40 CFR 2.507)

Consistent with E.O. 13891, the EPA is proposing procedures to allow the

public to petition the EPA for the modification or withdrawal of an active guidance document posted on the EPA Guidance Portal. The EPA Guidance Portal will provide clear and specific instructions to the public regarding how to request the modification or withdrawal of an active guidance document. The EPA is proposing that the public may submit petitions using one of the two following methods described on the EPA Guidance Portal: (1) An electronic submission through the EPA's designated submission system identified on the EPA Guidance Portal (*i.e.*, using a link labeled "Submit a petition for Agency modification or withdrawal of guidance documents"), or, (2) a paper submission to the EPA's designated mailing address listed on the EPA Guidance Portal.

1. Format and content elements for public petitions. The EPA is proposing the following formatting elements for petitions:

- The petitioner's name and a means for the EPA to contact the petitioner such as an email address or mailing address, in addition to any other contact information (such as telephone number) that the petitioner chooses to include; and
 - A heading, preceding its text that states, either "Petition to Modify a Guidance Document" or "Petition to Withdraw a Guidance Document."
- The EPA is proposing that a petition should include the following content elements:
- Identification of the specific title and the EPA unique identifier of the guidance document that the petitioner is requesting be modified or withdrawn;
 - The nature of the relief sought (*i.e.*, modification or withdrawal);
 - An explanation of the interest of the petitioner in the requested action;
 - If practicable, specification of the text that the petitioner request be modified or withdrawn, and, where possible, suggested text for the Agency to consider; and
 - A rationale for the requested modification or withdrawal.

Although the EPA may be able to consider incomplete petitions, petitions that omit the specified information may impede the EPA from fully evaluating the merits of the requested action. The EPA is proposing that a petition that is not submitted using one of the two methods described above (as well as on the EPA Guidance Portal), but that includes the required formatting and content elements, will be treated as a properly filed petition, received as of the time it is discovered and identified. The EPA notes that if a document does not include all of the format and content

¹⁵ See section 4(a)(iii)(A) of Executive Order 13891 (84 FR 55237) and Final Bulletin for Agency Good Guidance Practices. (72 FR 3432; 3438–3439).

¹⁶ See section 4(a)(iii)(B) of Executive Order 13891 (84 FR 55237) and, Q25 in Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M-20-02).

¹⁷ See Q5 in Guidance Implementing Executive Order 13891, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M-20-02).

¹⁸ EPA Guidelines for Preparing Economic Analyses. December 17, 2010 (updated May 2014). Accessible at <https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf>.

elements described above, the EPA may be unable to identify the document as a petition for modification or withdrawal of a guidance document. These will instead be treated according to the existing correspondence or other appropriate procedures of the EPA, and any suggestions contained in it will be considered at the discretion of the Administrator.

The EPA solicits comment on whether the procedural rule should specify any other information elements that should be addressed in a petition to modify or withdraw an active guidance document. The EPA requests that any such comments explain how additional information elements would enable the Agency to correctly identify and more completely evaluate a petition.

2. Required EPA response to public petitions. The EPA would respond to petitions in a timely manner, but no later than 90 calendar days after receipt of the petition. If the EPA requires more than 90 calendar days to consider a petition, the EPA would inform the petitioner that more time is required and indicate the reason why and provide an estimated decision date. The EPA will only extend the response date one time for a period not to exceed 90 calendar days before providing a response.

It is important to note that the response and the set timeframes for responding to the petition are not intended to capture the implementation of the response. For example, if the Agency agrees with a petitioner seeking a modification to a guidance document, the Agency will pursue the modification in accordance with applicable procedures. In such cases, the Agency intends for the response to the petition to include its approach for completing the modification of that guidance document.

Duplicative petitions and petitions submitted as part of a mass petitioning effort may be responded to in a single response to ensure an efficient and consistent response to the petitions. Petitions that request a change to the underlying statute or promulgated rules, rather than specific text in the guidance document, will not be considered valid petitions under this process because they are not petitions to modify or withdraw a guidance document.

The EPA requests comment on whether the Agency should create unified public petition procedures, similar to those proposed in this rule for guidance documents, for EPA rulemakings in addition to the public

petition right established in APA section 553(e).¹⁹

IV. Statutory and Executive Orders Reviews

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to OMB for review under Executive Orders 12866. The EPA does not anticipate that this rulemaking will have an economic impact on regulated entities. This is a rule of agency procedure and practice. The EPA expects the benefits of this rule to be improved transparency and management of the EPA's guidance documents.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an Executive Order 13771 regulatory action because it relates to "agency organization, management or personnel."

C. Paperwork Reduction Act (PRA)

This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This is a rule of agency procedure and practice. The EPA expects the benefits of this rule to be improved transparency and management of the EPA's guidance documents.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not 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.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children. Per the definition of "covered regulatory action" in section 2–202 of Executive Order 13891 and because this action does not concern an environmental health risk or safety risk, it is not subject to Executive Order 13045.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard.

List of Subjects in 40 CFR Part 2

Environmental protection, Administrative practice and procedure, Organization and functions (Government agencies).

Andrew Wheeler,
Administrator.

For the reasons set forth in the preamble, the Environmental Protection Agency proposes to amend 40 CFR part 2 as follows:

¹⁹ (Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 383.)

PART 2—PUBLIC INFORMATION

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717.

■ 2. Add subpart D to read as follows:

Subpart D—Guidance Procedures

Sec.

2.501 General.

2.502 Scope.

2.503 Definitions.

2.504 Public access to active guidance documents.

2.505 Guidance document general requirements and procedures.

2.506 Significant guidance document requirements and procedures.

2.507 Procedures for the public to petition for modification or withdrawal.

§ 2.501.2.501 General.

This subpart establishes procedures for the issuance of EPA guidance documents subject to Executive Order 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents” (October 15, 2019). This subpart also establishes procedures for the public to petition for modification or withdrawal of such guidance documents.

§ 2.502 Scope.

(a) The procedures in this subpart do not apply to guidance documents excepted from the requirements of Executive Order 13891 under Section 4(b) of the Executive order or that are not otherwise subject to Executive Order 13891.

(b) Subject to the qualifications and exemptions contained in this subpart, the procedures in this subpart apply to all active guidance documents as defined in this subpart, issued by all components of the Environmental Protection Agency (EPA) after [date of issuance for the final rule].

(c) Rescinded guidance documents are not active guidance documents pursuant to Executive Order 13891 and may only be used to establish historical facts.

(d) This subpart is intended to improve the internal management of the EPA. As such, it is for the use of EPA personnel only and 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, its officers or employees, or any other person.

(e) If Executive Order 13891, or any provision thereof, is rescinded or superseded, this subpart remains in force.

(f) The Agency may deviate from the procedures in this subpart, when

necessary, at the written direction of the Administrator. The decision to deviate from the procedures in this subpart is in the Administrator’s sole and unreviewable discretion.

§ 2.503 Definitions.

For the purposes of this subpart, the following definitions apply:

Guidance document means an Agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation, subject to the following exclusions:

(1) Rules promulgated pursuant to notice and comment under 5 U.S.C. 553, or similar statutory provisions;

(2) Rules exempt from rulemaking requirements under 5 U.S.C. 553(a);

(3) Rules of Agency organization, procedure, or practice;

(4) Decisions of Agency adjudications under 5 U.S.C. 554, or similar statutory provisions;

(5) Internal guidance directed to the EPA or its components or other agencies that is not intended to have substantial future effect on the behavior of regulated parties;

(6) Internal executive branch legal advice or legal opinions addressed to executive branch officials or courts, including legal opinions by the Office of General Counsel;

(7) Agency statements of specific, rather than general, applicability. This would exclude from the definition of “guidance” advisory or legal opinions directed to particular parties about circumstance-specific questions; notices regarding particular locations or facilities; and correspondence with individual persons or entities about particular matters, including congressional correspondence or notices of violation unless a document is directed to a particular party but designed to guide the conduct of the broader regulated public;

(8) Agency statements that do not set forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statute or regulation, including news updates like speeches and press releases, as well as statements of general applicability concerning participation in the EPA’s voluntary programs;

(9) Legal briefs and other court filings;

(10) Grant solicitations and awards; or

(11) Contract solicitations and awards.

Significant guidance document means a guidance document that is determined to be “significant” pursuant to Executive Order 12866 and Executive Order 13891.

§ 2.504 Public access to active guidance documents.

All active guidance documents shall appear on the EPA Guidance Portal on the EPA website.

§ 2.505 Guidance document general requirements and procedures.

(a) *Minimum guidance requirements.* In each guidance document, the EPA will:

(1) Include the term “guidance”;

(2) Identify the component office issuing the document;

(3) Provide the title of the guidance and the document identification number;

(4) Include the date of issuance;

(5) When practicable, identify the general activities to which and the persons to whom the document applies;

(6) Include the citation to the statutory provision (including the U.S.C. citation) or regulation (to the CFR) to which the guidance document applies or which it interprets;

(7) Note if the guidance document is a revision to a previously issued guidance document and, if so, identify the guidance document that it modifies or replaces;

(8) Include a short summary of the subject matter covered in the guidance document at the beginning of the document; and

(9) Include a disclaimer stating that the contents of the guidance document do not have the force and effect of law and that the Agency does not bind the public in any way and intends only to provide clarity to the public regarding existing requirements under the law or Agency policies, except as authorized by law or as incorporated into a contract. When a guidance document is binding because binding guidance is authorized by law or because the guidance is incorporated into a contract, the statement will reflect that.

(b) *Approval.* A guidance document issued by an EPA Regional Office must receive concurrence from the corresponding Presidentially-appointed EPA official (i.e., the relevant Assistant Administrator or an official who is serving in the acting capacity) at EPA headquarters who is responsible for administering the national program to which the guidance document pertains.

(c) *Avoid mandatory language.* A guidance document will avoid mandatory language such as “shall,” “must,” “required” or “requirement,” unless using these words to describe a statutory or regulatory requirement, or the language is addressed to EPA staff and will not foreclose consideration by the EPA of positions advanced by affected private parties.

(d) *Significance determinations.* The EPA will seek significance determinations from the Office of Information and Regulatory Affairs (OIRA) for certain guidance documents, as appropriate, in the same manner as for rulemakings.

§ 2.506 Significant guidance document requirements and procedures.

A significant guidance document will adhere to all the requirements described in § 2.505 and the requirements in this section.

(a) *Draft for public comment.* (1) The EPA will make available a draft significant guidance document, or draft modification or withdrawal of a significant active guidance document, for public comment before finalizing any significant guidance document. The EPA will post appropriately labeled draft guidance and any supporting documents on the EPA's website.

(2) The EPA will publish a notice in the **Federal Register** announcing the availability of a draft significant guidance document, or draft modification or withdrawal of a significant active guidance document, to open the public comment period.

(b) *Public comment process.* (1) Except as provided in paragraph (c) of this section, a draft significant guidance document, or a draft modification or withdrawal of a significant active guidance document, will have a minimum of 30 days public notice and comment before issuance of a final guidance document or issuance of the final modification or withdrawal of an active guidance document. Public comments shall be available to the public online, either in a docket or on the EPA website.

(2) The EPA shall respond to major concerns and comments in the final guidance document itself or in a companion document.

(c) *Exceptions to comment process.* The EPA will not seek or respond to public comment before the EPA implements a significant guidance document if at the sole discretion of the Administrator:

(1) Doing so is not feasible or appropriate because immediate issuance is required by a public health, safety, environmental, or other emergency requiring immediate issuance of the guidance document or a statutory requirement or court order that requires immediate issuance; or

(2) When the Agency for good cause finds (and incorporates such finding and a brief statement of reasons therefor into the guidance document) that notice

and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

(d) *Additional notices.* The EPA also will publish a notice in the **Federal Register** when it finalizes a significant guidance document or finalizes a modification or withdrawal of a significant active guidance document.

(e) *Approval.* The EPA Administrator or other Presidentially-appointed EPA official, or an official who is serving in the acting capacity of either of the foregoing, will approve a significant guidance document prior to its issuance and posting in the EPA Guidance Portal website.

(f) *Executive order compliance.* A significant guidance document shall comply with the requirements of Executive Orders 12866, 13563, 13609, 13771, 13777, and 13891.

§ 2.507 Procedures for the public to petition for modification or withdrawal.

(a) *Submission of a petition.* The public may submit a petition to the EPA for the modification or withdrawal of an active guidance document.

(b) *Petition methods.* A petitioner should only submit a petition to the EPA using one of the two methods in paragraphs (b)(1) and (2) of this section and not submit additional copies by any other method. A petition should be submitted through:

(1) An electronic submission through the EPA's designated submission system identified on the EPA Guidance Portal website; or

(2) A paper submission to the EPA's designated mailing address listed on the EPA Guidance Portal website.

(c) *Petition format.* A petition under this section should include:

(1) The petitioner's name and a means for the EPA to contact the petitioner such as an email address or mailing address, in addition to any other contact information (such as telephone number) that the petitioner chooses to include; and

(2) A heading, preceding its text that states, "Petition to Modify a Guidance Document" or "Petition to Withdraw a Guidance Document."

(d) *Petition content.* A petition for modification or withdrawal of an active guidance document should include the following elements:

(1) Identification of the specific title and the EPA unique identifier of the guidance document that the petitioner is requesting be modified or withdrawn;

(2) The nature of the relief sought (*i.e.*, modification or withdrawal);

(3) An explanation of the interest of the petitioner in the requested action (*i.e.*, modification or withdrawal);

(4) If practicable, specification of the text that the petitioner request be modified or withdrawn, and, where possible, suggested text for the Agency to consider; and

(5) A rationale for the requested modification or withdrawal.

(e) *Petition handling.* Failure to follow one of the submission methods described in paragraph (b) of this section and to include in a petition the elements in paragraphs (c) and (d) of this section may create delays in processing time and may result in the EPA being unable to evaluate the merits of the petition.

(1) The EPA may treat a petition that is not submitted as specified in paragraph (b) of this section, but that meets the other elements of this section, as a properly filed petition and received as of the time it is discovered and identified.

(2) The EPA may treat a document that fails to conform to one or more of the elements of paragraphs (c) and (d) of this section as if it is not a petition under this section. The EPA may treat such a document according to the existing correspondence or other appropriate procedures of the EPA, and any suggestions contained in it will be considered at the discretion of the Administrator.

(f) *Petition response timing.* (1) The EPA should respond to a petition in a timely manner, but no later than 90 calendar days after receipt of the petition.

(2) If, for any reason, the EPA needs more than 90 calendar days to respond to a petition, the EPA will inform the petitioner that more time is needed and indicate the reason why and an estimated response date. The EPA will only extend the response date one time not to exceed 90 calendar days before providing a response.

(g) *Petition response.* (1) The EPA may provide a single response to issues raised by duplicative petitions and petitions submitted as part of a mass petitioning effort.

(2) In order to be considered a valid petition under this section, the petition must address a specific issue in the guidance document in question and not merely underlying statutory or regulatory text.

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