

The EPA Administrator Andrew Wheeler signed the following final rule on September 14, 2020, and EPA is submitting it for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties and to seek informal public input. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of compliance or effectiveness. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (<https://www.govinfo.gov/app/collection/fr>) and on Regulations.gov (<https://www.regulations.gov>) in Docket EPA-HQ-OA-2020-0128. Notwithstanding the fact that EPA is posting a pre-publication version, the final rule will not be promulgated until published in the *Federal Register*. Once the official version of this document is published in the FR, this version will be removed from the Internet and replaced with a link to the official version.

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 2

[EPA-HQ-OA-2020-0128, FRL-10014-91-OP]

RIN 2010-AA13

EPA Guidance; Administrative Procedures for Issuance and Public Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes the procedures and requirements for how the U.S. Environmental Protection Agency (EPA) will manage the issuance of guidance documents consistent with the Executive Order 13891 entitled “Promoting the Rule of Law Through Improved Agency Guidance Documents.” Specifically, consistent with the Executive Order, this regulation provides a definition of guidance documents for the purposes of this rule, establishes general requirements and procedures for certain guidance documents issued by the EPA and incorporates additional requirements for guidance documents determined to be significant guidance. This regulation, consistent with the Executive Order, also provides procedures for the public to petition for the modification or withdrawal of active guidance documents as defined by this rule or to petition for the reinstatement of a rescinded guidance document. This regulation is

intended to increase the transparency of the EPA's guidance practices and improve the process used to manage EPA guidance documents.

DATES: This final rule is effective on **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OA-2020-0128. All documents in the docket are listed on the <https://www.regulations.gov> web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <https://www.regulations.gov>. For information on the EPA Docket Center services and the current status, please visit us online at <https://www.epa.gov/dockets>.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. 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.

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B. What action is the Agency taking?

After considering the public comments received on the proposal, the EPA is finalizing procedures that the Agency will use to issue guidance documents as defined in this regulation. These new procedures satisfy 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.

Specifically, consistent with the E.O., this regulation provides that the EPA will use an online portal (the EPA Guidance Portal) to identify EPA guidance documents for the public and will establish: definitions of “guidance document,” “significant guidance document,” and other key terms; standard elements for all guidance documents; additional requirements for significant guidance documents; procedures for the EPA to enable the public to comment on draft significant guidance documents; and procedures for the public to petition the Agency for modification or withdrawal of guidance documents.

In this final rule, the EPA has revised some of the proposed requirements in response to public comments. Most notably, the EPA is adding the opportunity for the public to petition the Agency to reinstate guidance documents that were rescinded. In addition, the EPA will make information publicly available regarding petitions received pursuant to the petition procedures. To provide additional clarity, the final regulatory text includes new definitions of “active guidance document” and “rescinded guidance document.” Other minor edits to the regulatory text are also being finalized to increase clarity.

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C. 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

Consistent with the proposal, the EPA 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.

The EPA received multiple public comments regarding the legal authority for this regulation. Several commenters expressed their concerns regarding the EPA citing the Federal Housekeeping Statute as the legal authority for the proposed rulemaking. For example, some

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”).

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commenters state that the Federal Housekeeping Statute does not confer any authority on the EPA to promulgate regulations because the EPA is not an “executive department” within the meaning of the statute. Even if the Federal Housekeeping Statute confers authority on the EPA, the commenters claim that this rulemaking exceeds the “day-to-day office housekeeping” authorized by the statute. These commenters disagree with the EPA that this rule is a procedural matter of “internal management” and claim that it is a substantive regulation that creates public rights and agency obligations. Further, the commenters state that opening the proposed rule to public comment contradicts the EPA’s claims that the rule is “internal management” with no substantive effect.

The EPA disagrees with these commenters. As the Supreme Court discussed in *Chrysler Corp. v. Brown*, the intended purpose of 5 U.S.C. 301 was to grant early Executive departments the authority “to govern internal departmental affairs.” *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979). As the Supreme Court further notes, section 301 authorizes “what the [Administrative Procedure Act] terms ‘rules of agency organization, procedure or practice’ as opposed to substantive rules.” *Id. at 310*.

The EPA is not one of the 15 “Executive Departments” listed at 5 U.S.C. 101. However, the EPA gained housekeeping authority through the Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970). The Reorganization Plan created the EPA, established the Administrator as “head of the agency[,]” and transferred functions and authorities of various agencies and Executive departments to the EPA. Section 2(a)(1)–(8) of the Reorganization Plan transferred to the EPA functions previously vested in several agencies and executive departments including the Departments of Interior and Agriculture. Section 2(a)(9) also transferred so much of the

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functions of the transferor officers and agencies “as is incidental to or necessary for the performance by or under the Administrator of the functions transferred.” The Federal Housekeeping Statute was existing law at the time the Reorganization Plan was enacted. Accordingly, the concomitant federal housekeeping authority to issue procedural rules was transferred to the EPA.

The Office of Legal Counsel has opined that the Reorganization Plan “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.”²

Courts have recognized the EPA to be an agency with section 301 housekeeping authority. The U.S. Court of Appeals for the Second Circuit, in *EPA v. General Elec. Co.*, 197 F.3d 592, 595 (2d Cir. 1999), found that “the Federal Housekeeping Statute, 5 U.S.C. 301, authorizes government agencies such as the EPA to adopt regulations regarding ‘the custody, use, and preservation of [agency] records, papers, and property.’” The Fourth Circuit Court of Appeals, in *Boron Oil Co. v. Downie*, 873 F.2d 67, 69 (4th Cir. 1989), held that the district court exceeded its jurisdiction where it compelled testimony by an Agency employee in a state court action to which the government was not a party, contrary to duly promulgated EPA regulations, which the EPA argued were authorized by section 301. Although the court assumed the EPA derived its housekeeping authority from 5 U.S.C. 301, these cases nonetheless recognized that

² 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”).

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the EPA had federal housekeeping authority. Indeed, if the EPA did not possess federal housekeeping authority, the EPA would not be able to carry out its daily functions, which would in turn preclude the EPA from exercising its duties as a federal regulatory agency. The same would hold true for other regulatory agencies that are not listed as an Executive department under 5 U.S.C. 101.

II. Background and Purpose

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."³ 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."⁴ 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. 13891.⁵

³ See section 4(a) of E.O. 13891 (October 15, 2019; 84 FR 55237).

⁴ See section 1 of E.O. 13891 (84 FR 55235).

⁵ *Guidance Implementing Executive Order 13891*, Dominic J. Mancini, Acting Director, OIRA, October 31, 2019, (M-20-02).

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On May 22, 2020, consistent with E.O. 13891 and OMB’s implementing memorandum, the EPA proposed new procedures for developing and issuing guidance documents as defined in the proposed rule, and establishing a petition process for public requests to modify or withdraw an active guidance document.⁶ The purpose of this action is to ensure that the EPA's guidance documents are:

- Developed with appropriate review;
- Accessible and transparent to the public; and,
- Benefit from 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 the regulated community. Moreover, this regulation defines “guidance document” to provide greater clarity to the public regarding the scope of documents subject to these procedures. This regulation will improve the ability of members of the public to identify the guidance documents that the EPA uses and relies upon, resolving any concerns over the difficulty assessing the final, effective, active guidance of the Agency.⁷

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

⁶ 85 FR 31104 (May 22, 2020).

⁷ This regulation defines the term “active guidance document” to mean a guidance document in effect that the EPA expects to cite, use, or rely upon. The term active guidance document is synonymous with “effective guidance document” and “guidance in effect.” Active guidance document is the term used on the EPA Guidance Portal website.

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EPA's guidance documents, provides appropriate flexibility for the EPA to take those actions necessary to accomplish its mission.

III. Guidance Document Procedures

This final rule establishes the EPA's internal policies and procedures for the issuance of future guidance documents pursuant to the directives included in E.O. 13891 and codifies the requirement that the Agency maintain an internet portal with a list of all effective, active EPA guidance documents meeting the definition in this regulation. The procedures contained in this final rule apply to guidance documents, as defined by this regulation, issued by the EPA and not excluded under Section 4(b) of E.O. 13891, as described in section III.A of this preamble.⁸

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 procedures established in this rule do not apply to guidance documents excepted from the requirements of E.O. 13891 under Section 4(b) of the E.O., as interpreted by M-20-02, or otherwise excepted by the Administrator of OIRA.

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

The EPA proposed definitions of the terms "guidance document" and "significant guidance document" consistent with the definitions in E.O. 13891 and OMB's implementing memorandum, M-20-02. Several commenters provided strong support for the EPA's definition

⁸ The EPA issues 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" in this regulation would qualify, regardless of name or format.

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of “guidance document” and stated that it is consistent with the targeted approach under E.O. 13891. The EPA agrees that the proposed definition is consistent with the E.O. 13891 definition.

Other commenters expressed their concerns that the definition of “guidance document” in this rulemaking does not provide sufficient clarity regarding what documents the EPA considers to be guidance documents subject to these requirements. A few commenters recommended that the EPA create three or more categories of EPA guidance documents, such as significant guidance documents, other important guidance documents on the EPA Guidance Portal, and other technical program guidance documents excluded from the EPA Guidance Portal. One commenter noted that the definition of “guidance document” could be interpreted to only encompass guidance documents that apply to regulated parties, not States, and recommended a revision to clarify applicability to States.

The EPA disagrees that the definition of guidance document is unclear. The EPA adopted the definition of guidance document set forth in E.O. 13891 with only minor modifications and believes the listed exclusions are helpful in distinguishing the types of documents that do not meet the definition. In common parlance, guidance can refer to many types of documents issued by the EPA and other agencies. The EPA does not intend to use this rule to parse the various nomenclatures and types of guidance that it uses. The definition of a “guidance document” and “significant guidance document” as used in this rule are specific to this rule. To provide further clarity in the implementation of this rule, the EPA has also included definitions for “active guidance document” and “rescinded guidance document.” Regarding the revision recommended by a commenter to clarify whether guidance documents can apply to States, the EPA disagrees with revising the proposed definition of guidance document. In some circumstances, States are

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regulated entities subject to EPA guidance documents while in other circumstances States are co-regulators. The EPA believes that the proposed definition adequately allows for this dual role of States.

The EPA received comments regarding the meaning of “active guidance document” and “rescinded guidance document.” One commenter stated that the EPA should clarify what it means for a guidance document to be “rescinded” or “in effect,” as neither term was expressly defined in the proposed rule or explained in the preamble and clarifying would ensure that the public understands which guidance documents have legal effect. The commenter stated that the EPA should clarify that a “rescinded” guidance document is a guidance document that is not included on the EPA Guidance Portal and means that the EPA cannot “cite, use, or rely on” it as explaining regulatory requirement except to establish historical facts. The commenter stated that the EPA should clarify that a guidance document “in effect” is one that meets the proposal’s definition of “guidance document” and is included in the EPA Guidance Portal, and thus means that the EPA may cite it.

The EPA agrees that these definitions would increase clarity and transparency. Based on comments received, the EPA is adding definitions for “active guidance document” and “rescinded guidance document.” Specifically, the EPA is defining “active guidance document” in this rule as a guidance document or significant guidance document in effect that EPA expects to cite, use, or rely upon. Conversely, the EPA is defining a “rescinded guidance document” in section 2.503 as a document that would otherwise meet the definition of a guidance document or significant guidance document, but that the EPA may not cite, use, or rely upon except to establish historical facts. This definition was adopted from the proposed section 2.502(c).

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Several commenters provided comments regarding how the definition of guidance document applied to scientific and technical documents. Several commenters recommended that the definition of “guidance document” should not exclude scientific or technical determinations. For example, several commenters recommended that scientific assessments produced by the EPA’s Integrated Risk Information System (IRIS) Program be included in the definition of guidance document. One commenter agreed with the EPA that health advisories are appropriately considered guidance with regards to the proposed rulemaking, while another commenter specifically requested that the EPA clarify whether water quality criteria documents (CWA Sec. 304(a)) qualify as guidance documents or significant guidance. Another commenter recommended that the EPA either clearly state that scientific documents are not covered by this rule or post all of the scientific documents that the EPA has relied on since 2008 on the EPA Guidance Portal.

EPA defines “guidance document” consistent with the definitions in E.O. 13891 and OMB’s implementing memorandum, which includes the term “technical issue.” Furthermore, for purposes of this rule, the EPA considers the term “scientific” to be a subset of “technical.” As such, the EPA has determined that the definition of “guidance document” includes certain scientific and/or technical documents. For example, the EPA has determined that drinking water health advisories and CWA 304(a) national recommended Water Quality Criteria issued by the Office of Water because they are statements of general applicability, set forth a policy on a technical issue, are intended to have future effect on the behavior of regulated parties, and are not subject to one of the listed exclusions. However, EPA releases a great deal of technical information (including scientific information) that would *not* be subject to this regulation

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because it is *not* a statement intended to affect the future behavior of regulated parties that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation. Due to the diversity of purpose and content of scientific and technical documents, it would be inconsistent with E.O. 13891 for the EPA to categorically determine whether all scientific and technical documents are “guidance documents.”

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

The EPA proposed that all active guidance documents issued by the Agency must be included on the EPA Guidance Portal,⁹ The EPA Guidance Portal was initially made publicly available on February 28, 2020, and was fully populated to include all active guidance documents on July 31, 2020. Starting on the effective date of this rule, as per section 2.504 of this final rule, all active guidance documents shall appear on the EPA Guidance Portal on the EPA website. Any guidance document (as defined in this regulation) excluded from the EPA Guidance Portal does not represent an active guidance document of the Agency and will have no effect except to establish historical facts.

The EPA proposed to inform the public via the EPA Guidance Portal that a new guidance document has been issued, an active guidance document has been modified, or an active guidance document has been withdrawn. The EPA solicited and received several comments related to the EPA Guidance Portal, the requirement for all active guidance to be on the EPA Guidance Portal, and the utility of using the EPA Guidance Portal 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.

⁹ The EPA Guidance Portal is available at <https://www.EPA.gov/guidance>.

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Most commenters supported the creation and use of the EPA Guidance Portal to maintain a consolidated online portal with lists of active guidance documents as an important method for the Agency to promote transparency, fairness, consistency, and regulatory compliance. One commenter stated that the EPA Guidance Portal will be especially helpful for smaller businesses with limited resources and personnel for regulatory compliance.

The EPA agrees with commenters that the establishment of the EPA Guidance Portal is an important achievement in promoting greater transparency with respect to the Agency's guidance documents.

Several commenters noted that it is difficult for an interested party to ascertain whether a document is not on the EPA Guidance Portal because it does not meet the definition of a guidance document or because it has been rescinded. Some commenters recommended that the EPA include new sections on the EPA Guidance Portal for documents that the EPA has determined not to be a "guidance document" and for guidance documents that are rescinded. One commenter suggested that the EPA could include a select list of rescinded guidance documents that would be of broad interest, another suggested a list of rescinded guidance documents would be helpful even if not comprehensive. One commenter recommended that the EPA be over-inclusive in its initial listing so that no essential guidance gets accidentally rescinded. Commenters requested that the EPA clarify when and the manner in which non-Agency parties may continue to rely on guidance that are not posted to the EPA Guidance Portal, and clarify that external parties are not subject to the same prohibition on citing, using, or relying on such guidance as the EPA.

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The EPA will work to continually improve the transparency of the EPA Guidance Portal, including exploring ways to inform the public of the status of documents not included on the EPA Guidance Portal. The EPA recommends that questions regarding specific guidance documents omitted from the EPA Guidance Portal should be directed to the relevant EPA program or regional office that issued the document.

Regarding the status of rescinded guidance documents, it is important to note that this rule only specifies the procedures that the Agency will follow. The EPA believes the proposed regulation was clear that the Agency could not rely on a rescinded guidance document except to establish historical facts. This regulation is not intended to affect the Agency's past actions that relied upon EPA guidance documents that are now rescinded; decisions made by the Agency are not invalidated because guidance used in reaching those decisions is now rescinded. Notwithstanding the general prohibition on EPA's use of rescinded guidance documents, the EPA cannot limit how non-Agency parties use rescinded guidance, as long as they do not represent rescinded guidance documents as current Agency policy.

Several commenters noted that the EPA Guidance Portal was missing specific documents or classes of documents or that it contained documents that should not be considered active guidance documents.

During the public comment period for this rule, the EPA Guidance Portal had not yet been fully populated, so some situations involving purportedly missing documents may have been resolved in the intervening time. The dispensation of specific documents on the EPA Guidance Portal is outside the scope of this rulemaking. The EPA recommends that any such questions regarding specific guidance documents should be directed to the relevant EPA

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program or regional office that issued the document. Additionally, as discussed in section III.E in this preamble, the EPA is adopting in section 2.507 new procedures for the public to petition for reissuance of a rescinded guidance document that the petitioner believes should be included on the EPA Guidance Portal.

Many commenters provided suggestions to improve the usability and functionality of the EPA Guidance Portal, for example, by making it easier to do a single search across all agency guidance. Suggestions included improving the search functionality across programs, adding automated notifications for new or modified documents (e.g., subscribed e-mail lists or listservs), using visual flags to denote changes or additions, curating the list into statutory or programmatic categories. One commenter opposed using the EPA Guidance Portal as the only source of information regarding new or modified guidance.

The EPA agrees with commenters that the usability and functionality of the EPA Guidance Portal could be improved. In consideration of these comments, the EPA will continue to evaluate and work to improve the functionality of the EPA Guidance Portal, such as improving search capabilities and notification mechanisms.

After consideration of these comments and consistent with the requirements of E.O. 13891, the EPA is finalizing the requirement that all active guidance documents be published on the EPA Guidance Portal and that any guidance document excluded from the list of active guidance documents published on the EPA Guidance Portal does not represent an active guidance document (as defined in this regulation) of the Agency and will have no effect, as

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proposed.¹⁰ When a new guidance document is issued, or an active guidance document is modified, or an active guidance document is withdrawn, the EPA will inform the public via the EPA Guidance Portal.

The EPA agrees that the EPA Guidance Portal is the most effective method to notify the public of changes to the list of active guidance documents because it provides the ability to sort or search by the most current date so that newly added or modified guidance documents appear at the top of the list. The EPA will work to improve the functionality of the Portal and will consider additional means of notifying the public of changes to the list of guidance documents in the future. In addition, the EPA will explore ways to inform the public of the status of documents not included on the EPA Guidance Portal.

As stated in the proposed rule, the list of active guidance documents on the EPA Guidance Portal is intended to contain only documents that meet the definition of “guidance document” and “significant guidance documents” as defined in this regulation. Documents that are excluded from that definition will not typically be included in the list of active guidance documents on the EPA Guidance Portal, although they may still be in effect. For example, the definition of guidance documents in this regulation excludes, among others, internal guidance directed to the EPA or its components or other agencies, statements of specific rather than general applicability, and internal executive branch legal advice or legal opinions addressed to executive branch officials, provided these actions are not intended to have substantial future effect on the behavior of regulated parties. Because excluded documents are not “guidance

¹⁰ See section 3(b) of E.O. 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).

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documents” under this regulation, their omission from the EPA Guidance Portal does not imply that they are “rescinded guidance documents.”

As noted in the proposal, the EPA Guidance Portal currently provides the 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;
- 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. As noted in the preamble to the proposed regulation, the EPA Guidance Portal will also include a link to this final regulation after publication in the *Federal Register* as well as to any future proposed or final amendments.¹¹

¹¹ The EPA Guidance Portal is available at <https://www.EPA.gov/guidance>.

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

The EPA proposed to require certain standard elements for all guidance documents issued after the effective date of this final rule, consistent with E.O. 13891. Specifically, the EPA proposed to require that each guidance document would include: the term "guidance;" the issuing office; the title; a unique identification number; the date issued; the general activities to which and persons to whom it applies (when practicable); a citation to the statutory provision or regulation; whether it was a revision to a previous document; a summary; and a disclaimer as to the non-binding nature of guidance documents.

The EPA received comments that were generally supportive of the minimum required elements for guidance documents. Several commenters supported the proposed disclaimer that clarifies that guidance documents are non-binding, would not have the force and effect of law, and are intended to clarify existing requirements. A few commenters recommended additional required elements, such as identification of an EPA contact person for the guidance document.

The EPA acknowledges the support for the minimum elements from most commenters but disagrees that the additional recommended elements would be appropriate to require for all guidance documents at this time. For example, the identification of a specific EPA contact person would become less useful over time, as individual staff change positions or leave the Agency. Instead, the requirement to identify the issuing office will provide sufficient transparency for the public to contact the Agency regarding the guidance. The EPA believes the current set of elements strikes the appropriate balance between consistency and flexibility.

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Most commenters supported the proposed requirement that guidance documents refrain from using mandatory language. Consistent with these comments, the EPA is finalizing the proposed requirement that guidance documents, given their legally nonbinding nature, 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.

Most comments were supportive regarding the requirement 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 before issuing a new guidance document developed by an EPA Regional Office. Therefore, the EPA is finalizing this concurrence requirement as proposed.

For significant guidance documents, the EPA proposed to require public notice in the *Federal Register* and a minimum 30-day comment period. However, several commenters recommended that the EPA expand the notice and comment requirement to cover most or all guidance covered by this rulemaking, not just those defined as “significant.” Some commenters stated that broader application of the notice and comment requirements could delay issuance of non-significant guidance.

The EPA disagrees that it is necessary to expand the notice and comment requirements for significant guidance documents to all guidance documents. As stated in the proposal preamble, the EPA has the authority to seek comment on any document that the Agency

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determines would benefit from public input and would do so when appropriate. In addition, all active guidance documents that meet the definition in this rulemaking will be available on the EPA Guidance Portal, and the public can petition the Agency to modify or rescind any of these guidance documents. Further, the EPA agrees that applying the notice and comment requirements to non-significant guidance could delay issuance. For these reasons, the EPA declines to expand the notice and comment requirement to all guidance documents.

Regarding determinations of whether a guidance document qualifies as significant, a few commenters requested clarification on the process that will be used to identify a guidance document as a significant guidance document. The EPA disagrees that more details on this process are required and believes that the regulation is clear. The EPA is finalizing the proposed requirement to seek significance determinations from OIRA for guidance documents, as appropriate, according to E.O. 12866 and E.O. 13891.

One commenter stated that if the Guidance Portal and the procedures within this rule are used to revoke guidance that has not been formally replaced, it could end up creating more confusion for regulated entities and stakeholders rather than helping to resolve it.

The EPA disagrees that the implementation of this rulemaking will cause confusion. In fact, this rulemaking will increase transparency regarding the issuance, modification, and rescission of guidance documents and benefit regulated entities and stakeholders by clarifying which guidance documents are active and in effect. If the EPA rescinds a guidance document that clarifies existing obligations, EPA will not utilize an alternative policy or interpretation in taking an action without providing sufficient and fair notice.

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

The EPA proposed additional requirements for significant guidance documents beyond the requirements for all guidance documents described in section III.C. of this preamble. These proposed requirements for significant guidance documents included announcements in the *Federal Register*, minimum 30-day comment period, response to comments, approval by Presidential appointees, review by OIRA under Executive Order 12866 before issuance, and compliance with other Executive Orders.

The EPA received several comments on these proposed requirements for significant guidance documents. Most commenters were supportive of the requirements to announce new, modified, and rescinded significant guidance documents in the *Federal Register* and to provide the public an opportunity to comment. For example, some commenters noted that these requirements would increase transparency and public participation that may not have occurred when the EPA previously issued significant guidance. Some commenters favored other mechanisms to announce significant guidance documents instead of or in addition to a *Federal Register* notice (e.g., using the EPA Guidance Portal, through program specific websites, notifications to states directly, notifications to the affected regulated community through trade associations).

Most commenters supported the 30-day comment period requirement for significant guidance documents. Some commenters recommended that the final rule clarify that the 30-day comment period is a minimum and that the EPA retains discretion to allow longer comment periods, while other commenters recommended that a 60-day comment period should be the minimum. Some commenters recommended additional engagement with states on a government-

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to-government basis, beyond the public comment process. One commenter recommended that the EPA make the comments received on guidance documents publicly available. Some commenters recommended that the EPA limit its response to comments on draft guidance to “major concerns” only (as specified in E.O. 13891, section 4(a)(iii)(A)) and recommended that the responses generally inform the public of the Agency’s thinking on key issues rather than create a detailed record.

The EPA agrees that the notice and comment requirements for significant guidance documents would increase transparency and public participation. As stated in the proposal preamble, the EPA reiterates that the 30-day public comment opportunity for significant guidance documents is a minimum, and the EPA retains discretion to use longer comment periods and will do so when it is warranted by the circumstances surrounding the issuance of a specific guidance document. As stated in the proposal preamble, 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’s *Bulletin for Agency Good Guidance Practices* (2007).¹² The EPA will continue to follow recognized best practices, such as those identified in the 2007 Bulletin, in responding to public comments received on guidance documents.

Many commenters supported the proposed exceptions to the comment requirement for significant guidance documents for “good cause” because there are emergencies when it is

¹² Office of Management and Budget. 2007. *Final Bulletin for Agency Good Guidance Practices* (72 FR 3432, January 25, 2007). While E.O. 13891 and the OMB Implementation Memorandum (M-20-02) issued on October 31, 2019 (the 2019 Memo) supersede the 2007 Bulletin, it is “noted that many of the practices specified by E.O. 13891 and explained in the 2019 Memo are identical to practices discussed in the 2007 Bulletin.” (Q3 from the 2019 Memo).

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essential for the EPA to be able to issue guidance quickly. However, other commenters claimed that the proposed exceptions were vague and not transparent.

The EPA agrees that there can be instances when it is in the public interest for the Agency to issue a significant guidance document without a public comment period, though such instances are expected to be rare. This good cause exception is consistent with E.O. 13891 (Section 4 (a)) and the APA requirement for regulations (5 USC 553(b)(3)(B)). After consideration of the public comments, the EPA is finalizing the additional specific requirements for significant guidance documents and the exceptions to the comment requirement, as proposed, with a minor modification to clarify that approval of significant guidance documents will occur on a non-delegable basis, consistent with E.O. 13891.

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

Consistent with E.O. 13891, the EPA proposed 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 proposed formatting and content elements for petitions to enable a full evaluation by the Agency of the merits of the requested action, including the petitioner's name and contact information, 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 by the petitioner, and the rationale for their request, among other elements.

Additionally, the proposed rule included requirements to ensure timely responses to petitions. The EPA would respond to petitions 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

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estimated decision date. The EPA would only extend the response date one time for a period not to exceed 90 calendar days before providing a response. The EPA noted in the proposed rule that the response and the set timeframes for responding to the petition are not intended to capture the implementation of the response.

The EPA received comments on the process for requesting modification or withdrawal of guidance documents. Several commenters supported the creation of petition process and noted that petitions can help the Agency be made aware of existing guidance that is of concern to impacted stakeholders. Many commenters were supportive of the minimum information to be included in petitions and noted that they had no suggestions for additional information to be included in petitions to modify or withdraw an active guidance document.

The EPA agrees with these supportive comments. After consideration of public comments, the EPA is finalizing these requirements with minor modifications. 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 finalizing 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.

The EPA received public comments requesting more transparency surrounding petitions submitted to the Agency. Several commenters noted that the EPA should make petitions received publicly available and some supported making public the Agency's response to petitions.

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Commenters also believed that the most appropriate place to identify information related to petitions is on the EPA Guidance Portal. One commenter suggested that the EPA publicize and provide a comment period to allow stakeholders and members of the public to comment on such a petition. Finally, a commenter noted that the EPA did not indicate how the Agency would notify the public of subsequent actions taken by the Agency pursuant to the petition.

The EPA agrees with public comments requesting additional transparency regarding petitions received. Therefore, the EPA is finalizing a requirement that the Agency make available to the public, information about petitions received, including the title of the putative guidance document to which the petition pertains. Please note, the information about petitions received may, from time to time, include references to invalid petitions (such as petitions that do not request that the Agency modify or rescind an active guidance document or reinstate a rescinded guidance document), and references to such invalid petitions is not an acknowledgement by the EPA that the documents referenced by those petitions are guidance documents as defined by these procedures.

Although the EPA is not finalizing a requirement for Agency responses to petitions to be made publicly available in this regulation, the EPA will evaluate the feasibility of doing so in the future once more information exists about the volume and complexity of petitions. The EPA disagrees with requiring the Agency to seek public comment on petitions received because such a process goes beyond E.O. 13891, would unduly complicate the petition process, and would be excessively burdensome for the Agency to implement. The additional time required for notice and comment on petitions received could delay the timeliness of the Agency's response to petitions. The public will have access to information regarding subsequent actions related to a

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petition to modify or withdraw a guidance document through the EPA Guidance Portal where the EPA will post newly modified guidance documents and remove rescinded guidance documents from the list of active guidance documents.

A few commenters noted that proposed section 2.507 does not contain procedures for the public to petition the EPA to add to the EPA Guidance Portal a guidance document that a stakeholder believes should be an active guidance document. Commenters requested that the EPA add a specific procedure by which any party can petition for the inclusion of an existing guidance document in the EPA Guidance Portal. One commenter stated that if the EPA declines to add a document to the Guidance Portal, then the EPA should be required to explain the basis for their decision.

The EPA agrees with these commenters that it is appropriate for the public to have a formal mechanism to request that a rescinded guidance document be included on the EPA Guidance Portal and is providing procedures for the public to petition the EPA for reinstatement of a rescinded guidance document. The EPA is limiting these procedures to rescinded guidance documents due to concerns about the potential administrative burden associated with processing petitions of unknown scope and number to reclassify other categories of documents as guidance documents. The EPA anticipates that a petition response would provide the basis for granting or denying the petition. Prior to petitioning the EPA to reinstate a rescinded guidance document, to determine the status of a guidance document excluded from the EPA Guidance Portal, the public is encouraged to contact the EPA program office or regional office that issued the guidance document.

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EPA also received comments regarding the applicability of the petition procedures. Specifically, one commenter noted that the scope specified in section 2.503(b) of the proposed rulemaking was inconsistent with the proposed petition procedures for modification or withdrawal of a guidance document. The proposed regulation would limit the applicability of the guidance procedures to “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].*” The commenter noted that limiting the applicability of the regulations to guidance documents “issued after” the proposed rulemaking was inconsistent with the petition procedures that apply to all active guidance documents on the EPA Guidance Portal, including those issued prior to the effective date of this regulation.

The EPA agrees that the petition process is intended to apply to all active guidance documents and has clarified the applicability in this final regulation. In response to comments, the EPA is clarifying that petition procedures for modification or withdrawal apply to all active guidance documents on the EPA Guidance Portal. For petitions for reinstatement, the procedures apply to guidance documents not currently on the EPA Guidance Portal.

F. Deviation from Procedures (proposed 40 CFR 2.502(f)).

The EPA proposed to allow the Agency to deviate from the procedures set forth in this regulation when necessary at the written direction of the Administrator and in the Administrator’s sole and unreviewable discretion.

Several commenters expressed concerns regarding the proposed provision that would allow the EPA to deviate from the required procedures. These commenters claimed that allowing deviation undermines the purpose of the proposed rulemaking, would decrease transparency and

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certainty, would be contrary to the fundamental principle of administrative law to explain the Agency's decisions, and would lower the likelihood of consistency through this and future administrations.

The EPA agrees with these commenters and is not finalizing this provision.

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 exempt from review by the Office of Management and Budget (OMB) because it is a rule of agency procedure and practice and is limited to agency management.

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

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

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.

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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 13045 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.

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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. This regulatory action is a procedural rule and does not have any impact on human health or the environment.

L. Congressional Review Act

This rule is exempt from the CRA because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

List of Subjects in 40 CFR Part 2

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

Andrew Wheeler,

Administrator.

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

PART 2 – PUBLIC INFORMATION

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

Authority: 5 U.S.C. 552, 552a, 553; 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717; Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970).

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, withdrawal, or reinstatement.

§ 2.501 General.

This subpart establishes procedures for the issuance of Environmental Protection Agency (EPA) guidance documents consistent with Executive Order 13891, “Promoting the Rule of Law Through Improved Agency Guidance Documents” (October 15, 2019). This subpart also

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establishes procedures for the public to petition for modification, withdrawal, or reinstatement of such guidance documents.

§ 2.502 Scope.

(a) The procedures in this subpart apply to guidance documents, as defined in §2.503, excluding those excepted under Section 4(b) of Executive Order 13981 or that are not otherwise subject to Executive Order 13891 or otherwise excepted by the Administrator of OIRA.

(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 EPA after **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**. The procedures and requirements described in §2.504 regarding public access to active guidance documents and §2.507 regarding the procedures for the public to petition for modification or withdrawal shall apply to all active guidance documents regardless of when they were issued. The procedures for petitioning for reinstatement of a rescinded guidance document apply to all guidance documents regardless of when they were issued.

(c) 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.

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

§ 2.503 Definitions.

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

Active guidance document means a guidance document or significant guidance document in effect that EPA expects to cite, use, or rely upon.

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. section 553, or similar statutory provisions;
- (2) Rules exempt from rulemaking requirements under 5 U.S.C. section 553(a);
- (3) Rules of Agency organization, procedure, or practice not intended to have substantial future effect on the behavior of regulated parties;
- (4) Decisions of Agency adjudications under 5 U.S.C. section 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, including legal opinions by the Office of General Counsel, not intended to have substantial future effect on the behavior of regulated parties;

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- (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 in the form of speeches, press releases, or similar communications, 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.

Rescinded guidance document means a document that would otherwise meet the definition of a guidance document or significant guidance document, but that the EPA may not cite, use, or rely upon except to establish historical facts.

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";

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- (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.

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(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 guidance documents pursuant to E.O. 12866.

§ 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 publicly available a draft significant guidance document, including a significant guidance document that is being reinstated, or draft modification 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 of a significant active guidance document, to open the public comment period.

(b) *Withdrawal of a significant guidance document.* (1) The EPA will seek public comment on the Agency's intent to withdraw a significant active guidance document.

(2) The EPA will publish a notice in the *Federal Register* announcing the Agency's intent to withdraw a significant active guidance document to open the public comment period.

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(c) *Public comment process.* (1) Except as provided in paragraph (d) 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 significant guidance document or issuance of the final modified significant guidance document, or withdrawal of an active significant 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 significant guidance document itself or in a companion document.

(d) *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 significant 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 significant guidance document) that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

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

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(f) *Approval.* On a non-delegable basis, 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.

(g) *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, withdrawal, or reinstatement.

(a) *Submission of a petition.* (1) The public may submit a petition to the EPA for the modification or withdrawal of an active guidance document, or reinstatement of a rescinded guidance document.

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

(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:

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(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,” “Petition to Withdraw a Guidance Document,” or “Petition to Reinstate a Guidance Document”

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

(1) Identification of the specific title the guidance document that the petitioner is requesting be modified, withdrawn, or reinstated;

(2) For petitions to modify or withdraw a guidance document only, the EPA unique identifier of the guidance document;

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

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

(5) For petitions to modify or withdraw a guidance document only, and only 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

(6) A rationale for the requested modification, withdrawal, or reinstatement.

(e) *Petitions received.* The EPA will make available to the public information about petitions received, including the title of the guidance document to which the petition pertains.

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(f) *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.

(g) *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.

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