

**EPN Comments on EPA's Proposed Rule entitled "EPA Guidance:  
Administrative Procedures for Issuance and Public Petitions"**

June 22, 2020

The Environmental Protection Network (EPN) is pleased to submit the following comment on EPA's Proposed Rule entitled "EPA Guidance: Administrative Procedures for Issuance and Public Petitions" (85 Fed. Reg. 31104 (May 22, 2020)). EPN is an organization comprised of more than 500 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health, and the environment. In brief, EPN believes that:

- I. The legal authority EPA cites for this rule, the federal Housekeeping Statute, does not provide an adequate basis for rulemaking of this nature.
- II. While much of the substance of the proposal is sound, the proposal as a whole creates a risk of making it as burdensome to issue guidance as to promulgate rules. Guidance is valuable to the Agency and to outside parties in many ways; therefore, discouraging its use would be damaging for all concerned.
- III. Therefore, EPN recommends:
  - a. The proposed actions should be adopted as a matter of Agency policy, not through a rule. The Housekeeping Statute does not provide statutory authority for such a rule, and a rule will tend to lead to a burdensome process that impedes the use of guidance.
  - b. Use of a portal to make guidance more transparent and accessible is desirable, as is the commitment to use disclaimers and other language clarifying that guidance is not legally binding. These do not require a rule, however, and ambiguity about what constitutes "guidance" will have to be considered in using the portal.
  - c. Soliciting public input during the development of guidance can be useful in appropriate cases but should be tailored to the nature and scope of the issues involved. EPA should consider a range of options for obtaining input on a case-by-case basis, rather than relying primarily on a rule-like notice and comment process. Similarly, EPA's response to public input should be focused on key issues, not a detailed administrative record of the kind created for rulemaking. The policy should emphasize flexibility rather than using terminology suggestive of a rule-like notice and comment process.

**I. The Housekeeping Statute does not provide legal authority for this proposal.**

EPA claims that it has authority to issue this regulation under the federal Housekeeping Statute, 5 U.S.C. § 301. That statute authorizes what the Administrative Procedure Act (APA) "terms 'rules of agency organization, procedure or practice' as opposed to substantive rules,"

Chrysler Corp. v. Brown, 441 U.S. 281, 310 (1979), and enables “department heads to make regulations governing day-to-day operation of the department.” *id.* at n. 41. A typical housekeeping rule would govern purely internal agency procedures and practices such as storage and transport of records. That is not what EPA is doing with this regulation, which establishes requirements that govern the development, use, and disclosure of guidance documents, and expressly requires that they be made available to the public and specifies how this must be done. It is explicitly intended for the benefit of external parties and not just to organize EPA’s internal activities.

The entire discussion of the legal basis for EPA’s use of the Housekeeping Statute as authority for this rule is as follows:

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.” The Agency considers this action a rule of agency organization, procedure, or practice that lacks the force and effect of law.

EPA offers no additional explanation of the nature, scope, or extent of the rulemaking authority EPA is now claiming the Housekeeping Statute provides. Its entire explanation of the substance and basis for using the statute is its claims that the rule is “incidental to the performance of” agency functions and that it “lacks the force and effect of law.” EPA does not even cite other authority for the rule, much less demonstrate that it has authority for such a rule.

EPA does not explain how the first is any limitation at all, since it would apply to any EPA rule (unless EPA claims it has authority to issue rules or establish procedures that do *not* in some way relate to performing its functions, which would be illegal (New York Stock Exch. LLC v. Sec. & Exch. Comm’n, No. 19-1042, 2020 WL 3248902, at \*9 (D.C. Cir. (June 16, 2020))). EPA offers no examples of circumstances when it has used the authority in the past, or any general principles for limiting its use (e.g., by spelling out the circumstances in which it can or cannot use the Housekeeping Statute as authority for *any* EPA rule that sets forth Agency procedures relating to the performance of Agency functions). In short, EPA offers no analysis to show that the Housekeeping Act authorizes it to issue this rule.

EPA is seeking public comment “as a matter of good government,” but claims that a housekeeping rule comes within the APA notice and comment requirement exemption for “interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.” But this is a rule governing agency policies and practice concerning the *external* disclosure, use, development, and modification of publicly available guidance documents; if such a rule can be issued under EPA’s purported housekeeping authority, exempt from APA notice requirements because it governs “agency organization, practice, or procedure” or its “day to day operation,” it would seem to follow that this rationale also exempts a host of other garden-variety EPA rulemakings that affect the public but implicate internal procedures or practices.

The second “limiting” principle is the claim that the regulation has no legal effect. But the relevant question is not whether the rule’s effects are legal, but whether they are internal or external to the agency. A rule cannot be issued under the housekeeping authority if it has effects beyond matters purely internal to the agency. Even so, we believe the rule is intended to have such effects.

The rule is issued under Executive Order (EO) 13891 “Promoting the Rule of Law Through Improved Agency Guidance Documents.” Section 4 of the EO directs each agency to issue regulations that impose requirements to implement this policy. And at least some provisions of the regulation are self-evidently intended to have significant effects well beyond internal agency operations. Even the three-sentence summary of the rule in the Federal Register declares that the rule establishes “procedures *for the public to petition* for the modification or withdrawal of active guidance documents” (FR 31104, emphasis added). A rule establishing “procedures for the public” to comment on the use or availability of agency documents is *not* the kind of purely internal housekeeping rule authorized under the Housekeeping Statute.

The rule provides detailed and prescriptive requirements for the use and development of guidance documents.<sup>1</sup> It imposes the following obligations on the agency in managing its external operations:

- It requires the agency to establish and maintain a website guidance portal that

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<sup>1</sup> The proposal “summarizes” the requirements for significant guidance documents as follows: 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.

contains or links to guidance documents that the EPA expects to “cite, use, or rely upon” and that makes the “documents readily available to the public.” This addresses the agency’s use of a document in decision-making and how the document will be available to the public, not within the agency.

- It requires that the portal include all active guidance documents issued by an agency. Because the portal is public, this, too, affects how the agency provides notice to the public of documents it will use or rely on in actions affecting the public.
- It provides that any guidance document excluded from the portal does not represent the final guidance of the agency and “will have no effect.” This addresses the agency’s ability to cite, use, or rely on the document in public actions.
- It requires “that agencies treat guidance documents as non-binding both in law and in practice.” This, too, affects the agency’s ability to use and rely on the guidance documents in decisions affecting the public.
- It sets “forth processes and procedures for issuing guidance documents” by identifying ten standard elements for all guidance documents and imposing additional requirements for “significant” guidance documents. Although this nominally addresses “processes and procedures,” those are not purely matters of internal agency operation because of how EPA will or will not use guidance documents in actions affecting the public. The requirements are as follows:
  - It mandates *public review and comment opportunities* “for all significant guidance documents.”
  - It requires a process “to *allow the public to petition the EPA* for the modification or withdrawal of an active guidance document.”
  - It requires a timely response to such a petition.
  - It precludes a Regional Office from issuing a new guidance document unless it is approved by the relevant national program manager.

In sum, it is preposterous to claim that the rule affects purely internal policies and procedures that have no effects beyond the agency.

Peculiarly and perversely, § 2.503 of the proposal expressly provides that its requirements do *not* apply to a procedure that logically might be covered by a genuine housekeeping rule:

- “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 2.503 (5).”

Moreover, the express exclusion for guidance “not intended” to “have substantial future effect on the behavior of regulated parties” underscores the fact that documents subject to the rule *are* intended to have such effect. Thus, the exclusion provides yet more evidence that the rule applies to guidance that will substantially affect the behavior of regulated parties. That is not an internal housekeeping matter.

In sum, the rule establishes norms and imposes legal requirements concerning the development, availability, use, and modification of guidance documents affecting the public, and specifies what types of actions or practices can or cannot be announced through such guidance documents. It also spells out what guidance documents have or do not have any “legal effect.” On its face, it is clearly intended to affect the public. That is something that cannot be done using a housekeeping rule.

## **II. The proposed approach could discourage the use of guidance, which would be bad for EPA and for the public.**

The proposed rule also raises serious policy concerns. In the view of EPN, it could have damaging consequences for agency practice with regard to the use of guidance.

### **a. Guidance is extremely valuable both for the Agency and for outside parties.**

EPN is concerned that this proposal, as currently designed, could have the effect of discouraging the use of guidance. It has been our experience that the use of nonbinding guidance and policy serves many valuable purposes, benefiting not only the Agency but regulated parties and the public.<sup>2</sup> As the proposal notes, guidance can “increase efficiency, and help improve the public’s understanding of the EPA’s policies.”<sup>3</sup>

Guidance can take many forms. (The sheer variety of statements, documents, or other actions that might constitute “guidance” is itself a reason to be careful about imposing uniform rules on all of them.) A few examples illustrate both the importance and diversity of guidance:

- Office of Chemical Safety and Pollution Prevention (OCSP) Harmonized Test Guidelines: There are eleven categories of guidelines, representing over 100 recommended study designs for the generation of scientific data used to satisfy information requirements in the pesticide and toxic substances regulatory programs. The scientific results from these studies, in turn, are interpreted in accordance with the roughly 200 consensus risk assessment guidance documents developed for use agency-wide. The risk assessments resulting from the integration of these two sets of guidance serve as a key component of the risk management decision-making process.

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<sup>2</sup> The Administrative Conference of the United States has stated that “Policy statements are important instruments of administration...and are of greatest value to agencies and the public alike.” The value and importance of guidance has also been emphasized by many administrative law scholars. See, e.g., Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 850 (2001) (guidance documents have benefits for the public as well as agencies; expansion of procedural requirements associated with guidance documents would force agencies to issue fewer of them). Other articles explaining the value of guidance include Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, (1992); Nicholas R. Parillo, *Federal Agency Guidance: An Institutional Perspective* 28-35 (2017) (report for the Administrative Conference of the United States).

<sup>3</sup> 85 FR at 31105 (May 22, 2020).

- Drinking Water Health Advisories: These advisories are non-regulatory, published for the benefit of federal, state, and local officials and managers of public water systems, addressing non-cancer effects.
- Superfund guidance: As an operating program requiring many operational and management decisions, as well as policy decisions, Superfund has a very wide range of highly detailed guidance on many different topics. These serve to help site managers make decisions consistently, inform them about complex technical and legal topics, inform them about current scientific developments, and help them apply complex regulations such as the Hazard Ranking System.
- Enforcement guidance: EPA's enforcement program also issues a wide range of guidance on the many policy, economic, and technical issues confronted by enforcement staff. These are updated regularly to remain current, and touch on issues as diverse as the calculation of penalties, handling of cases where a party has voluntarily disclosed a violation, and current enforcement priorities.

Thus, guidance provides important benefits, including:

- It helps to ensure that the Agency acts consistently from case to case and across regions.
- It helps to ensure that program staff use the best scientific information currently available.
- It allows the Agency to address regulatory issues at a far greater level of detail than would be possible in rules, and without being overly prescriptive because of the greater flexibility inherent in guidance or policy.

In this regard, it is worth quoting at length from the Administrative Conference of the United States, which has stated that:

Policy statements are important instruments of administration across numerous agencies, and are of great value to agencies and the public alike. Compared with adjudication or enforcement, policy statements can make agency decisionmaking faster and less costly, saving time and resources for the agency and the regulated public. They can also make agency decisionmaking more predictable and uniform and shield regulated parties from unequal treatment, unnecessary costs, and unnecessary risk, while promoting compliance with the law. Compared with legislative rules, policy statements are generally better for dealing with conditions of uncertainty and often for making agency policy accessible, especially to regulated parties who lack counsel. Further, the provision of policy statements often takes less time and resources than legislative rulemaking, freeing up the agency to, for instance, take other action within its statutory mission.<sup>4</sup>

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<sup>4</sup> Administrative Conference of the United States, Recommendation 2017-5 at 2.

In short, guidance helps staff process their responsibilities more efficiently and in some ways levels the playing field for all involved, rather than requiring staff to reinvent the wheel matter by matter.

It is important to understand why guidance, rather than rulemaking, is often necessary to achieve these aims. Rulemaking is almost always a very long and resource-intensive process. Although this is important in cases where regulations are being issued that will have the force of law, it limits the agency's ability to use rulemaking. It also limits the usefulness of rules in addressing matters that may change rapidly over time. Therefore, guidance fills the gap where there is a need for prompt direction and greater flexibility. Guidance also goes into greater detail than rules, and allows policy to be stated without the resource intensive effort required of rules.

EPA must think very carefully, then, before taking steps that would impede its ability to use guidance in the future.

**b. The proposal risks making the development of guidance highly burdensome.**

EPN is very concerned that this proposal will have the effect of making the process of issuing guidance as time-consuming and burdensome as rulemaking. This would largely undermine the value of guidance and its advantages in allowing the agency to act more quickly than rulemaking allows. Commentators have criticized the “ossification” of rulemaking, and the last thing that is needed is for this to extend to guidance as well.<sup>5</sup> The very complex process that currently exists for rulemaking stems from the implementation of one brief section of the Administrative Procedure Act, no more detailed than this proposal.<sup>6</sup> A similar evolution from apparently simple requirements to highly cumbersome practices can be envisioned if this rule is adopted as proposed.

It is true that a number of concerns have been raised in the past about the use of guidance. One is that guidance may not always be known to the public because it is issued internally and may not be adequately publicized. Another concern is that guidance can be misused by agency staff who treat it as binding both for their own purposes and in dealing with external parties. Concerns have also been raised that it is difficult for external parties to challenge guidance; guidance documents are not judicially reviewable at the time they are issued, but it may be difficult for individual affected parties to object effectively at the point when they are applied to specific decisions or actions.

EPA has sought to address these concerns in a variety of ways over time, without taking the step of issuing a rule. For example, the Agency has been increasingly careful to word guidance documents to make clear that they are not binding. As the proposal notes, public input is sought on some forms of particularly important guidance or policy. For example, the OCSPP test guidelines

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<sup>5</sup> Thomas O. McGarity, “Some Thoughts on ‘Deossifying’ the Rulemaking Process,” 41 Duke L.J. 1385 (1982).

<sup>6</sup> See 5 U.S.C. § 553.

have been vetted on the international stage as they are judged for consistency with the Organisation for Economic Co-operation and Development (OECD) test guidelines. Many of the risk assessment guidelines have gone through interagency review and external scientific peer review, often in a public forum, which provides the opportunity for public comment. Programs make many relevant documents available on their websites. Further steps of that nature are entirely appropriate. For instance, the OCSPP test guidelines are available on both the Office of Pollution Prevention and Toxics (OPPT) and Office of Pesticide Programs (OPP) websites. All of the risk assessment guidelines are available on the Office of Research and Development's (ORD's) Risk Assessment website.

However, this proposal goes further, and would impose a variety of uniform requirements by rule. This creates the risk of making the process of writing guidance as cumbersome as promulgating a rule. This would greatly reduce its value, with deleterious effects both inside and outside the Agency. We are worried that this is a backdoor way of discouraging Agency staff and regional offices, who are on the front lines of regulation and enforcement and for whom guidance increases efficiency and sets a level playing field, from developing guidance in appropriate circumstances.

**c. The proposal creates rigid rules where flexibility is needed.**

The risk of making it overly burdensome to issue guidance stems primarily from the use of a rule as the vehicle for setting expectations, and the use of rigid regulatory terminology within the rule rather than terms that emphasize flexibility.<sup>7</sup>

Many aspects of this proposal are conceptually sound. Providing a central portal to ensure transparency and accessibility is a good idea. Requiring a disclaimer making clear that guidance is not binding and avoiding the use of terms suggesting otherwise (such as “shall” or “must”) is longstanding agency practice and is fully appropriate. However, these do not require issuing a rule.

Inviting public comment on significant draft guidance is also appropriate. However, as drafted, the proposal calls for a uniform rule-like notice and comment process, which has the potential to become unduly burdensome and time-consuming. In the context of guidance, the goal of seeking public input should be to obtain key information that will inform and improve the document. For this purpose, it is not necessary, or desirable, to develop a detailed record of the kind used in rulemaking, addressing every comment in detail or preparing a comprehensive record for possible litigation. Similarly, the purpose of the agency's response should be to generally inform the public of its thinking on key issues, not to ensure a written response to every issue that might be

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<sup>7</sup> Because the rule is characterized as one of agency procedure or practice, EPA may believe that it would be more easily amended or repealed than typical rules. However, amending any rule would involve significant effort. Furthermore, outside parties will likely resist changes in the rule and demand the right to comment.



raised in subsequent litigation. Moreover, as has been noted, EPA guidance takes many different forms, making simplistic uniform procedures inappropriate. A more flexible approach, with the exact process designed on a case-by-case basis, should be used.<sup>8</sup>

Providing a clearer process through which the public may ask EPA to modify or withdraw guidance is not unreasonable, but it must be managed to ensure that the Agency is not overwhelmed with requests and can, if necessary, prioritize those it receives. EPA should not have to set aside other important work to respond to such requests, which may reflect the priorities of interest groups more than those of the Agency or the general public. As in the issuance of guidance, the level of analysis, documentation, and response should be commensurate with the significance of the document and the issues raised.

EPN is concerned that placing new process requirements in a rule could result in litigation over whether guidance was properly issued.<sup>9</sup> If this occurs, the likely result will be that over time, EPA programs become increasingly cautious and formal, handling public comment in a way similar to that used now for rules rather than engaging in an efficient dialogue. Terminology such as that in the proposal, which mirrors that of notice-and-comment rulemaking, would particularly invite such claims and could lead courts to impose rule-like process doctrines. Outside parties would then tend to act similarly, submitting massive comments that address every possible issue so as to lay a groundwork for litigation rather than focusing on key issues. More flexible policy on public input, and on the nature of the response expected from the agency, as we have recommended above, would reduce that risk.

Agency programs may also adopt a tendency to use rigid and formal procedures if a rule is adopted and particularly if the rule uses terminology similar to that of rulemaking. Programs will seek to implement the directive in good faith and may tend to gravitate toward uniform procedures simply for reasons of simplicity and efficiency or in anticipation of even remote risks of litigation. To avoid this, it is important to emphasize flexibility and tailoring of process on a case-by-case basis.

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<sup>8</sup> The Administrative Conference of the United States has stated: “Choosing a level and means of public participation that is appropriate to a policy statement’s likely impact and is practicable requires consideration of several factors. Given the complexity of these factors and their tendency to vary with context, it is appropriate to make decisions about whether or how to seek public participation on policy statements on a document-by-document or agency-by-agency basis. A government-wide requirement for inviting written input from the public on policy statements is not recommended, unless confined to the most extraordinary documents.” ACUS Recommendation 2017-5 at 6.

<sup>9</sup> The proposed rule states that it would not create rights enforceable by any outside party (§ 2.502(d)). If successful, this would reduce the risk discussed above. However, EPN is not certain that this position would be sustained since the entire aim of the public notice process is to benefit outside parties. As argued earlier, the proposed rule goes well beyond purely internal management, and it would seem disingenuous for EPA to establish strict procedures and then argue that it could not be held to them. Even if courts choose not to review such claims, there will likely be congressional or other oversight that would have the same effect on Agency behavior.

Finally, there will likely be a tendency for outside parties to submit massive, detailed comments if only to slow down the process of issuing guidance. Even if EPA's policy is to respond only to major issues, there will be a natural tendency to address most or all comments (especially if there is a perceived risk of later litigation).

**d. Regions should retain flexibility to adopt guidance.**

EPA is proposing to require that concurrence from headquarters be obtained (at the Assistant Administrator Level) before a regional office issues guidance. In many cases, this would be unnecessary and could be counterproductive by adding a time-consuming and unnecessary formal process when current regional-specific processes, such as informally consulting with regional programs, regional states, and other regional offices, when any of those may have issues similar to what a draft regional guidance addresses. Consultation with headquarters is appropriate if the guidance would be considered "significant" as provided in this proposed rule.

Typically, regional guidance is generated when the subject matter is unique or particular to the region, for example, fish consumption rates for tribes or other populations where the region has science-based information on which to base fish consumption rates for risk assessment purposes. In such cases, regional offices and their states are in a better position to write and evaluate guidance that is not necessarily relevant nation-wide. Another example is when the subject matter has national importance, but EPA Headquarters has demurred from issuing policy, and the region has determined it is necessary to do so on its own to protect human health and the environment, based on best available science, typically from EPA sources such as the Office of Research and Development. This might be true, for example, with chemical-specific exposure or toxicity guidance. In such cases the production of such guidance often is useful to other regional offices and may also prompt EPA Headquarters to consider adopting the principles incorporated in the regional guidance into national guidance. Having to go through senior management at EPA Headquarters prior to issuing regional guidance would add an unnecessary delay in addressing pressing matters affecting human health and the environment, and would require HQ personnel to come up to date on issues, such as area- and population- specific fish consumption rates, that they are unfamiliar with.<sup>10</sup>

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<sup>10</sup>A few examples of regional guidance, from Region X (all of which are on the guidance portal currently), are: [Executing Risk-Based LUST Site Closures in R10 Indian Country](#) (2015); [Framework for Selecting and Using Tribal Fish and Shellfish Consumption Rates for Risk-Based Decision Making at CERCLA and RCRA Cleanup Sites in Puget Sound and the Strait of Georgia](#) (2007); [Interim Final Guidance: Developing Risk-Based Cleanup Levels at Resource Conservation and Recovery Act Sites in Region 10](#) (1998). These illustrate the wide range of topics on which regions may have special needs and expertise.

### **III. EPA should adopt a more flexible approach through policy rather than a rule.**

As we have noted, EPN supports many of the ideas in this proposal. However, EPA can achieve all these aims in ways that do not create the risk of unduly burdensome processes that undermine the real value that guidance has for the Agency and its stakeholders.

First, the matters addressed in this rule would be better handled through agency policy. We have argued above that the Housekeeping Statute does not provide statutory authority for this type of rule. Even if it did, there is very little in the proposal that cannot be done by policy, and using policy will allow flexibility to adjust to circumstances as needed. As we have noted, guidance can take many forms, and it is likely that situations will arise that were not anticipated; the ability to tailor procedures is important.<sup>11</sup>

Creating a master portal to ensure, as fully as possible, that the public has access to guidance is a welcome step. It does not, of course, require a rule to implement. Guidance should also be placed on program websites since this is where stakeholders are most likely to look for them, and where they will be presented in context.

EPN does note that the sheer variety of types and forms of policy or guidance will pose a challenge to the idea of creating a single definitive repository. Guidance sometimes takes the form of a memorandum clearly labeled as such, but policy can appear in many other forms. EPN examined the contents of the portals of each of the major offices of the Agency as well as the regions and came to the conclusion that the Agency appears to be uncertain as to what constitutes “guidance.” The numbers of entries for each office/region varied widely from just one for the Office of Mission Support to 3,690 for the Office of Land and Emergency Management. Some listings in a portal seemed more suitable to be placed in a different one. Some titles clearly indicated the entry was guidance, others more likely not. Much policy is stated in the preambles to rules, but these do not appear to be included routinely in the portal.

This lack of clarity about what the rule would apply to could be a serious problem in implementing the portal. At a minimum, it will be important to require that an extremely careful search be made to identify, locate, and collect all guidance, to ensure rigorous adherence and to avoid inadvertently leaving something out. Time should be taken to conduct a thorough review before declaring guidance not on the portal to be of no effect, and if (as seems inevitable) policy

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<sup>11</sup>The proposal states that the Agency may deviate from the rule at the written direction of the Administrator. However, this means that exceptions will be infrequent and will require elevation of issues to the highest level of the Agency; in practice, programs will generally just follow the rule rather than go to that level of effort, even if the rule is not sensible in the circumstances.

statements are later determined to constitute “guidance,” the Agency should be able to nevertheless rely on them prospectively by placing them in the portal.<sup>12</sup>

Similarly, ensuring that documents are properly drafted does not require a rule to be carried out; programs are already counseled to that effect, and more formal directives could be issued if necessary. Other steps, such as training, could also be taken without a rule to ensure that program staff do not treat guidance as binding in practice.

EPN supports the general aim of giving the public an opportunity to provide input, especially on highly important guidance. However, this process should be designed to maximize the value of such input, without creating a highly formalized process similar to rulemaking. The aim should be to generate a useful exchange of information, not to create a record for litigation. Accordingly, the process for public involvement should be tailored to the specific circumstances. EPN supports the recommendation of the Administrative Conference of the United States (ACUS): “When an agency is contemplating adopting or modifying a policy statement, it should consider whether to solicit public participation, and, if so, what kind, before adopting the statement. Options for public participation include outreach to selected stakeholder representatives, stakeholder meetings or webinars, advisory committee proceedings, and invitation for written input from the public with or without a response.”<sup>13</sup> New technology further expands the range of available options. ACUS also sets out a number of factors to consider in deciding on the appropriate degree and type of input process to provide in any given case. As ACUS emphasizes, these factors vary widely from case to case; a one-size-fits-all rule is not appropriate. Therefore, whether public input is needed, and what form it should take, should be decided on a case-by-case basis, and the terms used should emphasize flexibility and the potential for tailoring the process to each situation.<sup>14</sup> Policies on public input should also allow for exceptions on the grounds listed in the proposal, such as exigent circumstances and legislative or judicial requirements.

It is also important to establish appropriate expectations regarding the agency’s response to such input. In this context, a highly detailed, point-by-point response of the kind typically provided in rulemaking is not necessary or productive. In the rulemaking context, such a response is necessary to provide the record for judicial review; that does not apply to guidance. In this context, it should be sufficient for EPA to respond in a general way to key issues raised by the public, to explain its thinking. The terminology used in proposed § 2.506 (b)(2), which states that EPA is to respond to

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<sup>12</sup> If a policy has truly been unknown to the public, and external parties have relied on other statements, fairness may call for not applying the policy to past actions or to compel undoing actions taken in good faith reliance. This is not, however, a reason to tie the agency’s hands in applying the policy prospectively.

<sup>13</sup> Administrative Conference of the United States, Recommendation 2017-5, recommendation 9.

<sup>14</sup> It makes sense to limit public input requirements to the most important guidance documents, as proposed. However, EPN finds the definition of “significant guidance” difficult to apply. If the proposal takes the form of a policy, this would allow reasonable judgment rather than regulatory definitions to control decisions about whether public involvement is appropriate in any given case.

“major concerns and comments,” is reasonable. Again, however, it is important to convey that, in this context, the response should serve the purpose of communicating the Agency’s thinking, not to create an administrative record of the kind used in rulemaking.<sup>15</sup> In addition, the policy should make clear that EPA has a high degree of discretion in responding to comments, so as to best inform the public about the issues without going into detail on minor concerns.

### **Conclusion**

EPN sees value in providing greater clarity with regard to guidance and in providing an opportunity for productive dialogue with the public in the development of guidance. However, EPN urges EPA in taking such steps to bear in mind the great value that guidance provides, and to ensure that new procedures support rather than discourage the use of guidance for the benefit of both the Agency and the public.

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<sup>15</sup> Guidance may not be challenged in court at the time it is issued, but may be challenged when applied later on. For that purpose, it would be good practice to retain comments, responses, and other documents supporting or used in developing the guidance for future reference. However, such review would not be limited to that record, so it is not necessary to address every comment or issue prior to releasing the guidance.