

August 16, 2018

**Submitted Electronically**

Hon. Andrew Wheeler  
Acting Administrator  
Environmental Protection Agency  
William Jefferson Clinton Building  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

Dear Acting Administrator Wheeler:

**Subject:       Comments of the National Rural Electric Cooperative Association on the  
U.S. Environmental Protection Agency's proposed rule, Strengthening  
Transparency in Regulatory Science. Docket No.: EPA-HQ-OA-2018-0259**

The National Rural Electric Cooperative Association (NRECA) appreciates this opportunity to comment on the U.S. Environmental Protection Agency's (EPA) proposed rule, Strengthening Transparency in Regulatory Science. 83 Fed. Reg. 18768 (April 30, 2018).

NRECA is the national service organization for America's electric cooperatives. The nation's member-owned, not-for-profit electric co-ops constitute a unique sector of the electric utility industry – and face a unique set of challenges. NRECA represents the interests of the nation's more than 900 rural electric utilities responsible for keeping the lights on for more than 42 million people across 47 states. Cooperatives serve an average of 7.4 consumers per mile of line and collect an annual revenue of approximately \$16,000 per mile of line, as compared to the industry average of 34 customers and annual revenue of between \$75,500 per mile of line for investor-owned and 48 consumers and \$113,000 per mile of line for publicly owned utilities or municipals.

NRECA's member cooperatives include 63 generation and transmission (G&T) cooperatives and 834 distribution cooperatives. The G&Ts are owned by the distribution cooperatives they serve. The G&Ts generate and transmit power to nearly 80 percent of the distribution cooperatives, those cooperatives that provide power directly to the end-of-the-line consumer-owners. Remaining distribution cooperatives receive power directly from other generation sources within the electric utility sector. Both distribution and G&T cooperatives share an obligation to serve their members by providing safe, reliable, and affordable electric service.

Electric cooperatives are private, independent electric utilities, owned by the members they serve. Most are small businesses (as defined by the Small Business Administration) and do not have investors to help defray the costs of regulations. The costs are borne directly by the farmers, ranchers, small businesses and other residents of the nation's rural communities –

including those in 93 percent of the nation's persistent poverty counties – who write a check each month to their co-op to pay for their electric service.

In the preamble of the proposed rule, EPA states that the rulemaking is being promulgated with the goal of ensuring that the data and models underlying the science supporting its significant regulatory actions is publicly available in a manner sufficient for validation and analysis. The NRECA supports this goal while noting that the proposed rule raises important questions regarding the scope and applicability of its requirements.

NRECA's comments are intended to support EPA's implementation of the concepts raised in the proposal in a manner consistent with relevant statutory authorities and with existing government wide policy regarding scientific integrity and data quality. NRECA believes all Americans value and deserve a healthy environment. In the context of this rulemaking and considering the unique economic challenges the electric cooperatives face, NRECA believes that sound public policy should be grounded in objective scientific data and analysis that is subject to rigorous standards of reproducibility and transparency. As discussed in detail below, NRECA recommends EPA evaluate the major, consensus-based procedures that have been recently developed by scientific organizations to address similar concerns.

## **I. Summary of Comments**

NRECA's comments are organized into several topic areas. First, we define some commonly misappropriated basic scientific terms to provide a foundation for our specific comments on the proposed rule. Secondly, we examine data transparency standards widely employed in the scientific community as a potential framework for EPA to model its requirements. Finally, we offer some specific suggestions regarding EPA's targeted requests for comment in the proposed rule.

## **II. Epistemology and Foundational Scientific Principles**

EPA could fundamentally improve the rulemaking through more precise definitions in both the preamble and regulatory text. Extensive media coverage of EPA's proposal has highlighted why these definitions are important; such coverage and commentary misappropriates and confuses fundamental terms like "science." The rule's definitions should start with grounding EPA's rulemaking in fundamental terms. We seek to define some of the most foundationally important terms here:

- **Science.** The study of nature as it is. Science can also refer to the collection of scientific facts and relationships between these facts. For example, biology is a branch of the study of nature that is concerned with living organisms.
- **Scientific fact.** A claim about nature that is objective and reproducible. A scientific fact must be transparent to be objective – no matter who the viewer or experimenter is, the same result of nature is observed. Objectivity is a necessary foundation for

reproducibility. If a claim is not transparent enough to be objective or reproducible, it is not a scientific fact.

- **Applied Science.** The use of scientific facts to create a tool. Fields like engineering, toxicology, economics use scientific facts to construct models, cell phones, bridges, dose-response relationships, markets, and many other things that give us longer, happier, and safer lives.

EPA's rulemaking's scope is applied science. EPA must use tools developed by the applied sciences to achieve its statutory responsibilities. Applied science gives us many tools for the same function; "build a better mousetrap and the world will beat a path to your door." Traditionally, terms important to EPA's purview such as "best available science" encompass both scientific facts and applied science constructions. Choosing among different models, dose-response relationships, or mousetraps involves judgement -- e.g., what is "available" and what is "best?"

This judgement is independent from the question of whether a claim is a scientific fact. Using only the scientific fact of  $F = ma$  as the model to design a rocket will not work well. Atmospheric friction, angular momentum, and other factors must be considered to calculate the necessary force to reach orbit. However, just because  $F = ma$  is not the best model for designing a rocket does not diminish that this relationship is a scientific fact. The error is the choice to apply it where it is not useful.

EPA's judgement occurs not only on which model to select, but throughout the applied science construction process. Modelers must select among data and must infer, simplify, and condense relationships to make computation tractable. Models have inherent uncertainty and often are designed to overcome uncertainty or complexity in how scientific facts are related (e.g., Gaussian plume models, linear low-dose extrapolations). As George Box stated, "Remember that all models are wrong; the practical question is how wrong do they have to be to not be useful." This practical question is EPA's judgement.

Using the word "judgement" for EPA's application of science carries with it a minimum expectation of transparency in our society. We expect almost all our government decisions of judgement to be open and to be able to be observed by all citizens. Trials, notice-and-comment rulemakings, permits, records of decision, and many government judgements contain opportunities for public comment and levels of transparency.

In summary, EPA's "regulatory science" is an applied science. Applied science inherently involves judgement. As Box summarized, the judgement EPA must make is how wrong an applied science tool must be to not be a useful tool for policy. EPA's rulemaking poses fundamental questions about what level of public transparency EPA's judgement should be subject to as it chooses among different, inherently "wrong" applications of scientific fact.

### **III. Scope of Transparency Requirements**

Since EPA's application of science always involves judgement and since this judgement is an exercise of government authority, our principled position is that all EPA applications of science should have minimum transparency standards. We know of no objective principle to separate permits, cleanup decisions, regulations, or other uses of EPA authority to arrive at the conclusion that one community deserves the ability to understand the government's judgement and reasoning and another does not.

We therefore recommend EPA expand the scope of the rule to all applications of science, not just to a particular model form like a dose-response relationship. Specifically, EPA commonly employs fate-and-transport models, route of exposure models, cost estimation models, statistical techniques to project analytic data beyond method detection limits, and numerous other specific applications of science. Again, since all these models involve judgement by EPA and by the application developers, we see no logical principle to require transparency for one application and not another. For example, a fate and transport model could have as much economic impact as a dose-response model.

The importance of this principle is highlighted by EPA's current proceedings within the U.S. Court of Appeals for the D.C. Circuit where the judges are unable to follow EPA's statistical methodology for calculating the best performing sources for a MACT standard. This case is instructive since it shows (1) the lack of transparency in other scientific applications besides dose-response models; (2) the cost in social resources when EPA fails to be transparent; and, (3) the risks that the lack of transparency may delay measures to protect human health and the environment.

We understand that there are practical limits and resource constraints that require EPA to set different transparency requirements for decisions with different levels of impact. As discussed below, we recommend EPA adopt existing tiering systems already widely employed by the scientific community.

### **IV. Applicability of the Transparency Requirement**

In addition to the scope of the proposed requirement, EPA asks for comment on what stage(s) of EPA's decision-making processes should the public be able to review EPA's judgements in its application of science. We recommend EPA make available its scientific facts and judgements at the following stages in EPA's decision-making:

- **First time they are used.** When EPA introduces a new applied science tool, the requirements of this rulemaking should apply, no matter the significance level or impact of the decision. EPA generally has discretion – judgement – as to when it introduces a new scientific application. If the applicability is limited only to economically significant regulatory actions or some other impact threshold, this tiering approach creates a perverse

incentive to introduce new, non-transparent tools in minor regulatory actions, permits, or product approvals. Once scientific applications are established in this manner, they could be inappropriately assigned policy weight once they are established. Once they are established, these applications may be granted deference as EPA policy and its precedent.

- **At the proposed or draft stage.** Providing the public with the opportunity to comment on the application of science concurrently with the public comment opportunity on the proposed EPA decision allows EPA to benefit from transparent stakeholder input and interagency review before rendering a final agency action. Transparency at this stage also benefits EPA by helping build a robust administrative record to support its policy decisions.

## V. Use Existing Transparency Tiering Systems

While all EPA applications of science should be covered by this rulemaking, we recommend that EPA draw from (or adopt) existing transparency screening tools developed by consensus in the scientific community to further define the scope and applicability of the rule's requirements.

Specifically, as the preamble states, the scientific community has recently become aware of the inability to reproduce scientific claims published in leading, peer-reviewed journals. To be a scientific fact, an observation must be objective and reproducible. As a practical matter, EPA and many of us assume that claims published in high-impact, peer-reviewed journals meet these criteria and are scientific facts. When these "facts" are unable to be reproduced, the foundation of science and applied science suddenly trembles.

Facing well-documented cases of scientific misconduct and the inability to reproduce numerous published, peer-reviewed papers, many scientific institutions developed requirements that scientists must follow to publish their claims in participating journals. There are several examples of such systems that have been developed with minimum levels of transparency to ensure a claim can be objective and reproducible.

One important, open source system, the Transparency and Openness Promotion (TOP) guidelines<sup>1</sup>, have been recently adopted by over 5,000 major scientific organizations and journals. Published in *Science* in 2015, the TOP guidelines include eight standards, each with three levels of increasing stringency. Journals select which of the eight transparency standards they wish to adopt for their journal and select a level of implementation for each standard. For example, the scientific journal *Science* adopted most of the Level III TOP standards effective January 1, 2017.

By clearly adopting a particular level to a specific application, a participating journal or organization allows the public to evaluate how likely claims made under its banner are scientific fact. Researchers know they must strive to meet Level III requirements and must take due care

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<sup>1</sup> <https://cos.io/our-services/top-guidelines/>

in their research to receive the benefits of publication in a high-impact journal with Level III requirements. Therefore, claims made in a journal requiring Level III disclosure are more likely to be recognized as scientific facts than those published to Level I standards.

**TABLE 1 -Summary of Transparency and Openness Promotion Guideline Requirements**

	<b>Level I</b>	<b>Level II</b>	<b>Level III</b>
<b>Citation Standards</b>	Journal encourages citation of data, code, and materials, or says nothing.	Journal describes citation of data in guidelines to authors with clear rules and examples.	Article provides appropriate citation for data and materials used consistent with journal's author guidelines.
<b>Data Transparency</b>	Journal encourages data sharing or says nothing.	Article states whether data are available, and, if so, where to access them.	Data must be posted to a trusted repository. Exceptions must be identified at article submission.
<b>Analytic Methods (Code) Transparency</b>	Journal encourages code sharing or says nothing.	Article states whether code is available, and, if so, where to access it.	Code must be posted to a trusted repository. Exceptions must be identified at article submission.
<b>Research Materials Transparency</b>	Journal encourages materials sharing or says nothing.	Article states whether materials are available, and, if so, where to access them.	Materials must be posted to a trusted repository. Exceptions must be identified at article submission.
<b>Design and Analysis Transparency</b>	Journal encourages design and analysis transparency or says nothing.	Journal articulates design transparency standards.	Journal requires adherence to design transparency standards for review and publication.

<b>Study Preregistration</b>	Journal says nothing.	Article states whether preregistration of study exists, and, if so, where to access it.	Article states whether preregistration of study exists, and, if so, allows journal access during peer review for verification.
<b>Analysis Plan Preregistration</b>	Journal says nothing.	Article states whether preregistration of study exists, and, if so, where to access it.	Article states whether preregistration with analysis plan exists, and, if so, allows journal access during peer review for verification.
<b>Replication</b>	Journal discourages submission of replication studies or says nothing.	Journal encourages submission of replication studies.	Journal encourages submission of replication studies and conducts results blind review.

While Table 1 summarizes the TOP criteria, the consortium has published more detailed requirements for each level.

The Level II and Level III requirements mirror somewhat the applicability of the proposed standards in EPA’s rulemaking. The tiered levels and specific requirements in TOP offers an existing, widely-used approach for EPA to consider that would allow it to prioritize its resources and its requirements with respect to applied science developers. EPA can calibrate the transparency requirements of particular science applications with the magnitude of the policy decision in question.

As a fundamental point of departure, we recommend that EPA require Level III transparency for all significant regulatory actions. By “significant regulatory actions,” we mean “regulatory actions” as defined in E.O. 13771 and “significant” as defined in Executive Order 12866, OMB’s Good Guidance bulletin, and other relevant guidance regarding regulatory planning and review. If researchers must comply with Level III procedures to receive one publication in *Science*, it seems reasonable to require the same level of disclosure for EPA decisions with millions (or billions) of dollars of annual economic impact.

We recommend all other EPA policy decisions have at least Level II standards for transparency to the public. As EPA takes comment on a proposed decision and notes that the underlying judgements in the applied science meet Level II criteria, the public could evaluate the claims and

provide valuable feedback to EPA regarding the appropriate rigor of its data transparency procedures. Based on these comments, EPA could decide that the final agency action requires Level III transparency.

The TOP criteria require researchers to post data, analytic methods, and research materials to a trusted depository. For EPA applications of science, this depository should be the public docket of a proposed rule or the accompanying administrative record associated with a proposed decision. However, for sensitive information, EPA should adopt the depository standards in common use by other federal agencies, journals, and EPA itself. For example, the Census Department has established stringent criteria for researchers seeking to review data that could allow individual responses to be identified. Similar procedures are in place to protect data from new drug trials in journal depositories. EPA has procedures for its contractors to review CBI – procedures that could be modified for non-government public commenters to use to review applied science that relies on sensitive data.

Another advantage of using an existing system is that EPA would reduce the burden on researchers and applied science developers. Since TOP and other systems are widely-adopted now and are growing in their reach, scientists understand their obligations under these systems if they want to be published in certain journals. If they must turn in their data to be published in *Science*, for example, turning it over to EPA for public review is not a significant additional burden.

## **VI. Specific EPA requests for comment**

### **Application to cooperative agreements and grants**

We recommend EPA require Level II or Level III standards for all its research to be consistent with the best and the current standards of science, regardless of whether the researchers are EPA employees, other federal agency employees, or private researchers employed by companies, universities, or other organizations. By adopting these standards in EPA's research enterprise, EPA's application of the funded science is ready to support policy judgements.

### **Criteria for EPA Waivers**

The proposed rule includes a provision allowing the Administrator to exempt significant regulatory decisions on a case-by-case basis if compliance is impracticable because it is unfeasible or unlawful to ensure that all dose response data and models underlying pivotal regulatory science are publicly available. We support the ability of the Administrator to waive these requirements based on specific, promulgated criteria.

We recommend EPA adopt specific criteria in the final rule for the Administrator to cite. We recommend EPA adopt criteria similar to those that permit emergency rulemaking and direct final rules under the Administrative Procedures Act (APA).



### **Retrospective application of the provisions**

Reopening existing administrative records of final agency actions could result in significant unintended consequences that could undermine EPA's ability to implement this rulemaking. NRECA therefore supports a forward-looking process in which EPA applies its new regulatory process to new proposed rules but does not disturb existing proposed rules or final rules. A forward-looking process that does not disrupt any previously-published proposed or final rule strikes a reasonable balance between EPA's positive efforts to increase transparency and the need for certainty, finality, and reasonable implementation burdens. However, notwithstanding the preference for a forward-looking application, should EPA elect a retrospective application we recommend that EPA could develop a process by which stakeholders could petition EPA based on objective criteria for the retrospective application of this rule to an existing administrative record for a final agency action. The criteria should require a demonstration that the lack of transparency in the past undermines confidence in policies that significantly and adversely impact today's consumers, economy, or environment. This process could draw from the existing petition for rulemaking processes under the APA and requests for data correction under the Data Quality Act.

### **Implementation**

EPA seeks comment on whether this rule, or particular subsets of regulatory actions that this rule intends to cover, should be subject to a phase-in period for its requirements to become effective. We find that that requirements of this rule can be implemented immediately if the scope and applicability are defined appropriately. However, we note that there could be practical considerations that would could make this infeasible. If so, we recommend that these criteria could also be employed during the transition period to full EPA compliance to address past instances of non-transparency consistent with existing law and policy.

### **VII. Conclusion**

We conclude our comments by applauding EPA's efforts to strengthen the transparency of regulatory science. We believe strongly that sound public policy should be grounded in objective scientific data and analysis that is subject to rigorous standards of reproducibility and transparency and look forward to working with the Administration to implement this rule.

Should you have any questions regarding our comments or should you need any assistance please contact me at [Daniel.Chartier@nreca.coop](mailto:Daniel.Chartier@nreca.coop).

Sincerely,



Daniel L. Chartier  
Regulatory Director, Environmental Policy