REQUEST FOR CORRECTION
NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE; PROPOSED RULE
75 Fed. Reg. 2938 (Jan. 19, 2010)

National Association of Manufacturers
March 22, 2010

Summary

The National Association of Manufacturers (NAM) submits this Request for Correction (RFC) pursuant to the Information Quality Act (IQA) (Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001), in accordance with the procedures set forth in Section 8.5 of EPA's Information Quality Guidelines (EPA IQG). This RFC concerns the Notice of Proposed Rulemaking on the National Ambient Air Quality Standard (NAAQS) for Ozone published at 75 Fed. Reg. 2938 (Jan. 19, 2010) (Proposed Reconsideration) and certain scientific documents disseminated by EPA in support of the Proposed Reconsideration. The contact information for this RFC is as follows:

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NAM is the nation's largest industrial trade association representing small and large manufacturers in every industrial sector and in all 50 states. Headquartered in Washington, D.C., NAM has more than 11,000 corporate members, representing a sector that employs millions of American workers. NAM's mission is to enhance the competitiveness of manufacturers and improve American living standards by shaping a legislative and regulatory environment conducive to U.S. economic growth. As the leading voice of manufacturing in the U.S., NAM is deeply concerned that crucial decisions on air pollution control policy reflect the best, unbiased scientific information possible. NAM members may also be subject to increased regulation as a result of the proposed revisions to the ozone NAAQS. Our members, and their employees and families, deserve that these important policy decisions be grounded in science. Thus, NAM and its members are affected persons.

In 2007, EPA proposed to revise the NAAQS for ozone, finding that the 1997 8-hour standard of 0.08 ppm was no longer requisite to protect public health and welfare (2007 Proposal). The 2007 Proposal relied on substantially the same information from the air quality criteria and review where EPA found the weight of the science supported the 1997 NAAQS, yet EPA reached a conclusion that the 1997 ozone NAAQS should be revised. In 2008, EPA finalized a revised ozone NAAQS of 0.075 ppm (75 ppb) (2008 Rule), finding any level below that was not necessary. This rule was challenged, and the litigation remains pending in the D.C. Circuit.

As part of the normal public comment process for the 2007 Proposal, the NAM submitted a Request for Correction (2007 RFC) in accordance with the EPA IQG.[1] For information disseminated as part of an APA notice-and-comment process, EPA's IQG require the Agency to incorporate its response to the RFC within its normal APA response to comments. EPA did this concurrent with its publication of the final ozone NAAQS revision.[2] Because EPA's response was inadequate and the Agency made none of the requested corrections, NAM filed a Request for Reconsideration in October 2008 (2008 RFR), which is included as Attachment 1 to this RFC.[3] EPA delivered an interim reply in January 2009, which is included as Attachment 2 to this RFC, informing NAM that the Agency intended to postpone responding substantively to the RFR because of litigation underway at the time in the U.S. Court of Appeals for the District of Columbia Circuit.[4] That suit remains in abeyance pending EPA's reconsideration of the ozone NAAQS revision, which EPA has committed to complete by August 31, 2010.

Although the EPA IQG says the Agency generally will respond in 90 days to an RFR, 17 months have passed without a substantive response. Meanwhile, EPA has relied upon the very same information challenged in the 2008 RFR to support the Proposed Reconsideration.[5] Many of the information quality issues raised in the 2008 RFR remain exactly as they were at the time the RFR was submitted. It is common sense that leads us to believe that EPA has a duty to fully, completely and transparently adhere to its own administrative procedures and respond to the 2008 RFR at this time, well before it makes any final decision on the Reconsideration. Moreover, the public has a right to review EPA's response to the RFR before providing new public comments on the scientific merits of the Proposed Reconsideration. Without the ability to review EPA's response, the public would be deprived of a meaningful opportunity to comment, in that it would be less than fully informed, which is contrary to the letter and spirit of the Clean Air Act.

Purportedly based on the same record as the 2008 Rule, EPA has "reconsidered" the level and now proposes to revise the primary standard to somewhere between 60 ppb and 70 ppb and to promulgate a different secondary standard. In addition to reasserting the scientific record for the 2008 Rule, EPA considers and relies on new information not in the 2008 Rule record. In re-disseminating the old information and disseminating the new information, EPA has not complied with the IQA, which requires that agencies disseminate information in a manner that ensures and maximizes its quality, objectivity, utility and

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[1] National Association of Manufacturers (2007), U.S. Environmental Protection Agency (2008b, p.16496) and U.S. Environmental Protection Agency (2002).

[2] U.S. Environmental Protection Agency (2008c).

[3] National Association of Manufacturers (2008).

[4] U.S. Environmental Protection Agency (2009a).

[5] U.S. Environmental Protection Agency (2010a, p. 2940): "This reconsideration is based on the scientific and technical information and analyses on which the March 2008 O_3 NAAQS rulemaking was based."

integrity. EPA has wholly failed to do so here. As a result, NAM is compelled to submit this RFC. The primary points raised in this RFC are summarized as follows:

- First, in Section I, the NAM explains why EPA must respond to its 2008 RFR. Section I of this document, thus, should not be treated as a new RFC, for it does not raise any new information quality issues that warrant a new reply in the response to comments EPA will publish along with any revised Final Rule. This section summarizes NAM's 2008 RFR and seeks only to remind EPA of its duty to respond.
- In Section II, the NAM then outlines some of the material errors in the Proposed Reconsideration that constitute new IQA violations that must be considered as part of a new RFC. Section II identifies new IQA violations related to the new science cited in support of the Proposed Reconsideration and the manner in which Administrator Jackson has relied upon it. Specifically, EPA cites a review of limited new scientific information prepared by the Agency ("Provisional Assessment of Recent Studies on Health and Ecological Effects of Ozone Exposure," September 2009) (Provisional Assessment). The Proposed Reconsideration relies upon the Provisional Assessment for scientific support for lowering the primary ozone standard and setting a new secondary standard. However, the Provisional Assessment does no such thing. It is an egregious violation of the information quality presentational objectivity standard to misrepresent the contents of a scientific document in an effort to support a decision made on nonscientific grounds. The information quality errors alleged therein should be treated as part of a new RFC.
- Section III expands upon information quality errors identified in the 2008 RFR because the same errors arise in some of the new science EPA relies on in the Proposed Reconsideration. Thus, this Section should be treated as a reminder of EPA's duty to respond to the 2008 RFR with respect to the influential scientific information challenged therein and as a new RFC with respect to the influential scientific information disseminated and relied upon in the Proposed Reconsideration. We suggest a path forward that EPA can take to ensure its adherence to information quality principles and policies in the context of the Proposed Reconsideration. These same actions may be helpful in responding to the 2008 RFR.
- Section IV expands upon a problem identified in the 2007 RFC and 2008 RFR concerning EPA's reliance on Federally-conducted or sponsored statistical studies that do not adhere to Federal statistical policy standards and guidelines for

nonresponse bias.[6] Federal policy is explicit regarding the need for agencies that conduct or sponsor information collections achieve the highest practical rates of response in order to avoid the potential for bias from low response rates.[7]

These mandatory Federal standards are not met in the studies that the Government funded and which EPA relies upon to inform the Administrator's judgment to propose to lower the standard to a level between 60 and 70 ppb. Nonetheless, EPA is bound by applicable statistical policy standards and information quality guidance to assure that the information EPA disseminates meets these statistical standards.[8] In particular, EPA must ensure that the statistical information it relies upon meets Federal statistical policy standards for response rates, and where response rates are below prescribed thresholds, ensure that nonresponse bias analyses are performed. EPA cannot evade Federal statistical policy standards by outsourcing to third parties the production of scientific information that does not meet Federal statistical policy standards, then disseminate it as authoritative. EPA relied on these studies in the 2007 Proposed Rule and 2008 Final Rule, and NAM identified and raised nonresponse bias as material information quality error in the 2007 RFC and 2008 RFR. Despite having not replied to the 2008 RFR, EPA relies on the same information again in the Proposed Reconsideration, thus generating a new round of

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[6] The statistical policy standards apply to "Federal censuses and surveys whose statistical purposes include the description, estimation, or analysis of the characteristics of groups, segments, activities, or geographic areas in any biological, demographic, economic, environmental, natural resource, physical, social, or other sphere of interest." Office of Management and Budget (2006, p. 1). For statistical policy purposes, an observational epidemiology study is a special purpose survey intended to describe, estimate, and analyze the extent to which exposure to various environmental agents may have potentially adverse health effects on a population of interest.

[7] Office of Management and Budget (2006, p. i) provides that:

> Agencies *must* design the survey to achieve the highest practical rates of response, commensurate with the importance of survey uses, respondent burden, and data collection costs, to ensure that survey results are representative of the target population so that they can be used with confidence to inform decisions (emphasis added).

Furthermore, these Guidelines have very specific requirements that must be met when actually response rates turn out to be too low:

> Nonresponse bias analyses *must* be conducted when unit or item response rates or other factors suggest the potential for bias to occur (emphasis added).
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> *Id.*

[8] Office of Management and Budget (2006, p. iii): "**Standard 6.1:** Agencies are responsible for the quality of information that they disseminate and *must* institute appropriate content/subject matter, statistical, and methodological review procedures to comply with OMB and agency Information Quality Guidelines" (emphasis added).

information quality errors. Thus, this Section should be treated as a reminder of EPA's duty to respond to the 2008 RFR with respect to the influential statistical information challenged therein and as a new RFC with respect to the influential statistical information disseminated and relied upon in the Proposed Reconsideration. We suggest a path forward that EPA can take to ensure its adherence to information quality principles and policies in the context of the Proposed Reconsideration. These same actions may be helpful in responding to the 2008 RFR.

- Section V outlines information quality errors resulting from EPA's penchant for making irreconcilable claims about scientific information in different settings depending on whether it supports or contradicts the policy decision it seeks to support. EPA's Proposed Reconsideration suffers from similar problems outlined in the 2008 RFR, raising new IQA errors that must be corrected. For ozone, EPA insists that self-administered and often self-reported lung function test data are valid and reliable for demonstrating adverse effects, but for nitrogen dioxide EPA said [r]eliable data are notoriously difficult to come by using portable peak flow measuring devices."[9] These irreconcilable statements are documented in the 2008 RFR. Since the 2008 RFR, EPA has published revised documents for nitrogen oxides in which the statement describing these data as unreliable was simply deleted. While this may have eliminated new *evidence* of EPA's material abuse of scientific information in support of predetermined policy objectives, it did not eliminate the *fact*. EPA continues to rely on erroneous scientific information to inform the Administrator's judgment in determining the appropriate level of the standard in the Proposed Reconsideration. Thus, this Section should be treated as a reminder of EPA's duty to respond to the 2008 RFR with respect to the influential statistical information challenged therein and as a new RFC with respect to the influential statistical information disseminated and relied upon in the Proposed Reconsideration.[10] We suggest a path forward that EPA can take to ensure its adherence to information quality principles and policies in the context of the Proposed Reconsideration. These same actions may be helpful in responding to the 2008 RFR.

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[9] U.S. Environmental Protection Agency (2007, p. 3-16). EPA also explains the significance of poor data collection methods: "This may help explain why, in contrast to studies with supervised measurements, none of the nine studies using home peak flow measurements reported any significant associations with ambient NO_2." *Id.* EPA displays no such caution in interpreting the same studies with respect to ozone.

[10] This issue was raised in the 2007 RFC and the 2008 RFR, to which EPA still has a duty to respond. Section V raises them as a new RFC because EPA has committed similar errors again, and the 2008 RFR cannot address errors committed after it was filed or based on a subsequent record.

- Section VI concerns EPA's continued problems managing input from the CASAC in ways that are compatible with information quality. NAM raised this issue in the 2007 RFC and 2008 RFR. NAM does so again here because EPA has exacerbated the problem, and thus committed new errors, in the preamble to the Reconsideration by continuing to rely on CASAC input without clearly distinguishing between CASAC's scientific input and its policy advice. The Proposed Reconsideration appears to abdicate to CASAC duties and obligations reserved to the Administrator under Sections 108 and 109 of the Clean Air Act. This magnifies the information quality errors embedded in the 2008 Rule by eliminating what limited clarity there was concerning the distinction between CASAC's scientific review and its policy advice. The Proposed Reconsideration thus contains a new round of information quality errors that warrant a new RFC and should be treated as such.[11] We suggest a path forward that EPA can take to ensure its adherence to information quality principles and policies in the context of the Proposed Reconsideration. These same actions may be helpful in responding to the 2008 RFR.

Within each Section, NAM suggests specific remedies that, at a minimum, EPA must provide in order to ensure the information it has disseminated related to the Proposed Reconsideration meets the level of quality, objectivity and usefulness required by the IQA and the Clean Air Act. Only in providing this relief, can the public be properly informed and meaningfully participate in the rulemaking process.

In sum, EPA must follow its own procedures and respond to the 2008 RFR at this time and must do so *before* making any final decision on the Proposed Reconsideration. Without a meaningful opportunity to review EPA's response, public comments will be seriously uninformed and there will not be an opportunity for meaningful public participation, in contravention of Clean Air Act requirements.

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[11] This issue was raised in the 2007 RFC and the 2008 RFR, to which EPA still has a duty to respond. Section VI raises them as a new RFC because EPA has committed similar errors again, and the 2008 RFR cannot address errors committed after it was filed or based on a subsequent record.

I. EPA's RECONSIDERATION CONFIRMS INFORMATION QUALITY DEFECTS IDENTIFIED AND DESCRIBED IN NAM's 2008 REQUEST FOR RECONSIDERATION BUT TO WHICH EPA HAS NOT SUBSTANTIVELY RESPONDED.

It is important to establish the baseline for discussing information quality issues related to the Proposed Reconsideration. A baseline is essential because, as noted above, EPA has not responded to the 2008 RFR despite 17 months to do so. Yet EPA states in the preamble that it is relying on the same scientific record that EPA Administrator Stephen Johnson relied upon in support of his 2008 decision—the same scientific record that we challenged.

In this Section, we deal exclusively with a portion of EPA's scientific record as it existed when NAM filed the 2007 RFC. To that record is added the 2008 Rule and EPA's Response to Comments. EPA's inadequate responses, and its often complete failure to respond at all, were described in the 2008 RFR.

A. The Information Quality Act and Applicable Information Quality Guidelines.

The IQA directs the Office of Management and Budget (OMB) to exercise by regulation or guidance certain authorities delegated to it in the Paperwork Reduction Act of 1995.[12] Specifically, the law directed OMB to provide, by a date certain, policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.

The law directs OMB to "require that each Federal agency" publish its own agency-specific guidelines "ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency," and to "establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply." An agency's administrative mechanism thus must include a bona fide way by which affected parties can challenge agency errors ("*seek* … correction") and a way for errors to actually be corrected ("and *obtain* correction"). A process that enables affected persons to *seek* a correction, but not to actually *obtain* it, does not conform to OMB's government-wide guidelines[13] or to the plain language of the law.

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[12] 44 U.S.C. § 3501 *et seq.*; 44 U.S.C § 3516 note (Policy and Procedural Guidelines).

[13] Office of Management and Budget (2002).

B. NAM's 2007 Request for Correction (2007 RFC)

Pursuant to the procedures set forth in the EPA IQG, NAM submitted a petition styled according to EPA's preferences as a "Request for Correction" or RFC on October 9, 2007,[14] as part of the prescribed public comment process on EPA's 2007 proposed revision to the ozone NAAQS. The EPA IQG commits the Agency to reply to the RFC in the normal course of its response to public comments, as required by the Administrative Procedure Act. EPA's responses to public comments in this case are governed by Clean Air Act Section 307(d)(6)(B).

C. EPA's Response to Comments

EPA scattered its responses to the 2007 RFC throughout the 210-page Response to Comments document, in many cases without clear attribution.[15] After an extensive review, it became clear that this response was seriously deficient on multiple levels. Sixteen times, EPA simply "rejected" NAM's information quality error claims, often without the presentation of any substantive data or even logical argument. Twelve times EPA merely said it "disagrees" with NAM regarding the objectivity of a purported statement of fact, knowledge, or scientific inference, as if representations of fact or knowledge are nothing more than opinion. EPA rarely provided any support for its responses, largely choosing to assert an unbounded authority to simply ignore the substance of NAM's claims.

Based on this review, NAM concluded that it was necessary to exercise our statutory right to seek *and obtain* the correction of error by means of the appeal procedures established in the IQA and OMB, and set forth in the EPA IQG.

D. NAM's 2008 Request for Reconsideration (2008 RFR)

In our review of EPA's response, we identified the following critical defects:

1. <u>EPA's response offered no evidence that the Agency adhered to its own information quality principles, policies and procedures.</u>

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[14] National Association of Manufacturers (2007).

[15] U.S. Environmental Protection Agency (2008c, p. 1): "Due to the large number of comments that addressed similar issues, as well as the sheer volume of the comments received, this response-to-comments document does not generally cross-reference each response to the commenter(s) who raised the particular issue involved, although commenters are identified in some cases where they provided particularly detailed comments that were used to frame the overall response on an issue."

As we stated in the 2008 RFR:

> EPA's Response to Comments proves beyond any reasonable doubt that until we submitted our RFC, EPA staff, management, and policy officials had devoted no attention to information quality in the revision of the ozone NAAQS. In every EPA staff document, beginning with the Review Plan, proceeding to the Criteria Document, the Exposure Assessment and Risk Assessment, and the Staff Paper, there is no mention, discussion, analysis or any other content mentioning, discussing or applying the requirements of the Information Quality Act, the government-wide implementing guidance issued to all agencies by the Office of Management and Budget, or EPA's own implementing guidelines.[16]

This complete absence of attention to information quality also extended to EPA's relationship with CASAC:

> [I]nformation quality was omitted from the panel's charge. CASAC meetings are dialogues between panel members and EPA managers and staff, yet the transcripts of each in-person meeting show that neither the principles nor the procedural and substantive requirements of information quality were ever mentioned by any EPA manager or staff member.[17]

EPA's disregard of information quality in every aspect of the ozone NAAQS review was complete and comprehensive. Yet in its Response to Comments, EPA said it "rejects," "disagrees" with, or otherwise denies each and every information quality error claim in the 2007 RFC:

> EPA has reviewed NAM's RFC and finds that there is no merit to their [sic] objections. EPA disagrees with NAM's allegations that EPA has not complied with the requirements of the Information Quality Act or the Agency's policies for ensuring information quality. EPA has responded to NAM's significant comments in the preamble to the final rule or in this document.[18]

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[16] National Association of Manufacturers (2008, p. 11, internal citations omitted).
[17] National Association of Manufacturers (2008, p. 12).
[18] National Association of Manufacturers (2008, p. 12, citing EPA's Response to Comment at p. 158). As noted above, we found nothing in the preamble to the Final Rule that could be construed as part of EPA's response to the 2007 RFC.

We noticed three patterns in EPA's responses to the errors we identified in the 2007 RFC:

(a) EPA mischaracterized some scientific issues as matters determined by law or policy judgment.

This presumably was intended to try to make the scientific issue exempt from information quality challenge. But *information* is clearly distinguishable from *opinion* or *judgment.* The term *information* in the Information Quality Act has a specific regulatory definition promulgated by OMB pursuant to authority delegated to it by Congress in the Paperwork Reduction Act of 1995:

> Information means any statement or estimate of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic or other media.[19]

OMB modified this definition for purposes of its Information Quality Guidelines, specifically exempting *opinion* except when it could be reasonably construed as a factual statement about the opinions of others (making it *information* once again), or when the opinion could be reasonably construed as views held by the agency:

> ''Information'' means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.[20]

EPA's definition in its Information Quality Guidelines is much less expansive, but on the critical matter relevant to the 2007 RFC it is consistent with OMB:

> "Information," for purposes of these Guidelines, generally includes any communication or representation of knowledge such as facts or data, in any medium or form.[21]

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[19] 5 C.F.R. § 1320.3(h).

[20] Office of Management and Budget (2002, p. 8460, Sec. V.5)

[21] U.S. Environmental Protection Agency (2002, p. 15). In any case where EPA's definition might be construed to conflict with OMB's definition, OMB's definition must rule. Nothing in the Information Quality Act permits

(Footnote Continued on Next Page.)

Thus, EPA cannot legally construe or deem something exempt from information quality challenge if it falls within the definition of *information.*

(b) EPA characterized some of our information quality claims accurately, but responded to an irrelevant or unrelated issue or merely responded with boilerplate.

Logical *non-sequiturs* abounded in EPA's response. We addressed them in our 2008 RFR.

(c) EPA responded to our complaint of information quality error by committing <u>new</u> information quality error, typically by making new representations of fact or knowledge that fail the substantive and/or presentational objectivity standards of OMB's and EPA's Information Quality Guidelines.

Where time permitted, we noted in the 2008 RFR the new information quality errors in the Response to Comments and raised them as additional claims for correction.

2. <u>EPA's Response to the 2007 RFC relied on a fundamentally biased approach to the use and interpretation of scientific information that requires all evidence to support staff policy views, be interpreted as mixed or equivocal, or be discarded.</u>

We described this biased approach by analogizing human health risk as a risk "envelope" or "balloon." EPA staff process information to ensure that the envelope never retracts or the balloon never gets smaller:

> Science suggesting the potential for greater risk pushes the risk envelope outward or adds air to the balloon. Science that is equivocal supports the envelope at its current location or maintaining the balloon at its current size. Science suggesting lower risk moves the envelope inward or removes air from the balloon, but EPA staff will use such information only under conditions that are so restrictive as to be nearly impossible to meet. Science that does not meet these conditions is "discussed" or "considered," but ultimately discarded. The principles of information quality play a severely constrained role:

(Footnote Continued from Previous Page.)

an agency to issue guidelines that conflict with or contradict OMB's Guidelines, which apply government-wide.

> they are used only as barriers to the admission of evidence indicating lower risk.[22]

We identified a long list of ways that EPA staff enforced this biased approach upon the scientific record on which Administrator Johnson relied to make his policy decision in setting the ozone NAAQS:

- EPA staff omitted any reference to information quality principles and the Agency's own Information Quality Guidelines from every document in the ozone NAAQS review, stretching from the 2005 Review Plan to the 2007 NPRM.
- EPA staff "considered" and "discussed" a phenomenal quantity of scientific information, but only used information in accordance with the biased approach described above.
- EPA staff made crucial scientific claims that are easily refutable.
- EPA staff used ad hoc statistical analyses devised after data were obtained to support predetermined conclusions.
- EPA staff disseminated risk characterizations based on epidemiological studies that relied on un-validated self-reported data collected in diaries.
- EPA staff disseminated risk characterizations based on lung function data obtained through a low-resolution clinical diagnostic procedure that cannot reliably or accurately detect effects as subtle as might be observed across ppb-level changes in ambient ozone and which are not judged by clinicians as important.
- EPA staff disseminated risk characterizations based on epidemiological studies using lung function data in which the research design discarded measurement uncertainty, thus making weak associations with air pollutants appear to be much more certain than they actually are.
- EPA staff disseminated risk characterizations based on epidemiological studies of lung function data in which the research design required the use of biased estimates.
- EPA staff disseminated risk characterizations based on epidemiological studies of unrepresentative samples, or samples whose representativeness had not been validated.
- EPA staff disseminated risk characterizations based on epidemiological studies with unaccounted for or unreported nonresponse bias.
- EPA staff disseminated risk characterizations based on ambient monitoring data as a proxy for personal exposure despite very low correlation.

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[22] National Association of Manufacturers (2008, p. 13, and Text Box 1 on p. 14).

- EPA staff relied on studies that they rejected as unreliable and invalid in other NAAQS contexts.

In the 2008 RFR, we discussed each of these types of error and provided concrete examples. Consistent with the OMB and EPA guidelines, the RFR did not raise policy disputes or seek policy-related remedies but rather raised proper challenges under the IQA. We noted that Section 8.6 of the EPA IQG requires an independent review of the 2008 RFR and a well-documented and comprehensive response to each information quality error that we continued to allege.

E. EPA's Decision to Postpone Delivering a Substantive Response

On January 15, 2009, EPA sent NAM an interim response on the 2008 RFR.[23] In this letter, Principal Deputy Assistant Administrator Robert J. Meyers stated that we sought "more 'cogent answers' than EPA provided in the final Response to Comments document included in the docket for the NAAQS for ozone." Apparently, EPA has chosen to fundamentally misread the 2008 RFR and the specific remedies we requested. The 2008 RFR did not merely suggest that EPA's response to the 2007 RFC was confused; we said it was scientifically wrong, and that EPA had to correct the IQA violations NAM identified.

In this interim reply Mr. Meyers indicated that EPA was "deferring consideration" of the 2008 RFR because of ongoing litigation in the U.S. Court of Appeals for the D.C. Circuit. EPA has persuaded the Court to hold this case in abeyance while the Agency pursues the Reconsideration of the rulemaking. Thus, there is no longer any conceivable justification for continued delay, which at this writing is now 17 months long. Moreover, failing to respond as required to the 2008 RFR would violate the purpose of the Court's decision, which was to resolve as many issues as possible before briefing is resumed. Surely, disputes about the objectivity, integrity, and utility of the scientific record, upon which Administrator Jackson must rely to make her decisions, are squarely within the range of activities that EPA must perform as part of the Reconsideration for it to adhere to the Court's orders.

F. EPA Must Immediately Fulfill Its Duty to Respond to NAM's 2008 RFR

EPA must fulfill its obligation to respond to the October 2008 RFR. EPA cannot simply rely on its Response to Comments on the 2007 Proposal, nor can it attempt to avoid its duty by addressing the RFR in its Response to Comments on the Proposed Reconsideration. The EPA IQG outlines specific procedures EPA must follow. To date, EPA has failed to comply with these procedures, now resulting in a Proposed Reconsideration

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[23] U.S. Environmental Protection Agency (2009a).

that perpetuates and expands upon the previous errors. Moreover, we strongly believe that the public comment process for the Proposed Reconsideration is fatally flawed precisely because EPA chose not to reply to the 2008 RFR as required by the procedures set forth in EPA IQG Section 8.7, on or before the date of publication of the Proposed Reconsideration.[24]

These procedures specify that a three-member executive panel be created for the specific purpose of examining the claims made in the RFR and reaching an independent, nonpolitical conclusion on the merits. The Chief Information Officer and Assistant Administrator for the Office of Environmental Information must chair the panel. The Assistant Administrator for the Office of Air and Radiation is automatically recused because of a direct conflict of interest. Normally, EPA's Science Advisor and Assistant Administrator for Research and Development would serve on the panel, but because so many of the errors we found were committed by personnel within ORD, this official also must be recused.

We respectfully request that EPA adhere to its own procedures and perform this review forthwith. Further, EPA should not finalize its Reconsideration until after it has submitted its response on the 2008 RFR and made it available to the public for review and comment. Without EPA's reply, the public is left to wonder about its commitment to scientific integrity. Providing the public a way to comment on EPA's reply to the 2008 RFR would advance the objective of President Obama's January 2009 memoranda on Transparency and Open Government and the Freedom of Information Act.[25]

EPA has no credible basis for further delaying its long overdue reply when it purports to be seeking informed comment from the public on the Proposed Reconsideration. To make public comment effective, President Obama has made clear that it is an agency's duty to create the environment necessary for it to be effective:

> *Government should be participatory*. Public engagement enhances the Government's effectiveness and improves the quality of its decisions. Knowledge is widely dispersed in society, and public officials benefit from having access to that dispersed knowledge. Executive departments and agencies should offer Americans increased opportunities to participate in policymaking and to provide their Government with the benefits of their collective expertise and information.[26]

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[24] *See* U.S. Environmental Protection Agency (2002, pp. 34-35).
[25] Obama (2009a, 2009b).
[26] Obama (2009b, p. 4685)

The President also has instructed agencies not to withhold information just to protect those who have committed error:

> The Government should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors and failures might be revealed, or because of speculative or abstract fears. Nondisclosure should never be based on an effort to protect the personal interests of Government officials at the expense of those they are supposed to serve.[27]

As the President said, "agencies should adopt a presumption in favor of disclosure" and "not wait for specific requests from the public." To date, EPA has acted in a manner that rejects the President's directive in toto. This is despite Administrator Jackson's April 2009 directive to EPA staff, which conveys unwavering support:

> It is crucial that we apply the principles of transparency and openness to the rulemaking process. This can only occur if EPA clearly explains the basis for its decisions and the information considered by the Agency appears in the rulemaking record.[28]

II. EPA's Dissemination of New Information and Analysis in Support of its Proposed Reconsideration Fails to Comply with the IQA.

The IQA requires federal agencies to ensure and maximize "the quality, objectivity, utility, and integrity of information (including statistical information)" they disseminate.[29] Quality is an encompassing term defined to include utility, objectivity and integrity.[30] "'Utility' refers to the usefulness of the information to its intended users, including the public."[31] Objectivity includes two elements -- presentation and substance. Both elements of objectivity are intended to ensure that the information disseminated is accurate, reliable, and unbiased. Presentational objectivity ensures that the information is being presented in an accurate, clear, complete, and unbiased manner. Substantive objectivity involves a focus on ensuring accurate, reliable and unbiased information: "In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods."[32] Moreover, influential scientific, financial or statistical information "shall include a high degree of

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[27] Obama (2009a, p. 4683).
[28] Jackson (2009).
[29] Office of Management and Budget (2002, p. 8452).
[30] Office of Management and Budget (2002, p. 8459).
[31] Office of Management and Budget (2002, p. 8459).
[32] Office of Management and Budget (2002, p. 8459).

transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."[33]

In the Proposed Reconsideration, EPA repeats many of the same IQA errors identified in the 2008 RFR. By disseminating the information again, EPA commits these errors again. The Proposed Reconsideration and supporting documents also commit new information quality errors, primarily with respect to the limited and selective review of new studies and the way in which the Proposed Reconsideration relies on this review as an ostensibly scientific justification for the proposal.

Rather than address the ozone level in the context of EPA's next scheduled ozone NAAQS review (which had already begun) in which EPA could properly take into account recent studies and give the public and CASAC adequate time to review and comment, EPA conducted a Provisional Assessment of those studies.[34] EPA placed the document in the docket for the 2008 Rule in *November 2009*. The title proclaims that it is "provisional," which means subject to change.[35] The document contains no disclaimer indicating that it is a draft or that it has been publicly distributed solely for peer review. So far as we can tell, what EPA means by *provisional* is that the document consists of a review of *some but not all* of the new scientific literature published since the 2006 Criteria Document, the precise choice of which literature to be examined may be arbitrary or selective.[36]

A. Administrator Jackson clearly relies on the Provisional Assessment to provide a scientific justification for proposing to lower the primary standard below the one selected by Administrator Johnson in 2008.

Statements to the contrary elsewhere notwithstanding, the Proposed Reconsideration clearly indicates that Administrator Jackson relied on this document in proposing to change Administrator Johnson's 2008 decision:

> EPA conducted a provisional assessment of ''new'' scientific papers of scientific literature evaluating health and ecological effects of O_3 exposure published since the close of the 2006 Criteria Document upon which the 2008 O_3 NAAQS were based. The Administrator notes that the provisional assessment of ''new'' science found that such studies did not materially change the conclusions in the 2006 Criteria

[33] Office of Management and Budget (2002, p. 8460).
[34] U.S. Environmental Protection Agency (2009b).
[35] Two definitions are relevant: (1) providing or serving for the time being only; existing only until permanently or properly replaced; temporary: a provisional government; and (2) accepted or adopted tentatively; conditional; probationary.
[36] U.S. Environmental Protection Agency (2009b, p. 1).

> Document. This provisional assessment is supportive of the Administrator's decision to reconsider parts of the 2008 final rule at this time, based on the scientific and technical information available for the 2008 final rule, as compared to foregoing such reconsideration and taking appropriate action in the future as part of the next periodic review of the air quality criteria and NAAQS, which will include such scientific and technical information.[37]

B. The Provisional Assessment is incomplete and selective, and thus is incapable of serving its intended purpose.

The Provisional Assessment states that it was intended "to determine if studies published since the 2006 O_3 AQCD materially change the conclusions of that document."[38] To accomplish that task, the document should be complete and comprehensive, and at a minimum representative of both the strength of evidence and its uncertainties. But EPA acknowledges that the document is not complete and comprehensive (it "should not be considered a complete literature review") and no claim is even made suggesting that it is representative. Thus, it is impossible for the Provisional Assessment to fulfill its stated purpose *at this time*.[39]

C. EPA draws inferences from the Provisional Assessment that go well beyond what the actual evidence supports, even if EPA is assumed to have summarized it objectively.

Given the nature of Administrator Jackson's proposed change, one would expect the Provisional Assessment to include many reports of new scientific data showing that ozone exposure below 75 ppb has identifiable adverse effects on public health or welfare, and that these effects are materially greater than EPA believed them to be when the 2006 Criteria Document was written. Leaving aside problems arising from the document's admitted incompleteness and selectivity, which alone make reliance upon it problematic, the Provisional Assessment does not even claim to include such new information. The preamble to the Proposed Reconsideration thus violates the information quality standard of presentational objectivity; even taken at face value, the Provisional Assessment does not say what the Proposed Reconsideration says it does.

In the Introduction to the Provisional Assessment, the EPA staff authors claim that the "new information and findings"—

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[37] U.S. Environmental Protection Agency (2010a, p. 2944).
[38] U.S. Environmental Protection Agency (2009b, p. 1).
[39] A future version—one that is complete, comprehensive, and unbiased—*could* serve this purpose.

- "do not materially change any of the broad scientific conclusions regarding the health and ecological effects of ozone exposure made in the 2006 O_3 AQCD"
- "strengthen[] conclusions in the 2006 O_3 AQCD related to the potential for health effects at exposure concentrations of less than 80 ppb"[40]

The second of these claims has no informational value for the Proposed Reconsideration. At a minimum, "strengthening" the conclusions in the 2006 Criteria document regarding ambient ozone levels below 80 ppb requires more evidence, which the Provisional Reassessment lacks. Moreover, this particular threshold (80 ppb) does not tell you whether Administrator Jackson's proposal to lower the primary standard from 75 ppb to between 60 and 70 ppb is a reasonable policy judgment since all of these values are less than 80 ppb.

D. Taken at face value, the Provisional Assessment does not show that the published studies reviewed therein support the scientific inference that ozone exposure in the 60 to 75 ppb range is riskier that EPA staff believed it to be in 2008.

Taking the Provisional Assessment at face value—i.e., assuming arguendo that the studies included are representative and interpreted objectivity by EPA staff—the "new" science would have to show that health risks blow 75 ppb are materially greater than EPA staff characterized them in the 2006 Criteria Document. The Provisional Assessment does not make this case.

1. Controlled human exposure studies

EPA's conclusion in the 2006 Criteria Document was that "young healthy nonsmoking adults exposed to ≥ 80 ppb O_3 developed transient, reversible decrements in lung function; increased respiratory symptoms; increased nonspecific airway responsiveness; and inflammatory responses compared to filtered air as a control exposure." Moreover, "at the time the 2006 O_3 AQCD was completed, there was limited evidence of decreased pulmonary function and increased respiratory symptoms occurring with O_3 exposure below 80 ppb."[41]

Nothing reported in the Provisional Assessment suggests that there has been any change in the body of scientific evidence. Most of the text consists of a defense of a controversial internal EPA memorandum (Brown 2007a, p. 158) summarizing a post-hoc analysis of cherry-picked data from Adams (2006). We cited this memorandum in the 2007

[40] U.S. Environmental Protection Agency (2009b, p. 1).
[41] U.S. Environmental Protection Agency (2009b, p. 2).

RFC and 2008 RFR as an example of multiple fatal information quality defects.[42] Moreover, the primary author of the Provisional Assessment also happens to be the primary author of the memorandum. Thus, on this point the Provisional Assessment consists of nothing new, and it cannot be remotely construed to be an independent work product. It is never permissible to entrust to the colleagues of an author the responsibility for independently peer reviewing his work.

The Provisional Assessment includes reviews of three articles published since the 2006 Criteria Document.[43] Brown et al. (2008) is a revised version of the internal EPA memorandum.[44] Even if it were assumed to be valid, it contains no new data or insight beyond what EPA relied upon in 2008.[45] Thus, it cannot be the used as new scientific evidence indicating that the risks posed by ozone exposure between 60 and 75 ppb are materially greater than EPA represented them to be in 2008.[46]

McDonnell et al. (2007) is a report on an empirical model that predicts average FEV_1 response as a function of ozone concentration, utilizing existing data generated in EPA's Human Studies Facility in Chapel Hill, North Carolina.[47] The paper contains no new data, and the discussion about it in the Provisional Assessment does not include anything suggesting that the risks posed by ozone exposures below 0.075 ppb are materially greater than EPA represented them to be in 2008.

Schelegle et al. (2009) is a new controlled human exposure study of the effects of 6.6-hour exposures to ozone at mean concentrations of 60, 70, 80, and 87 ppb on respiratory symptoms and lung function in 31 young healthy adults.[48] Statistically significant effects were observed at the highest three exposure levels after 6.6 hours, but not at 60 ppb. Average changes in FEV_1 were 2.72% (SE = 0.27) and 5.34% (SE = 0.25) at 60 ppb and 70 ppb, respectively. However, instead of treating this result as a confirmation of the statistically *nonsignificant* results obtained by Adams (2006) at 60 ppb, the Provisional Assessment says this study "further supports a smooth dose-response curve without evidence of a threshold for exposures between 40 and 120 ppb O_3" (p. 3). In short, EPA

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[42] *See* Brown (2007b) and our information quality critique in the 2008 RFR (2008, pp. 15-16 and 63-79).

[43] Brown et al. (2008), McDonnell et al. (2007), and Schelegle et al. (2009).

[44] Curiously, Brown et al. (2008) was published in a U.S. Government journal rather than in the independent scholarly journal where the original study had been published.

[45] Brown (Brown 2007a) was not included in the 2006 Criteria Document, but nonetheless EPA relied on it heavily in 2008. It was added at the last minute, after public comment and peer review were complete. EPA could have disclosed an earlier version (Brown 2007b) for public comment and peer review, but did not do so.

[46] As noted above, Brown is the primary author of the Provisional Assessment. It is an conflict of interest to vest in the author of any scientific work the responsibility for peer reviewing it.

[47] McDonnell et al. (2007).

[48] Schelegle et al. (2009). Data were collected at 1, 2, 3, 4.6, 5.6, and 6.6 hours.

treats statistically significant results as probative evidence of an effect, and effects that are not statistically significant as probative evidence of a trend.[49]

As noted in the 2008 RFR and again in Section III(F) below, the reported confidence intervals in Schelegle et al. (2009), as well as previous controlled human subject studies, are narrower than they would be if the researchers had retained instead of discarded inter-maneuver variability in the respiratory function tests they performed. Inter-maneuver variability arises because subjects perform multiple forced expiratory maneuvers, from which a single value is incorrectly used as if it were "the" correct value. Schelegle et al. (2009, p. 266), for example, report that their subjects "performed two to four forced expiratory maneuvers" and "FVC and FEV_1 values were selected on the basis of American Thoracic Society guidelines."[50] This means that the authors discarded the inter-maneuver variability.

The changes Schelegle et al. (2009) observed and attributed to ozone exposure at 60 ppb are about the same magnitude as the standard deviation of inter-maneuver variability obtained by Vaughan et al. (1989) for spirometric testing.[51] ATS guidelines say that "acceptable" maneuvers may vary by as much as 150 mL, or about 6% of the approximately 4 L/s FEV_1 baseline reported in a similar cohort.[52] Thus, subjects in Schelegle et al. easily could have displayed 3% variation by chance *within a single respiratory function test.* Had Schelegle et al. captured this variability instead of discarding it, their standard errors would have been much larger. Effects observed at 70 ppb (and perhaps higher) that they describe as statistically significant are likely to be nonsignificant if inter-maneuver variability had been taken into account.[53]

2. Mortality associated with short-term exposure

EPA's conclusion in the 2006 Criteria Document, as summarized in the Provisional Assessment, is that there is a "positive association between increasing ambient O_3

[49] This is another example of how EPA uses evidence that supports EPA's position while ignoring or reinterpreting evidence that does not in a way to make it appear more supportive.

[50] Schelegle et al. (2009, p. 266). ATS guidelines require a minimum of three (not two) "acceptable" maneuvers and that the data from each maneuver be retained, not discarded (Miller, Hankinson et al. 2005, p. 325, Table 5). Schelegle et al. did not actually follow the ATS guidelines with respect to the number of maneuvers, and it isn't known whether they retained the data.

[51] Schelegle et al. report an average FEV_1 change of 2.72% at 60 ppb. Vaughan et al. report inter-maneuver standard deviation of 3.01% across three FEV_1 maneuvers. Both percentages are likely to have been reported with excess precision.

[52] Adams (2006, p. 130, Table 1).

[53] We addressed the matter of discarded intra-maneuver variability in the 2007 RFC, and we do so again in Section x below. It applies to all controlled human subject studies (including Adams (2006)), but it is a much greater problem in the context of observational epidemiology studies relying on lung function tests.

concentrations and excess risk for non-accidental and cardiopulmonary-related daily mortality."[54] The Provisional Assessment mentions nine new studies, seven of which it says support an association between ozone and mortality. Each study identified important confounders (e.g., high unemployment, lower prevalence of central air conditioning, coincident congestive heart failure or diabetes). It describes the positive studies as "consistent with the conclusions of the 2006 O_3 AQCD." Nothing in the discussion even hints at a result that was stronger than what EPA reported in the 2006 Criteria Document or one of the other studies it relied on in 2008.

Taking at face value EPA's characterization of these studies, nothing in the Provisional Assessment suggests that mortality risks posed by ozone exposure below 75 ppb are materially greater than EPA represented them to be in 2008. Thus, this section of the Provisional Assessment has no demonstrable practical utility for the purpose to which Administrator Jackson has applied it, which is giving objective scientific support to her proposed decision to lower the primary standard.

3. Respiratory morbidity

EPA's conclusion in the 2006 Criteria Document, as summarized in the Provisional Assessment, was that "clear evidence of causality for the associations observed between acute (≤ 24 h) O_3 exposure and relatively small, but statistically significant declines in lung function [were] observed in numerous recent epidemiologic studies. Declines in lung function were particularly noted in children, asthmatics, and adults who work or exercise outdoors."[55]

The Provisional Assessment reports on several new studies related to respiratory morbidity. Taking at face value EPA's characterizations of these studies, it appears that nothing has changed:

> Overall, the findings reported in the new studies of respiratory morbidity are consistent with those in the 2006 O_3 AQCD conclusions, particularly the numerous new studies of hospital admissions and emergency department visits.[56]

As in the case of the section on mortality studies, this section of the Provisional Assessment also has no demonstrable practical utility for the purpose to which Administrator Jackson

[54] U.S. Environmental Protection Agency (2009b, p. 5).
[55] U.S. Environmental Protection Agency (2009b, p. 7).
[56] U.S. Environmental Protection Agency (2009b, pp. 7-8).

has applied it, which is giving objective scientific support for her proposed decision to lower the primary standard.[57]

Many of these studies rely on respiratory function tests. In every case, researchers incorrectly assumed that inter-maneuver variability was zero. This understates the spread of the confidence intervals used for hypothesis testing and overstates the statistical significance of the results.

Some of these studies also suffer from other methodological limitations previously identified in the 2007 RFC and the 2008 RFR as severe information quality defects. These limitations include such matters as self-administration and self-reporting through diaries (both of which are prone to error, bias, and data invention), and nonresponse bias. In the scientific record for the 2008 Rule, EPA ignored these known defects, treating studies that contained them probative evidence of risk if the researchers had obtained results that supported EPA staff policy views but diminishing or discarding them if they did not, and ignoring nonresponse bias as if it did not exist. The Provisional Assessment continues to follow these same practices.

4. Cardiovascular morbidity

EPA's conclusion in the 2006 Criteria Document, as summarized in the Provisional Assessment, was that the "generally limited body of evidence is highly suggestive that O_3 directly and/or indirectly contributes to cardiovascular-related morbidity." The Provisional Assessment summarizes several new studies and concludes that "[t]he results of the more recent studies presented here are consistent with those of the 2006 O_3 AQCD."[58]

Taking it at face value, nothing in the Provisional Assessment supports the inference that the risks of cardiovascular mortality at ambient ozone levels below 75 ppb are greater than EPA represented them to be in 2008. Thus, this section of the Provisional Assessment also has no demonstrable practical utility for the purpose to which Administrator Jackson has applied it, which is giving objective scientific support for her proposed decision to lower the primary standard.

5. Health effects associated with long-term exposure

EPA's conclusions in the 2006 Criteria Document, as summarized in the Provisional Assessment, were that:

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[57] As before, the objectivity of EPA's characterizations of these studies is easily challenged, as is EPA's choice of studies to include or exclude. As before, we do not make that effort at this time because the absence of practical utility for the Administrator's intended purpose is itself a fatal information quality defect.

[58] U.S. Environmental Protection Agency (2009b, p. 15).

- "an insufficient amount of evidence exists 'to suggest a causal relationship between chronic O_3 exposure and increased risk for mortality in humans'"[59]
- "the epidemiologic data, collectively, indicates that the current evidence is suggestive, but inconclusive for respiratory health effects from long-term O_3 exposure"[60]
- "the weight of evidence from recent animal toxicological studies and a very limited number of epidemiologic studies do not support ambient O_3 as a pulmonary carcinogen"[61]
- "O_3 [is] not an important predictor of several birth-related outcomes including intrauterine and infant mortality, premature births, and low birth weight"[62]
- "the 2006 O_3 AQCD did not include a summary statement on the effect of O_3 on neurobehavioral effects because, although multiple toxicological studies have been performed examining the association between O_3 exposure (mean O_3 concentration 26.5 ppb) and neurobehavioral effects, there were no epidemiologic studies published at the time"[63]

With regard to each of these effects, the Provisional Assessment:

- took no position on whether new studies altered the EPA staff opinion regarding mortality[64]
- described the results of studies on respiratory effects as "generally mixed"[65]
- took no position on whether new studies altered the EPA staff opinion regarding lung cancer[66]
- describes the results of studies looking for reproductive and developmental outcomes as "inconsistent"[67]
- took no position on whether new studies altered the EPA staff opinion regarding neurobehavioral effects[68]

Taking it at face value, nothing in the Provisional Assessment supports the inference that any of these risks at ambient ozone levels below 75 ppb are greater than EPA

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[59] U.S. Environmental Protection Agency (2009b, p. 19).
[60] U.S. Environmental Protection Agency (2009b, p. 20).
[61] U.S. Environmental Protection Agency (2009b, p. 22).
[62] U.S. Environmental Protection Agency (2009b, p. 24).
[63] U.S. Environmental Protection Agency (2009b, p. 25).
[64] U.S. Environmental Protection Agency (2009b, pp. 19-20).
[65] U.S. Environmental Protection Agency (2009b, p. 20).
[66] U.S. Environmental Protection Agency (2009b, pp. 22-23).
[67] U.S. Environmental Protection Agency (2009b, p. 23).
[68] U.S. Environmental Protection Agency (2009b, p. 25).

represented them to be in 2008. Thus, this section of the Provisional Assessment also has no demonstrable practical utility for the purpose to which Administrator Jackson has applied it, which is giving objective scientific support for her proposed decision to lower the primary standard.

6. Vulnerability or susceptibility

EPA's conclusions in the 2006 Criteria Document, as summarized in the Provisional Assessment, were that "exercising (moderate to high physical exertion) children and adolescents appear to demonstrate increased responsiveness to ambient concentrations of O_3 and may be more likely to experience O_3-induced health effects." The Provisional Assessment identifies one study that is germane to this question; it is the same one that was discussed in the short-term morbidity section, and it contained only 16 participants.[69] In any case, the Provisional Assessment does not claim that this study alters the scientific evidence, so it cannot be interpreted as scientific support for Administrator Jackson's proposal to lower the primary standard.

In sum, the Provisional Assessment does not make any claims at all about the new science published since the preparation of the Criteria Document. Nothing in the document suggests that EPA staff now believe that in 2008 they underestimated risks for ambient ozone exposures below 75 ppb. Therefore, the Provisional Assessment has no practical utility as scientific support for Administrator Jackson's proposal to lower the primary standard below 75 ppb. EPA has used the Provisional Assessment in a manner that clearly contravenes the presentational objectivity standard, claiming that it provides an objective scientific justification for lowering the primary standard when it plainly does not—even when the contents of the Provisional Assessment are taken at face value.

Policy judgments are exempt from the Information Quality Act and its implementing guidelines. Thus, our information quality challenge is directed at an unambiguous abuse—attempting to characterize as a *scientific* inference what is transparently a matter of pure *policy*. Administrator Jackson disagrees with the policy judgment made by Administrator Johnson in 2008. , However, rather than acknowledge that her disagreement is strictly a difference in policy views, Administrator Jackson sought to rely on new "science" to support her view. While we have numerous disputes with the EPA staff regarding the objective interpretation of scientific evidence (disputes we have raised in the 2008 RFR and raise here), we also believe that EPA officials should clearly distinguish

[69] U.S. Environmental Protection Agency (2009b, p. 25).

between plausibly objective scientific work and policy choices. As shown above, the Provisional Assessment does not provide scientific support for a lower standard.[70]

To remedy this IQA violation, we request that EPA correct the record with regard to unsupportable claims that the Provisional Assessment provides scientific support for lowering the primary standard below 75 ppb.

III. MANAGING THE PROBLEMS RELATED TO LUNG FUNCTION TESTING IN THE CONTEXT OF ADMINISTRATOR JACKSON'S PROPOSAL TO LOWER THE PRIMARY OZONE STANDARD

The 2007 RFC and 2008 RFR were directed at the scientific information upon which Administrator Johnson made his determination concerning what level of ambient ozone protected public health with an ample margin of safety. The fact that Administrator Jackson has proposed a different determination in no way vanquishes EPA's duty to respond to the 2008 RFR.

In the Proposed Reconsideration, EPA again disseminates the same erroneous scientific information in violation of the IQA and the Clean Air Act. The violation is more pronounced because if the errors are corrected, the scientific record would be less supportive of what Administrator Jackson proposes than it was of what Administrator Johnson decided.

This section addresses a particular suite of information quality errors in several studies EPA relied on in the 2008 Rule and continues to rely on in the Proposed Reconsideration. We identify paths forward by which EPA could begin to correct these errors.

A. Focus on information quality errors in lung function tests

Much of the scientific information EPA has cited and which Administrator Jackson relies upon for the Proposed Reconsideration utilizes lung function testing. We devoted considerable attention to this in the 2008 RFR. These errors included:

- Validity and reliability problems arising because of potential investigator bias, which may result from the need to "coach" research subjects in effective performance[71]

[70] We believe the Administrator has done something similar with respect to CASAC. We address this in Section xx below.

[71] National Association of Manufacturers (2008, p. 53).

- Validity and reliability problems arising because these tests were intended for low-resolution clinical purposes, not the high-resolution purposes of environmental epidemiology[72]
- Validity and reliability of problems related to self-administered tests, especially tests involving children, with information recorded in research subjects' diaries[73]

One or more of these problems appears to infect each of the studies on which EPA relied. We are aware of no evidence showing that researchers avoided investigator bias in the administration of lung function test; or that they interpreted correctly the test data they obtained; or that they validated their data before applying often-sophisticated statistical procedures. We also are unaware of any effort made by EPA to perform the "especially rigorous robustness checks" that the EPA IQG requires when original data are not available for public inspection.[74]

In its Response to Comments, EPA did not dispute the substance of these complaints. For example, EPA correctly characterized the second of these information quality defects (the validity and reliability of self-reporting via diaries) but simply ignored the third (the validity and reliability of self-administered tests). The Agency's response consisted of a string of *non-sequiturs* and incorrect statements about the scientific literature, which this time we feel compelled to diagram, sentence by sentence in Table I below. The Proposed Reconsideration places greater reliance on studies that utilize these methods, increasing the magnitude of the information quality error.

B. Validity and reliability problems related to the use of low-resolution clinical tests for high-resolution environmental epidemiology

The published reports for most of the observational epidemiology studies that rely on lung function testing say that researchers adhered to American Thoracic Society (ATS) testing guidelines.[75] These guidelines were written for a clinical purpose—to establish consistent standards and practices for pulmonologists in the diagnosis of respiratory disease.

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[72] National Association of Manufacturers (2008, pp. 50-52).
[73] National Association of Manufacturers (2008, pp. 53-55).
[74] U.S. Environmental Protection Agency (2002, p. 21).
[75] *See* Miller, Hankinson et al. (2005). In Section III(F), we note that whereas the ATS guidelines call for no less than three maneuvers per test, some researchers conducted just two. Collecting fewer observations reduces inter-maneuver variance—indeed, it can be reduced to zero by conducting a single maneuver—but it decreases accuracy.

A separate ATS guideline addresses how to interpret pulmonary function tests (PFTs).[76] These guidelines are directed to "medical directors of hospital-based laboratories that perform PFTs, and physicians who are responsible for interpreting the results of PFTs most commonly ordered for clinical purposes. Specifically, this section addresses the interpretation of spirometry, bronchodilator response, carbon monoxide diffusing capacity (DL,CO) and lung volumes."[77]

The guidelines are *not* directed to research epidemiologists, though it is reasonable for epidemiologists to use them—provided that they interpret the results as ATS intended. What has happened is that research epidemiologists have (mostly) adopted the ATS guidelines for *conducting* the tests (which is convenient to do), but ignored the ATS guidelines on *interpreting* the results (which is impossible to do and still achieve their research objectives).

The ATS interpretation guidelines establish five categories of abnormal lung function based on FEV_1 testing, where abnormality is defined in terms of how the test result compares with what is predicted based on the subject's characteristics. These categories are reproduced in Table II below.[78]

[76] Pellegrino et al. (2005).
[77] Pellegrino et al. (2005, p. 948).
[78] The ATS acknowledges that professional judgment is involved: "The number of categories and the exact cut-off points are arbitrary." *See* Pellegrino et al. (2005, p. 957).