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December 1, 2008

Mr. Marcus A. Peacock  
Deputy Administrator  
EPA Ariel Rios Building  
1200 Pennsylvania Ave., N.W.  
Mail Code 1102A  
Washington, D.C. 20460

Re: Comments of the Utility Air Regulatory Group on EPA's Risk and Exposure Assessment to Support the Review of the NO<sub>2</sub> Primary National Ambient Air Quality Standard (November 2008)

Dear Mr. Peacock:

We are writing to you on behalf of the Utility Air Regulatory Group ("UARG")<sup>1</sup> regarding the final "Risk and Exposure Assessment to Support the Review of the NO<sub>2</sub> Primary National Ambient Air Quality Standard" (the "REA") released by the Office of Air Quality Planning and Standards on the evening of November 21, 2008. We want to bring to your attention the manner in which this document -- and the procedures by which it was developed and released -- deviate from the revised NAAQS review process that you instituted after your careful examination of how NAAQS reviews have historically been conducted. Specifically, the final REA includes suggestions concerning the appropriateness of the standards and recommendations for revising such standards. These are the very types of policy judgments that you explained should be part of a policy assessment presented in an Advance Notice of Proposed Rulemaking. We ask that you again clarify for your staff (the "Staff") the line between scientific evaluation and analysis that belongs in the REA and judgments that must be reserved for the policy assessment document.

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<sup>1</sup> UARG is a voluntary, nonprofit group of electric generating companies and organizations and four national trade associations (the Edison Electric Institute, the National Rural Electric Cooperative Association, the American Public Power Association, and the National Mining Association). UARG's purpose is to participate on behalf of its members collectively in EPA's rulemaking and other Clean Air Act ("CAA") proceedings that affect the interests of electric generators, and in related litigation. Since 1977, UARG has participated in virtually all key CAA rulemakings affecting electric utility companies and in subsequent litigation related to those rulemakings.

Environmental Protection Agency

December 1, 2008

Page 2

Moreover, even if we are wrong about the type of judgments that are properly included in an REA, there can be little doubt that the judgments and recommendations presented in the final REA are the type of judgments that should only be reached after the public has had an opportunity to comment on them. In this case, however, there has been no opportunity for public comment. The judgments appear for the first time in the final document. This, too, is clearly contrary to the careful procedures that you developed, which emphasize the importance of public comment. Indeed, as we explain in more detail below, the public's opportunity to comment on the REA has been repeatedly thwarted by the release of late or incomplete drafts of the document. We ask that you again remind the Staff of the important role that public comment plays in the NAAQS review process.

### Background

As you have noted, the REA is an important component of EPA's review of the primary NO<sub>2</sub> NAAQS. It is intended to serve as a tool to assist the Administrator in understanding the implications of the latest relevant scientific information, as reflected in the Integrated Science Assessment for Oxides of Nitrogen (the "ISA"), for the risks to health that the public faces as a result of exposure to NO<sub>2</sub> in the ambient air. Letter from Marcus C. Peacock, Deputy Administrator of EPA, to Dr. George Gray, Assistant Administrator, Office of Research and Development and Bill Wehrum, Acting Assistant Administrator, Office of Air and Radiation (Dec. 7, 2006) at 2. Thus, it should aid the Administrator in judging whether the current primary NO<sub>2</sub> NAAQS, which is to protect the public health with an adequate margin of safety, is set at the level requisite to fulfill this purpose. *See* CAA 109(b)(1), 42 U.S.C. § 7409(b)(1).<sup>2</sup> Unfortunately, the final REA fails to fulfill its intended role and instead places the remainder of the NAAQS review process for NO<sub>2</sub> in jeopardy.

### The Policy Judgments Set Forth in Chapter 10 of the REA Are Inappropriate.

Chapter 10 of the final REA, entitled "Evidence- and Exposure/Risk-Based Considerations Related to the Primary NO<sub>2</sub> NAAQS" ("Chapter 10") includes recommendations that extend well beyond the intended role of the REA. For example, after appropriately discussing the evidence-based considerations drawn from the available science and exposure- and risk-based considerations,<sup>3</sup> the Staff concludes "consideration should be given to revising the current standard so as to provide increased public health protection, especially for sensitive groups, from NO<sub>2</sub>-related adverse health effects associated with short-term, and potential long-term, exposures." REA at 290. Furthermore, they conclude that "the science reasonably supports a

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<sup>2</sup> Citations hereinafter are given only to the CAA.

<sup>3</sup> As we mention below, we believe that discussion of the evidence in this manner is appropriate in the REA. We do not agree that all of the evidentiary interpretations are appropriate.

range of standard levels [for a 1-hour standard] from 50 ppb to 200 ppb, with strong support for a level at or below 100 ppb.” *Id.* at 309.

Recently, in a memo intended to clarify the proper procedure for the NAAQS review process, you reiterated that the advance notice of proposed rulemaking (the “ANPR”) is intended to be the document to “bridge the gap between the Agency’s scientific assessment and the judgments required of the Administrator.” Letter from Marcus C. Peacock, Deputy Administrator of EPA, to Rogene Henderson, Ph.D., Chair of the Clean Air Scientific Advisory Committee (Sept. 8, 2008) (hereinafter “Peacock Sept. 2008”) at 3. The REA is to include a “broader discussion of the science and how uncertainties may effect decisions on the standard,” as well as to include all relevant information regarding “risk assessment and weight of evidence methodologies.” *Id.* To be clear, the ANPR must “continue to serve as the policy document that follows the development of the scientific and risk assessment information.” *Id.* The Staff’s recommendations in Chapter 10 inappropriately address policy issues left to the Administrator’s discretion and should not have been included in the REA. Nor should any similar chapter be included in future REAs.

EPA’s Administration of the REA Development Process Has Hindered Public Participation in the NAAQS Review.

The CAA explicitly states that the public should be allowed to comment on documents related to the NAAQS, and you have recently acknowledged the importance of public comments to the NAAQS review process on behalf of EPA. *See, e.g.,* Peacock Sept. 2008 at 2. However, EPA’s administration of the NAAQS review process for NO<sub>2</sub> has not reflected this sentiment.

The Staff announced at a teleconference of the Clean Air Scientific Advisory Committee (“CASAC”) on October 22, 2008 that the final REA would be released on November 21<sup>st</sup> and that it would include an additional chapter that was not included in the first or second drafts of the REA. Although notice of neither the release of the REA nor of any public comment period on the new material has been published in the *Federal Register*, the Staff stated during the October CASAC teleconference that it would accept public comments on the REA until November 28, 2008. In scheduling a brief (2-hour) CASAC teleconference on the final REA for December 5<sup>th</sup>, EPA indicated that written comments to CASAC would be accepted until December 1<sup>st</sup>. Even if this provided a realistic amount of time in which to develop comments on Chapter 10 and the completely new interpretations introduced therein, UARG notes that an opportunity to provide comments to CASAC on the final REA is not a substitute for an opportunity to comment to EPA on a draft of the REA.

Environmental Protection Agency

December 1, 2008

Page 4

This current informal, ad hoc, call for comments marks the latest incident in a series of actions that have complicated and hindered the ability of the public to comment on the REA for NO<sub>2</sub>. When the first draft of the REA was released, the public was initially to be allowed only eighteen days to comment. 73 Fed. Reg. 20045. Three days before the comment period was to end, EPA extended the deadline by a month in response to requests from UARG and others. 73 Fed. Reg. 22363. When the second draft of the REA was released, it did not include the chapter addressing the exposure assessment and health risk characterization, or portions of the appendices that corresponded to that chapter. EPA denied UARG's request for an extension to allow the public to review the document in its entirety and provide comprehensive comments. The missing chapter was posted on the EPA's website over a month later but was removed within 24 hours, due to a "small error affecting some of the exposure results" which EPA never explained. It was later re-released and the public was given fourteen days, only nine of which were business days, to review the documents and provide comments.

While UARG understands EPA's time constraints, which result from the review schedule to which EPA agreed in a consent decree, these time constraints do not excuse depriving the public of its opportunity to provide comment. Nor is this an excuse to limit public comment to disjointed reviews of pieces of a document in isolation, or to allow an inadequate period for the public to review a document and develop comments. This approach to public comment impairs the integrity of the entire NAAQS review process. It should not be repeated.

#### The Staff's Recommendations in Chapter 10 are Not Justified By the Science.

The Staff's recommendations to the Administrator contained in Chapter 10 are not well founded in the latest scientific information relevant to adverse public health effects of NO<sub>2</sub>. We believe that these problems are, at least in part, attributable to the Staff's failure in this review to follow the procedures that you developed (with, we note, input from the Staff). While we understand that you may not be in a position to address these flaws in the Staff's analysis, we are bringing some of our concerns to your attention to illustrate the problems that have resulted from the procedural failures. The three most serious issues with the Staff's recommendations are (i) the assertion that the NAAQS should be revised based on the results of modeling that adjusts current ambient air quality to just meet the current standard and various alternative standards, (ii) the Staff's reliance on an unpublished, meta-analysis of clinical studies that have never been subject to peer review; and (iii) the Staff's continued willingness to overlook serious flaws in the epidemiological research and case studies on which they base their recommendations.

Chapter 10 of the final REA recommends that the current 0.053 parts per million ("ppm") annual average standard for NO<sub>2</sub> should be amended to a 1-hour standard in the range of 0.05 to 0.2 ppm, with "strong support" for setting the standard below 0.1 ppm. REA at 309. This would be

Environmental Protection Agency

December 1, 2008

Page 5

a dramatic revision of the current standard. Such a substantial revision to the NAAQS must be firmly based in the latest scientific knowledge available regarding adverse health effects caused by “the presence of such pollutant in the ambient air, in varying quantities.” *See* CAA § 108(a)(1)(A). Instead, the Staff’s recommendation is based on modeling that simulates NO<sub>2</sub> concentration levels far above current monitored levels.

The Staff’s recommendation that the NAAQS be substantially revised is not based on current air quality, but on modeling that simulates air quality that is much worse than current ambient air quality. Chapter 10 states that “[i]n examining the exposure- and risk-based information with regard to the adequacy of the current annual NO<sub>2</sub> standard to protect the public health, [results] indicate risks associated with air quality adjusted upward to simulate just meeting the current standard that can reasonably be judged important from a public health perspective [and that] reinforce the scientific evidence in supporting the conclusion that consideration should be given to revising the current standard.” REA at 290. In fact, EPA acknowledges in Chapter 10 that ambient air monitoring indicates that the current annual standard is met throughout the U.S. today, and that “1-hour NO<sub>2</sub> concentration greater than 0.20 ppm. are unlikely to occur.” *Id.* at 287. As UARG reported in its comments to the second draft of the REA, EPA’s most recent trends report indicates that concentrations of NO<sub>2</sub> decreased by 30% nationwide between 1990 and 2006, and that as of 2006, “[a]ll recorded concentrations were well below the level of the national standard.” EPA, Latest Findings on National Air Quality, Status and Trends Through 2006 at 21 (Jan. 2008).

EPA has not identified any circumstance which would lead to such a dramatic decline in ambient air quality. In fact, EPA explains that the “[upward] adjustment does not reflect a judgment that levels of NO<sub>2</sub> are likely to increase under the current standard or any of the potential alternative standards under consideration. Rather, these adjustments reflect the fact that the current standard, as well as some of the alternatives under consideration, *could* allow for such increases in ambient NO<sub>2</sub> concentrations.” REA at 284 (emphasis added). This policy judgment is inappropriate, particularly in the REA. The CAA requires that the Administrator establish NAAQS that he judges are “*requisite* to protect public health from the adverse effects of the pollutant in the ambient air.” CAA § 109(b)(1) (emphasis added). The Supreme Court has clarified that “requisite,” in this context, “means sufficient, but not more than necessary,” or, “not lower or higher than is necessary” to protect public health. *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 473 (2001). In order to properly support a determination by the Administrator that the NAAQS should be revised, the Staff would have to identify a specific scenario that would be likely to lead to such a deterioration of ambient air quality. That type of analysis might be appropriate in the REA, but it is not there. As long as the current standard is requisite to protect the public health, it is inappropriate for EPA to consider a more stringent standard.

With regard to the second of the major flaws, -- reliance on an unpublished meta-analysis that has not been publicly released or peer-reviewed -- reliance on such an analysis is contrary to the Review Plan that the Staff prepared in accordance with your NAAQS review procedures. *See*, EPA, INTEGRATED REVIEW PLAN FOR THE PRIMARY NATIONAL AMBIENT AIR QUALITY STANDARD FOR NITROGEN DIOXIDE 11 (2007). Nevertheless, this meta-analysis “formed a large part of the basis for potential health benchmark levels.” REA at 285. It is also a part of the basis for the recommendation of a 1-hour averaging time for a new standard, *Id.* at 293, and for the recommendation for consideration of a standard at or below 0.1 ppm. *Id.* at 304.

In addition to evaluating the latest scientific knowledge relevant to the NAAQS, the REA is to address “how uncertainties may effect decisions on the standard.” Peacock Sept. 2008 at 3. In the REA, EPA correctly discusses the “range of uncertainties that are inherent in the scientific evidence and analyses.” REA at 275. The following are few of the uncertainties mentioned in Chapter 10:

- In modeling predictions that simulate air quality that just meets the current standard, EPA assumed that the shape of the distribution of NO<sub>2</sub> concentrations would remain consistent, although there is no way to determine what shape that distribution would take (*Id.* at 284);
- Based on comparisons to measured data, NO<sub>2</sub> concentration levels simulated by AERMOD are likely over-predicted by up to 50% at the upper levels (*Id.* at 286);
- Single pollutant models may produce overestimates of NO<sub>2</sub> effects (*Id.* at 287);
- EPA is unable to distinguish any effects of NO<sub>2</sub> in vehicle exhaust from the effects of the mixture of co-pollutants that comprise vehicle exhaust (*Id.* at 281); and
- EPA is uncertain whether there is a causal relationship between NO<sub>2</sub> and emergency department visits (*Id.* at 286).

These are very serious uncertainties that the Administrator must consider when reviewing the NAAQS. Although EPA mentions them in the REA, it dismisses them and relies on the information that it has characterized as uncertain to advocate revising the NAAQS for NO<sub>2</sub>. EPA states, for example, that “[w]hen evaluated as a whole, NO<sub>2</sub> effect estimates in [multi-pollutant] models generally remained robust,” REA at 281, and “when taken together, the results of epidemiologic and experimental studies form a plausible and coherent data set that supports a relationship between NO<sub>2</sub> exposures and respiratory endpoints, including symptoms and [emergency department] visits.” *Id.* at 282. It is inappropriate for EPA to dismiss these

Environmental Protection Agency

December 1, 2008

Page 7

uncertainties. It is the Administrator's role to evaluate the science, along with the uncertainties that surround it, and to determine independently whether to retain or revise the NAAQS. The policy judgments and suggestions offered by the Staff in Chapter 10 inappropriately usurp the policy making role left solely to the Administrator's discretion. The ANPR should include discussion of the full range of options for the NAAQS for NO<sub>2</sub> -- wider than the range of standards suggested by the Staff in the REA -- including retention of the current standard.

In summary, the disorganized manner in which EPA has conducted the release of the REA at all stages of the review process, as well as the inappropriate policy driven conclusions and misleading scientific information contained therein has been shocking. UARG urges you to ensure the return of procedural integrity to the NAAQS review process.

Sincerely,

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E. Carter Chandler Clements

Counsel to the Utility Air Regulatory Group

cc: Docket ID No. EPA-HQ-OAR-2006-0922