

**Summary Minutes of the
U.S. Environmental Protection Agency (EPA)
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
Oxides of Nitrogen Primary National Ambient Air Quality Standard (NAAQS) Review
Panel
Public Teleconference
August 10, 2009**

Committee Members: (See Roster – Attachment A)

Scheduled Date and Time: From 1:00 p.m. (Eastern Time) to 4:00 p.m. (Eastern Time) August 10, 2009. (See Federal Register Notice, Attachment B)

Location: By teleconference.

Purpose: to provide comments concerning EPA's proposed rule on the nitrogen dioxide Primary National Ambient Air Quality Standard (NAAQS).

Attendees:

Panel Members:	Dr. Jonathan Samet Prof. Ed Avol Dr. Joseph Brain Dr. Ellis B. Cowling Dr. James Crapo Dr. Terry Gordon Dr. Dale Hattis Dr. Rogene Henderson Dr. Patrick Kinney Dr. Steven Kleeberger Dr. Timothy Larson Dr. Edward Postlethwait Dr. Armistead (Ted) Russell Dr. Richard Schlesinger Dr. Christian Seigneur Dr. Elizabeth A. (Lianne) Sheppard Dr. Frank Speizer Dr. George Thurston Dr. James Ultman, Dr. Ronald Wyzga
SAB Staff Office:	Dr. Angela Nugent, EPA SAB Staff Office, Designated Federal Officer (DFO)

Meeting Summary –

The discussion addressed the topics included in the Proposed Meeting Agenda (See Meeting Agenda - Attachment C) and roughly followed the sequence summarized below.

Opening of Public Meeting

Dr. Angela Nugent, Designated Federal Officer (DFO) for the CASAC Oxides of Nitrogen Primary NAAQS Review Panel, opened the teleconference at 1:00 p.m. Dr. Nugent noted that two individuals had requested opportunities for public comment and two sets of written public comments had been submitted and provided to panel members.

Dr. Jonathan Samet, CASAC chair, welcomed members. He reviewed the agenda and the importance of CASAC advice on EPA's proposed NAAQS revisions for nitrogen dioxide (NO₂). He indicated that several members of the CASAC panel had prepared draft text related to science issues in the proposal (Attachment E). He noted that the purpose of the call was to reach agreement on substantive points to include in the CASAC letter commenting on EPA's proposed rule.

Public Comments

Dr. Julie Goodman of Gradient Corporation presented comments on behalf of the American Petroleum Institute. Her oral comments summarized written comments in Attachment F. In response to a question regarding Gradients' new meta-analysis, Dr. Goodman stated that Gradient had submitted the analysis for publication in a peer reviewed journal.

Ms. Janice E. Nolen, Assistant Vice President, National Policy and Advocacy, American Lung Association, summarized written comments in Attachment G.

EPA's proposed new short-term standard and retention of annual standard and alternative approach to setting the level of a new short-term standard

At the invitation of the chair, Dr. George Thurston introduced CASAC discussion of EPA's proposed standard and alternatives. He noted that he and other CASAC panel health scientists preparing for the call affirmed the need for both an annual and short-term standard for NO₂. For the short-term standard, these panelists observed that EPA will need to rely on the epidemiology literature, which depends on area-wide monitoring for NO₂ health associations and dose-responses. Because data on near-roadway exposures were lacking in epidemiology studies, the scientists were concerned EPA's proposal to use near-roadway monitoring for determining NAAQS attainment. He also noted that these scientists generally agreed that a standard range could be lower, if the form of the standard were the 98th percentile, as compared with the 99th percentile. Dr. Terry Gordon added that the group discussed a range of 80 to 100 ppb within the context of the 99th percentile.

Proposed monitoring network requirements and alternative monitoring network requirements

At the request of the CASAC chair, Dr. Armistead Russell discussed the preliminary views of several CASAC panelists who focused on network and monitoring design issues. He noted that the scientists were "uniformly uncomfortable" with EPA's proposed near-road monitoring for attainment demonstration. He observed that roadside monitors can be susceptible

to extreme events and scientists do not understand how area-wide observations relate to roadside network observations. Concentrations at roadside monitors will vary, depending on the exact distance and height of monitors relative to the road. The Agency proposal to locate monitors in areas of maximum traffic may not identify the highest exposures, because they would not necessarily capture high rates of diesel emissions and identify areas with limited dispersions (e.g., street canyons might not be monitored because they might not have most traffic). Local observations made at near-road monitors may not be relevant to exposures two-to-three miles down a freeway.

Dr. Russell commented that CASAC panel scientists are highly supportive of starting a network of near-road monitors to begin research collecting data on near-road exposures. They envision that such a network would be small (numbering a “couple of dozen” monitors) and would monitor several pollutants. They viewed this as consistent with EPA’s 2008 approach outlined in the document, *Ambient Air Monitoring Strategy for State, Local, and Tribal Air Agencies*. These scientists provided preliminary comments that the science did not currently support using a roadside monitor system was to assess the effectiveness of NO₂ control programs.

The committee briefly discussed the utility of European experience with near-road monitors for NAAQS setting. Members noted that American experience with street canyon exposures are difficult to simulate with European data if there are different plumes. Members noted that Table 1 in the proposal included range of values for several cities outside the United States, but that these data relied on available monitors, which are not necessarily near roadways

General Discussion

The chair then initiated a general discussion of science issues in the proposal. A panel member emphasized the importance of chamber studies that show definitive responses at 100 ppb among sensitive asthmatics. He acknowledged the difficulty of starting a near-road monitoring program, but argued that those difficulties were balanced by the need to monitor for one-hour peak exposures. He noted that a substantial fraction of the population was exposed through near road exposures.

The panel then considered whether near-road monitoring would happen if only area-wide monitoring required. Some members referenced EPA’s 2008 report on ambient air monitoring and noted that EPA was considering developing near-road monitoring for particulate matter and carbon monoxide. Decisions about placement of near-road monitors might best be determined by considering all the NAAQS pollutants, not just NO₂ alone. Mr. Louis Weinstock (Chief of the Ambient Air Monitoring Group in EPA’s Office of Air Quality Planning and Standards) asked for the opportunity to comment. He offered a personal view that a regulatory framework was needed to drive development of near-road monitoring, and that a research-only system of near-road monitors was unlikely to develop within the next cycles of NAAQS review.

In response to a question from the chair, Mr. Weinstock noted that the proposed rule included criteria for area-wide monitoring that will identify new monitors needed in states with no previous history of area-wide monitoring. A panel member commented on the importance of states having adequate monitoring to ensure compliance with national standards for public health

protection. Members briefly discussed the appropriateness of a threshold of 350,000 as the population threshold for monitoring cities. One member observed that the cutoff was slightly low and that the Agency should evaluate available modeling and monitoring inventories to identify locations for monitors.

To focus panel discussion on the key science issues before the panel, Dr. Samet asked the CASAC panel members to discuss text describing the Agency's proposed approach and alternatives described on page 34439 of the proposal. Acknowledging that the proposal involved several inter-related issues, he asked members first to address whether they supported a standard based on a two-tiered system that includes near-road monitoring or a standard based on the current approach of area-wide monitoring. Some members found it difficult to choose. Several stated that they "wanted data from road-side monitoring, separate from setting a standard" and voiced concern about the uncertainties associated with basing standards on the two-tiered system. After receiving feedback from all the panel members, the Chair concluded that it was the sense of the group that "it leaned towards the EPA (two-tiered) proposal with some concern."

Members supporting the two-tier systems drew on the following rationales: chamber studies focused on acute exposures; controlled human studies produce effects in asthmatic and non-asthmatic children; the need to protect people near roadways; the need to begin collecting data for road-side exposures; and the problematic issue of basing regulations on area-wide monitoring because that approach requires embedding uncertain assumptions about the relationship between area-wide and road-side monitoring into the area-wide standard. One member noted that he would support the approach of road-side monitors if the total number of monitors were increased and EPA could assure that road-side monitors generated measurements reflective of population exposures near roadways. Another member supported the approach, but voiced concern about setting an unduly protective range of levels, given the instability expected from road-side measurements

Members supporting the current approach, instead of the two-tiered system, identified the following rationales: difficulties linking epidemiology data to concentrations from near-roadway network, relative uncertainty around the correlation of area-wide concentrations to near roadway concentrations; potential instability of concentrations with road-side monitors; and the risk to the Agency in basing standards on road-side monitors without supporting epidemiology data.

The chair asked the panel to consider the broader question of CASAC's desire for near-roadway data. He asked whether the motivation for collecting such data should more appropriately be a research agenda to understand the relationship between traffic source emissions and human health, to understand exposures to particulate matter, aldehydes, and volatile organic compounds, rather than the NO₂ NAAQS rule. The group briefly discussed the merits of engaging the CASAC Ambient Air Monitoring Subcommittee on this broader issue.

The panel then addressed the topic of the appropriate form of the standard, given a two-tiered monitoring network that would include near-roadway monitoring. Panel members noted that the proposal does not provide information about how form varies with level near roadways. Despite that missing information, the panel preferred the 98th percentile to the 99th percentile because it appeared to be a more stable form with fewer numbers of large excursions.

In regard to the range of acceptable levels at the 98th percentile, the group again noted the significant uncertainties associated with the actual level that will be measured by the near-road monitors and the relationship of near-road monitoring to measurements obtained at area-wide monitors. One member noted that the health data is fairly certain that mild asthmatics will experience effects at 100 ppb. Levels as high as 150 ppb, suggested as one alternative, were deemed unacceptable by CASAC. Members also noted that adverse effects that might be suffered by severe asthmatics could push the low end of the range to as low as 80 ppb, allowing for susceptibility and a margin of safety

Several members cautioned against setting the range too low, (i.e., lower than 80 ppb) because of uncertainties associated with road-side monitoring. A member suggested that the CASAC panel could describe the likely impacts of setting the range somewhere between 65 and 100 ppb and inform the Administrator of the uncertainties of the science, so she can make an informed policy choice.

Members briefly discussed the difficulty of responding to the complex and novel elements in the NO₂ proposal. They noted difficulty in commenting on major changes in EPA's regulatory approach after publication in the Federal Register. A member noted, however, the value of EPA's considering the road-side monitoring option proposed in the Federal Register

Summary of Next Steps Related to the Review of the draft Risk and Exposure Assessment

The chair informed the panel that he would work with the DFO to develop a draft letter based on the discussion and circulate the draft within the next ten days for concurrence.

At the chair's request, the Designated Federal Officer adjourned the meeting at 3:05 p.m

Respectfully Submitted:

Angela Nugent
Designated Federal Officer
/signed/
Certified as True:

/signed/
Jonathan Samet
Chair

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by committee members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

Attachments

Attachment A	Roster
Attachment B	Federal Register Notice
Attachment C	Meeting Agenda
Attachment D	List of science questions in EPA's proposed Primary National Ambient Air Quality Standard for Nitrogen Dioxide; Proposed Rule
Attachment E	Preliminary Draft Text to Assist CASAC Panel Deliberations at the August 10, 2009 Teleconference
Attachment F	Dr. Julie E. Goodman's Comments on EPA's Proposed Revisions to the NO ₂ NAAQS Gradient on behalf of the American Petroleum Institute
Attachment G	Ms. Janice E. Nolen's Statement on EPA's Proposals for the National Ambient Air Quality Standards for Nitrogen Dioxide on Behalf of the American Lung Association

Attachment A: Roster

U.S. Environmental Protection Agency Clean Air Scientific Advisory Committee (CASAC) Sulfur Oxides Primary NAAQS Review Panel

CHAIR

Dr. Jonathan M. Samet, Professor and Chair of the Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

CASAC MEMBERS

Dr. Joseph Brain, Philip Drinker Professor of Environmental Physiology, Department of Environmental Health, Harvard School of Public Health, Harvard University, Boston, MA

Dr. Ellis B. Cowling, University Distinguished Professor At-Large, Emeritus, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

Dr. James Crapo, Professor of Medicine, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. H. Christopher Frey, Professor, Department of Civil, Construction and Environmental Engineering, College of Engineering, North Carolina State University, Raleigh, NC, USA

Dr. Donna Kenski, Data Analyst, Lake Michigan Air Directors Consortium, Des Plaines, IL

Dr. Armistead (Ted) Russell, Professor, Department of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

CONSULTANTS

Professor Ed Avol, Professor, Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, CA

Dr. John R. Balmes, Professor, Department of Medicine, Division of Occupational and Environmental Medicine, University of California, San Francisco, CA

Dr. Douglas Crawford-Brown, Professor and Director, Department of Environmental Sciences and Engineering, Carolina Environmental Program, University of North Carolina at Chapel Hill, Chapel Hill, NC

Dr. Terry Gordon, Professor, Environmental Medicine, NYU School of Medicine, Tuxedo, NY

Dr. Dale Hattis, Research Professor, Center for Technology, Environment, and Development, George Perkins Marsh Institute, Clark University, Worcester, MA

Dr. Rogene Henderson, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Patrick Kinney, Associate Professor, Department of Environmental Health Sciences,
Mailman School of Public Health , Columbia University, New York, NY

Dr. Steven Kleeberger, Professor, Lab Chief, Laboratory of Respiratory Biology, National
Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle
Park, NC

Dr. Timothy V. Larson, Professor, Department of Civil and Environmental Engineering,
University of Washington, Seattle, WA, USA

Dr. Kent Pinkerton, Professor, Regents of the University of California, Center for Health and the
Environment, University of California, Davis, CA

Dr. Edward Postlethwait, Professor and Chair, Department of Environmental Health Sciences,
School of Public Health, University of Alabama at Birmingham, Birmingham, AL

Dr. Richard Schlesinger, Associate Dean, Department of Biology, Dyson College, Pace
University, New York, NY

Dr. Christian Seigneur, Director, Atmospheric Environment Center, Université Paris-Est,
Champs-sur-Marne, France

Dr. Elizabeth A. (Lianne) Sheppard, Research Professor, Biostatistics and Environmental &
Occupational Health Sciences, School of Public Health, University of Washington, Seattle, WA

Dr. Frank Speizer, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical
School, Boston, MA

Dr. George Thurston, Professor, Environmental Medicine, NYU School of Medicine, New York
University, Tuxedo, NY

Dr. James Ultman, Professor, Chemical Engineering, Bioengineering Program, Pennsylvania
State University, University Park, PA

Dr. Ronald Wyzga, Technical Executive, Air Quality Health and Risk, Electric Power Research
Institute, Palo Alto, CA

SCIENCE ADVISORY BOARD STAFF

Dr. Angela Nugent, Designated Federal Officer, 1200 Pennsylvania Avenue, NW
1400F, Washington, DC, Phone: 202-343-9981, Fax: 202-233-0643, (nugent.angela@epa.gov)

Attachment B: Federal Register Notice

Science Advisory Board Staff Office; Clean Air Scientific Advisory Committee (CASAC); Notification of a Public Advisory Committee Teleconference of the CASAC Oxides of Nitrogen Primary NAAQS Review Panel

[Federal Register: July 16, 2009 (Volume 74, Number 135)]

[Notices]

[Page 34575-34576]

From the Federal Register Online via GPO Access [wais.access.gpo.gov]

[DOCID:fr16jy09-45]

ENVIRONMENTAL PROTECTION AGENCY
[FRL-8932-1]

Science Advisory Board Staff Office; Clean Air Scientific Advisory Committee (CASAC); Notification of a Public Advisory Committee Teleconference of the CASAC Oxides of Nitrogen Primary NAAQS Review Panel

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office announces a public teleconference of the Clean Air Scientific Advisory Committee's (CASAC) Oxides of Nitrogen Primary NAAQS Review Panel (Panel) to provide comments concerning EPA's proposed revisions to the National Ambient Air Quality Standards for nitrogen dioxide.

DATES: The teleconference will be held on Monday, August 10, 2009 from 1 p.m. to 4 p.m. (Eastern Daylight Time).

ADDRESSES: The public teleconference will be conducted by telephone only.

FOR FURTHER INFORMATION CONTACT: Members of the public who wish to obtain the call-in number and access code to participate in the teleconference may contact Dr. Angela Nugent, Designated Federal Officer (DFO), EPA Science Advisory Board (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; via telephone/voice mail (202) 343-9981; fax (202) 233-0643; or e-mail at nugent.angela@epa.gov. General information concerning the CASAC can be found on the EPA Web site at <http://www.epa.gov/casac>.

SUPPLEMENTARY INFORMATION:

[[Page 34576]]

Background: Pursuant to the Federal Advisory Committee Act, Public

Law 92-463 5 U.S.C., App. 2 (FACA), notice is hereby given that the CASAC Oxides of Nitrogen Primary National Ambient Air Quality Standards (NAAQ) Review Panel will hold a public teleconference to provide comments concerning EPA's announced plans to propose revisions to National Ambient Air Quality Standards for nitrogen dioxide. The Clean Air Scientific Advisory Committee (CASAC) was established under section 109(d)(2) of the Clean Air Act (CAA or Act) (42 U.S.C. 7409) as an independent scientific advisory committee. CASAC provides advice, information, and recommendations on the scientific and technical aspects of air quality criteria and national ambient air quality standards (NAAQS) under sections 108 and 109 of the Act. The CASAC Panel will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Section 109(d)(1) of the CAA requires that the Agency periodically review and revise, as appropriate, the air quality criteria and the NAAQS for the six ``criteria'' air pollutants, including oxides of nitrogen. The CASAC Oxides of Nitrogen Primary NAAQS Review Panel has provided advice and review of key technical documents associated with EPA's reassessment of the NAAQS for oxides of nitrogen, including the Agency's Integrated Science Assessment for Oxides of Nitrogen--Health Criteria and Risk and Exposure Assessment to Support the Review of the NO₂ Primary National Ambient Air Quality Standard. The public may access completed CASAC advisory reports related to the primary NAAQS review of oxides of nitrogen at the CASAC site at <http://yosemite.epa.gov/sab/sabproduct.nsf/WebReportsbyTopicCASAC!OpenView>.

On June 29, 2009, EPA announced proposed revisions to the NAAQS for nitrogen dioxide (NO₂), the indicator chosen for oxides of nitrogen. The proposed revisions for NO₂ can be found on the EPA Web site at http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_fr.html. Primary standards set limits to protect public health, including the health of ``sensitive'' populations such as asthmatics, children, and the elderly.

The purpose of the public teleconference meeting on August 10, 2009 is for the CASAC Panel to provide comments concerning the proposed revisions of the primary NAAQS for NO₂.

Technical Contact: Any questions concerning the Agency's proposed rule for the revision of the NAAQS for lead should be directed to Dr. Scott Jenkins, OAR (by telephone (919) 541-1167 or e-mail jenkins.scott@epa.gov).

Availability of Meeting Materials: The draft agenda and other materials for the public teleconference of the CASAC Panel will be posted on the CASAC's Web site at <http://www.epa.gov/casac> prior to the meetings.

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral information for the CASAC Panel to consider during the advisory process. Oral Statements: Interested members of the public may submit relevant written or oral information for the SAB Panel to consider during the advisory process. In general, individuals or groups requesting an oral presentation at a public teleconference will be limited to three minutes per speaker, with no more than a total of 30 minutes for all speakers. Interested parties should contact Dr. Angela Nugent, DFO, in writing (preferably via e-mail) by August 5, 2009 at the contact information noted above to be placed on the public speaker list for this meeting. Written Statements: Written statements for the public meeting should be received by Dr. Angela Nugent at the contact information above by August 5, 2009, so that the information may be made available to the Panel for their consideration prior to the teleconference. Written

statements should be supplied to the DFO in the following formats: One hard copy with original signature (optional), and one electronic copy via e-mail (acceptable file format: Adobe Acrobat PDF, MS Word, MS PowerPoint, or Rich Text files in IBM-PC/Windows 98/2000/XP format). Submitters are asked to provide versions of each document submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Nugent at the phone number or e-mail address noted above, preferably at least ten days prior to the teleconference, to give EPA as much time as possible to process your request.

Dated: July 10, 2009.
Vanessa T. Vu,
Director, EPA Science Advisory Board Staff Office.

Attachment C: Meeting Agenda

U.S. Environmental Protection Agency – Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
Oxides of Nitrogen (NO_x) Primary Review Panel
Public Teleconference
August 10, 2009
1:00 a.m. to 4:00 p.m. Eastern time
Agenda

Purpose: to provide comments concerning EPA's proposed rule on the nitrogen dioxide Primary National Ambient Air Quality Standard (NAAQS).

1:00 p.m.	Convene the planning teleconference; take roll	Dr. Angela Nugent, EPA SAB Staff Office, Designated Federal Officer
1:05 p.m.	Agenda review and summary of CASAC process preparing for the call	Dr. Jonathan Samet, Chair
1:10 p.m.	Public Comments	TBA
1:20 p.m.	Proposed new short-term standard and retention of annual standard (questions 1-5) and alternative approach to setting the level of a new short-term standard (questions 1-2)	Lead Discussants: Dr. George Thurston Dr. Frank Speizer, Dr. Terry Gordon CASAC Discussion
2:30 p.m.	Proposed monitoring network requirements (questions 1-4.) and alternative monitoring network requirements (questions 1-2). Advancing technology -Monitoring method for NO ₂	Lead Discussant: Dr. Armistead Russell CASAC Discussion
3:20 p.m.	General discussion	CASAC panel
3:45 p.m.	Summary and Identification of next steps	Dr. Jonathan Samet
4:00 p.m.	Adjourn	Dr. Angela Nugent

Attachment D

List of science questions in EPA's proposed *Primary National Ambient Air Quality Standard for Nitrogen Dioxide; Proposed Rule*, 74 FR 34404-34466
<http://www.epa.gov/fedrgstr/EPA-AIR/2009/July/Day-15/a15944.pdf>

I. PROPOSED REVISIONS to Standard and Related Monitoring Requirements

Proposed new short-term standard and retention of annual standard:

1. Appropriateness of the proposed approach to setting a new short-term NO₂ primary standard with an averaging time of 1-hour (pp. 34430-34438). Specifically, under the proposed approach the standard would reflect the maximum allowable NO₂ concentration anywhere in an area, including locations in close proximity to major roads.
2. Appropriateness of the proposed range of standard levels (≥ 80 ppb and ≤ 100 ppb) and the rationale supporting that range (pp. 34430-34438), including:
 - The weight placed on the epidemiologic evidence, the controlled human exposure evidence, the exposure/risk information, and the uncertainties associated with each of these.
 - The use of available information on the NO₂ concentration gradient around roadways (i.e., that concentrations near roadways can be 30 to 100% higher than concentrations in the same area but not near the road) to inform an appropriate range of standard levels.
 - The most appropriate part of the proposed range in which to set the standard level given the available scientific evidence, exposure/risk information, NO₂ air quality information, and the uncertainties associated with each.
3. With regard to the standard level, EPA also solicited comment on:
 - Appropriateness of setting a standard level above 100 ppb and up to 150 ppb, recognizing the uncertainties of the scientific evidence. (p. 34438)
 - Appropriateness of setting a standard level as low as 65 ppb (30% higher than an area-wide concentration of 50 ppb), based on considerations that near-road concentrations may be determined to be closer to 30% higher than area-wide concentrations or to the extent that additional emphasis is placed on the possibility that exposures to NO₂ concentrations below 100 ppb could increase airway responsiveness in some asthmatics. (p. 34438)
4. Appropriateness of the proposed forms for a 1-hour daily maximum standard (pp. 34429-34430), which are (i) a three-year average of the 99th percentile of the annual distribution of daily maximum 1-hour average concentrations and (ii) a three-year average of the annual 4th-highest daily maximum 1-hour average concentrations. EPA also solicited comment on both a three-year average of the 98th percentile or a three-year average of the 7th- or 8th-highest forms., noting that "a 98th percentile form could be appropriate, particularly for standard levels at the low end of the range considered in the REA".

5. Appropriateness of retaining the current annual standard to provide protection against health effects potentially associated with long-term exposures to NO₂. (p. 34439)

Proposed Monitoring Network Requirements:

1. Appropriateness of the proposed two-tier monitoring network design to provide data for comparison with both a new 1-hour standard and the existing annual standard. As proposed, the first tier would be comprised of monitoring in areas of expected maximum 1-hour concentrations, such as near major roads (where no significant monitoring is currently being done), and the second tier would be comprised of area-wide monitoring, such as is currently being done. (pp. 34441-34442)

2. Appropriateness of proposed minimum monitoring requirements for monitoring near major roads in larger urban areas, with minimum requirements triggered for metropolitan areas based on population thresholds and the traffic-related metric annual average daily traffic (AADT). Appropriateness of proposal that Regional Administrator would have discretion to require additional monitoring as necessary to address situations where the required near-road monitors do not represent a location where the expected maximum hourly NO₂ concentrations exist in an urban area (such as a location downwind of a stationary source). (pp. 34442-34445)

3. Appropriateness of proposed minimum monitoring requirements for monitoring at area-wide spatial scales, with minimum requirements triggered for metropolitan areas based on a population threshold, and the proposal that a Regional Administrator would have discretion to require additional monitoring on a case-by-case basis. (p. 34445).

4. Appropriateness of proposed data quality objectives for the proposed NO₂ network, which are meant to identify acceptable measurement uncertainty. (p. 34446, second column, first full paragraph)

II. ALTERNATIVE APPROACH (not proposed)

Alternative Approach to setting level of new short-term standard:

1. EPA solicited comment on, but did not propose, an alternative approach to setting a new 1-hour NO₂ primary standard. Under this approach, the standard level would reflect the maximum allowable NO₂ concentration measured at an area-wide monitoring site (such a site would not be located in close proximity to major roads and, for a given area, would not be the location of the maximum NO₂ concentration anywhere in that area) (pp. 34438-34439).

2. In conjunction with this alternative approach, EPA solicited comment on a lower range of levels (≥ 50 to ≤ 75 ppb) to provide a similar degree of public health protection to that intended by the proposed approach and proposed range of levels (in conjunction with the same forms as those proposed). (pp. 34438-34439).

Monitoring network requirements associated with alternative approach to setting standard:

1. EPA solicited comment on, but did not propose, an alternative monitoring network design to complement the alternative approach to setting a new 1-hour standard, in which only monitors sited at area-wide spatial scales (not near-road monitors) are required, which is identical to the second tier of the proposed monitoring network except for having a different population threshold for minimum required monitoring. (pp. 34445-34446).
2. In conjunction with this alternative approach network design, EPA solicited comment on the appropriate definition of area-wide NO₂ concentrations and how best to use data representing these concentrations to determine compliance with a 1-hour standard reflecting the alternative approach of selecting a level for maximum area-wide concentrations on which EPA is seeking comment. (pp. 34445-34446).

III. MONITORING METHOD for NO₂

1. No revision was proposed for the NO₂ monitoring method, but comment was solicited on the advantages and disadvantages of advancing technology, such as the photolytic-chemiluminescence method or the use of existing open-path or remote sensing FRM and FEM technology as alternative methods to supplement the approved chemiluminescence FRMs already deployed across the US at NO₂ monitoring sites (pp. 34439-34440)

**Attachment E: Preliminary Draft Text to Assist CASAC Oxides of Nitrogen Primary NAAQS Panel
Deliberations at the August 10, 2009 Public Teleconference Call**

Please Do not Cite or Quote -- This draft text is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered CASAC and does not represent EPA policy.

Health Standards-Related Issues

Appropriateness of the proposed range of standard levels (≥ 80 ppb and <100 ppb), the rationale supporting that range, and alternatives described in the proposal including: The weight placed on the epidemiologic evidence, the controlled human exposure evidence, the exposure/risk information, and the uncertainties associated with each of these.

As noted in the Federal Register (July 15, 2009, pg. 34436): "In making judgments regarding the weight to place on the scientific evidence and exposure/risk information, the Administrator has considered the results of epidemiologic studies, controlled human exposure studies, and exposure/risk analyses as well as the uncertainties associated with this evidence and these analyses. Specifically, she notes the following: The ISA concluded that epidemiologic studies provide the strongest support for the relationship between short-term exposure to NO₂ and respiratory morbidity. "

While it is recognized that the epidemiologic studies likely included people exposed along roadways among those affected populations, those epidemiologic studies that are relied upon by the Administrator (e.g., those displayed in Figures 4 and 5 of the Federal Register) did not generally use near-roadway exposure data, but instead usually relied upon conventional area-wide monitoring in developing their reported NO₂-health effects associations relied upon by the Administrator. As such, in the face of a lack of sufficient near-roadway health effects studies to develop direct exposure-health effects relationships, CASAC has concerns about including near-roadway concentrations in the standard-setting process at this time, feeling that the standard would better be set on the same area-wide monitoring basis as employed in the epidemiologic studies upon which it now relies.

As indicated in the Federal Register on the proposed Rule with regard to the level and form of a new short-term NO₂ standard, the Administrator indicated that in using the results of the epidemiological studies, controlled human studies, and exposure/risk analyses to inform her decisions, the uncertainties associated with these analyses were considered. Issues of both confounding by co-occurring pollutants as well as the clinical significance of NO₂-associated changes in airways responsiveness in asthmatics are reported to have played important roles in the Administrator's decisions. CASAC similarly considered these issues in its deliberations. These considerations led to our original suggestions that because there did not appear to be a threshold for the occurrence of excess risk in the epidemiological studies and greater than 50% of asthmatics exposed to 100 ppb of NO₂ in clinical studies had increases in airways responsiveness and that such changes in asthmatic children would be considered an adverse outcome, that the maximum proposed standard should not exceed 100 ppb. Thus, the issue of uncertainty relates to the degree of protection below 100 ppb that should be considered.

As part of the rule making consideration, with regard to alternative approaches to setting the standard (page 44438) the Administrator has sought comments as to how uncertainty should be treated if either the standard were to exceed 100 ppb or be below the level of 65 ppb. There

**Preliminary Draft Text to Assist CASAC Oxides of Nitrogen Primary NAAQS Panel
Deliberations at the August 10, 2009 Public Teleconference Call**

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1 seems little biological question or uncertainty that the occurrence of increased airways
2 responsiveness in a substantial fraction of asthmatic children results in clinically significant
3 exacerbation of their disease. Raising the standard to above 100 ppb (proposed for consideration
4 is 150 ppb) would with a high degree of certainty only increase the fraction of asthmatic subjects
5 who would be responsive and thus cannot be justified. Since below 100 ppb there are no clinical
6 studies, the only information that can be used is that those individuals studied at 100 ppb
7 necessarily represented mostly mild asthmatic subjects. Thus, it is likely with a moderate degree
8 of certainty that more severe asthmatics would be more responsive and potentially more likely to
9 respond at levels below 100 ppb. .

10 With regard to a lower bound of the potential range of the standard the Administrator
11 requested comments on essentially two issues. One relates to how the monitoring site would
12 affect exposure (see para xx of this letter). The second is how the uncertainty regarding the issue
13 of co-pollutants would affect the consideration of level. The data on co-pollutants presented in
14 the ISA and considered in the REA suggest that despite the potential for confounding, the
15 estimates for NO₂ effects remain robust in the multi-pollutant models, "...and that the evidence
16 supports a direct effect of NO₂ exposures on respiratory morbidity, independent of associations
17 with other traffic-related pollutants" (page 34436). Since there does not appear to be evidence
18 for a threshold risk in the epidemiologic data, the uncertainty with regard to the lower bound is
19 much more impacted by the judgment of the appropriateness of the monitoring site in its
20 translation to the population exposure estimates, rather than an issue of co-pollutants. Given the
21 potential for mixing in ambient atmospheres, there is little likelihood to suggest that the
22 directionality of the correlation of co-pollutants would substantially change at lower levels of
23 NO₂ exposure (they might change at higher levels depending upon local sources). Further, given
24 what is known about the additive responsiveness of the respiratory tract to multiple
25 environmental agents, and that no threshold can be identified, the risk from NO₂ would appear to
26 remain linearly related to the shape of the response curve. Thus, consideration by the
27 Administrator of what level would afford an adequate margin of safety should not be impacted
28 by uncertainty of effects of co-pollutants.

29
30 Appropriateness of the proposed forms for a 1-hour daily maximum standard (pp. 34429-34430),
31 which are (i) a three-year average of the 99th percentile of the annual distribution of daily
32 maximum 1-hour average concentrations and (ii) a three-year average of the annual 4th-highest
33 daily maximum 1-hour average concentrations.

34
35 CASAC recognizes the importance of considering the combination of form and level in setting
36 the NO_x NAAQS. As requested, we have considered the Administrator's alternate proposal for
37 an area-wide standard with a proposed range of 50 to 75 ppb. Based upon the epidemiologic and
38 controlled human studies described in the ISA and REA, we maintain our previously
39 communicated opinion that an area-wide standard should be below 100 ppb and the standard
40 should be set at the lower end of a range from 80 to 100 ppb. Previously (Samet 2008), we
41 recommended that the percentile which is chosen for a one-hour standard must be appropriate for
42 a health protective level and propose that 98th and 99th percentile forms would be appropriate
43 for a standard level at the lower and upper boundaries of the proposed range, respectively. In

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1 considering the current annual standard, we concur with the Administrator's recommendation
2 that the annual standard be retained. This is based upon the limited evidence related to potential
3 long-term effects of NO₂ exposure and the lack of evidence that a new short-term standard of 1-
4 hour would protect against long-term effects.
5

6
7 **Monitoring/Network Design**
8

9 **I. General Comments on Proposed NO₂ Monitoring Requirements**

10 Uniformly uncomfortable with using a new roadside monitoring network for attainment
11 demonstration. In addition to concerns that past epidemiological studies and recent CASAC
12 deliberations were based on measurements from monitors more representative of areal NO₂
13 levels, a number of additional issues were raised that are specific to roadside monitoring and
14 their use in attainment demonstration, including issues specific to the proposed rule:
15

- 16 A. Roadside monitors will be more susceptible to very extreme events because they are
17 nearer to sources and more susceptible to periods of episodically high emissions, low
18 dispersion and other events that could lead to high peak monitored levels that are not
19 reflective of more widespread levels (e.g., heavy congestion near a monitor, trucks idling
20 near the monitor, etc.). In the absence of more detailed roadside measurements, it would
21 be difficult to identify the causes of extreme near-road NO₂ concentrations, or to
22 understand how such extreme values are reflected in exposures of near-by urban
23 populations. Further analyses are needed to determine the causes and frequencies of
24 extreme, concentrations monitored by near-road monitors and to understand how such
25 peak concentrations relate to those measured in the current, population-orientated
26 network.
- 27 B. The concentrations monitored will be very sensitive to the specific location of near-road
28 monitors, including exact distance from the roadway, height(s) of monitor inlet(s),
29 orientation with respect to prevailing wind directions (during peak traffic periods), etc.
30 Differences in the microscale environments of different roadside monitors may result in
31 one area being out of attainment even though it actually has similar, and possibly lower,
32 maximum NO₂ levels to another. This possibility also exists for area-representative
33 monitoring, but the likelihood is reduced since the monitors are not trying to capture the
34 extreme end of the distribution. Various practical logistical considerations are likely to
35 further constrain the options for establishing new roadside monitoring sites. This could
36 lead to an area trying to "follow the rules" but settling for a location that has lower
37 maximum values. Unless siting criteria are very tightly constrained, data will not be
38 directly comparable across different sites, and the value of a large multi-site network will
39 be limited.
- 40 C. Identifying the location of maximum NO₂ levels will be quite difficult, and the proposed
41 approach will likely miss where the maxima would occur. The proposed approach is
42 insufficient, being based primarily on traffic count. Diesel trucks emit more NO_x than
43 cars, and it would be expected that the actual maximum levels would be found in areas of

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1 high diesel activity (including rail yards and shipping) with reduced dispersion (e.g.,
2 street canyons). Open freeways that have high usage by light duty vehicles would not
3 necessarily have the highest levels. In the design of a network to identify the maximum
4 NO₂ levels in an area, we would support a more broad assessment to locate the locations
5 of the likely highest NO₂ levels based upon investigation of model results (e.g., CMAQ
6 and LUR, and Gaussian plume, if available) and emissions inventories. One could also
7 use diesel truck activity as well (the traffic data bases include activities by various classes
8 of vehicles)

9 D. The expected high spatial variability of roadside NO₂ concentrations also raises questions
10 about the spatial representativeness of roadside monitor results. How large a non-
11 attainment area is defined by a roadside violation? What population (if any) is assumed to
12 be affected by the roadside concentrations? What is the public health message (avoid this
13 state, AQCR, county, roadway, intersection, sidewalk)? Will the daily AQI for the
14 county be driven by the relatively highest measurement from among neighborhood-scale
15 (8-hr) ozone, (24-hour) PM_{2.5} monitors and roadside 1-hour NO₂ – the latter of which by
16 design does not represent the populations covered by the PM and O₃ monitors? Would an
17 effective control strategy be to reroute traffic from the high-speed urban freeway (with
18 the monitor) onto low speed urban residential streets (without monitors)?

19 E. A new roadside monitoring network with hundreds of sites with just NO_x monitors and
20 meteorological instrumentation would provide significantly less information than a
21 smaller roadside network with more comprehensive measurements to better characterize
22 near-road exposures to and gradients for the complex mixture of mobile source
23 pollutants. In addition to NO₂, NO and meteorology, such monitoring should include CO,
24 continuous PM, with speciation as possible (e.g., include EC or BC, continuous nitrate
25 and sulfate, as possible, and possibly CO₂ and gaseous VOCs). Such an alternative
26 network, as discussed below, would not be designed to have all monitors necessarily
27 placed in locations with the highest NO₂, but would also include locations that are
28 impacted by heavy duty vehicle emissions, light duty vehicle emissions and suspended
29 road dust, as well. It may, or may not, be oriented towards areas with minimal dispersion
30 (street canyons).

31 F. The justification for the meteorological measurements is unclear in regards to assessing
32 attainment. The need for, and uses of, such data should be better supported. CASAC
33 would find such monitoring very useful at comprehensive monitoring sites.
34

35 CASAC strongly supports a special purpose monitoring network oriented towards roadside
36 monitoring that is not used for attainment purposes at this point, and it would not be designed
37 specifically to identify the locations of maximum NO₂ in an area. It would be designed to
38 characterize pollutants in areas with high exposure to traffic-derived pollutants of all types,
39 including heavy duty and light-duty vehicle emissions, tire and break wear and road dust, and
40 would include pollutants beyond NO and NO₂ as discussed above. Detailed meteorological
41 measurements would be well justified at these more intensive sites, as would automated traffic
42 counters. These data would not be used for attainment demonstration.
43

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1 Further, such a special network would specifically include variability in terms of site location
2 (different distances to the facility, different highway characteristics) and type of monitoring done
3 to provide the type of data that would better inform our understanding of pollutant dynamics,
4 control strategy effectiveness and how a future road-side network should be designed for use in
5 attainment decisions and standard setting. Further, such a network should go in quickly to
6 capture the changes in emissions that are occurring in response to various controls. Funding for
7 such special purpose monitoring may have to come predominantly from EPA. One approach
8 would be through competitive grants to state and local agencies. The network would likely be
9 much more limited in number (possibly on the order of 20 to 50 sites: the network could evolve
10 with time), which would be appropriate given the objectives. A single city might have multiple
11 near-road special purpose monitors to address issues in siting near-road monitors, and to
12 understand relationships between roadside concentrations and larger population exposures.
13 Cities with various characteristics should be chosen for assessing near-road monitoring issues.
14 This approach appears to fit well with a recent EPA document, "Ambient Air Monitoring
15 Strategy for State, Local, and Tribal Air Agencies," that states:

16
17 "With this background, EPA's Strategy currently recognizes (1) the importance of near
18 roadway exposures, and (2) the need for further exploration of the meaning of these
19 exposures to both NAAQS-oriented monitoring networks and air toxics networks.
20 Monitoring near roadways has, to date, been limited to research-level monitoring. As
21 monitoring networks evolve, it is vital that monitoring near roadways be further
22 investigated and eventually integrated into the monitoring networks. Currently, EPA and
23 others continue to evaluate strategies for incorporating this monitoring into the other
24 components of the monitoring Strategy primarily as a means of determining health risks
25 and impacts on urban attainment. EPA intends to consult with SLTs and other
26 stakeholders about the eventuality of developing the near-roadway component of ambient
27 monitoring. The primary consideration would be to operate a small number of sites
28 spaced in varying geographical areas of the country in an initial attempt to address near-
29 roadway issues. Outcomes from EPA's Office of Research and Development's (ORD)
30 near-roadway studies that began in 2006 and extend through 2009 or 2010 would heavily
31 influence where, how, and when a near-roadway monitoring pilot would occur."

32
33 Assuming that the decision is made to not use near-road monitors for attainment demonstration,
34 CASAC strongly supports further analysis of the current NO₂ data, diesel truck activity data,
35 model results and emissions inventories to identify where area-representative sites might be
36 placed to capture more broad areas of higher NO₂ levels. For example, CMAQ results, if
37 available at a 4 or 12 km resolution, could be used to help inform analyses of locations with
38 likely higher area-wide NO₂ levels (though would be less informative of locations of the very
39 highest NO₂ levels in a city).

40
41 We question the need for monitoring in cities down to a population of 350,000. To be supportive
42 of this choice, we would need to see additional analysis to suggest that such locations have area-

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1 wide concentrations approaching 100 ppb. The population cut-off should be further justified,
2 e.g., by using related monitoring results or modeling.

3
4 A concern raised in regard to the current proposal was the suggestion that building tops may be
5 used. This should be done with caution as building tops may not be informative of much higher
6 levels in areas just below where dispersion is inhibited.

7
8 **1. Appropriateness of the Proposed two-tier monitoring network design**

9
10 If an appropriate level of further analysis and review were conducted to support a primary NO₂
11 NAAQS using roadside monitoring, the utility of a two-tier approach for attainment
12 demonstration is not apparent. The area-wide monitoring would support showing progress in
13 reducing NO_x for NO₂, ozone and PM control programs, and would also continue to support
14 health analyses. Whereas new roadside measurements of NO₂ alone, would provide minimal
15 information on near-road multi-pollutant exposures, and would have questionable value in
16 supporting future health studies.

17
18
19 If there is a mechanism to begin roadside monitoring, but not include such data in attainment
20 determination, then a two tier mechanism is potentially attractive for support of health studies
21 that could be used in future NAAQS reviews. However, such monitoring should not be for just
22 NO and NO₂, but should include CO, continuous PM mass, and continuous TC/EC (or BC).
23 Without this additional data, the results would be significantly less informative. If, as part of the
24 current CO and PM reviews, a network of roadside monitoring of all of these species were
25 proposed, it would be very attractive and could potentially be used in supporting a future
26 NAAQS revision for those species and would be more readily used in a multi-pollutant air
27 quality control program and determination of control effectiveness. NO/ NO₂ alone would not
28 be overly informative.

29
30
31 **2. Appropriateness of proposed requirements for near major roads**

32 Again, a similar problem exists (that a roadside monitoring network for attainment
33 demonstration is not currently supported). The determination should be based on modeling
34 of peak NO₂ levels, and related air quality data analysis, and should take in to account
35 population density. Specific criteria to be followed by the RA and the State/Local agencies
36 should be further developed and reviewed, e.g., by the CASAC Ambient Air Quality
37 Standards Committee (AAMS).

38
39 3. Giving the RA some discretion is appropriate, though it is not apparent that further area-wide
40 monitoring is needed, and any changes and additions should largely come from analysis of NO₂
41 data and modeling results. Specific criteria to be followed by the RA and the State/Local
42 agencies should be further developed and reviewed, e.g., by the AAMS.

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- 1 3. Data quality objectives are fine.
2

3 **II. Alternative Approach.**
4

5 First, we prefer the alternative approach, and the standard should be, as CASAC advised, about
6 0.10 ppm. (We should look up how it was phrased.)
7

- 8 1. Area wide monitoring is appropriate, and would be similar to the system currently
9 employed. Preferably the NO/ NO₂ monitoring would be done in locations that include
10 CO, ozone and PM species monitoring as well.
11 2. We should follow the past CASAC recommendation.
12 3. Having the state/local air quality managers assess how the current network satisfies the
13 goal of providing data representative or area-wide (not maximum) concentrations is
14 appropriate. As noted above, the population threshold may be too low, and such a choice
15 needs further support and review. One could consider requiring that removing NO/ NO₂
16 monitors is not allowed, and repositioning would need to have RA approval. Having the
17 RA also have discretion to require additional monitoring to address community impacts is
18 justified.
19 4. The definition of “area-wide” is not very specific, though reflects the realities of
20 monitoring. It is now possible to use annual modeling to assess how representative a
21 monitor location is of more area-wide levels, and this should be employed to demonstrate
22 reasonableness of site locations. It would be good to specify a minimum distance that a
23 monitor could be placed from a major facility (including freeways and highways), e.g.,
24 that a monitor that is representative of area-wide NO/ NO₂ should not be placed within
25 100 m of a major facility (with a further definition of major facility in terms of expected
26 NO_x emissions. For roads this could be in terms of NO_x per 100m).
27

28 **III. Monitoring Method**
29

- 30 1. The chemiluminescent approach is appropriate. It would be good to improve and extend
31 the technique to give both true NO₂ as well as NO_y. However, that would not be viable
32 within the time frame of this rulemaking.
33 2. It is not apparent what the meteorological measurements contribute in terms of attainment
34 demonstration or understanding the processes leading to peak values as those processes
35 are already understood. The desire to have three dimensional winds, and the associated
36 standard deviations, appears more research-oriented. Further, there is no detail as to the
37 data quality requirements of the wind measurements. I did not find the desired time scale
38 used for determining the fluctuations in the wind velocities. It should also be noted that
39 sonic anemometry may suffer from instrument durability.
40
41

Attachment F: Comments on US EPA's Proposed Revisions to the NO₂ NAAQS

**Julie E. Goodman, Ph.D., DABT
Gradient Corporation, Cambridge, MA**

**on behalf of the American Petroleum Institute
August 10, 2009**

EPA conducted a meta-analysis of controlled exposure studies in asthmatics and concluded that short-term exposure to 0.1 ppm NO₂ can cause increases in response to nonspecific airway challenges. Gradient conducted more rigorous meta-analyses and meta-regressions, including 10 additional studies, and using more current and appropriate meta-analysis techniques. Gradient found there is no evidence to suggest that NO₂ leads to significant adverse effects at any of the exposures tested, up to 0.6 ppm. Furthermore, according to the NO₂ REA, the current annual NO₂ NAAQS of 0.053 ppm protects against short term exposures of 0.4 ppm and higher and there are no nonattainment areas at the current annual standard. **Thus, the data do not support a short term standard for NO₂.**

One difference between our analysis and EPA's analysis is that EPA evaluated only the fraction affected in a limited number of available studies, but did not evaluate the dose-response or other measures of effect. We assessed dose-response in a number of ways. We conducted meta-analyses for 0.1 ppm exposure increments and conducted meta-regressions. We also did not limit our analysis to the fraction of subjects with effects, but looked at the difference of ΔFEV_1 ($\Delta\Delta FEV_1$) following and airway challenge and provocative dose (ΔPD) of and airway challenge with and without NO₂ exposure. In no case did the dose-response approach statistical significance. In addition, there is no indication that any effects could be considered adverse. For example, the changes in ΔFEV_1 for each study ranged from +1.5% to -5.3%, with the meta-effect of -1.6%. Although this slightly differs from 0, it is highly statistically significantly different from 15%, the ΔFEV_1 that is considered adverse.

While statistically significant effects were found in our meta-analysis, these are highly unlikely to be a result of NO₂ exposure for a few reasons. The associations didn't hold for high exposures, and it does not seem biologically plausible that lower exposures cause effects while higher exposures do not. We also assessed the associations in studies using chamber exposures only. With one exception, there were no statistically significant effects on fraction affected or $\Delta\Delta FEV_1$ at any exposure or overall, suggesting mouthpiece exposures could have contributed to some of the observed statistical significance in the main analyses. It should also be noted that the assumptions made in our analyses were biased

towards finding an effect. This also could have contributed to statistically significant results in the meta-analyses.

For EPA to conclude that the clinical studies show effects at 0.1 ppm NO₂ and perhaps lower, there would need to be significant dose-response associations. This is not the case. There is no dose-response whatsoever, suggesting any statistical significance observed at specific doses is not a result of NO₂, but rather chance or some other factor. In addition, epidemiology studies do not support associations at lower exposures, as they generally report statistically significant findings in single-pollutant, but not multi-pollutant, models, and no finding is large, robust, or consistent. **Together, these data do not support a short-term standard for NO₂.**

Figure 1. Association between NO₂ exposure and the fraction of asthmatics with greater airway hyper-responsiveness following NO₂ exposure

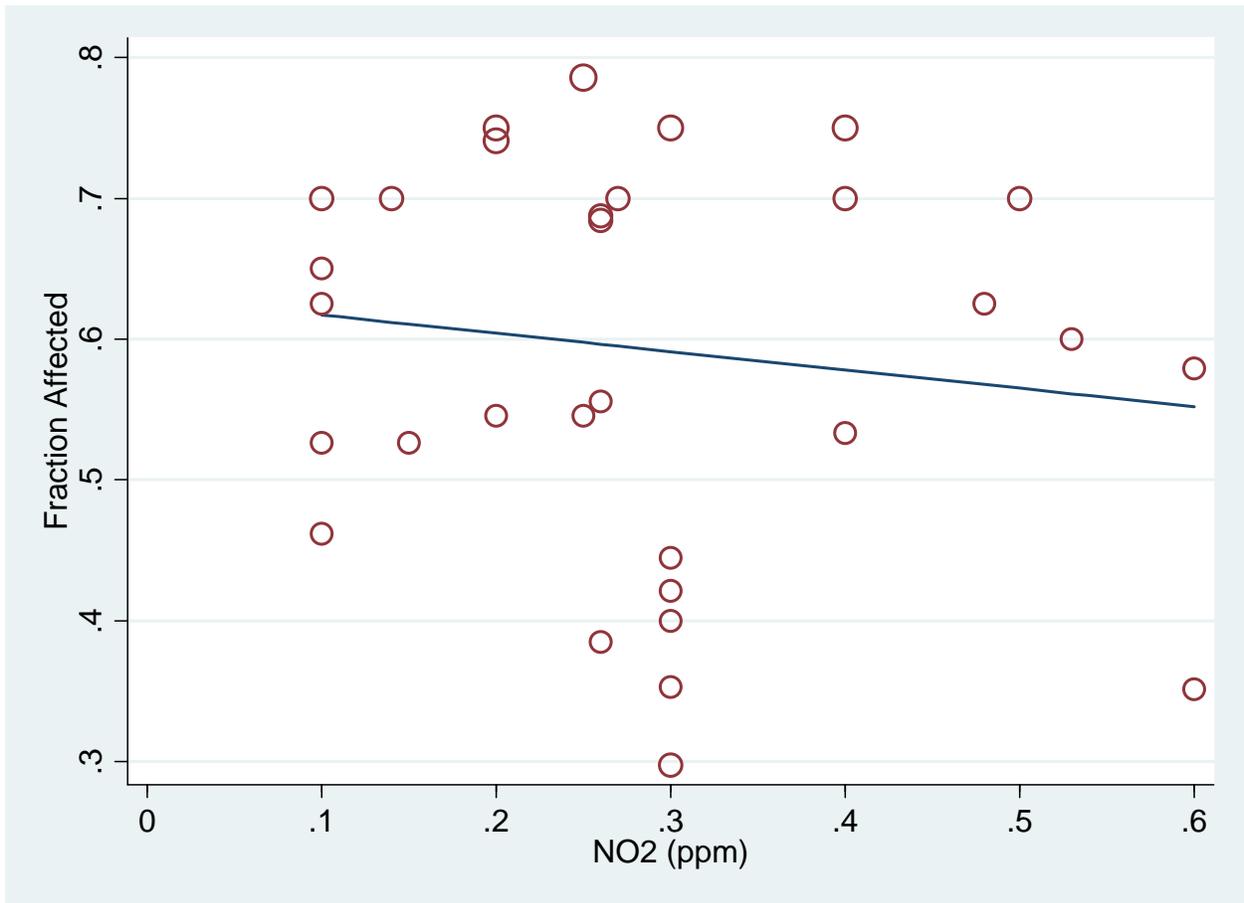


Figure 2. Association between NO₂ exposure and the difference between airway challenge provocative dose following exposure to NO₂ vs. air based on summary statistics (Δ PD_g)

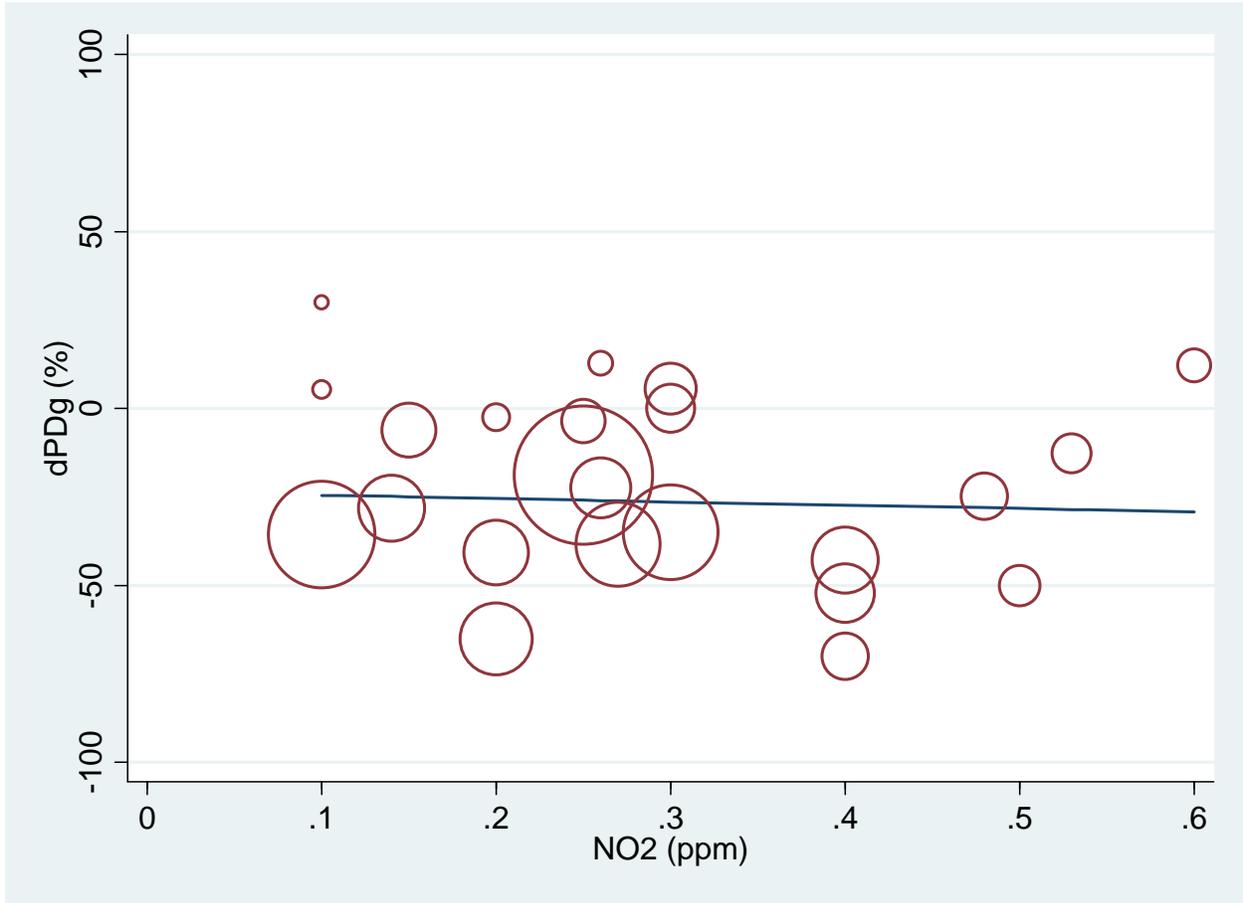


Figure 3. Association between NO₂ exposure and the difference between airway challenge provocative dose following exposure to NO₂ vs. air based on individual data (Δ PD_i)

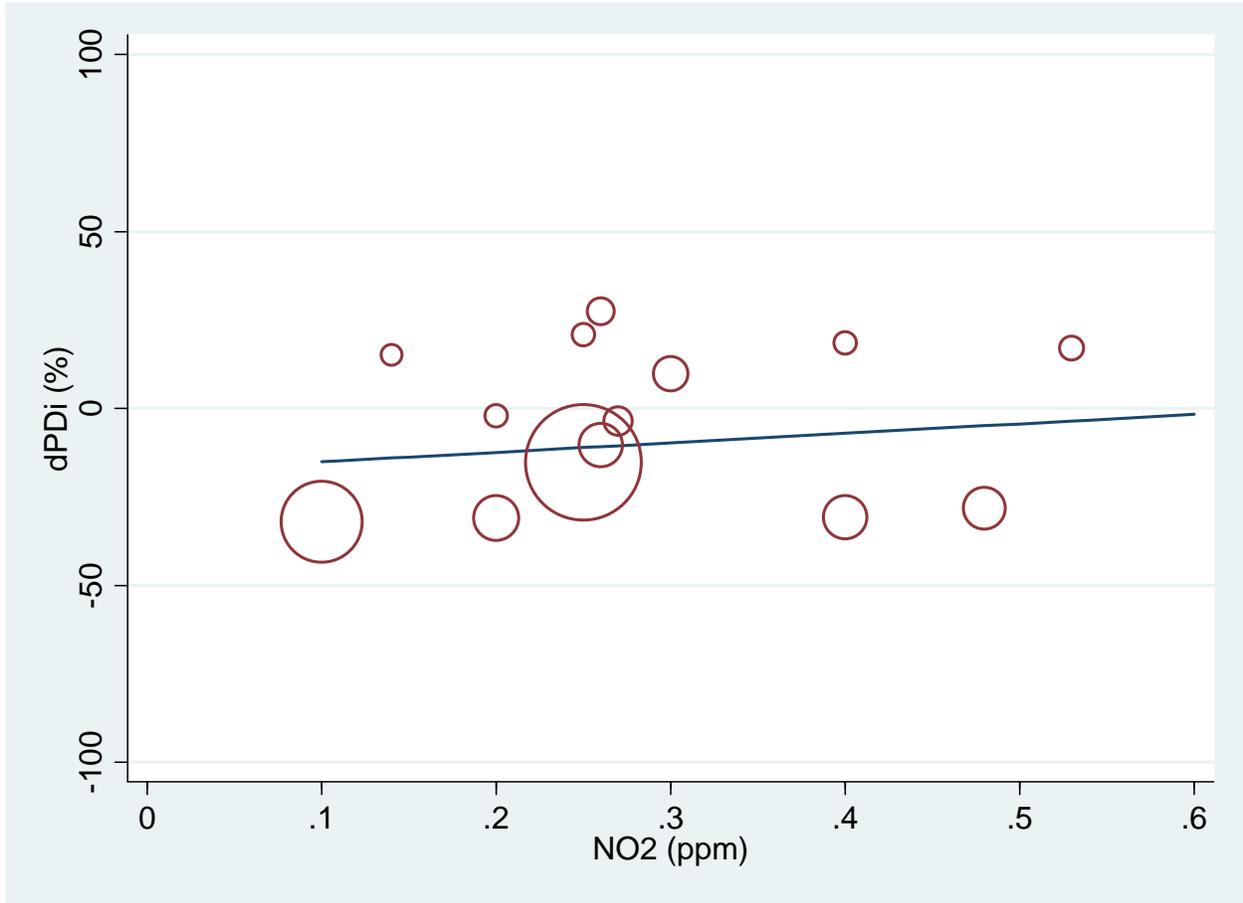
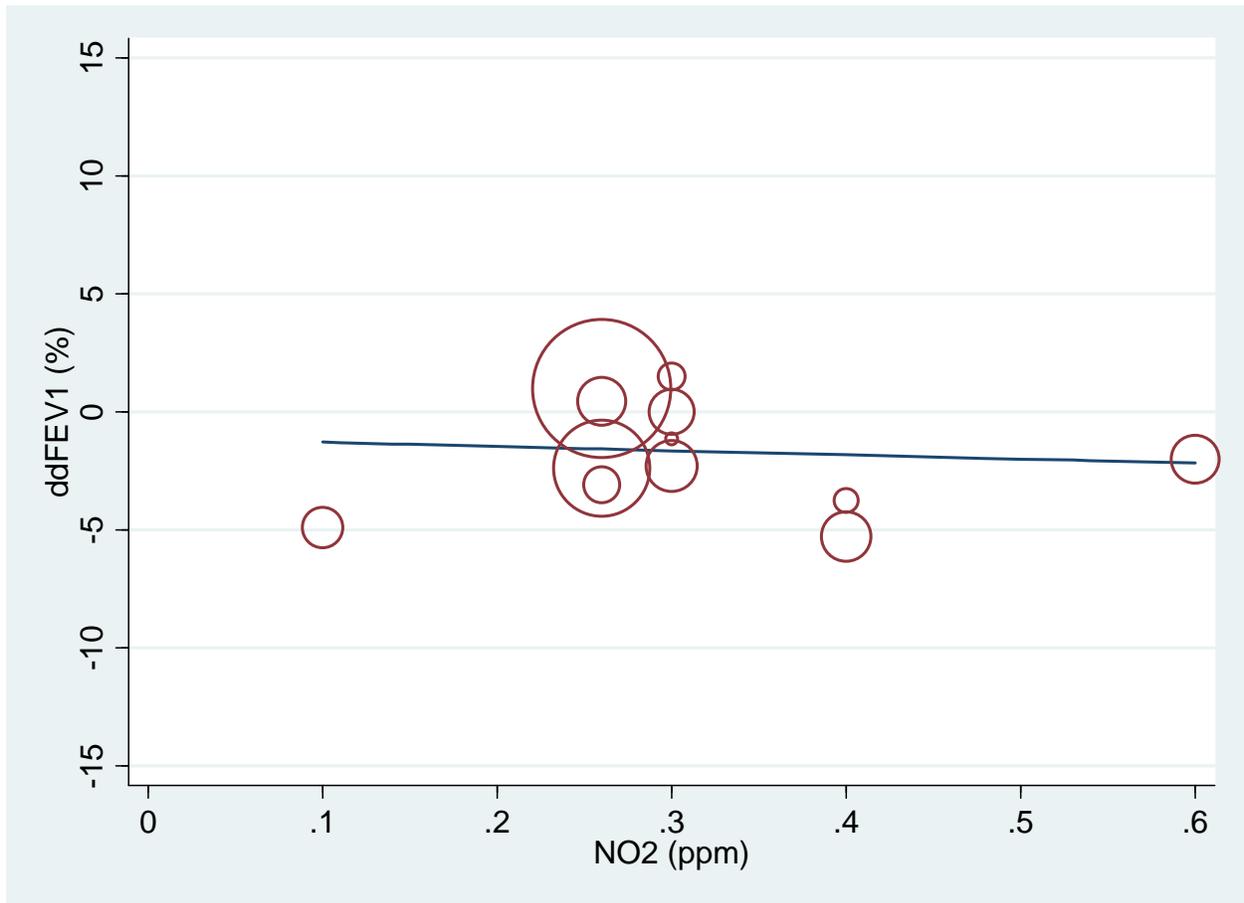


Figure 4. Association between NO₂ exposure and the differences between the change in FEV₁ induced by an airway challenge following exposure to NO₂ vs. air ($\Delta\Delta$ FEV₁)



**Attachment G: Statement of Janice E. Nolen
Assistant Vice President, National Policy and Advocacy
American Lung Association**

to the Clean Air Scientific Advisory Committee

**On EPA's Proposals for the
National Ambient Air Quality Standards for Nitrogen Dioxide**

August 10, 2009

My name is Janice Nolen, and I'm assistant vice president of national policy and advocacy for the American Lung Association.

Since 1971, the U.S. has had one standard for nitrogen dioxide: an annual average concentration of 53 parts per billion. The Lung Association is pleased that EPA has now proposed a second standard to protect against shorter, peak exposures—a standard that would limit one-hour episodes.

This important addition moves us in the right direction. We need both an annual and a short-term standard.

However, we believe that EPA is underestimating what is needed to protect the health of the public, especially those 36 million people who live near or work on or near transportation routes.

The American Lung Association recommends EPA adopt a one-hour standard of not more than 50 parts per billion set at the 99th percentile, and a stronger annual standard similar to the level that California adopted, 30 parts per billion.

We applaud the proposal for a national network of nitrogen dioxide monitors located near highways. This must be only the beginning of what is truly needed—comprehensive transportation monitoring for the other pollutants, including particulate matter.

We disagree with the proposal that would trade off these monitors in return for setting the standard at a more protective level. We need much tighter standards. We need a transportation monitoring network. We need EPA to take both steps to protect the health of those most at risk. The Lung Association does not believe that the level of a national air quality standard should depend on the extent of the monitoring.

With respect to the proposed hourly standard, the meta-analysis of clinical studies provides clear evidence of harm for adults with mild asthma breathing NO₂ at levels within the proposed range. To protect against harm to these adults, much less to children, seniors or anyone with more severe asthma or other lung disease, requires a much lower level. Further, the

epidemiological studies, point to more serious health effects, occurring at much lower concentrations of NO₂.

In addition, the exposure assessment, risk assessment, and air quality analysis all demonstrate that of the options considered, only an hourly standard of no more than 50 ppb would protect against harm from peak exposures.

EPA may be making the assumption that the one-hour standard represents anticipated traffic exposures. If so, we disagree. Traffic in far too many cities has grown into a constant stream. To protect people who live or work near highways against nitrogen dioxide exposures, a stringent long-term standard is needed.

Thank you.