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 NAAQS Review Panel
Public Meeting
September 9-10, 2008

Committee Members: (See Roster – Attachment A)

Scheduled Date and Time: From 8:30 a.m. to 5:30 p.m. (Eastern Time) on September 9, 2008; and from 9:00 a.m. to 2:00 p.m. (Eastern Time) on September 10, 2008. (See Federal Register Notice, Attachment B)

Location: Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC, 27703

Purpose: To conduct a peer review of EPA's *Risk and Exposure Assessment (REA) to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft*

Attendees: Panel Members:

Dr. Rogene Henderson
Dr. Ed Avol
Dr. John R. Balmes (by phone)
Dr. Ellis B.Cowling (09-10-08 only)
Dr. James Crapo (in person, 09-09-08; by phone, 09-10-08)
Dr. Douglas Crawford-Brown (by phone)
Dr. Terry Gordon
Dr. Dale Hattis (by phone)
Dr. Donna Kenski
Dr. Patrick Kinney
Dr. Steven Kleeberger
Dr. Timothy Larson
Dr. Kent Pinkerton
Dr. Edward Postlethwait
Dr. Armistead (Ted) Russell
Dr. Jonathan Samet (in person, 09-09-08; by phone, 09-10-08)
Dr. Richard Schlesinger (by phone, 09-09-08 only)
Dr. Christian Seigneur
Dr. Elizabeth A. (Lianne) Sheppard
Dr. Frank Speizer (by phone, 09-09-08 only)
Dr. George Thurston
Dr. James Ultman (by phone)
Dr. Ronald Wyzga

SAB Staff Office: Dr. Angela Nugent, EPA SAB Staff Office, Designated Federal Officer (DFO)

Dr. Anthony Maciorowski, Deputy Director of the EPA SAB Staff Office

EPA Participants Listed on the Agenda

Ms. Lydia Wegman, (EPA OAR)
Dr. Stephen Graham (EPA OAR)
Mr. Harvey Richmond (EPA OAR)
Dr. Scott Jenkins (EPA OAR)

Meeting Summary – September 9, 2008

The discussion addressed the topics included in the Proposed Meeting Agenda (See Meeting Agenda - Attachment C) and 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 public meeting at 8:35 a.m. She noted that the panel complied with the requirements of the Federal Advisory Committee Act and that the SAB Staff Office had determined that members were in compliance with the Ethics and Government Act, as it related to the charge before CASAC. Dr. Anthony Maciorowski welcomed CASAC panel members and thanked them for their work. Dr. Rogene Henderson thanked members for the pre-meeting comments and reviewed the agenda.

Introduction to Second Draft Risk and Exposure Assessment (REA) for Nitrogen Dioxide (NO_2)

Ms. Lydia Wegman reviewed the schedule for completing the REA, including completion of chapter 8 on exposure, and the schedule for drafting an Advance Notice of Proposed Rulemaking for CASAC review in January. She noted that she wished to do additional planning, after reflecting on the September 8, 2008 letter from the Deputy Administrator to Dr. Henderson about the NAAQS review process. She stated that she may have additional information for the CASAC on the oxides of nitrogen (NO_x) schedule soon after the panel meeting.

Dr. Stephen Graham, Mr. Harvey Richmond, and Dr. Scott Jenkins gave an introduction to EPA's Second Draft *Risk and Exposure Assessment* (see Attachment D). The CASAC panel members posed clarifying questions to assist them in addressing the charge questions provided by the Agency (Attachment E).

First Public Comment Period

Dr. Angela Nugent introduced two members of the public who requested the opportunity to provide public comment.

The first commenter was Dr. Shelley Green from the Office of Environmental Health

Hazard Assessment of California EPA. Dr. Greene discussed her Office's regulatory approach to $NO_{x.}$ Her presentation is included in Attachment F. Next, Dr. Deborah Shprentz spoke on behalf of the American Lung Association. She spoke of the evidence of adverse respiratory effects in asthmatics. Her written statement is included as Attachment G.

<u>Members' Discussion and Deliberation</u>

After the public comments were complete, the panel proceeded to discuss and deliberate on the charge questions related to the ISA, (see Attachment E), as described in the agenda.

At 10:15, EPA Administrator Stephen L. Johnston joined the teleconference. He announced that he had named Dr. Jonathan Samet as the new chair of CASAC at the conclusion of Dr. Henderson's term. He recognized Dr. Henderson's service and contributions to the NAAQS review. Dr. Anthony Maciorowski then thanked Dr. Douglas Crawford Brown for his service as a CASAC member and announced that Dr. Joseph Brain and Dr. Christpher Frey had been appointed by the Administrator to begin their service as CASAC members at the start of Fiscal Year 2009.

The members discussed characterization of health effects evidence and selection of potential alternative standards for analysis and air quality modeling issues. After lunch, panel members received an update on the status of EPA's work on the exposure assessment chapter, Chapter 8, of the REA from Dr. Stephen Graham (see Attachment H). Dr. Jenkins mentioned that OAR would work to set up an advisory teleconference call with the DFO for CASAC panel review of this chapter once it was completed in early October.

The panel then discussed characterization of health risks and identified the need for a chapter that would summarize all the health, effects, and exposure analyses in the REA. The meeting on September 9th concluded with a writing and revising session for subgroups. The meeting recessed for the day at 5 p.m.

On September 10, 2008, the panel met to discuss a draft report (Attachment I), based on the previous day's discussion. Members revised the draft report and called for the following substantive changes:

- Insert language commending EPA for major improvements in the second REA.
- Remove the extended discussion of AERMOD that was part of the Panel's report on the first draft REA from the air quality discussion of the second draft REA.
- Insert language calling for CASAC review of the completed REA. The next draft of the REA should include both a completed Chapter 8 and an integration of the results of all the analyses based on clinical and epidemiological studies.
- Insert language stating that the REA should develop a scientific foundation for any decision regarding retaining or revising the long term NAAQS for NO_2.
- Include discussion of multi-pollutants effects: i.e., including such language as "One uncertainty that needs to be mentioned is the possible effect of lowering the level of one pollutant on the level of co-pollutants." The document should address that multi-pollutant modeling in the risk assessment assumes co-pollutants are unchanged across alternative standards and should discuss implications for estimates."

- Insert language clarifying why EPA has chosen NO_2 was as an indicator for NO_x in the REA and that NO_x is the criteria pollutant identified in the Clean Air Act.

Second Public Comment Session

Mr. Robert Paine of ENSR Corporation presented public comments on behalf of the American Petroleum Institute (Attachment J).

Approval of Major Substantive Points related to the NO_2 REA Letter and Summary of Next Steps

In response to a question from the chair enquiring whether any panel member did not support the report going forward with the major points identified in the draft and panel discussion, no member opposed accepting the report. The Chair concluded the meeting with a brief discussion of next steps. She asked the DFO to work with her to revise and reformat the letter and circulate it to the panel for final edits. She also asked the DFO to work with the Agency on next steps for scheduling a review of Chapter 8 of the REA.

At the chair's request, the Designated Federal Officer adjourned the meeting at 11:30 a.m.

Respectfully Submitted:

/S/

Angela Nugent
Designated Federal Officer

Certified as True:

/S/

Rogene Henderson
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	Presentation: Overview of the First Draft Risk and Exposure Assessment to Support the NO_2 Primary NAAQS
Attachment E	Agency Charge Questions
Attachment F	Presentation from Dr. Shelley Green, Office of Environmental Health Hazard Assessment/CalEPA
Attachment G	Statement of Dr. Deborah Shprentz on behalf of the American Lung Association
Attachment H	Presentation: Overview of the Second Draft Risk and Exposure Assessment to Support the NO_2 Primary NAAQS
Attachment I	Draft Advisory Report for CASAC Discussion on September 10, 2008
Attachment J	Presentation by Mr. Robert Paine on behalf of the American Petroleum Institute

Attachment A: Roster

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

CHAIR

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

CASAC MEMBERS

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. 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. 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

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

CONSULTANTS

Dr. 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. 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. 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

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, Vice President, Atmospheric & Environmental Research, Inc., San Ramon, CA

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

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

Dr. George Thurston, Associate 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 Meeting of the CASAC Oxides of Nitrogen Primary NAAQS Review Panel

[Federal Register: July 25, 2008 (Volume 73, Number 144)]
[Notices]
[Page 43444-43445]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr25jy08-70]

ENVIRONMENTAL PROTECTION AGENCY

[FRL-8697-9]

Science Advisory Board Staff Office; Clean Air Scientific Advisory Committee (CASAC); Notification of a Public Advisory Committee Meeting 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 meeting of the Clean Air Scientific Advisory Committee's (CASAC) Oxides of Nitrogen Primary NAAQS Review

[[Page 43445]]

Panel (Panel) to conduct a peer review of the EPA's Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft.

DATES: The meeting will be held from 8:30 a.m. (Eastern Time) on Tuesday, September 9, 2008 through 2 p.m. (Eastern Time) on Wednesday, September 10, 2008.

ADDRESSES: The September 9-10, 2008 meeting will take place at the Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC

27703, telephone (919) 941-6200.

FOR FURTHER INFORMATION CONTACT: Any member of the public who wishes to submit a written or brief oral statement (five minutes or less) or wants further information concerning this meeting must 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 and the CASAC documents cited below can be found on the EPA Web site at http://www.epa.gov/casac.

SUPPLEMENTARY INFORMATION:

Background: 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 is a Federal advisory committee chartered under the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. The 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 ($NO_x$). EPA is in the process of reviewing the primary NAAQS for nitrogen dioxide ($NO_2$) as an indicator for $NO_x$. Primary standards set limits to protect public health, including the health of ``sensitive'' populations such as asthmatics, children, and the elderly.

CASAC has previously provided consultative advice on EPA's Integrated Review Plan for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide (August 2007) and conducted peer review of the first and second drafts of EPA's Integrated Science Assessment for Oxides of Nitrogen--Health Criteria. CASAC also provided consultative advice on EPA's Nitrogen Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment and conducted peer review of EPA's Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: First Draft. The CASAC advisory reports are available on the EPA Web site at http://www.epa.gov/casac. The purpose of this meeting is for CASAC to conduct a peer review of the Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft.

Technical Contact: Any questions concerning EPA's Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft should be directed to Dr. Scott

Jenkins, OAR (by telephone (919) 541-1167, or e-mail jenkins.scott@epa.gov.

Availability of Meeting Materials: EPA-OAR's Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft will be accessible via the Agency's Office of Air Quality Planning and Standards Web site at http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_rea.html on or about August 12, 2008. Agendas and materials supporting the meeting will be placed on the EPA Web site at http://www.epa.gov/casac before the meeting.

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: In general, individuals or groups requesting an oral presentation at a public meeting will be limited to five minutes per speaker, with no more than a total of one hour for all speakers. Interested parties should contact Dr. Angela Nugent, DFO, in writing (preferably via e-mail) by September 2, 2008 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 September 2, 2008, so that the information may be made available to the Panel for their consideration prior to this meeting. 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).

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 meeting, to give EPA as much time as possible to process your request.

Dated: July 21, 2008.

Anthony F. Maciorowski,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. E8-17093 Filed 7-24-08; 8:45 am].

Attachment C: Meeting Agenda

U.S. Environmental Protection Agency – Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
Oxides of Nitrogen (
) Primary Review Panel
Public Meeting
September 9-10, 2008
Marriott at Research Triangle Park, 4700 Guardian Drive, Durham, NC, 27703

Meeting Agenda

Purpose: to conduct a peer review of EPA's *Risk and Exposure Assessment (REA) to Support the Review of the* NO_2 *Primary National Ambient Air Quality Standard: Second Draft*.

<u>Tuesday, September 9, 2008</u>

8:30 a.m.	Welcome	Dr. Angela Nugent, EPA SAB Staff Office, Designated Federal Officer Dr. Anthony Maciorowski, EPA, SAB Staff Office
8:40 a.m.	Review of Agenda and Agency Charge Questions for the Peer Review of the Second Draft *Risk and Exposure Assessment*	Dr. Rogene Henderson, Chair
8:50 a.m.	Introduction to EPA's Second Draft *Risk and Exposure Assessment*	Ms. Lydia Wegman Dr. Stephen Graham Mr. Harvey Richmond Dr. Scott Jenkins EPA Office of Air and Radiation
9:20 a.m.	Public Comments	To be announced

Members' Discussion and Deliberations

9:35 a.m.	Characterization of Health Effects Evidence and Selection of Potential Alternative Standards for Analysis (Chapter 3, 4, and 5)	*Discussants*: Dr. James Crapo Dr. Jonathan M. Samet Prof. Avol Dr. John R. Balmes (by phone) Dr. Douglas Crawford-Brown (by phone) Dr. Terry Gordon Dr. Steven Kleeberger Dr. Kent Pinkerton Dr. Edward Postlethwait Dr. Richard Schlesinger (by phone) Dr. George Thurston
10:15	Break	
10:30	Continued Discussion of Health Effects	
11:15 a.m	Characterization of Air Quality (Chapters 2, 6, and 7)	*Discussants:* Dr. Armistead (Ted) Russell Dr. Christian Seigneur (by phone) Dr. Timothy V. Larson Dr. James Ultman (by phone) Dr. Dale Hattis (by phone) Dr. Donna Kenski
12:15 p.m.	Lunch	
1:15 p.m.	Characterization of Health Risks (Chapters 7, 8, and 9)	*Discussants:* Dr. Douglas Crawford-Brown (by phone) Q-1 Prof. Ed Avol Q-1 Dr. Terry Gordon (Q-2) Dr. Kent Pinkerton (Q-2) Dr. George Thurston (Q-3) Dr. Frank Speizer (Q-3) (by phone) Dr. John Balmes (Q-4) (by phone) Dr. Ellis Cowling
2:45 p.m	Break	
3:00 p.m	Update on Issues Relating to Exposure (Chapter 8 and a revised Appendix B)	Dr. Stephen Graham EPA Office of Air and Radiation
3:15 p.m	Exposure Issues	*Discussants*: Dr. Lianne Sheppard Dr. Patrick Kinney Dr. Ronald Wyzga
4:00 p.m	Writing and Revising Session for Subgroups	
5:00 p.m.	Recess for day	Dr. Angela Nugent

September 10, 2008		
9:00 a.m.	Reconvene the Panel Meeting	Dr. Angela Nugent
9:05 a.m.	Discussion of Draft Text	*Discussants:* Dr. James Crapo Dr. Lianne Shephard Dr. Armistead Russell Prof. Ed Avol Dr. Douglas Crawford-Brown (by phone)
10:30 a.m.	Break	
10:45 a.m.	Continued Discussion of Draft Text	
11:00 a.m.	Second Public Comment Period*	
11:30 a.m.	Lunch	
12:30 a.m.	Approval of Major Points Responding to Agency Charge Questions and to Other Issues	Chartered CASAC Members and Panel
1:30 p.m.	Summary of Next Steps	Dr. Rogene Henderson
2:00 p.m.	Adjourn the Meeting	Dr. Angela Nugent

*Members of the public wishing to provide short oral statement on the panel draft text are asked to contact the DFO in person or by email (nugent.angela@epa.gov) before 10 a.m. September 10, 2008

Attachment D

Presentation: Introduction to EPA's Second Draft *Risk and Exposure Assessment*

Overview of the Second Draft Risk and Exposure Assessment to Support the NO_2 Primary NAAQS

Presentation to CASAC

September 9, 2008

Overview of Presentation

- Timeline of current review
- Identification of potential alternative standards for analysis
- Identification of potential health benchmark levels
- Air quality analysis and risk characterization
- Epidemiology-based risk assessment
- To be discussed this afternoon: Status of exposure analysis and exposure-based risk characterization

2

Timeline for Review

Major Milestones		Projected Completion Date	Projected CASAC Review Date
Integrated Review Plan	Draft Final	April 2007 June 2007	May 2007
Integrated Science Assessment	First Draft Second Draft Final	August 2007 March 2008 July 2008	October 2007 * May 2008 *
Risk/Exposure Assessment	Plan First Draft **Second Draft** Final	September 2007 March 2008 **August 2008** November 2008	October 2007 * May 2008 * **September 2008**
Rulemaking	ANPR Proposed Final	December 2008 May 2009 December 2009	January 2009

*Indicates that a single CASAC meeting will address both documents

3

Alternative Standards for Analysis

- Indicator: NO_2
  - Majority of information regarding health effects and exposure is for NO_2
- Averaging time: 1-hour (daily max)
  - We focused analytic efforts on endpoints for which scientific evidence (as judged in ISA) is strongest
- Form: 98^{th} and 99^{th} percentiles averaged over 3 years
  - Goal is to provide a balance between protecting the public from peak NO_2 levels and providing a stable regulatory target
- Levels: based on epidemiology and controlled human exposure studies
  - For key U.S. epidemiologic studies, we identified $98^{th}/99^{th}$ percentile 1-hour daily maximum NO_2 levels from highest monitor
  - For controlled human exposure studies we focused on increased airway responsiveness in asthmatics
    - ISA concludes that "transient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control"
    - Findings on airway responsiveness contribute to the plausibility and coherence of epidemiologic evidence linking NO_2 and emergency department visits/hospitalizations

4

Identification of Alternative Standard Levels

- 0.20 ppm
  - Based on highest NO_2 levels associated with epidemiologic studies (2 studies in LA) and on 30-minute exposure levels associated with increased airway responsiveness in asthmatics
- 0.15 ppm
  - Based on providing margin of safety relative to 0.20 ppm and on the range of 1-hour and 30-minute exposure levels associated with increased airway responsiveness in asthmatics
- 0.10 ppm
  - Based on NO_2 levels associated with epidemiologic studies in several cities (NYC, Atlanta, Cleveland/Cincinnati) and on 1-hour exposure levels associated with increased airway responsiveness in asthmatics
- 0.05 ppm
  - Based on the lowest NO_2 levels associated with an epidemiologic study (Alpine, CA), of the key U.S. studies evaluated, and on providing a margin of safety relative to 0.10 ppm

5

Alternative Standards for Analysis

- Indicator: NO_2
  - Majority of information regarding health effects and exposure is for NO_2
- Averaging time: 1-hour (daily max)
  - We focused analytic efforts on endpoints for which scientific evidence (as judged in ISA) is strongest
- Form: 98^{th} and 99^{th} percentiles averaged over 3 years
  - Goal is to provide a balance between protecting the public from peak NO_2 levels and providing a stable regulatory target
- Levels: based on epidemiology and controlled human exposure studies
  - For key U.S. epidemiologic studies, we identified $98^{th}/99^{th}$ percentile 1-hour daily maximum NO_2 levels from highest monitor
  - For controlled human exposure studies we focused on increased airway responsiveness in asthmatics
    - ISA concludes that "transient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control"
    - Findings on airway responsiveness contribute to the plausibility and coherence of epidemiologic evidence linking NO_2 and emergency department visits/hospitalizations

4

Identification of Potential Health Benchmark Levels

- Purpose of benchmarks:
  - Compare to air quality/exposure levels to help characterize health risks
  - Provide perspective on NO_2 health risks under different air quality scenarios
    - Current air quality
    - Just meeting current/alternative standards
- Based largely on a meta-analysis of controlled human exposure studies of airway responsiveness in asthmatics
- Benchmark levels
  - 0.10, 0.15, 0.20, 0.25, 0.30 ppm

6

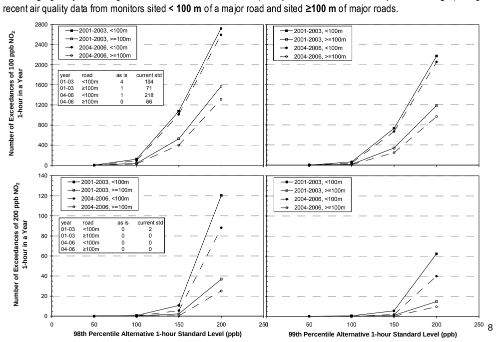
Air Quality Analysis: Overview of Approach

- Ambient air quality data from monitors across U.S. were screened
- 18 specific locations were identified for analysis based on NO_2 levels
  - Rest of U.S. was grouped together into 2 non-specific categories
- 1-hour NO_2 levels exceeding health benchmarks were estimated in each location
  - Exceedances were estimated for ambient and on-road levels of NO_2
  - On-road NO_2 estimates were based on literature-derived ratios of ambient levels to roadway levels
- Scenarios considered…
  - Air quality as-is
  - Air quality adjusted to simulate just meeting current annual standard
  - Air quality adjusted to simulate just meeting potential alternative standards

7

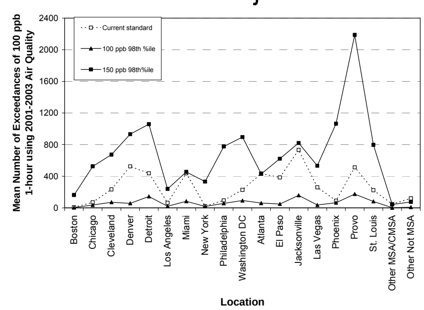
Air Quality Analysis: General Trends for Alternative Standards and Monitor Siting

Figure 7-2. Estimated **mean** number of exceedances of potential health effect benchmarks (100 ppb, top; 200 ppb, bottom) in **Chicago** given just meeting alternative 1-hour standard levels (**98th percentile, left; and 99th percentile, right**) using recent air quality data from monitors sited **< 100 m** of a major road and sited **≥100 m** of major roads.



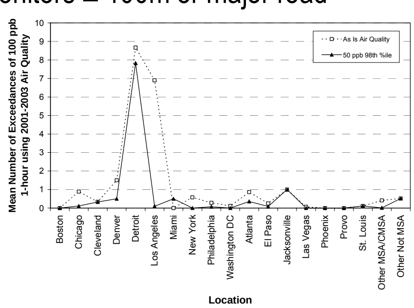
8

Air Quality Analysis: General Trends - CS Monitors ≥ 100m or major road



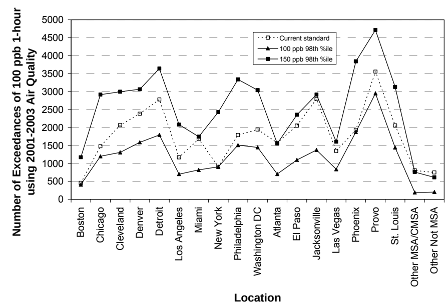
9

Air Quality Analysis: General Trends - As Is Monitors ≥ 100m or major road



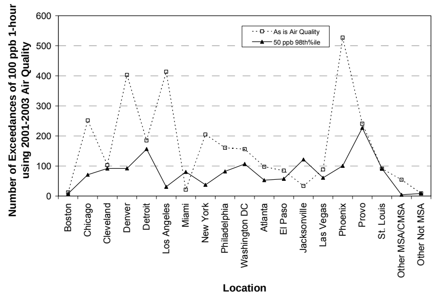
10

Air Quality Analysis: General Trends - CS On-Road Estimation



11

Air Quality Analysis: General Trends - As is On-Road Estimation



12

Quantitative Risk Assessment: Overview of Approach

- Focused assessment of NO_2-related respiratory ED visits for the Atlanta urban area
  - Case study to illustrate magnitude of changes in NO_2-related health impacts associated with recent air quality, just meeting the current standard, and just meeting alternative 1-hr standards
  - Agency's views on policy options considering the assessments and the scientific evidence in the ISA to be presented in ANPR
- General approach to estimating risk illustrated in Figure 9-1

13

Quantitative Risk Assessment: Overview of Approach

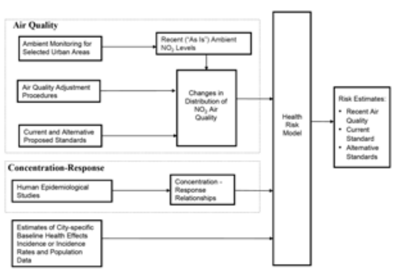


Figure 9-1. Major components of nitrogen dioxide health risk assessment for emergency department visits.

14

Inputs to Risk Assessment

- Air quality information
  - "As is" (recent air quality) from monitor used in Tolbert et al. (2007) study for 2005-2007
  - Calculated 3-day moving average of 1-h maximum NO2 concentration as input to risk assessment
  - Proportional air quality adjustment to simulate just meeting annual standard and alternative 1-h standards
- Concentration-response functions
  - Included both single- and multi-pollutant models from the Tolbert et al. (2007) study
  - C-R functions based on 3-day moving average of 1-h daily maximum NO_2 concentration
- Baseline health effects incidence data
  - Obtained from authors – 41 of 42 hospitals with emergency depts provided data
  - Most recent year (2004) included 36 of 42 hospitals, so baseline incidence is somewhat underestimated - ~122,000 ED visits annually

15

Quantitative Risk Assessment: Results

Table 9-3. Estimated Incidence of Respiratory ED Visits Associated with "As Is" NO_2 Concentrations and NO_2 Concentrations that Just Meet Alternative Standards in Atlanta, GA, Based on Adjusting 2007 NO_2 Concentrations.*

Other Pollutants in Model	Incidence of Respiratory Emergency Department Visits Associated with "As is" NO_2 Concentrations and NO_2 Concentrations that Just Meet the Current and Alternative Standards**									
	"as is"	current annual standard	Alternative 98th percentile 1-hr daily maximum standards (ppm)				Alternative 99th percentile 1-hr daily maximum standards (ppm)			
			0.05***	0.1	0.15	0.2	0.05	0.1	0.15	0.2
none	3400 (1800 - 4900)	9800 (5300 - 14200)	2400 (1300 - 3500)	4700 (2500 - 6900)	7000 (3800 - 10200)	9300 (5000 - 13400)	2200 (1200 - 3300)	4400 (2400 - 6400)	6500 (3500 - 9500)	8600 (4700 - 12500)
CO	2900 (1000 - 4800)	8400 (2900 - 13700)	2000 (700 - 3400)	4000 (1300 - 6700)	6000 (2000 - 9900)	7900 (2700 - 12900)	1900 (600 - 3200)	3800 (1300 - 6200)	5600 (1900 - 9200)	7400 (2500 - 12100)
O_3	1700 (-100 - 3500)	5100 (-200 - 10100)	1200 (-100 - 2500)	2400 (-100 - 4900)	3600 (-200 - 7200)	4800 (-200 - 9500)	1100 (-100 - 2300)	2200 (-100 - 4500)	3300 (-200 - 6700)	4400 (-200 - 8900)
$PM_{2.5}$	1200 (-700 - 3000)	3600 (-2100 - 8900)	800 (-500 - 2200)	1700 (-1000 - 4300)	2500 (-1500 - 6400)	3400 (-1900 - 8400)	800 (-400 - 2000)	1600 (-900 - 4000)	2400 (-1400 - 5900)	3100 (-1800 - 7800)
$PM_{2.5}$, O_3	700 (-1300 - 2600)	2100 (-4000 - 7800)	500 (-900 - 1900)	1000 (-1800 - 3700)	1500 (-2800 - 5500)	1900 (-3700 - 7300)	500 (-900 - 1700)	900 (-1700 - 3500)	1400 (-2600 - 5100)	1800 (-3400 - 6800)

*Estimated incidences of respiratory emergency department visits are based on the concentration-response functions estimated in Tolbert et al. (2007) [results corresponding to Figure 2 in Tolbert et al. (2007) were obtained via personal communication with P. Tolbert]. All models use a 3-day moving average of the daily 1-hr. maximum NO_2 concentration and apply to all ages.

**Incidence was quantified down to 0 ppb. Incidences are rounded to the nearest 100.

***Alternative 1-hr daily maximum standards are characterized by a concentration of m ppm and an nth percentile, requiring that the average of the 3 annual nth percentile 1-hr daily maxima over a 3-year period be at or below m ppm.

Note: Numbers in parentheses are 95% confidence intervals based on statistical uncertainty surrounding the NO_2 coefficient.

16

Uncertainty and Variability

- Causality – while uncertainty exists, ISA concludes a likely causal relationship with NO_2 itself or NO_2 acting as an indicator for itself and other components of ambient air associated with combustion processes
- Uncertainty about estimated C-R relationships
  - Confidence intervals reflect statistical uncertainty, but not uncertainties about whether correct model form or possible role of co-pollutants
  - Risk estimates presented for both single and multi-pollutant models
- Adequacy of ambient NO_2 monitors as surrogate for population exposure to ambient NO_2
- Adjustment of air quality distribution to simulate just meeting standards
- Baseline incidence
  - Possible year-to-year variability
  - Underestimate of incidence since have 36 of 42 emergency departments included
- Uncertainty about extent to which risk estimates for Atlanta are representative of other urban locations in U.S.

17

Key Observations

- Respiratory-related ED visits estimated to result from exposures to NO_2 for a single urban area (Atlanta) upon just meeting current standard and several alternative 1-hr standards
  - Provides useful perspective on likely overall magnitude and pattern of NO_2-related ED visits for urban areas in the U.S.
- Largest risk estiamtes associated with single-pollutant C-R functions
- Risk estimates redcued for various co-pollutant models (with CO, O_3, and PM_{10}), often by factor of two or greater and wider confidence intervals
- Only 1-h standards resulting in reduction in estimated risks (from as is case) were the 98th and 99th percentile 1-h standards set at 0.05 ppm
- Changing level of potential 1-h standards has bigger impact on risks than form of standard (98th vs. 99th percentile)
- Overall pattern of risks similar across three year period examined

18

Attachment E
Agency Charge Questions

Characterization of Air Quality (Chapters 2, 6, and 7)

1. To what extent are the air quality characterizations and analyses technically sound, clearly communicated, appropriately characterized, and relevant to the review of the primary NO_2 NAAQS?

2. In order to simulate just meeting potential alternative 1-hour daily maximum standards, we have adjusted NO_2 air quality levels using the same approach that was used in the first draft to simulate just meeting the current annual standard. To what extent is this approach clearly communicated and appropriately characterized?

3. Because of the impact of mobile sources on ambient NO_2, we have estimated on-road NO_2 concentrations. To what extent is the approach taken technically sound, clearly communicated, and appropriately characterized? Do Panel members have comments on the relevance of this procedure for reviewing the primary NO_2 NAAQS?

4. What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability?

Characterization of Health Effects Evidence and Selection of Potential Alternative Standards for Analysis (Chapters 3, 4, 5)

1. The presentation of the NO_2 health effects evidence is based on the information contained in the NO_2 Integrated Science Assessment. What are the views of the Panel on the overall characterization of the health evidence for NO_2? To what extent is the presentation clear and appropriately balanced?

2. The specific potential alternative standards that have been selected for analysis are based on both controlled human exposure studies and on epidemiological studies conducted in the United States. What are the Panel's views on the appropriateness of these potential alternative standards (in terms of indicator, averaging time, form, and level) for the purpose of conducting air quality, exposure, and risk assessments and on the rationale used to select them for that purpose?

Characterization of Exposure (Chapters 6 and 8):

1. To what extent is the assessment, interpretation, and presentation of the results of the exposure analysis technically sound, clearly communicated, and appropriately characterized?

2. The second draft assessment document evaluates exposures in Atlanta. What are the views of the Panel on the approach taken and on the interpretation of the results of this analysis?

3. What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability?

Characterization of Health Risks (Chapters 7, 8, 9):

1. Based on conclusions in the final ISA regarding airway responsiveness, we have expanded the range of potential health effect benchmark values to include 0.1 ppm. Do Panel members have comments on the range of potential health effects benchmark values chosen to characterize risks associated with 1-hour NO_2 exposures?

2. To what extent are the assessment, interpretation, and presentation of health risk results technically sound, clearly communicated, and appropriately characterized?

3. A focused risk assessment has been conducted for emergency department visits in Atlanta, GA. To what extent are the assessment, interpretation, and presentation of health risk results technically sound, clearly communicated, and appropriately characterized? What are the views of the Panel on the approach taken and on the interpretation of the results of this analysis?

4. What are the views of the Panel regarding the clarity and adequacy of the discussion of uncertainty and variability with respect to the characterization of health risks.

Attachment F
Presentation from Dr. Shelley Green, Office of Environmental Health Hazard Assessment/CalEPA

Comments on the "Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft"

September 9, 2008

Shelley Green, Ph.D.
Air Pollution Epidemiology Section
Office of Environmental Health Hazard Assessment, California EPA

1

California Ambient Air Quality Standard for Nitrogen Dioxide

- Reviewed by Air Quality Advisory Committee (Peer review committee appointed by University of California, Office of the President)
- Approved by the California Air Resources Board February 22, 2007
- Effective March 20, 2008

2

New NO_2 Standard for California

- Reduced level of current 1-hr standard from 0.25 ppm to **0.18 ppm**, not to be exceeded
- Established a new annual average standard of 0.030 ppm, not to be exceeded
- Retained current monitoring method for NO_2 – gas-phase chemiluminescence

3

Basis for NO_2 1-hour Standard of 0.18 ppm

- Enhanced inflammatory response in asthmatics at 0.26 ppm for 15-30 min, followed by exposure to airborne allergen
- Increased airway reactivity in asthmatics at 0.2 - 0.3 ppm for 30 min- 2 hrs

4

Basis for NO_2 1-hour standard (con't)

- Added margin of safety for:
  - Children and other susceptible populations (e.g. more severe asthmatics)
  - Possible effects at lower concentrations
  - Proposed 1-hr avg standard but effects observed after 15-30 minutes
- Effects observed in epidemiologic time-series and panel studies may be due to short-term exposures

5

Basis for Annual Average Standard of 0.030 ppm

- Studies of hospital admissions and ER visits for asthma, and asthma exacerbation, particularly in children, in areas with annual averages of 0.023 to 0.037 ppm
- Studies showing long term exposures to NO_2 may lead to changes in lung function growth in children in areas with annual averages of 0.030 to 0.044 ppm
- Potential effects of NO_2 on serious outcomes including mortality, ER, hospitalization for cardiac and respiratory disease and arrythmias

6

Considerations for new standard setting for NO_2 by US EPA

- New scientific evidence since California standard in 2007 may support a lower 1-hour standard than 0.18 ppm
- A new annual average standard may be necessary to protect the public from the effects of long-term exposure to NO_2
- The 1-hour standard may not ensure adequately low levels for the annual average
  - In the South Coast Air Basin of California the ratio of the 99th percentile of the 2004 1-hour maximum to the annual average was 3.80. A 1-hr standard of 0.20 ppm may allow an annual average as high as 0.053 This is higher than the current California annual standard of 0.030 ppm, and long-term effects have been observed in areas with annual averages lower than 0.053 ppm.

7

Attachment G
Statement of Dr. Deborah Shprentz on behalf of the American Lung Association

The American Lung Association offers these preliminary comments on EPA's Draft Risk and Exposure Assessment for Nitrogen Dioxide.

We are concerned about the National Ambient Air Quality Standards (NAAQS) for nitrogen dioxide (NO_2) because there is strong evidence from all three branches of investigation -- epidemiologic, controlled human exposure, and animal toxicology studies -- of adverse respiratory effects in asthmatics.

The current standard for NO_2 -- an annual average standard -- was set in 1971 and has not been revised since then. In the past 35 plus years there has been a great deal of evidence pointing to the need for a short-term standard.

According to the Integrated Science Assessment (ISA), new evidence confirms earlier findings that short-term NO_2 exposures are associated with increased airway responsiveness, often in conjunction with respiratory symptoms, particularly in children and asthmatics. Studies of respiratory symptoms, emergency department visits and hospital admissions report increased risks associated with NO_2 even in areas where daily concentrations never go above the level of the current annual average standard (53 ppb).

In 2005, the World Health Organization reaffirmed its recommendation for both an annual average and a 1-hour standard for NO_2.[1] In 2007, after an extensive review, the California Air Resources Board established a new annual average NO_2 standard of 30 ppb and lowered the 1-hour limit to 180 ppb, not to be exceeded.

While everyone likes to see more analysis, the bottom line under the Clean Air Act is that EPA must revise the NO_2 standard without regard to the air quality data, exposure assessment and risk assessment. Whatever the output of these analyses, EPA can not report to the people of this nation and the world that the current standard for nitrogen dioxide represents a safe level of air pollution.

With that, we would like to offer a few comments on specific chapters of the draft REA.

Chapter 4: Health Effects

Since the last review, over 50 peer-reviewed epidemiological studies have been published examining the effect of short-term nitrogen dioxide concentrations on the rate of emergency and hospital admissions for respiratory diseases. We concur with the draft document's conclusion in Chapter 4 that the positive associations with nitrogen dioxide are consistent for children and older adults when looking at all respiratory outcomes (asthma, bronchitis, emphysema, pneumonia, upper and lower respiratory infections) and among children and subjects of all ages for asthma admissions. The results are robust to the effects of co-pollutants, and are coherent with findings from toxicological and controlled human exposure studies. There is also strong new evidence of respiratory symptoms, particularly in children, from the epidemiological studies.

Furthermore, there is clear evidence from the controlled human exposure studies that NO_2 enhances the responsiveness of the airways to allergens. This airway hyperresponsiveness -- a narrowing of the airways in response to various stimuli -- is a hallmark of asthma. A meta-analysis using individual level data from 19 clinical studies reports that 66 percent of subjects experience an increase in airway responsiveness following 1-hour exposures to 100 ppb NO_2 , the lowest level studied. It cannot be overemphasized that these studies typically include only mildly asthmatic adults. Thus safety factors must be incorporated to account for interindividual variability and potential effects on infants, children, and those with moderate or severe asthma or other respiratory disease. Typically, in other standard-setting arenas, EPA determines the lowest observed adverse effect level (LOAEL) from the experimental studies and applies several safety factors of ten each to account for various uncertainties, thus setting the standard at $1/10^{th}$, $1/100^{th}$, or 1/1000 of the LOAEL.

Additionally, an important development in environmental health research in recent years has been the growing use

[1] The WHO guidelines for NO_2 are 21 ppb annual average standard and 104.5 ppb 1-hour standard.

of studies based on geographic information systems to assess the effects of air pollution. In particular, since EPA's last review of the NO_2 standard, a large number of studies have been published relating traffic air pollution to a variety of health endpoints. These studies show that people that live near roads with heavy traffic are at increased risk of adverse health effects from roadway pollution.

We are concerned that a large body of studies of the effects of traffic pollution exposure measured as distance to roadway have not been included and evaluated as part of this review. The traffic studies, which evaluate residency in proximity to major roadways, have particular relevance to the question of the effects of long-term exposures.

Chapter 4 identifies potential health effect benchmark values of 100, 200, 250, and 300 ppb derived from the controlled human exposure studies. We believe the upper values are far too high to be considered further. Not only are the majority of subjects are found to be responsive at 100 ppb, but even those studies have focused largely on mild asthmatics. To be blunt, the upper benchmarks of 250 and 300 ppb should be dropped.

In addition, we believe it is extremely confusing to define benchmarks of concern that differ from the potential alternative standards analyzed in the risk assessment. It will not be obvious to policy makers that the health effects benchmarks are based on the clinical studies only, and don't consider epidemiology studies showing effects at lower concentrations.

Chapter 5: Identification of Potential Alternative Standards for Analysis

Chapter 5 includes a discussion of potential alternative standards -- including a discussion of a potential indicator pollutant, averaging time, form, and level -- to provide some inputs for analysis in the quantitative risk assessment.

We strongly agree with EPA's judgment in Chapter 5 that it is appropriate to consider a new short-term standard, and that a 1-hour averaging time seems suitable in light of the effects observed in chamber and laboratory studies.

From the discussion, it appears that EPA may be dismissing the need for the annual average standard. This would be entirely premature. At minimum, the annual average standard is important to lowering the full distribution of exposures, not just the peak 1-hour concentrations. Furthermore, the ISA does not thoroughly discuss the distance to roadway studies that measure the effects of long-term exposures to traffic pollution. In its recent review of the NO_2 standard, California decided to establish a new annual average standard based on the traffic studies, as well as the potential effects of NO_2 on serious health endpoints suggested by the traditional epidemiology studies, and the toxicology studies showing alterations in lung structure in young animals due to long-term exposures. California, unlike the ISA, recognized that roadway studies measure the effects of long-term exposures to traffic pollution. Among the criteria pollutants, NO_2 and PM are likely to be the best markers of traffic-related pollution. It is too early in the process to dismiss the importance of an annual average standard.

The American Lung Association has a longstanding objection to percentile forms of the standard. It is inappropriate to dismiss 1 or 2 percent or more of the highest monitor readings from the compliance determination when the goal of the short-term standard is to avoid peak concentrations.

Both the 98th and 99th percentile forms of the standard are inappropriate considering that the goal of a short-term standard is to limit peak exposures. For instance, the 98th percentile form would dismiss 175 of the highest hourly readings from the compliance determination. The single exceedance or "not to be exceeded" form of the standard is far preferable.

With respect to the levels of the standard, it appears that EPA has selected both the upper end and the lower end of the range at levels clearly associated with adverse effects in the human clinical and epidemiological studies, including the Delfino et al. 2002 study that demonstrated increases in asthma symptoms at 50 ppb. Such an approach is inappropriate because it precludes the provision of a margin of safety to protect sensitive populations. The Clean Air Act requires inclusion of a margin of safety in any final standard. Furthermore, as discussed below, consideration of the epidemiological studies of respiratory symptoms, respiratory emergency department visits and hospital admissions would lead to selection of a far lower bottom end of the range.

Chapter 7: Ambient Air Quality Assessment and Health Risk Characterization

Since the last review, the number of NO_2 monitors nationwide has declined by 37 percent, down from 440 (in 1998) to 289 monitors in 2007.[2] Thus our ability to characterize ambient concentrations has diminished in the face of dramatic new evidence of short-term effects at contemporary concentrations. This chapter should include a discussion of the strengths and weaknesses of the current monitoring network with respect to the siting criteria and the ability to detect maximum NO_2 concentrations from stationary and mobile sources. With only 289 monitors to detect NO_2 concentrations over a land area of over 3.5 million square miles, there must be significant uncertainties about the spatial and temporal extent of maximum concentrations.

Given the paucity of monitoring data, we do not understand why areas with incomplete data were excluded. Information on the peak hourly values at these sites may be of interest, even though readings are not available for all the hours. In the analysis of hourly concentrations, it is really the peak rather than the average concentrations that are most relevant.

To state the obvious, assessments of current concentrations are not informative with respect to potential future emissions increases.

Chapter 8: Exposure Assessment and Health Risk Characterization

We will reserve our discussion pending release of this chapter, except to note that exposure assessments are based on numerous assumptions and fraught with uncertainty. Far too often they serve to minimize the impact on populations at risk. Exposure assessments are not an appropriate basis for standard setting under the Clean Air Act.

The ISA concludes correctly that evidence shows positive associations of short-term NO_2 concentrations below the current NAAQS level with increased numbers of ED visits and hospital admissions for respiratory causes, especially asthma. Standards must be set to protect against these and other respiratory effects, regardless of the number of estimated exposures.

Chapter 9: Characterization of Health Risks Using Data From Epidemiological Studies

EPA has chosen an extraordinarily narrow approach to the risk assessment, focusing only on emergency department visits in Atlanta. The danger of such a limited approach is that focuses attention on the quantified risks, which are only a small subset of the health risks, to the exclusion of the vast majority of risks, which are unquantified. Moreover, by looking at just one city, EPA is taking too conservative an approach, failing to extrapolate risk estimates beyond the cities included in the original studies.

Of the range of standards analyzed, the draft risk assessment reports potential benefits in Atlanta only at the 50 ppb standard level. According to the ISA, a number of studies of ED visits and hospital admissions for respiratory causes reported positive associations where mean 24-hour concentrations were in the range of 3 to 50 ppb. (ISA p. 5-11.) This result suggests that both the upper and lower ends of the range of alternative standards are too high, since risks are evident only at the lower end of the analyzed range.

We note that a number of factors in the analysis, such as the limited availability of baseline emergency visit data, lead to underestimates in reported risks.

Recent multi-city epidemiological studies have also reported associations between ambient NO_2 concentrations and respiratory symptoms at relatively low concentrations.
Positive associations were observed in cities where the median range was 18 to 26 ppb for a 24-hour average (Schildcrout et al., 2006) and where the mean NO_2 level was 32 ppb for a 4-hour average (Mortimer et al., 2002).

---

2 http://iaspub.epa.gov/airsdata/adaqs.count?geotype=us&geocode=USA&geoinfo=us%7EUSA%7EUnited+States&pol=NO2&year=1998&fld=siteid&fld=address&fld=city&fld=county&fld=stabbr&fld=regn&rpp=25

EPA should consider broadening the risk assessment to examine respiratory symptoms in a range of cities.

Attachment H
Overview of the Second Draft Risk and Exposure Assessment to Support the NO2 Primary NAAQS

Overview of the Second Draft Risk and Exposure Assessment to Support the NO_2 Primary NAAQS

Presentation to CASAC

September 9, 2008

Overview of Presentation

- Timeline of current review
- Identification of potential alternative standards for analysis
- Identification of potential health benchmark levels
- Air quality analysis and risk characterization
- Epidemiology-based risk assessment
- To be discussed this afternoon: Status of exposure analysis and exposure-based risk characterization

2

Timeline for Review

Major Milestones		Projected Completion Date	Projected CASAC Review Date
Integrated Review Plan	Draft Final	April 2007 June 2007	May 2007
Integrated Science Assessment	First Draft Second Draft Final	August 2007 March 2008 July 2008	October 2007 * May 2008 *
Risk/Exposure Assessment	Plan First Draft **Second Draft** Final	September 2007 March 2008 **August 2008** November 2008	October 2007 * May 2008 * **September 2008**
Rulemaking	ANPR Proposed Final	December 2008 May 2009 December 2009	January 2009

*Indicates that a single CASAC meeting will address both documents

3

Alternative Standards for Analysis

- Indicator: NO_2
  - Majority of information regarding health effects and exposure is for NO_2
- Averaging time: 1-hour (daily max)
  - We focused analytic efforts on endpoints for which scientific evidence (as judgec in ISA) is strongest
- Form: 98th and 99th percentiles averaged over 3 years
  - Goal is to provide a balance between protecting the public from peak NO_2 levels and providing a stable regulatory target
- Levels: based on epidemiology and controlled human exposure studie
  - For key U.S. epidemiologic studies, we identified 98th/99th percentile 1-hour daily maximum NO_2 levels from highest monitor
  - For controlled human exposure studies we focused on increased airway responsiveness in asthmatics
    - ISA concludes that "transient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control"
    - Findings on airway responsiveness contribute to the plausibility and coherence of epidemiologic evidence linking NO_2 and emergency department visits/hospitalizatior

4

Identification of Alternative Standard Levels

- 0.20 ppm
  - Based on highest NO_2 levels associated with epidemiologic studies (2 studies in LA) and on 30-minute exposure levels associated with increased airway responsiveness in asthmatics
- 0.15 ppm
  - Based on providing margin of safety relative to 0.20 ppm and on the range of 1-hour and 30-minute exposure levels associated with increased airway responsiveness in asthmatics
- 0.10 ppm
  - Based on NO_2 levels associated with epidemiologic studies in several cities (NYC, Atlanta, Cleveland/Cincinnati) and on 1-hour exposure levels associated with increased airway responsiveness in asthmatics
- 0.05 ppm
  - Based on the lowest NO_2 levels associated with an epidemiologic study (Alpine, CA), of the key U.S. studies evaluated, and on providing a margin of safety relative to 0.10 ppm

5

Identification of Potential Health Benchmark Levels

- Purpose of benchmarks:
  - Compare to air quality/exposure levels to help characterize health risks
  - Provide perspective on NO_2 health risks under different air quality scenarios
    - Current air quality
    - Just meeting current/alternative standards
- Based largely on a meta-analysis of controlled human exposure studies of airway responsiveness in asthmatics
- Benchmark levels
  - 0.10, 0.15, 0.20, 0.25, 0.30 ppm

6

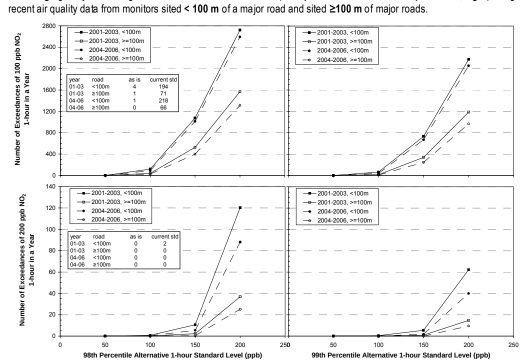
Air Quality Analysis: Overview of Approach

- Ambient air quality data from monitors across U.S. were screened
- 18 specific locations were identified for analysis based on NO_2 levels
  - Rest of U.S. was grouped together into 2 non-specific categories
- 1-hour NO_2 levels exceeding health benchmarks were estimated in each location
  - Exceedances were estimated for ambient and on-road levels of NO_2
  - On-road NO_2 estimates were based on literature-derived ratios of ambient levels to roadway levels
- Scenarios considered…
  - Air quality as-is
  - Air quality adjusted to simulate just meeting current annual standard
  - Air quality adjusted to simulate just meeting potential alternative standards

7

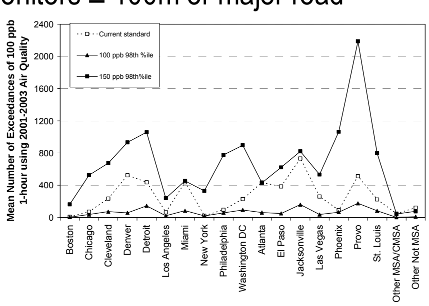
Air Quality Analysis: General Trends for Alternative Standards and Monitor Siting

Figure 7-2. Estimated **mean** number of exceedances of potential health effect benchmarks (100 ppb, top; 200 ppb, bottom) in **Chicago** given just meeting alternative 1-hour standard levels (**98th percentile, left; and 99th percentile, right**) using recent air quality data from monitors sited **< 100 m** of a major road and sited **≥100 m** of major roads.



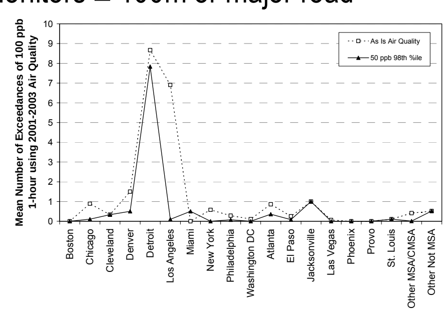
8

Air Quality Analysis: General Trends - CS Monitors ≥ 100m or major road



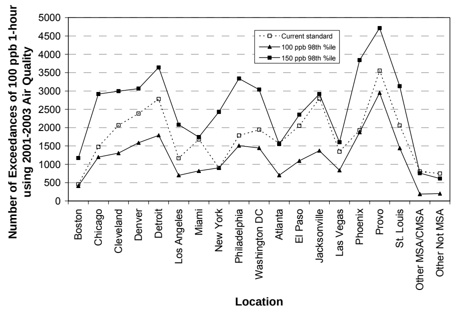
9

Air Quality Analysis: General Trends - As Is Monitors ≥ 100m or major road

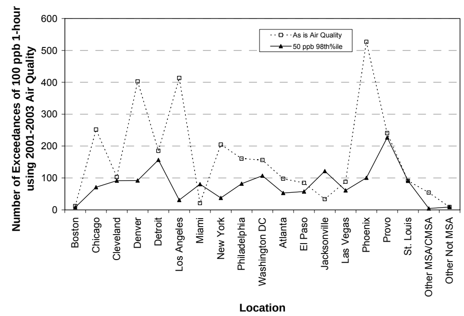


10

Air Quality Analysis: General Trends - CS On-Road Estimation



Air Quality Analysis: General Trends - As is On-Road Estimation



Quantitative Risk Assessment: Overview of Approach

- Focused assessment of NO_2-related respiratory ED visits for the Atlanta urban area
  - Case study to illustrate magnitude of changes in NO_2-related health impacts associated with recent air quality, just meeting the current standard, and just meeting alternative 1-hr standards
  - Agency's views on policy options considering the assessments and the scientific evidence in the ISA to be presented in ANPR
- General approach to estimating risk illustrated in Figure 9-1

Quantitative Risk Assessment: Overview of Approach

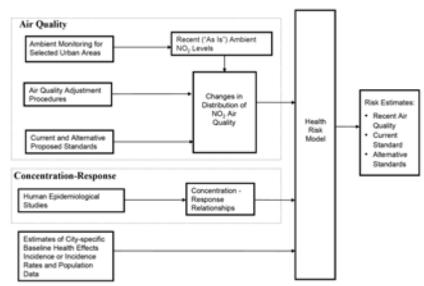


Figure 9-1. Major components of nitrogen dioxide health risk assessment for emergency department visits.

Inputs to Risk Assessment

- Air quality information
  - "As is" (recent air quality) from monitor used in Tolbert et al. (2007) study for 2005-2007
  - Calculated 3-day moving average of 1-h maximum NO2 concentration as input to risk assessment
  - Proportional air quality adjustment to simulate just meeting annual standard and alternative 1-hr standards
- Concentration-response functions
  - Included both single- and multi-pollutant models from the Tolbert et al. (2007) study
  - C-R functions based on 3-day moving average of 1-h daily maximum NO_2 concentration
- Baseline health effects incidence data
  - Obtained from authors – 41 of 42 hospitals with emergency depts provided data
  - Most recent year (2004) included 36 of 42 hospitals, so baseline incidence is somewhat underestimated - ~122,000 ED visits annually

Quantitative Risk Assessment: Results

Table 9-3. Estimated Incidence of Respiratory ED Visits Associated with "As Is" NO_2 Concentrations and NO_2 Concentrations that Jus Meet Alternative Standards in Atlanta, GA, Based on Adjusting 2007 NO_2 Concentrations.*

Other Pollutants in Model	Incidence of Respiratory Emergency Department Visits Associated with "As is" NO_2 Concentrations and NO_2 Concentrations that Just Meet the Current and Alternative Standards**									
	"as is"	current annual standard	Alternative 98th percentile 1-hr daily maximum standards (ppm)				Alternative 99th percentile 1-hr daily maximum standards (ppm)			
			0.05***	0.1	0.15	0.2	0.05	0.1	0.15	0.2
none	3400 (1800 - 4900)	9800 (5300 - 14200)	2400 (1300 - 3500)	4700 (2500 - 6900)	7000 (3800 - 10200)	9300 (5000 - 13400)	2200 (1200 - 3300)	4400 (2400 - 6400)	6500 (3500 - 9500)	8600 (4700 - 125
CO	2900 (1000 - 4800)	8400 (2900 - 13700)	2000 (700 - 3400)	4000 (1300 - 6700)	6000 (2000 - 9900)	7900 (2700 - 12900)	1900 (600 - 3200)	3800 (1300 - 6200)	5600 (1900 - 9200)	7400 (2500 - 121
O_3	1700 (-100 - 3500)	5100 (-200 - 10100)	1200 (-100 - 2500)	2400 (-100 - 4900)	3600 (-200 - 7200)	4800 (-200 - 9500)	1100 (-100 - 2300)	2200 (-100 - 4500)	3300 (-200 - 6700)	4400 (-200 - 890
PM_{10}	1200 (-700 - 3000)	3600 (-2100 - 8900)	800 (-500 - 2200)	1700 (-1000 - 4300)	2500 (-1500 - 6400)	3400 (-1900 - 8400)	800 (-400 - 2000)	1600 (-900 - 4000)	2400 (-1400 - 5900)	3100 (-1800 - 78
PM_{10}, O_3	700 (-1300 - 2600)	2100 (-4000 - 7800)	500 (-900 - 1900)	1000 (-1800 - 3700)	1500 (-2800 - 5500)	1900 (-3700 - 7300)	500 (-900 - 1700)	900 (-1700 - 3500)	1400 (-2600 - 5100)	1800 (-3400 - 68

*Estimated incidences of respiratory emergency department visits are based on the concentration-response functions estimated in Tolbert et al. (2007) [results correspondin to Figure 2 in Tolbert et al. (2007) were obtained via personal communication with P. Tolbert]. All models use a 3-day moving average of the daily 1-hr. maximum NO_2 concentration and apply to all ages.

**Incidence was quantified down to 0 ppb. Incidences are rounded to the nearest 100.

***Alternative 1-hr daily maximum standards are characterized by a concentration of m ppm and an nth percentile, requiring that the average of the 3 annual nth percentile 1-hr daily maxima over a 3-year period be at or below m ppm.

Note: Numbers in parentheses are 95% confidence intervals based on statistical uncertainty surrounding the NO_2 coefficient.

Uncertainty and Variability

- Causality – while uncertainty exists, ISA concludes a likely causal relationship with NO_2 itself or NO_2 acting as an indicator for itself and other components of ambient air associated with combustion processes
- Uncertainty about estimated C-R relationships
  - Confidence intervals reflect statistical uncertainty, but not uncertainties about whether correct model form or possible role of co-pollutants
  - Risk estimates presented for both single and multi-pollutant models
- Adequacy of ambient NO_2 monitors as surrogate for population exposure to ambient NO_2
- Adjustment of air quality distribution to simulate just meeting standards
- Baseline incidence
  - Possible year-to-year variability
  - Underestimate of incidence since have 36 of 42 emergency departments included
- Uncertainty about extent to which risk estimates for Atlanta are representative of other urban locations in U.S.

17

Key Observations

- Respiratory-related ED visits estimated to result from exposures to NO_2 for a single urban area (Atlanta) upon just meeting current standard and several alternative 1-hr standards
  - Provides useful perspective on likely overall magnitude and pattern of NO_2-related ED visits for urban areas in the U.S.
- Largest risk estiamtes associated with single-pollutant C-R functions
- Risk estimates redcued for various co-pollutant models (with CO, O_3, and PM_{10}), often by factor of two or greater and wider confidence intervals
- Only 1-h standards resulting in reduction in estimated risks (from as is case) were the 98^{th} and 99^{th} percentile 1-h standards set at 0.05 ppm
- Changing level of potential 1-h standards has bigger impact on risks than form of standard (98^{th} vs. 99^{th} percentile)
- Overall pattern of risks similar across three year period examined

18

Attachment I
Draft committee letter for panel and CASAC discussion

Insert date

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Clean Air Scientific Advisory Committee's (CASAC) Peer Review of EPA's *Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft*

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC), augmented by subject-matter-experts to form the CASAC Oxides of Nitrogen Primary National Ambient Air Quality Standards (NAAQS) Review Panel (hereafter referred to as the panel, roster provided in Enclosure A) held a public meeting on September 9-10, 2008 to review EPA's *Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: First Draft*. EPA requested that CASAC address charge questions listed below that fell into four categories (characterizations of air quality, health effects evidence and selection of potential alternative standards for analysis, exposure, and health risks). Panel consensus comments on how the ISA might be further strengthened appear below in the form of responses to the Agency's charge questions within those categories. Individual comments from CASAC panel members are enclosed in Enclosure

The purpose of the assessment is to communicate EPA's assessment of exposures and risks associated with ambient NO_2. Overall, CASAC finds that the second draft assessment (??INSERT LANGUAGE HERE CHARACTERIZING THE OVERALL ASSESSMENT, PROGRESS SINCE LAST DRAFT, IMPORTANCE FOR NAAQS REVIEW?)…

<u>Characterization of Air Quality (Chapters 2, 6, and 7)</u>

5. *To what extent are the air quality characterizations and analyses technically sound, clearly communicated, appropriately characterized, and relevant to the review of the primary NO_2 NAAQS?*

The air quality characterizations, analyses, and uncertainty and variability discussions are generally improved, but in some cases additional clarification is needed. There are inconsistencies in the air quality metrics used in the analyses and those considered as alternative standards. The REA now focuses on short term, higher concentrations, both in terms of benchmark levels and alternative standards. These concepts, and their differences, should be clarified. Currently, the approach proposes using 98th and/or 99th percentile levels, but then switches between using the overall 98th/99th hourly value, the daily maximum and the annual mean among the various monitors in a city. These multiple metrics are confusing, and make some of the analyses less informative to setting a standard.

The derivation and use of the on-road enhancement factor, m, needs to be strengthened, with improved documentation and more explicit comparison with observations. Staff should consider using different weightings over the range of m values employed, based on a strengthened uncertainty characterization). The discussion of the measurements upon which m are based needs to address how those measurements represent on- and near-roadway exposures. Similarly, additional discussion about how the monitoring network provides meaningful information for exposure analysis is desired. This should include a better characterization of vertical concentration gradients and how monitoring height might impact the relationship between observed levels and exposure. There is some concern that the importance of the biases associated with monitoring height and monitor interferences might be misinterpreted.

6. *In order to simulate just meeting potential alternative 1-hour daily maximum standards, we have adjusted NO_2 air quality levels using the same approach that was used in the first draft to simulate just meeting the current annual standard. To what extent is this approach clearly communicated and appropriately characterized?*

7. *Because of the impact of mobile sources on ambient NO_2, we have estimated on-road NO_2 concentrations. To what extent is the approach taken technically sound, clearly communicated, and appropriately characterized? Do Panel members have comments on the relevance of this procedure for reviewing the primary NO_2 NAAQS?*

The approach for calculating the on-road concentrations is based on an empirical relationship with parameters derived from published monitoring studies conducted at various distances from roadways. It would add scientific credibility to this study to conduct an evaluation of this approach using an independent data set. For example, the maximum NO_2 concentration may not necessarily occur on the roadway because NO will become oxidized to NO_2 as the roadway becomes dispersed and mixes with the background ozone. The extreme of the NO_2 concentration distributions may occur in configurations such as street canyons that are not treated in the current analysis. If it is not possible to address such extreme situations in the current framework, this limitation should be explicitly stated and its implications on the uncertainties of the results should be discussed.

The APEX model plays a central role in the exposure assessment and some evaluation of this model (or reference to a previous evaluation) would be useful.

At present, the metrics provided to assess performance of AERMOD for Philadelphia are limited, and the information provided suggests performance might be satisfactory for two monitors but is extremely poor at the third receptor with underestimations on the order of a factor of 3 to 4. The evaluation should be more extensive, and the distributions (e.g., cdf's) of the AERMOD results should be compared with observations. The use of a homogeneous background to correct the AERMOD predictions does not correct the poor modeling of the spatial NO_2 concentrations across the area. Two approaches can be used to correct this perfidious modeling result (the two approaches could be used in combination): (1) a more complete emission inventory can be used for AERMOD to provide a better representation of sources in the vicinity of the receptor where concentrations are significantly underestimated and/or (2) the data fusion (i.e., combination of AERMOD modeling results and monitoring concentrations) is conducted by using the modeling results to interpolate among the three receptors.

The fact that only the resident population is treated in the exposure assessment should be explicitly mentioned and an estimate of the commuting population who may be exposed in Philadelphia County during working hours for example should be provided.

The cities for which there are sufficient data to perform a detailed analysis (similar to the Philadelphia analysis) should be identified. Be upfront as to what are the possibilities (how many cities, what fraction of the city, etc.) should be made explicit so we can actually provide informed advice.

If the decision is made to use epidemiologic results, the REA will need to address co-pollutant issues. In particular, while the data is limited as to how NO2 correlates with species such as EC, that should be highlighted.

8. *What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability?*

<u>Characterization of Health Effects Evidence and Selection of Potential Alternative Standards for Analysis (Chapters 3, 4, 5)</u>

3. *The presentation of the NO_2 health effects evidence is based on the information contained in the NO_2 Integrated Science Assessment. What are the views of the Panel on the overall characterization of the health evidence for NO_2? To what extent is the presentation clear and appropriately balanced?*

Chapter 3 covers susceptibility, describing the range of populations found to be susceptible, both to air pollution generally and to NO_2 specifically. The document would be improved by sharpening its conclusions. Clearly, one important overall finding is that a large number of people could be susceptible, when considering the full range of groups identified. On the other hand, the experimental and epidemiological evidence would appear to converge in finding that asthmatics are the most susceptible. The concept of vulnerability, as distinct from susceptibility, is introduced, and appropriately followed through.

This draft REA appropriately reflects the NO_x *Integrated Science Assessment* (ISA) in summarizing conclusions regarding the currently available health evidence related to NO_2 exposures. The choice to express the overall evaluation of the data on the major findings in terms of five levels of "confidence" is applauded, since a consistent application of this approach can bring a new level of rigor and consistency to this type of evaluation. The REA concludes that a "likely causal relationship" can be inferred from the data for short-term NO_2 exposure and adverse effects on the respiratory system at near ambient levels of exposure – and that the susceptible populations include subjects with asthma or airways hyperresponsiveness (AHR) and the young and elderly. The ISA and the REA conclude that there is suggestive, but not sufficient, data to infer a causal relationship between short term concentrations near those associated with ambient NO_2 exposure and cardiopulmonary mortality and between long-term NO2 exposure and respiratory morbidity. The existing data are considered inadequate to infer the presence or absence of a relationship between long-term concentrations near those leading to ambient NO_2 exposure and overall mortality.

The basis for the above conclusions should be more clearly defined in the REA, particularly in drawing linkages to the ISA. Both the ISA and the REA build on primary conclusions related to strength of evidence for causality. The ISA needs to have a full discussion of the application of the Hill criteria, as adapted by the Agency for its review process: strength of association, experimental evidence, consistency, biological plausibility, coherence, temporal relationship and the presence of an exposure-response relationship. The ISA should refer to each of these criteria and assess the data with respect to each for each of the major health outcomes considered. If done in the ISA, the causal conclusions could then be summarized in the REA with explicit reference to the ISA. It is not clear that the 7 criteria were consistently considered in coming to the final conclusions for the various health outcomes. Absent such in-depth analyses, the conclusions of the ISA and consequently the basis for the REA are weakened.

This set of evaluations for NO_2 uses the five-level classification of strength of evidence for causation. On page 32, lines 1-3, the staff makes the judgment that it will focus on endpoints for which the ISA "concludes that the available evidence is sufficient to infer either a causal or a likely casual relationship". This represents a decision that sets a precedent with regard to the level of evidence in support of outcomes that will be considered in the REA. Given the precedent-setting nature of the decision, clearer justification is needed.

A remaining task for this document is to compare and synthesize the results of the assessments based on the epidemiologic studies and the human clinical studies. One challenge in accomplishing this is addressing differences in doses received in these two different contexts. Human clinical studies involve controlled exposures to NO_2 concentrations at the breathing zone of the subject while the epidemiology studies rely on a small number of fixed monitors that are commonly 4-5 meters above the ground and which do not necessarily represent the actual human exposure concentrations. The REA needs to consider the representativeness of NO_2 concentrations measured at this height for estimating personal exposures of the general population.

A stronger justification is needed to set aside the studies of indoor NO_2. The stated rationale acknowledges that these studies focused on NO_2 alone to the extent possible and that the exposure situation indoors differs from that outdoors. On the other hand, the experimental literature is based on exposure to NO_2 alone as well. Given the emphasis placed on the human clinical studies, there does not appear to be a solid rationale for setting aside the studies directed at exposure to NO_2 from indoor sources.

4. *The specific potential alternative standards that have been selected for analysis are based on both controlled human exposure studies and on epidemiological studies conducted in the United States. What are the Panel's views on the appropriateness of these potential alternative standards (in terms of indicator, averaging time, form, and level) for the purpose of conducting air quality, exposure, and risk assessments and on the rationale used to select them for that purpose?*

In general, the bases for selecting the indicator, averaging time, form, and level for the NO_2 NAAQS are clearly stated. The averaging time of 1-hour is reflective of the duration of the experimental studies and the finding that there are adverse health effects. CASAC would recommend that consideration be given to exploring scenarios for the 24-hour averaging time as well.

The proposed alternative form of the standard is considered appropriate. The REA should better define the strengths and weaknesses of using the 98th or 99th percentile form for the standard – including defining how the exposure distribution influences how well these parameters reflect both the magnitude and extent of high level exposures. The epidemiological studies that form the basis for the proposed alternative standards are well described in the REA. However, the REA should more clearly describe how controlled human exposures were used to establish or validate the proposed range for NO_2 analyses.

With regard to level, the document provides a clear rationale for assessing a lower range extending to 0.05 ppm, with which CASAC agrees. The upper end of the range is quite reasonable, due to the experimental findings.

The REA states that alternative long-term standards to the current annual value will not be considered. The REA does not establish that a short-term standard alone would be sufficient to meet the public health protection mandate of the Clean Air Act. Are there areas of the United States that would be in compliance with a short-term standard but not with a long-term standard? The REA needs a discussion of the utility of the current long-term standard for NO_2. The REA should develop a scientific foundation for any decision regarding retaining or revising the long term NAAQS for NO_2.

Characterization of Exposure (Chapters 6 and 8):

4. *To what extent is the assessment, interpretation, and presentation of the results of the exposure analysis technically sound, clearly communicated, and appropriately characterized?*

5. *The second draft assessment document evaluates exposures in Atlanta. What are the views of the Panel on the approach taken and on the interpretation of the results of this analysis?*

6. *What are the views of the Panel regarding the adequacy of the assessment of uncertainty and variability?*

Staff provided an update on progress since Chapter 8 is still under revision. The Atlanta case study location is a reasonable one. The panel commends the responsiveness of staff and their ongoing consideration of adequate prediction of air quality. The strategies Staff have outlined to improve the modeling are likely to bring the model results closer to observed concentrations. There is some concern that the modeling approach may underestimate high exposures to residents who live near roads. We encourage Staff to include a clear characterization of biases and additional assessment of the predicted versus observed concentrations. Though not discussed at this meeting, the rest of the exposure modeling is expected to be similar to the first draft REA, which we previously commented on. The personal exposure data from Atlanta should also be compared with the model results.

PERHAPS SAY SOMETHING ABOUT THE NEED FOR THE CASAC TO PROVIDE ADDITIONAL ADVICE ON THE FURTHER DEVELOPMENT OF THE EXPOSURE ASSESSMENT AT A FUTURE TELECONFERENCE?

Characterization of Health Risks (Chapters 7, 8, 9):

5. *Based on conclusions in the final ISA regarding airway responsiveness, we have expanded the range of potential health effect benchmark values to include 0.1 ppm. Do Panel members have comments on the range of potential health effects benchmark values chosen to characterize risks associated with 1-hour NO_2 exposures?*

6. *To what extent are the assessment, interpretation, and presentation of health risk results technically sound, clearly communicated, and appropriately characterized?*

7. *A focused risk assessment has been conducted for emergency department visits in Atlanta, GA. To what extent are the assessment, interpretation, and presentation of health risk results technically sound, clearly communicated, and appropriately characterized? What are the views of the Panel on the approach taken and on the interpretation of the results of this analysis?*

8. What are the views of the Panel regarding the clarity and adequacy of the discussion of uncertainty and variability with respect to the characterization of health risks?

The health risk assessment methodology described in Chapters 7 and 9 is well-developed and generally of high quality. The basis for expanding the range of exposure levels considered in the REA to include 0.1 ppm NO2 is well-developed in the document. It is less clear, however, why a value as low as 0.05 ppm is not proposed, given results in the ISA. This decision should be more clearly justified, or the range expanded downward accordingly. At a minimum, 50 ppb and 100 ppb should be included in the Chapter 7 exceedances tables (e.g., 7-5 thru 7-16) to allow comparisons across cities at relevant ambient conditions. On a related note, it would be more informative for the tables and discussion to include the rate of exceedances as well as the absolute number.

The case for selecting Atlanta as the representative site for detailed exposure and risk calculations is not clearly made in the current version of the REA. An improved description of the rationale leading to this selection would improve understanding of the selection's implications. Justification for Atlanta's results being generalizable is needed, given the ultimate objective of assessing national health risks and the potential for possible recommendation of an alternate national air quality standard.

The topics of uncertainty and variability are central to interpretation of the analyses in the REA. The presentation of these concepts throughout the document is uneven, repetitive, and lacking sufficient specificity. The discussion should highlight the most important and relevant sources of uncertainty and variability for the main analyses. Key points and issues should be addressed in the document, with supporting additional details located in appropriate appendices.

In closing, the CASAC was pleased to review this second draft of the *Risk and Exposure Assessment* for the primary NO_x review. We look forward to reviewing the Advance Notice of Proposed Rulemaking in January 2009 and to continuing to advise you as you complete your assessment of the NO_x primary standard.

Sincerely,

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Attachment J
Presentation by Mr. Robert Paine on behalf of the American Petroleum Institute

Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard: Second Draft

Comments to CASAC: September 10, 2008

Robert Paine, CCM, QEP, founding AERMIC member

ENSR Corporation, Westford, Massachusetts

ENSR | AECOM

ENSR | AECOM

Outline of Presentation

- Concerns about the NO_2 NAAQS review process
- Problem with roll-up for peak 1-hr NO_2 concentrations
- Example of correction to the roll-up procedure
- Concerns about exposure modeling analysis
- Modeling limitations for 1-hr NO_2 and roadway emissions

ENSR | AECOM

NAAQS Review Process Is Being Compromised

- The air quality modeling is a key element of the REA and belonged in the August draft, BUT….
- Information provided on September 9 is highly incomplete, and did not support the conclusion of September 8, 2008 Graham memo:
  - "…we feel that these improvements to the model inputs, and given our current understanding of model performance, that the updated AERMOD modeling results should provide adequate estimates of hourly air concentrations for input to the risk and exposure assessment to support the review of the NO2 primary NAAQS".
- The optimistic 2-week estimate to conclude the work and report to CASAC (September 23) is only 3 days before the public comment period ends for the second draft REA

ENSR | AECOM

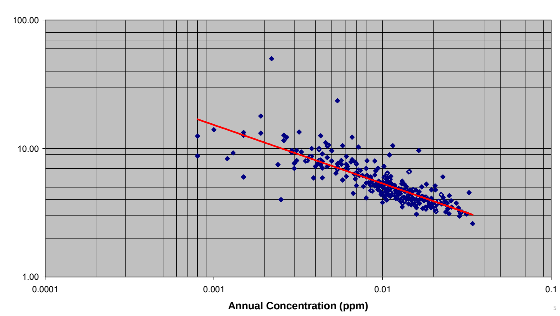
Method to Determine Peak 1-hr Conc. When Just Meeting Current Annual NO_2 NAAQS – Invalid

- The peak-to-mean ratio developed is assumed to be linear; this results in large errors for a reactive pollutant like NO_2
- Resulting errors affect all results in the Risk Assessment for peak 1-hr conc. based on "just meeting" annual NAAQS
- Corrected roll-up indicates that current annual standard is more protective than indicated in the Risk Assessment

---

ENSR | AECOM

Ratio of 2nd High 1-Hr NO_2 to Annual Average NO_2 versus Annual Average NO_2 (2007) Shows Strong Negative Correlation



Example Correction to NO_2 Roll-up Method

ENSR | AECOM

- Regression analysis of 10 years of NO_2 monitoring data
  - Uses 1998-2007 monitors with > 90% data capture
  - 2nd high 1-hr to annual peak-to-mean ratio adjusted based upon plotted regression line
  - Implication: when the annual average NO_2 is increased, the peak 1-hour concentrations also increase, but not linearly
  - Results of correction for 2007 monitoring sites exceeding 25.6 ppb (level used in the 2nd Draft REA)

Estimation Method	Number of Monitors with Second-high 1-hour NO_2 Exceeding			
	150 ppb	200 ppb	250 ppb	300 ppb
Roll-up	9	1	0	0
Corrected	1	0	0	0

Concerns about Exposure Modeling

ENSR | AECOM

- General issue: roadway sources have peak NO_2 impacts, but modeling approach / accuracy is highly uncertain
- Philadelphia
  - Of 3 monitors evaluated, 2 are > 1000 m from major highway, one is about 200 m away
  - Calibration method of adjusting modeled concentrations by adding the average difference monitor-model is "unacceptable" (App. W)
  - Model performance for 2003 is markedly inconsistent in comparison to 2001 and 2002 and should be further investigated
  - Philadelphia Airport emissions from aircraft appear to be underestimated by a factor of 10
- Atlanta
  - Initial peak NO_2 predictions too high by factor of 2
  - Distances of monitors from highway ranges from 350 to over 1000 m

Limitations in Modeling Short-Term NO_2 and Roadways

ENSR | AECOM

- Mobile sources are very important, but there is virtually no applicable AERMOD evaluation, especially in urban areas
- Vertical dispersion of roadway sources is underestimated – there is substantial turbulence with traffic flow not modeled
- Geometry is critical – wind flow along or across roadway – significantly affects off-roadway concentration gradient
- Short-term emission estimates are very challenging
- Short-term ozone concentrations are critical; how to allocate available ozone to multiple sources still a question
- Many of these problems are not as critical for annual average modeling as they are for short-term modeling

Overall Conclusions

ENSR | AECOM

- The comment period need to be extended; there is not enough information available to the public at this time
- Short-term estimates based on a peak-to-mean ratio using "just met" annual averages are too high
- For short-term NO_2 concentrations, AERMOD has limitations due to complications with roadway sources - modeling procedures still being developed and tested
- In urban areas, AERMOD evaluation is very limited, especially for roadway sources
- In Philadelphia and Atlanta, monitors are at least 200 m from major roadways – no test of critical 100-m zone
- Sept 08 results for any short- term NO_2 evaluation using AERMOD are likely to be preliminary and misleading