ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 58

[EPA–HQ–OAR–2006–0922; FRL–8926–3]

RIN 2060–AO19

Primary National Ambient Air Quality Standard for Nitrogen Dioxide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Based on its review of the air quality criteria for oxides of nitrogen and the primary national ambient air quality standard (NAAQS) for oxides of nitrogen as measured by nitrogen dioxide (NO_2), EPA proposes to make revisions to the primary NO_2 NAAQS in order to provide requisite protection of public health. Specifically, EPA proposes to supplement the current annual standard by establishing a new short-term NO_2 standard based on the 3-year average of the 99th percentile (or 4th highest) of 1-hour daily maximum concentrations. EPA proposes to set the level of this new standard within the range of 80 to 100 ppb and solicits comment on standard levels as low as 65 ppb and as high as 150 ppb. EPA also proposes to establish requirements for an NO_2 monitoring network that will include monitors within 50 meters of major roadways. In addition, EPA is soliciting comment on an alternative approach to setting the standard and revising the monitoring network. Consistent with the terms of a consent decree, the Administrator will sign a notice of final rulemaking by January 22, 2010.

DATES: Comments must be received on or before September 14, 2009. Under the Paperwork Reduction Act, comments on the information collection provisions must be received by OMB on or before August 14, 2009.

Public Hearings: EPA intends to hold public hearings on this proposed rule in August 2009 in Los Angeles, California and Arlington, VA. These will be announced in a separate **Federal Register** notice that provides details, including specific times and addresses, for these hearings.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2006–0922 by one of the following methods:

- *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.
- *E-mail*: a-and-r-Docket@epa.gov.
- *Fax*: 202–566–9744
- *Mail*: Docket No. EPA–HQ–OAR–2006–0922, Environmental Protection Agency, Mail code 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery*: Docket No. EPA–HQ–OAR–2006–0922, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2006–0922. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Dr. Scott Jenkins, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504–06, Research Triangle Park, NC 27711; telephone: 919–541–1167; fax: 919–541–0237; e-mail: *jenkins.scott@epa.gov*.

SUPPLEMENTARY INFORMATION:

General Information

What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments*. When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—the agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.

- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Availability of Related Information

A number of the documents that are relevant to this rulemaking are available through EPA's Office of Air Quality Planning and Standards (OAQPS) Technology Transfer Network (TTN) Web site at *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_index.html*. These documents include the Integrated Review Plan and the Health Assessment Plan, available at *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_pd.html*, the Integrated Science Assessment (ISA), available at *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=194645*, and the Risk and Exposure Assessment (REA), available at *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_rea.html*. These and other related documents are also available for inspection and copying in the EPA docket identified above.

Table of Contents

The following topics are discussed in this preamble:

I. Background
A. Legislative Requirements
B. Related NO_2 Control Programs
C. Review of the Air Quality Criteria and Standards for Oxides of Nitrogen
II. Rationale for Proposed Decisions on the Primary Standard
A. Characterization of NO_2 Air Quality
1. Current Patterns of NO_2 Air Quality
2. NO_2 Air Quality and Gradients Around Roadways
B. Health Effects Information
1. Adverse Respiratory Effects and Short-Term Exposure to NO_2
a. Emergency Department Visits and Hospital Admissions
b. Respiratory Symptoms
c. Impaired Host Defense
d. Airway Response
e. Airway Inflammation
f. Lung Function
g. Conclusions From the ISA
2. Other Effects With Short-Term Exposure to NO_2
a. Mortality
b. Cardiovascular Effects
3. Health Effects With Long-Term Exposure to NO_2
a. Respiratory Morbidity
b. Mortality
c. Carcinogenic, Cardiovascular, and Reproductive/Developmental Effects
4. NO_2-Related Impacts on Public Health
a. Pre-Existing Disease
b. Age
c. Genetics
d. Gender
e. Proximity to Roadways
f. Socioeconomic Status
g. Size of the At-Risk Population
C. Human Exposure and Health Risk Characterization
1. Evidence Base for the Risk Characterization
2. Overview of Approaches
3. Key Limitations and Uncertainties
D. Considerations in Review of the Standard
1. Background on the Current Standard
2. Approach for Reviewing the Need to Retain or Revise the Current Standard
E. Adequacy of the Current Standard
1. Evidence-Based Considerations
2. Exposure- and Risk-Based Considerations
3. Summary of Considerations From the REA
4. CASAC Views
5. Administrator's Conclusions Regarding Adequacy of the Current Standard
F. Conclusions on the Elements of a New Short-Term Standard and an Annual Standard
1. Indicator
2. Averaging Time
a. Short-Term Averaging Time
b. Long-Term Averaging Time
c. CASAC Views
d. Administrator's Conclusions on Averaging Time
3. Form
4. Level
a. Evidence-Based Considerations
b. Exposure- and Risk-Based Considerations
c. Summary of Consideration From the REA
d. CASAC Views
e. Administrator's Conclusions on Level for a 1-Hour Standard
f. Alternative Approach to Setting the 1-Hour Standard Level
g. Level of the Annual Standard
G. Summary of Proposed Decisions on the Primary Standard
III. Proposed Amendments to Ambient Monitoring and Reporting Requirements
A. Monitoring Methods
B. Network Design
1. Background
2. Proposed Changes
a. Monitoring in Areas of Expected Maximum Concentrations Near Major Roads
b. Area-Wide Monitoring at Neighborhood and Larger Spatial Scales
3. Solicitation for Comment on an Alternative Network Design
C. Data Reporting
IV. Proposed Appendix S—Interpretation of the Primary NAAQS for Oxides of Nitrogen and Proposed Revisions to the Exceptional Events Rule
A. Background
B. Interpretation of the Primary NAAQS for Oxides of Nitrogen
1. Annual Primary Standard
2. 1-Hour Primary Standard Based on the Annual 4th Highest Daily Value Form
3. 1-Hour Primary Standard Based on the Annual 99th Percentile Value Form
C. Exceptional Events Information Submission Schedule
V. Clean Air Act Implementation Requirements
A. Designations
B. Classifications
C. Attainment Dates
1. Attaining the NAAQS
2. Consequences of Failing to Attain by the Statutory Attainment Date
D. Section 110(a)(2) NAAQS Infrastructure Requirements
E. Attainment Planning Requirements
1. Nonattainment Area SIPs
2. New Source Review and Prevention of Significant Deterioration Requirements
3. General Conformity
4. Transportation Conformity
VI. Communication of Public Health Information
VII. Statutory and Executive Order Reviews
References

I. Background

A. Legislative Requirements

Two sections of the Clean Air Act (Act or CAA) govern the establishment and revision of the NAAQS. Section 108 of the Act directs the Administrator to identify and list air pollutants that meet certain criteria, including that the air pollutant ''in his judgment, cause[s] or contribute[s] to air pollution which may reasonably be anticipated to endanger public health and welfare'' and ''the presence of which in the ambient air results from numerous or diverse mobile or stationary sources.'' 42 U.S.C. 21 7408(a)(1)(A) & (B). For those air pollutants listed, section 108 requires the Administrator to issue air quality criteria that ''accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in ambient air * * *'' 42 U.S.C. 7408(2).

Section 109(a) of the Act directs the Administrator to promulgate ''primary'' and ''secondary'' NAAQS for pollutants for which air quality criteria have been issued. 42 U.S.C. 7409(1). Section 109(b)(1) defines a primary standard as one ''the attainment and maintenance of which in the judgment of the Administrator, based on [the air quality] criteria and allowing an adequate margin of safety, are requisite to protect the public health.'' [1] 42 U.S.C. 7409(b)(1). A secondary standard, in turn, must ''specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on [the air quality] criteria, is requisite to protect the public

[1] The legislative history of section 109 indicates that a primary standard is to be set at ''the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,'' and that for this purpose ''reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.'' S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

welfare from any known or anticipated adverse effects associated with the presence of such pollutant in the ambient air.'' [2] 42 U.S.C. 7409(b)(2).

The requirement that primary standards include an adequate margin of safety is intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It is also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *Lead Industries Association* v. *EPA,* 647 F.2d 1130, 1154 (D.C. Cir 1980), *cert. denied,* 449 U.S. 1042 (1980); *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1186 (D.C. Cir. 1981), *cert. denied*, 455 U.S. 1034 (1982). Both kinds of uncertainties are components of the risk associated with pollution at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that include an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree.

In addressing the requirement for a margin of safety, EPA considers such factors as the nature and severity of the health effects involved, the size of the at-risk population(s), and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *Lead Industries Association* v. *EPA, supra,* 647 F.2d at 1161–62.

In setting standards that are ''requisite'' to protect public health and welfare, as provided in section 109(b), EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, EPA may not consider the costs of implementing the standards. *Whitman* v. *American Trucking Associations,* 531 U.S. 457, 471, 475–76 (2001).

Section 109(d)(1) of the Act requires the Administrator to periodically undertake a thorough review of the air quality criteria published under section 108 and the NAAQS and to revise the criteria and standards as may be appropriate. 42 U.S.C. 7409(d)(1). The Act also requires the Administrator to appoint an independent scientific review committee composed of seven members, including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies, to review the air quality criteria and NAAQS and to ''recommend to the Administrator any new standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.'' 42 U.S.C. 7409(d)(2). This independent review function is performed by the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board.

B. Related NO_2 Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once EPA has established them. Under section 110 of the Act, 42 U.S.C. 7410, and related provisions, States are to submit, for EPA approval, State implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The States, in conjunction with EPA, also administer the prevention of significant deterioration program that covers these pollutants. *See* 42 U.S.C. 7470–7479. In addition, Federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act, 42 U.S.C. 7521—7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and aircraft emissions; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emission standards for hazardous air pollutants under section 112 of the Act, 42 U.S.C. 7412.

Currently there are no areas in the United States that are designated as nonattainment of the NO_2 NAAQS. If the NO_2 NAAQS is revised as a result of this review, however, some areas could be classified as non-attainment. Certain States would then be required to develop SIPs that identify and implement specific air pollution control measures to reduce ambient NO_2 concentrations to attain and maintain the revised NO_2 NAAQS, most likely by requiring air pollution controls on sources that emit oxides of nitrogen (NO_X [3]).

While NO_X is emitted from a wide variety of source types, the top three categories of sources of NO_X emissions are on-road mobile sources, electricity generating units, and non-road mobile sources. EPA anticipates that NO_X emissions will decrease substantially over about the next 20 years as a result of the ongoing implementation of mobile source emissions standards. In particular, Tier 2 NO_X emission standards for light-duty vehicle emissions began phasing into the fleet beginning with model year 2004, in combination with low-sulfur gasoline fuel standards. For heavy-duty engines, new NO_X standards are phasing in between the 2007 and 2010 model years, following the introduction of ultra-low sulfur diesel fuel. Lower NO_X standards for nonroad diesel engines, locomotives, and certain marine engines are becoming effective throughout the next decade. In future decades, these lower-NO_X vehicles and engines will become an increasingly large fraction of in-use mobile sources, effecting large NO_X emission reductions.

C. Review of the Air Quality Criteria and Standards for Oxides of Nitrogen

On April 30, 1971, EPA promulgated identical primary and secondary NAAQS for NO_2 under section 109 of the Act. The standards were set at 0.053 parts per million (ppm) (53 ppb), annual average (36 FR 8186). EPA completed reviews of the air quality criteria and NO_2 standards in 1985 and 1996 with decisions to retain the standard (50 FR 25532, June 19, 1985; 61 FR 52852, October 8, 1996).

EPA initiated the current review of the air quality criteria for oxides of nitrogen and the NO_2 primary NAAQS on December 9, 2005 (70 FR 73236) with a general call for information. EPA's draft Integrated Review Plan for the Primary National Ambient Air Quality Standard for Nitrogen Dioxide (EPA, 2007a) was made available in February 2007 for public comment and was discussed by the CASAC via a publicly accessible teleconference on May 11, 2007. As noted in that plan, NO_X includes multiple gaseous (*e.g.*, NO_2, NO) and particulate (*e.g.*, nitrate) species. Because the health effects

[2] EPA is currently conducting a separate review of the secondary NO_2 NAAQS jointly with a review of the secondary SO_2 NAAQS.

[3] In this document, the terms ''oxides of nitrogen'' and ''nitrogen oxides'' (NO_X) refer to all forms of oxidized nitrogen (N) compounds, including NO, NO_2, and all other oxidized N-containing compounds formed from NO and NO_2. This follows usage in the Clean Air Act Section 108(c): ''Such criteria [for oxides of nitrogen] shall include a discussion of nitric and nitrous acids, nitrites, nitrates, nitrosamines, and other carcinogenic and potentially carcinogenic derivatives of oxides of nitrogen.'' By contrast, within the air pollution research and control communities, the terms ''oxides of nitrogen'' and ''nitrogen oxides'' are restricted to refer only to the sum of NO and NO_2, and this sum is commonly abbreviated as NO_X. The category label used by this community for the sum of all forms of oxidized nitrogen compounds including those listed in Section 108(c) is NO_Y.

associated with particulate species of NO_X have been considered within the context of the health effects of ambient particles in the Agency's review of the NAAQS for particulate matter (PM), the current review of the primary NO_2 NAAQS is focused on the gaseous species of NO_X and does not consider health effects directly associated with particulate species.

The first draft of the Integrated Science Assessment for Oxides of Nitrogen-Health Criteria (ISA) and the Nitrogen Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment (EPA, 2007b) were reviewed by CASAC at a public meeting held on October 24–25, 2007. Based on comments received from CASAC and the public, EPA developed the second draft of the ISA and the first draft of the Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard (Risk and Exposure Assessment (REA)). These documents were reviewed by CASAC at a public meeting held on May 1–2, 2008. Based on comments received from CASAC and the public at this meeting, EPA released the final ISA in July of 2008 (EPA, 2008a). In addition, comments received were considered in developing the second draft of the REA, which was released for public review and comment in two parts. The first part of this document, containing chapters 1–7, 9 and appendices A and C as well as part of appendix B, was released in August, 2008. The second part of this document, containing chapter 8 (describing the Atlanta exposure assessment) and a completed appendix B, was released in October of 2008. This document was the subject of CASAC reviews at public meetings on September 9 and 10, 2008 (for the first part) and on October 22, 2008 (for the second part). In preparing the final REA (EPA, 2008b), EPA considered comments received from the CASAC and the public at those meetings.

In the course of reviewing the second draft REA, CASAC expressed the view that the document would be incomplete without the addition of a policy assessment chapter presenting an integration of evidence-based considerations and risk and exposure assessment results. CASAC stated that such a chapter would be ''critical for considering options for the NAAQS for NO_2'' (Samet, 2008a). In addition, within the period of CASAC's review of the second draft REA, EPA's Deputy Administrator indicated in a letter to the chair of CASAC, addressing earlier CASAC comments on the NAAQS review process (Henderson, 2008), that the risk and exposure assessment will include ''a broader discussion of the science and how uncertainties may effect decisions on the standard'' and ''all analyses and approaches for considering the level of the standard under review, including risk assessment and weight of evidence methodologies'' (Peacock, 2008, p.3; September 8, 2008).

Accordingly, the final REA included a new policy assessment chapter. This policy assessment chapter considered the scientific evidence in the ISA and the exposure and risk characterization results presented in other chapters of the REA as they relate to the adequacy of the current NO_2 primary NAAQS and potential alternative primary NO_2 standards. In considering the current and potential alternative standards, the final REA document focused on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: indicator, averaging time, form [4], and level. These elements, which together serve to define each standard, must be considered collectively in evaluating the health protection afforded. CASAC discussed the final version of the REA, with an emphasis on the policy assessment chapter, during a public teleconference held on December 5, 2008. Following that teleconference, CASAC offered comments and advice on the NO_2 primary NAAQS in a letter to the Administrator (Samet, 2008b).

The schedule for completion of this review is governed by a judicial order resolving a lawsuit filed in September 2005, concerning the timing of the current review. The order that now governs this review, entered by the court in August 2007 and amended in December 2008, provides that the Administrator will sign, for publication, notices of proposed and final rulemaking concerning the review of the primary NO_2 NAAQS no later than June 26, 2009 and January 22, 2010, respectively.

This action presents the Administrator's proposed decisions on the current primary NO_2 standard. Throughout this preamble a number of conclusions, findings, and determinations proposed by the Administrator are noted. While they identify the reasoning that supports this proposal, they are not intended to be final or conclusive in nature. The EPA invites general, specific, and/or technical comments on all issues involved with this proposal, including all such proposed judgments, conclusions, findings, and determinations. Further, EPA invites specific comments from CASAC on the proposed approach of establishing a new 1-hour NO_2 standard in conjunction with a revised monitoring network that includes a substantial number of monitors placed near major roads. In addition to requesting comment on the overall approach, EPA invites specific comment on the level, or range of levels, appropriate for such a standard, as well as on the rationale that would support that level or range of levels.

[4] The ''form'' of a standard defines the air quality statistic that is to be compared to the level of the standard in determining whether an area attains the standard.

II. Rationale for Proposed Decisions on the Primary Standard

This section presents the rationale for the Administrator's proposed decision to revise the existing NO_2 primary standard by supplementing the current annual standard with a 1-hour standard and to specify the standards to the nearest parts per billion (ppb). As discussed more fully below, this rationale takes into account: (1) Judgments and conclusions presented in the ISA and the REA; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA and REA at public meetings, in separate written comments, and in CASAC's letter to the Administrator (Samet, 2008b); and (3) public comments received at CASAC meetings during the development of the ISA and the REA.

In developing this rationale, EPA has drawn upon an integrative synthesis of the entire body of evidence on human health effects associated with the presence of NO_2 in the air. As discussed below, this body of evidence addresses a broad range of health endpoints associated with exposure to NO_2. In considering this entire body of evidence, EPA focuses in particular on those health endpoints for which the ISA finds associations with NO_2 to be causal or likely causal (*see* section II.B below). This rationale also draws upon the results of quantitative exposure and risk assessments.

As discussed below, a substantial amount of new research has been conducted since the last review of the NO_2 NAAQS, with important new information coming from epidemiologic studies in particular. The newly available research studies evaluated in the ISA have undergone intensive scrutiny through multiple layers of peer review and opportunities for public review and comment. While important uncertainties remain in the qualitative and quantitative characterizations of health effects attributable to exposure to ambient NO_2, the review of this

information has been extensive and deliberate.

The remainder of this section discusses the rationale for the Administrator's proposed decisions on the primary standard. Section II.A presents a discussion of NO_2 air quality, including discussion of the NO_2 concentration gradients that can exist around roadways, and the current NO_2 monitoring network. Section II.B includes an overview of the scientific evidence related to health effects associated with NO_2 exposure. This overview includes discussion of the health endpoints and at-risk populations considered in the ISA. Section II.C discusses the approaches taken by EPA to assess exposures and health risks associated with NO_2, including a discussion of key uncertainties associated with the analyses. Section II.D presents the approach that is being used in the current review of the NO_2 NAAQS with regard to consideration of the scientific evidence and exposure-/risk-based results related to the adequacy of the current standard and potential alternative standards. Sections II.E and II.F discuss the scientific evidence and the exposure-/risk-based results specifically as they relate to the current and potential alternative standards, including discussion of the Administrator's proposed decisions on the standard. Section II.G summarizes the Administrator's proposed decisions with regard to the NO_2 primary NAAQS.

A. Characterization of NO_2 Air Quality

1. Current patterns of NO_2 Air Quality

The size of the State and local NO_2 monitoring network has remained relatively stable since the early 1980s, and currently has approximately 400 monitors reporting data to EPA's Air Quality System (AQS) database.[5] At present, there are no minimum monitoring requirements for NO_2 in 40 CFR part 58 Appendix D, other than a requirement for EPA Regional Administrator approval before removing any existing monitors, and that any ongoing NO_2 monitoring must have at least one monitor sited to measure the maximum concentration of NO_2 in that area (though, as discussed below monitors in the current network do not measure peak concentrations associated with on-road mobile sources that can occur near major roadways because the network was not designed for this purpose). EPA removed the specific minimum monitoring requirements for NO_2 of two monitoring sites per area with a population of 1,000,000 or more in the 2006 monitoring rule revisions (71 FR 61236), based on the fact that there were no NO_2 nonattainment areas at that time, coupled with trends evidence showing an increasing gap between national average NO_2 concentrations and the current annual standard. Additionally, the minimum requirements were removed to provide State, local, and Tribal air monitoring agencies flexibility in meeting higher priority monitoring needs for pollutants such as ozone and $PM_{2.5}$, or implementing the new multi-pollutant sites (NCore network) required by the 2006 rule revisions, by allowing them to discontinue lower priority monitoring. There are requirements in 40 CFR part 58 Appendix D for NO_2 monitoring as part of the Photochemical Assessment Monitoring Stations (PAMS) network. However, of the approximately 400 NO_2 monitors currently in operation, only about 10 percent may be due to the PAMS requirements.

An analysis of the approximately 400 monitors comprising the current NO_2 monitoring network (Watkins and Thompson, 2008) indicates that the current NO_2 network has largely remained unchanged in terms of size and target monitor objective categories since it was introduced in the May 10, 1979 monitoring rule (44 FR 27571). The review of the current network found that the assessment of concentrations for general population exposure and maximum concentrations at neighborhood and larger scales were the top objectives. A review of the distribution of listed spatial scales of representation shows that only approximately 3 monitors are described as microscale, representing an area on the order of several meters to 100 meters, and approximately 23 monitors are described as middle scale, which represents an area on the order of 100 to 500 meters. This low percentage of smaller spatially representative scale sites within the network of approximately 400 monitoring sites indicates that the majority of monitors have, in fact, been sited to assess area-wide exposures on the neighborhood, urban, and regional scales, as would be expected for a network sited to support the current annual NO_2 standard and PAMS objectives. The current network does not include monitors placed near major roadways and, therefore, monitors in the current network do not necessarily measure the maximum concentrations that can occur on a localized scale near these roadways (as discussed in the next section). It should be noted that the network not only accommodates NAAQS related monitoring, but also serves other monitoring objectives such as support for photochemistry analysis, ozone modeling and forecasting, and particulate matter precursor tracking.

2. NO_2 Air Quality and Gradients Around Roadways

On-road and non-road mobile sources account for approximately 60% of NO_X emissions (ISA, table 2.2–1) and traffic-related exposures can dominate personal exposures to NO_2 (ISA section 2.5.4). While driving, personal exposure concentrations in the cabin of a vehicle could be substantially higher than ambient concentrations measured nearby (ISA, section 2.5.4). For example, mean in-vehicle NO_2 concentrations have been reported to be 2 to 3 times higher than non-traffic ambient concentrations (ISA, sections 2.5.4 and 4.3.6). In addition, estimates presented in the REA suggest that on/near roadway NO_2 concentrations could be approximately 40% (REA, compare Tables 7–11 and 7–13) or 80% (REA, section 7.3.2) higher on average than concentrations away from roadways and that roadway-associated environments could be responsible for the large majority of 1-hour peak NO_2 exposures (REA, Figures 8–17 and 8–18). Because monitors in the current network are not sited to measure peak roadway-associated NO_2 concentrations, individuals who spend time on and/or near major roadways could experience NO_2 concentrations that are considerably higher than indicated by monitors in the current area-wide NO_2 monitoring network.

Research suggests that the concentrations of on-road mobile source pollutants such as NO_X, carbon monoxide (CO), directly emitted air toxics, and certain size distributions of particulate matter (PM), such as ultrafine PM, typically display peak concentrations on or immediately adjacent to roads (ISA, section 2.5). This situation typically produces a gradient in pollutant concentrations, with concentrations decreasing with increasing distance from the road, and concentrations generally decreasing back to near area-wide ambient levels, or typical upwind urban background

[5] It should be noted that the ISA Section 2.4.1 references a different number of active monitors in the NO_2 network. The discrepancy between the ISA numbers and the number presented here is due to differing metrics used in pulling data from AQS. The ISA only references SLAMS, NAMS, and PAMS sites with defined monitoring objectives, while the Watkins and Thompson, 2008 value represents all NO_2 sites reporting data at any point during the year. These differences in numbers of active monitors per year also explain why the Watkins and Thompson 2008 document characterized the NO_2 network size as relatively stable since the early 1980s.

levels, within several hundred meters downwind. While this general concept is applicable to almost all roads, the actual characteristics of the gradient and the distance that the mobile source pollutant signature from an individual road can be differentiated from background or upwind concentrations are heavily dependent on factors including traffic volumes, local topography, roadside features, meteorology, and photochemical reactivity conditions (Baldauf, *et al.*, 2009; Beckerman *et al.*, 2008; Clements *et al.*, 2008; Hagler *et al.*, 2009; Janssen *et al.*, 2001; Rodes and Holland, 1980; Roorda-Knape *et al.*, 1998; Singer *et al.*, 2004; Zhou and Levy, 2007).

Because NO_2 in the ambient air is due largely to the atmospheric oxidation of NO emitted from combustion sources (ISA, section 2.2.1), elevated NO_2 concentrations can extend farther away from roadways than the primary pollutants also emitted by on-road mobile sources. More specifically, review of the technical literature suggests that NO_2 concentrations may return to area-wide or typical urban background concentrations within distances up to 500 meters of roads, though the actual distance will vary with topography, roadside features, meteorology, and photochemical reactivity conditions (Baldauf *et al.*, 2009; Beckerman *et al.*, 2008; Clements *et al.*, 2008; Gilbert *et al.* 2003; Rodes and Holland, 1980; Singer *et al.*, 2004; Zhou and Levy, 2007). Efforts to quantify the extent and slope of the concentration gradient that may exist from peak near-road concentrations to the typical urban background concentrations must consider the variability that exists across locations and for a given location over time. As a result, we have identified a range of concentration gradients in the technical literature which indicate that, on average, peak NO_2 concentrations on or immediately adjacent to roads may typically be between 30 and 100 percent greater than concentrations monitored in the same area but farther away from the road (ISA, Section 2.5.4; Beckerman *et al.*, 2008; Gilbert *et al.*, 2003; Rodes and Holland, 1980; Roorda-Knape *et al.*, 1998; Singer *et al.*, 2004). This range of concentration gradients has implications for revising the NO_2 primary standard and for the NO_2 monitoring network (*see* sections II.F.4 and III).

B. Health Effects Information

In the last review of the NO_2 NAAQS, the 1993 NO_X Air Quality Criteria Document (1993 AQCD) (EPA, 1993) concluded that there were two key health effects of greatest concern at ambient or near-ambient concentrations of NO_2 (ISA, section 5.3.1). The first was increased airway responsiveness in asthmatic individuals after short-term exposures. The second was increased respiratory illness among children associated with longer-term exposures to NO_2. Evidence also was found for increased risk of emphysema, but this appeared to be of major concern only with exposures to NO_2 at levels much higher than then current ambient levels (ISA, section 5.3.1). Controlled human exposure and animal toxicological studies provided qualitative evidence for airway hyperresponsiveness and lung function changes while epidemiologic studies provided evidence for increased respiratory symptoms with increased indoor NO_2 exposures. Animal toxicological findings of lung host defense system changes with NO_2 exposure provided a biologically-plausible basis for the epidemiologic results. Subpopulations considered potentially more susceptible to the effects of NO_2 exposure included persons with preexisting respiratory disease, children, and the elderly. The epidemiologic evidence for respiratory health effects was limited, and no studies had considered endpoints such as hospital admissions, emergency department visits, or mortality (ISA, section 5.3.1).

As discussed below, evidence published since the last review generally has confirmed and extended the conclusions articulated in the 1993 AQCD (ISA, section 5.3.2). The epidemiologic evidence has grown substantially with the addition of field and panel studies, intervention studies, time-series studies of endpoints such as hospital admissions, and a substantial number of studies evaluating mortality risk associated with short-term NO_2 exposures. While not as marked as the growth in the epidemiologic literature, a number of recent toxicological and controlled human exposure studies also provide insights into relationships between NO_2 exposure and health effects. The body of evidence that has become available since the last review focuses the current review on NO_2-related respiratory effects at lower ambient and exposure concentrations.

The ISA, along with its associated annexes, provides a comprehensive review and assessment of the scientific evidence related to the health effects associated with NO_2 exposures. For these health effects, the ISA characterized judgments about causality with a hierarchy that contains five levels (ISA, section 1.3): sufficient to infer a causal relationship, sufficient to infer a likely causal relationship (*i.e.*, more likely than not), suggestive but not sufficient to infer a causal relationship, inadequate to infer the presence or absence of a causal relationship, and suggestive of no causal relationship. Judgments about causality were informed by a series of aspects that are based on those set forth by Sir Austin Bradford Hill in 1965 (ISA, Table 1.3–1). These aspects include strength of the observed association, availability of experimental evidence, consistency of the observed association, biological plausibility, coherence of the evidence, temporal relationship of the observed association, and the presence of an exposure-response relationship. A summary of each of the five levels of the hierarchy is provided in Table 1.3–2 of the ISA.

Judgments made in the ISA about the extent to which relationships between various health endpoints and exposure to NO_2 are likely causal have been informed by several factors. As discussed in the ISA in section 1.3, these factors include the nature of the evidence (*i.e.*, controlled human exposure, epidemiological, and/or toxicological studies) and the weight of evidence. The weight of evidence takes into account such considerations as biological plausibility, coherence of the evidence, strength of associations, and consistency of the evidence. Controlled human exposure studies provide directly applicable information for determining causality because these studies are not limited by differences in dosimetry and species sensitivity, which would need to be addressed in extrapolating animal toxicology data to human health effects, and because they provide data relating health effects specifically to NO_2 exposures, in the absence of the co-occurring pollutants present in ambient air. Epidemiologic studies provide evidence of associations between NO_2 concentrations and more serious health endpoints (*e.g.*, hospital admissions and emergency department visits) that cannot be assessed in controlled human exposure studies. For these studies the degree of uncertainty introduced by confounding variables (*e.g.*, other pollutants) affects the level of confidence that the health effects being investigated are attributable to NO_2 exposures alone and/or in combination with co-occurring pollutants.

In using a weight of evidence approach to inform judgments about the degree of confidence that various health effects are likely to be caused by exposure to NO_2, confidence increases with the number of studies consistently reporting a particular health endpoint,

with increasing support for the biological plausibility of the health effects, and with the strength and coherence of the evidence. Conclusions regarding biological plausibility, consistency, and coherence of evidence of NO_2-related health effects are drawn from the integration of epidemiologic studies with controlled human exposure studies and with mechanistic information from animal toxicological studies. As discussed below, the weight of evidence is strongest for respiratory morbidity endpoints (*e.g.*, respiratory symptoms, hospital admissions, and emergency department visits) associated with short-term (*e.g.*, 1 to 24 hours) NO_2 exposures.

For epidemiologic studies, strength of association refers to the magnitude of the association and its statistical strength, which includes assessment of both effect estimate size and precision. In general, when associations yield large relative risk estimates, it is less likely that the association could be completely accounted for by a potential confounder or some other bias. Consistency refers to the persistent finding of an association between exposure and outcome in multiple studies of adequate power in different persons, places, circumstances and times. Based on the information presented in the ISA and summarized below in sections II.B.1–II.B.3, this section discusses judgments concerning the extent to which relationships between various health endpoints and ambient NO_2 exposures have been judged in the ISA to be likely causal.

As noted above, this section is devoted to discussion of health effects associated with NO_2 exposure, as assessed in the ISA. Section II.B.1 below discusses respiratory morbidity associated with short-term exposure to NO_2. The specific endpoints considered in this section are respiratory-related emergency department visits and hospital admissions, respiratory symptoms, lung host defense and immunity, airway responsiveness, airway inflammation, and lung function. Section II.B.2 discusses mortality and cardiovascular effects associated with short-term exposures. Section II.B.3 discusses effects that have been associated with long-term NO_2 exposures including respiratory morbidity, mortality, cancer, cardiovascular effects, and reproductive/developmental effects. Section II.B.4 discusses the potential NO_2-related impacts on public health.

1. Adverse Respiratory Effects and Short-Term Exposure to NO_2

The ISA concluded that, taken together, recent studies provide scientific evidence that is sufficient to infer a likely causal relationship between short-term NO_2 exposure and adverse effects on the respiratory system (ISA, section 5.3.2.1). This determination was based on consideration of the broad array of relevant scientific evidence, as well as the uncertainties associated with that evidence. Specifically, this determination is supported by the large body of recent epidemiologic evidence as well as findings from human and animal experimental studies.

In considering the uncertainties associated with the epidemiologic evidence, the ISA (section 5.4) noted that it is difficult to determine ''the extent to which NO_2 is independently associated with respiratory effects or if NO_2 is a marker for the effects of another traffic-related pollutant or mix of pollutants.'' On-road vehicle exhaust emissions are a nearly ubiquitous source of combustion pollutant mixtures that include NO_X and can be an important contributor to NO_2 levels in near-road locations. Although this complicates efforts to quantify specific NO_2-related health effects, a number of epidemiologic studies have evaluated associations with NO_2 in models that also include co-occurring pollutants such as PM, O_3, CO, and/or SO_2. The evidence summarized in the ISA indicates that NO_2 associations generally remain robust in these multi-pollutant models and supports a direct effect of short-term NO_2 exposure on respiratory morbidity (*see* ISA Figures 3.1–7, 3.1–10, 3.1–11 and Figures 1 through 3 below). The plausibility and coherence of these effects are also supported by epidemiologic studies of indoor NO_2 as well as experimental (*i.e.*, toxicologic and controlled human exposure) studies that have evaluated host defense and immune system changes, airway inflammation, and airway responsiveness (*see* subsequent sections of this proposal and the ISA, section 5.3.2.1). The ISA (section 5.4) concluded that the robustness of epidemiologic findings to adjustment for co-pollutants, coupled with data from animal and human experimental studies, support a determination that the relationship between NO_2 and respiratory morbidity is likely causal, while still recognizing the relationship between NO_2 and other traffic related pollutants.

BILLING CODE 6560–50–P

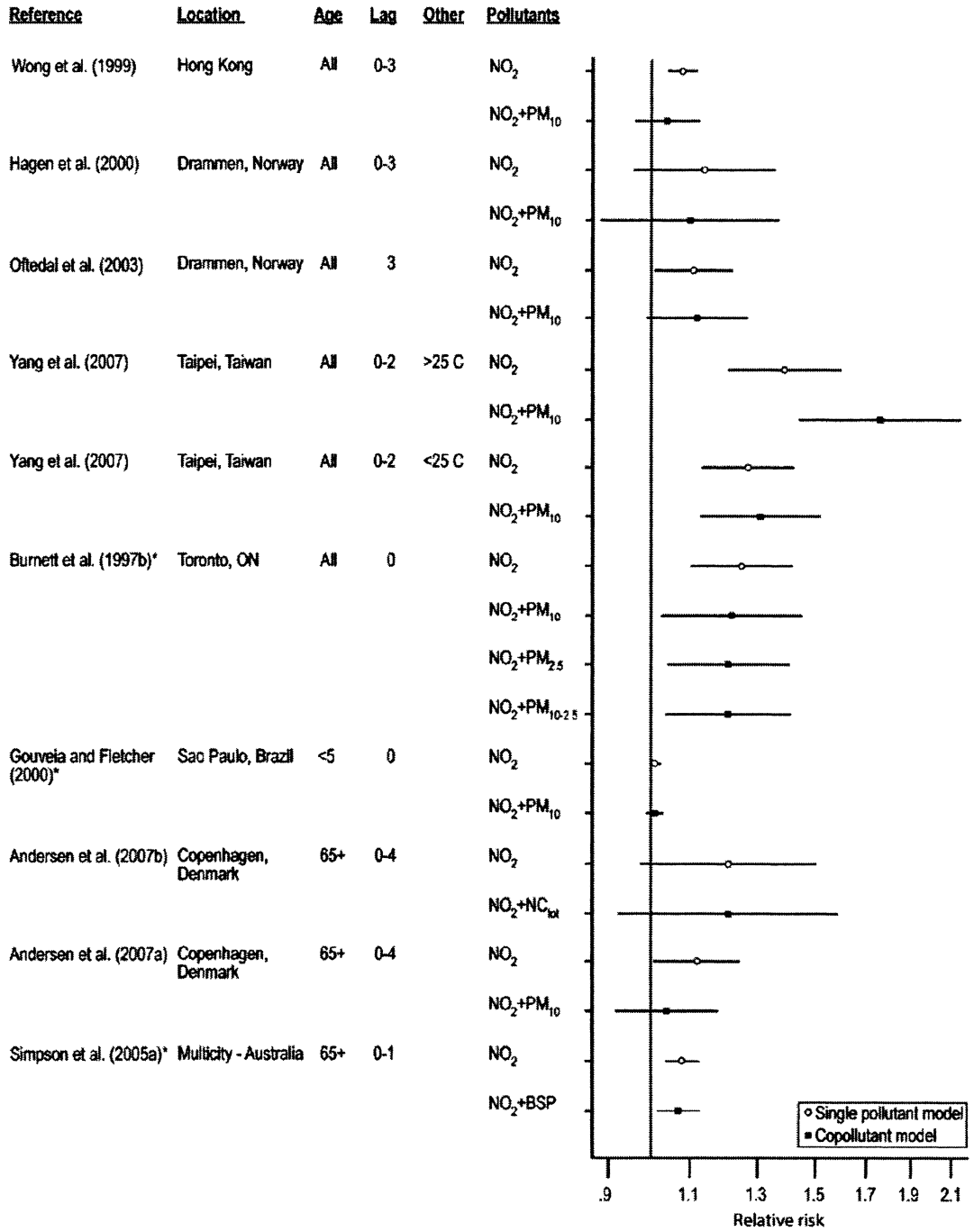


Figure 1. Relative risks and 95% confidence intervals for hospital admissions or emergency department visits for all respiratory causes, standardized from 2-pollutant models adjusted for particle concentration (ISA, Figure 3.1-10).

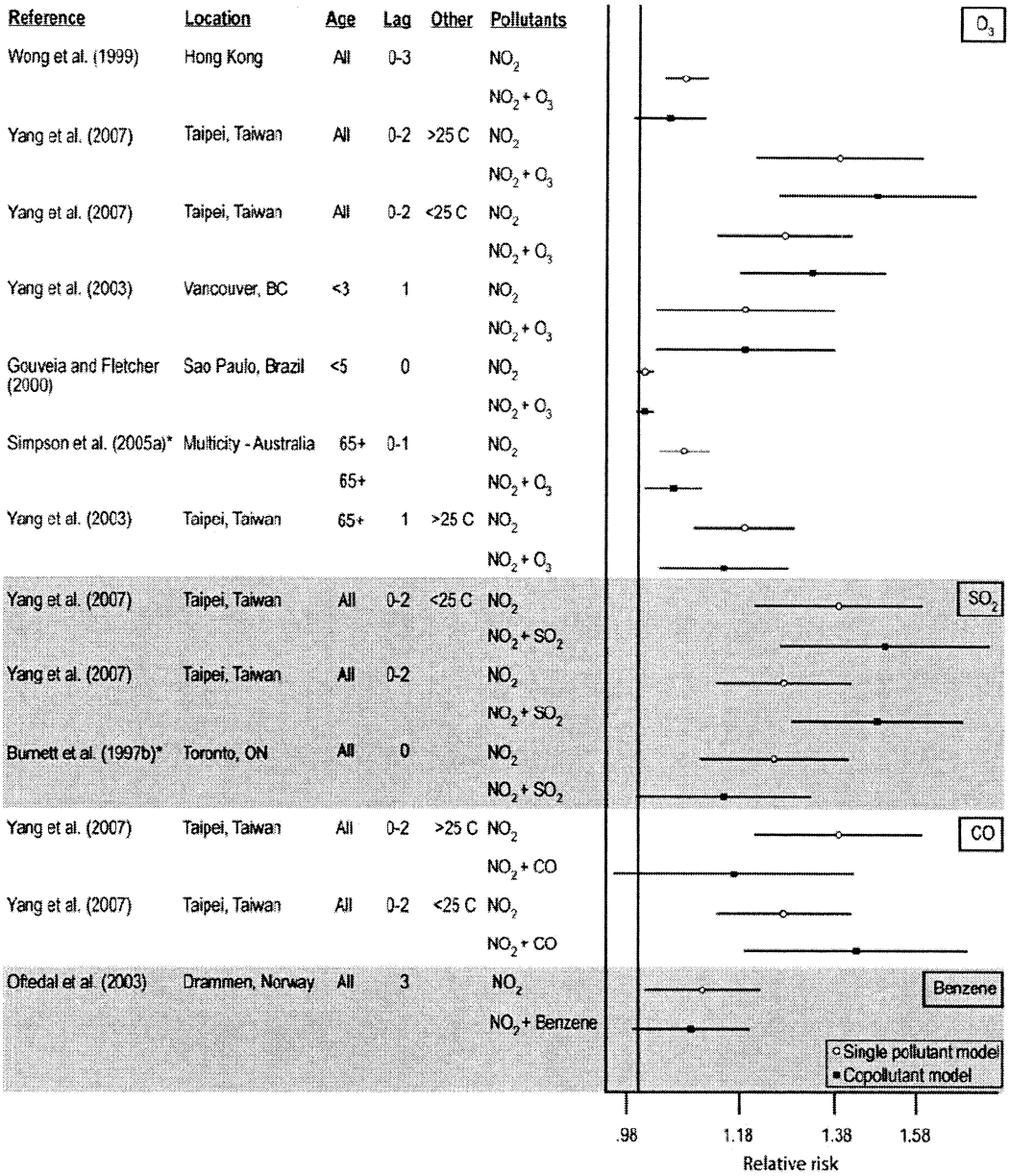


Figure 2. Relative risks and 95% confidence intervals for hospital admissions or emergency department visits for all respiratory causes, standardized from 2-pollutant models adjusted for gaseous pollutant concentration (ISA, Figure 3.1-11).

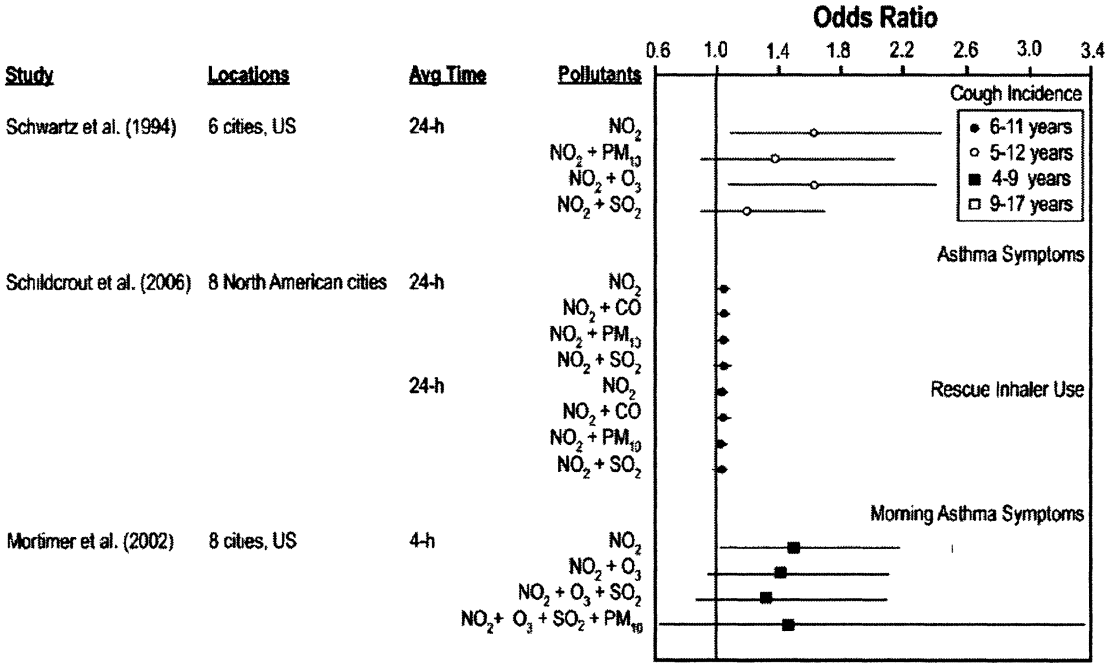


Figure 3. Odds ratios and 95% confidence intervals for associations between asthma symptoms and NO2 concentrations from multi-pollutant models (ISA, Figure 3.1-7).

BILLING CODE 6560–50–C

The epidemiologic and experimental studies encompass a number of endpoints, including emergency department visits and hospitalizations, respiratory symptoms, airway hyperresponsiveness, airway inflammation, and lung function. Effect estimates from epidemiologic studies conducted in the United States and Canada generally indicate a 2–20% [6] increase in risks for emergency department visits and hospital admissions and higher risks for respiratory symptoms (ISA, section 5.4). The findings relevant to these endpoints, which provide the rationale to support the judgment of a likely causal relationship, are described in more detail below.

a. Emergency Department Visits and Hospital Admissions

Epidemiologic evidence exists for positive associations of short-term ambient NO_2 concentrations below the current NAAQS with increased numbers of emergency department visits and hospital admissions for respiratory causes, especially asthma (ISA, section 5.3.2.1). Total respiratory causes for emergency department visits and hospitalizations typically include asthma, bronchitis and emphysema (collectively referred to as COPD), pneumonia, upper and lower respiratory infections, and other minor categories. Temporal associations between respiratory emergency department visits or hospital admissions and ambient levels of NO_2 have been the subject of over 50 peer-reviewed research publications since the review of the NO_2 NAAQS that was completed in 1996. These studies have examined morbidity in different age groups and have often utilized multi-pollutant models to evaluate potential confounding effects of co-pollutants. Associations are particularly consistent among children (< 14 years) and older adults (> 65 years) when all respiratory outcomes are analyzed together (ISA, Figures 3.1–8 and 3.1–9) and among children and subjects of all ages for asthma admissions (ISA, Figures 3.1–12 and 3.1–13). When examined with co-pollutant models, associations of NO_2 with respiratory emergency department visits and hospital admissions were generally robust and independent of the effects of co-pollutants (*i.e.*, magnitude of effect estimates remained relatively unchanged) (ISA, Figures 3.1–10 and 3.1–11). The plausibility and coherence of these effects are supported by experimental (*i.e.*, toxicologic and controlled human exposure) studies that evaluate host defense and immune system changes, airway inflammation, and airway responsiveness (see subsequent sections of this document and ISA, section 5.3.2.1).

Of the respiratory emergency department visit and hospital admission studies reviewed in the ISA, 6 key studies were conducted in the United States (ISA, Table 5.4–1). Of these 6 studies, 4 evaluated associations with NO_2 using multi-pollutant models (Peel *et al.*, 2005 and updated in Tolbert *et al.*, 2007 in Atlanta; New York Department of Health (NYDOH), 2006 and Ito *et al.*, 2007 in New York City), while 2 studies evaluated only single pollutant models (Linn *et al.*, 2000 in Los Angeles; Jaffe *et al.*, 2003 in Cleveland/Cincinnati, OH). In the study by Peel and colleagues, investigators evaluated respiratory emergency department visits among all ages in Atlanta, GA during the period from 1993 to 2000. Using single pollutant models, a 2.4% (95% CI: 0.9%, 4.1%) increase in respiratory emergency department visits was associated with a 30-ppb increase in 1-hour maximum NO_2 concentrations. For asthma visits, a 4.1% (95% CI: 0.8%, 7.6%) increase was estimated in individuals 2 to 18 years of age. Tolbert and colleagues reanalyzed these data with 4 additional years of information and found essentially similar results in single pollutant models (2.0% increase, 95% CI: 0.5%, 3.3%). This same study found that the associations were positive, but not statistically significant, in multi-pollutant models that included PM_{10} or O_3 (Figure 2 in published manuscript). In the study conducted by the NYDOH, investigators evaluated asthma

[6] Effect estimates in the ISA were standardized to a 30 ppb increase in NO_2 concentrations and to a 20 ppb increase for studies that evaluated 24-hour average concentrations.

emergency department visits in Bronx and Manhattan, New York over the period of January 1999 to November 2000. In Bronx, a 6% (95% CI: 1%, 10%) increase in visits was estimated per 20 ppb increase in 24-hour average concentrations of NO_2 and a 7% (95% CI: 2%, 12%) increase in visits was estimated per 30 ppb increase in daily 1-hour maximum concentrations. These effects were not statistically significant in 2-pollutant models that included $PM_{2.5}$ or SO_2 (Tables 4a and 9 in manuscript). In Manhattan, the authors found non-significant decreases (3% for 24-hour and a 2% for daily 1-hour maximum) in asthma-related emergency department visits associated with increasing NO_2. In the study by Ito and colleagues (2007), investigators evaluated respiratory emergency department visits for asthma in New York City during the years 1999 to 2002. A 12% (95% CI: 7%, 15%) increase in risk was estimated per 20 ppb increase in 24-hour ambient NO_2. Risk estimates were robust and remained statistically significant in multi-pollutant models that included $PM_{2.5}$, O_3, CO, and SO_2 (figure 8 in manuscript). With regard to the studies that evaluated only single pollutant models, Linn *et al.* (2000) detected a statistically significant increase in respiratory hospital admissions and Jaffe *et al.* (2003) detected a positive, but not statistically significant, increase in respiratory emergency department visits associated with 24-hour NO_2 concentrations.

b. Respiratory Symptoms

Evidence for associations between NO_2 and respiratory symptoms is derived primarily from the epidemiologic literature, although the experimental evidence for airway inflammation and immune system effects (described in the ISA, section 3.1) does provide support for the plausibility and coherence for the epidemiologic results (ISA, section 5.3.2.1). Consistent evidence has been observed for an association of respiratory effects with indoor and personal NO_2 exposures in children (ISA, sections 3.1.5.1 and 5.3.2.1) and with ambient levels of NO_2, as measured by area-wide monitors (ISA, sections 3.1.4.2 and 5.3.2.1, *see* Figure 3.1–6). In the results of multi-pollutant models, NO_2 associations in multicity studies are generally robust to adjustment for co-pollutants including O_3, CO, and PM_{10} (ISA, sections 3.1.4.3, 5.3.2.1 and Figure 3.1–7). Specific studies of respiratory symptoms are discussed in more detail below.

Epidemiologic studies using community ambient monitors have found associations between ambient NO_2 concentrations and respiratory symptoms (ISA, sections 3.1.4.2 and 5.3.2.1, Figure 3.1–6) in cities where the entire range of 24-hour average NO_2 concentrations were well below the level of the current NAAQS (0.053 ppm annual average). Several studies have been published since the last review including single-city studies (*e.g.*, Ostro *et al.*, 2001; Delfino *et al.*, 2002) and multicity studies in urban areas covering the continental United States and southern Ontario (Schwartz *et al.*, 1994; Mortimer *et al.*, 2002; Schildcrout *et al.*, 2006).

Schwartz *et al.* (1994) studied 1,844 schoolchildren, followed for 1 year, as part of the Six Cities Study that included the cities of Watertown, MA, St. Louis, MO, Kingston-Harriman, TN, Steubenville, OH, Topeka, KS, and Portage, WI. Respiratory symptoms were recorded daily. The authors reported a significant association between 4-day mean NO_2 levels and incidence of cough among all children in single-pollutant models, with an odds ratio (OR) of 1.61 (95% CI: 1.08, 2.43) standardized to a 20-ppb increase in NO_2. The incidence of cough increased up to approximately mean NO_2 levels (13 ppb) ($p = 0.01$), after which no further increase was observed. The significant association between cough and 4-day mean NO_2 level remained unchanged in models that included O_3 but lost statistical significance in two-pollutant models that included PM_{10} (OR = 1.37 [95% CI: 0.88, 2.13]) or SO_2 (OR = 1.42 [95% CI: 0.90, 2.28]).

Mortimer *et al.* (2002) studied the risk of asthma symptoms among 864 asthmatic children in New York City, NY, Washington, DC, Cleveland, OH, Detroit, MI, St Louis, MO, and Chicago, IL. Subjects were followed daily for four 2-week periods over the course of nine months with morning and evening asthma symptoms and peak flow recorded. The greatest effect was observed for morning symptoms using a 6-day moving average, with a reported OR of 1.48 (95% CI: 1.02, 2.16) per 20 ppb increase in NO_2. Although the magnitudes of effect estimates were generally robust in multi-pollutant models that included O_3 (OR for 20-ppb increase in NO_2 = 1.40 [95% CI: 0.93, 2.09]), O_3 and SO_2 (OR for NO_2 = 1.31 [95% CI: 0.87, 2.09]), or O_3, SO_2, and PM_{10} (OR for NO_2 = 1.45 [95% CI: 0.63, 3.34]), they were not statistically significant.

Schildcrout *et al.* (2006) investigated the association between ambient NO_2 and respiratory symptoms and rescue inhaler use as part of the Childhood Asthma Management Program (CAMP) study. The study reported on 990 asthmatic children living within 50 miles of an NO_2 monitor in Boston, MA, Baltimore, MD, Toronto, ON, St. Louis, MO, Denver, CO, Albuquerque, NM, or San Diego, CA. Symptoms and use of rescue medication were recorded daily, resulting in each subject having an average of approximately two months of data. The authors reported the strongest association between NO_2 and increased risk of cough for a 2-day lag, with an OR of 1.09 (95% CI: 1.03, 1.15) for each 20-ppb increase in NO_2 occurring 2 days before measurement. Multi-pollutant models that included CO, PM_{10}, or SO_2 produced similar results (ISA, Figure 3.1–5, panel A). Additionally, increased NO_2 exposure was associated with increased use of rescue medication, with the strongest association for a 2-day lag. In the single-pollutant model, the relative risk (RR) for increased inhaler usage was 1.05 (95% CI: 1.01, 1.09).

Evidence supporting increased respiratory symptoms following NO_2 exposures is found in studies focused on indoor sources of NO_2 (ISA, section 3.1.4.1). These studies are not confounded by the same mix of co-pollutants present in the ambient air or by the contribution of NO_2 to the formation of secondary particles or O_3 (ISA, section 3.1.4.1). Specifically, in a randomized intervention study in Australia (Pilotto *et al.*, 2004), asthmatic students attending schools that switched out unvented gas heaters, a major source of indoor NO_2, experienced a decrease in both levels of NO_2 and in respiratory symptoms (*e.g.*, difficulty breathing, chest tightness, and asthma attacks) compared to students in schools that did not switch out unvented gas heaters (ISA, section 3.1.4.1). An earlier indoor study by Pilotto and colleagues (1997) also found that students in classrooms with higher levels of NO_2 due primarily to indoor sources had higher rates of respiratory symptoms (*e.g.*, sore throat, cold) and absenteeism than students in classrooms with lower levels of NO_2. This study detected a significant concentration-response relationship, strengthening the argument that NO_2 is causally related to respiratory morbidity. A number of other indoor studies conducted in homes with gas appliances have also detected significant associations between indoor NO_2 and respiratory symptoms (ISA, section 3.1.4.1).

c. Impaired Host Defense

Impaired host-defense systems and increased risk of susceptibility to both viral and bacterial infections after NO_2 exposures have been observed in

epidemiologic, controlled human exposure, and animal toxicological studies (ISA, section 3.1.1 and 5.3.2.1). A recent epidemiologic study (Chauhan *et al.*, 2003) provides evidence that increased personal exposure to NO_2 worsened virus-associated symptoms and decreased lung function in children with asthma. The limited evidence from controlled human exposure studies indicates that NO_2 may increase susceptibility to lung injury by subsequent viral challenge at exposures of as low as 600 ppb for 3 hours in healthy adults (Frampton *et al.*, 2002). Toxicological studies have shown that lung host defenses, including mucociliary clearance and immune cell function, are sensitive to NO_2 exposure, with effects observed at concentrations of less than 1000 ppb (ISA, section 3.1.7). When taken together, epidemiologic and experimental studies linking NO_2 exposure with viral illnesses provide coherent and consistent evidence that NO_2 exposure can result in lung host defense or immune system effects (ISA, sections 3.1.7 and 5.3.2.1). This group of outcomes also provides some plausibility for other respiratory system effects. For example, effects on ciliary action (clearance) or immune cell function (*i.e.* macrophage phagocytosis) could be the basis for the effects observed in epidemiologic studies, including increased respiratory illness or respiratory symptoms (ISA, section 5.3.2.1). Proposed mechanisms by which NO_2, in conjunction with viral infections, may exacerbate airway symptoms are summarized in the ISA (Table 3.1–1).

d. Airway Response

In acute exacerbations of asthma, bronchial smooth muscle contraction occurs quickly to narrow the airway in response to exposure to various stimuli including allergens or irritants. Bronchoconstriction is the dominant physiological event leading to clinical symptoms and interference with airflow (National Heart, Lung, and Blood Institute, 2007). Inhaled pollutants such as NO_2 may enhance the inherent responsiveness of the airway to a challenge by allergens and nonspecific agents (ISA, section 3.1.3). In the laboratory, airway responses can be measured by assessing changes in pulmonary function (*e.g.*, decline in FEV1) or changes in the inflammatory response (*e.g.*, using markers in bronchoalveolar lavage (BAL) fluid or induced sputum) (ISA, section 3.1.3).

The ISA (section 5.3.2.1) drew two broad conclusions regarding airway responsiveness in asthmatics following NO_2 exposure. First, the ISA concluded that NO_2 exposure may enhance the sensitivity to allergen-induced decrements in lung function and increase the allergen-induced airway inflammatory response at exposures as low as 260 ppb NO_2 for 30 minutes (ISA, section 5.3.2.1 and Figure 3.1–2). Second, exposure to NO_2 has been found to enhance the inherent responsiveness of the airway to subsequent nonspecific challenges in controlled human exposure studies (section 3.1.3.2). In general, small but significant increases in nonspecific airway responsiveness were observed in the range of 200 to 300 ppb NO_2 for 30-minute exposures and at 100 ppb NO_2 for 60-minute exposures in asthmatics. These conclusions are consistent with results from animal toxicological studies which have detected 1) increased immune-mediated pulmonary inflammation in rats exposed to house dust mite allergen following exposure to 5000 ppb NO_2 for 3-h and 2) increased responsiveness to non-specific challenges following sub-chronic (6–12 weeks) exposure to 1000 to 4000 ppb NO_2 (ISA, section 5.3.2.1).

Enhanced airway responsiveness could have important clinical implications for asthmatics since transient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control (ISA, section 5.4). In addition, the ISA cited the controlled human exposure literature on the NO_2 airway response as being supportive of the epidemiologic evidence on respiratory morbidity (ISA, section 5.4). Because studies on airway responsiveness have been used to identify potential health effect benchmark values and to inform the identification of potential alternative standards for evaluation (*see* REA, sections 4.5 and 5), more detail is provided below on the specific studies that form the basis for the conclusions in the ISA regarding this endpoint.

Folinsbee (1992) conducted a meta-analysis using individual level data from 19 NO_2 controlled human exposure studies measuring airway responsiveness in asthmatics (ISA, section 3.1.3.2). These studies included NO_2 exposure levels between 100 and 1000 ppb and most of them used nonspecific bronchoconstricting agents such as methacholine, carbachol, histamine, or cold air. The largest effects were observed for asthmatics at rest. Among asthmatics exposed at rest, 76% experienced increased airway responsiveness following exposure to NO_2 levels between 200 and 300 ppb. Results from an update of this meta-analysis, which focused only on data for nonspecific responsiveness, are presented in the ISA (Table 3.1–3).[7] When exposed at rest, 66% of asthmatics experienced an increase in airway responsiveness following exposure to 100 ppb NO_2, 67% of asthmatics experienced an increase in airway responsiveness following exposure to NO_2 concentrations between 100 and 150 ppb (inclusively), 75% of subjects experienced an increase in airway responsiveness following exposure to NO_2 concentrations between 200 and 300 ppb (inclusively), and 73% of subjects experienced an increase in airway responsiveness following exposure to NO_2 concentrations above 300 ppb. Effects of NO_2 exposure on the direction of airway responsiveness were statistically significant at all of these levels. Because this meta-analysis evaluated only the direction of the change in airway responsiveness, it is not possible to discern the magnitude of the change from these data. However, the results do suggest that short-term (*i.e.*, 30-min to 3-h) exposures to NO_2 at near-ambient levels (<300 ppb) can alter airway responsiveness in people with mild asthma (ISA, section 3.1.3.2).

Several studies published since the 1996 review evaluate the potential for low-level exposures to NO_2 to enhance the response to specific allergen challenge in mild asthmatics (ISA, section 3.1.3.1). These studies suggest that NO_2 may enhance the sensitivity to allergen-induced decrements in lung function and increase the allergen-induced airway inflammatory response. Strand *et al.* (1997) demonstrated that single 30-minute exposures to 260 ppb NO_2 increased the late phase response to allergen challenge 4 hours after exposure, as measured by changes in lung function. In a separate study (Strand *et al.*, 1998), 4 daily repeated exposures to 260 ppb NO_2 for 30 minutes increased both the early and late-phase responses to allergen, as measured by changes in lung function. Barck *et al.* (2002) used the same exposure and challenge protocol in the earlier Strand study (260 ppb for 30 min, with allergen challenge 4 hours after exposure), and performed BAL 19 hours after the allergen challenge to determine NO_2 effects on the allergen-induced inflammatory response. Compared with air followed by allergen, NO_2 followed by allergen caused an

[7] The updated meta-analysis added a study that evaluated non-specific airway responsiveness following exposure to 260 ppb NO_2 and removed a study that evaluated allergen-induced airway responsiveness following exposure to 100 ppb NO_2.

increase in the BAL recovery of polymorphonuclear (PMN) cells and eosinophil cationic protein (ECP) as well as a reduction in total BAL fluid volume and cell viability. ECP is released by degranulating eosinophils, is toxic to respiratory epithelial cells, and is thought to play a role in the pathogenesis of airway injury in asthma. Subsequently, Barck *et al.* (2005) exposed 18 mild asthmatics to air or 260 ppb NO_2 for 15 minutes on day 1, followed by two 15 minute exposures separated by 1 hour on day 2, with allergen challenge after exposures on both days 1 and 2. Sputum was induced before exposure on day 1 and after exposures (morning of day 3). Compared to air plus allergen, NO_2 plus allergen resulted in increased levels of ECP in both sputum and blood and increased myeloperoxidase levels in blood.

All exposures in these studies (Barck *et al.*, 2002, 2005; Strand *et al.*, 1997, 1998) used subjects at rest. They used an adequate number of subjects, included air control exposures, randomized exposure order, and separated exposures by at least 2 weeks. Together, they indicate the possibility for effects on allergen responsiveness in some asthmatics following brief exposures to 260 ppb NO_2. Other recent studies have failed to find effects using similar, but not identical, approaches (ISA, section 3.1.3.1). The differing findings may relate in part to differences in timing of the allergen challenge, the use of multiple versus single-dose allergen challenge, the use of BAL versus sputum induction, exercise versus rest during exposure, and differences in subject susceptibility (ISA, section 3.1.3.1).

e. Airway Inflammation

Effects of NO_2 on airway inflammation have been observed in controlled human exposure and animal toxicological studies at higher than ambient levels (400–5000 ppb). Controlled human exposure studies provide evidence for increased airway inflammation at NO_2 concentrations of <2000 ppb. The onset of inflammatory responses in healthy subjects appears to be between 100 and 200 ppm-minutes, *i.e.*, 1000 ppb for 2 to 3 hours (ISA, Figure 3.1–1). Increases in biological markers of inflammation were not observed consistently in healthy animals at levels of less than 5000 ppb; however, increased susceptibility (as indicated by biochemical markers of inflammation) to NO_2 concentrations of as low as 400 ppb was observed when lung vitamin C was reduced (by diet) to levels that were <50% of normal. The few available epidemiologic studies were suggestive of an association between ambient NO_2 concentrations and inflammatory response in the airway in children, though the associations were inconsistent in the adult populations examined (ISA, section 3.1.2 and 5.3.2.1). These data provide some evidence for biological plausibility and one potential mechanism for other respiratory effects, such as exacerbation of asthma symptoms and increased emergency department visits for asthma (ISA, section 5.3.2.1).

f. Lung Function

Recent epidemiologic studies that examined the association between ambient NO_2 concentrations and lung function in children and adults have produced inconsistent results (ISA, sections 3.1.5.1 and 5.3.2.1). Controlled human exposure studies generally did not find direct effects of NO_2 on lung function in healthy adults at levels as high as 4000 ppb (ISA, section 5.3.2.1). For asthmatics, the direct effects of NO_2 on lung function also have been inconsistent at exposure concentrations of less than 1000 ppb NO_2.

g. Conclusions From the ISA

As noted previously, the ISA concluded that the findings of epidemiologic, controlled human exposure, and animal toxicological studies provide evidence that is sufficient to infer a likely causal relationship for respiratory effects following short-term NO_2 exposure (ISA, sections 3.1.7 and 5.3.2.1). The ISA (section 5.4) concluded that the strongest evidence for an association between NO_2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms, emergency department visits, and hospital admissions. These studies include panel and field studies, studies that control for the effects of co-occurring pollutants, and studies conducted in areas where the whole distribution of ambient 24-hour average NO_2 concentrations was below the current NAAQS level of 53 ppb (annual average). With regard to this evidence, the ISA concluded that NO_2 epidemiologic studies provide ''little evidence of any effect threshold'' (ISA, section 5.3.2.9, p. 5–15). In studies that have evaluated concentration-response relationships, they appear linear within the observed range of data (ISA, section 5.3.2.9).

Overall, the epidemiologic evidence for respiratory effects has been characterized in the ISA as consistent, in that associations are reported in studies conducted in numerous locations with a variety of methodological approaches. Considering this large body of epidemiologic studies alone, the findings have also been characterized as coherent in that the studies report associations with respiratory health outcomes that are logically linked together. In addition, a number of these associations are statistically significant, particularly the more precise effect estimates (ISA, section 5.3.2.1). These epidemiologic studies are supported by evidence from toxicological and controlled human exposure studies, particularly those that evaluated airway hyperresponsiveness in asthmatic individuals (ISA, section 5.4). The ISA concluded that together, the epidemiologic and experimental data sets form a plausible, consistent, and coherent description of a relationship between NO_2 exposures and an array of adverse respiratory health effects that range from the onset of respiratory symptoms to hospital admissions.

2. Other Effects With Short-Term Exposure to NO_2

a. Mortality

The ISA concluded that the epidemiologic evidence is suggestive, but not sufficient, to infer a causal relationship between short-term exposure to NO_2 and all-cause and cardiopulmonary-related mortality (ISA, section 5.3.2.3). Results from several large U.S. and European multicity studies and a meta-analysis study indicate positive associations between ambient NO_2 concentrations and the risk of all-cause (nonaccidental) mortality, with effect estimates ranging from 0.5 to 3.6% excess risk in mortality per standardized increment (20 ppb for 24-hour averaging time, 30 ppb for 1-hour averaging time) (ISA, section 3.3.1, Figure 3.3–2, section 5.3.2.3). In general, the NO_2 effect estimates were robust to adjustment for co-pollutants. Both cardiovascular and respiratory mortality have been associated with increased NO_2 concentrations in epidemiologic studies (ISA, Figure 3.3–3); however, similar associations were observed for other pollutants, including PM and SO_2. The range of risk estimates for excess mortality is generally smaller than that for other pollutants such as PM. In addition, while NO_2 exposure, alone or in conjunction with other pollutants, may contribute to increased mortality, evaluation of the specificity of this effect is difficult. Clinical studies showing hematologic effects and animal toxicological studies showing biochemical, lung host defense, permeability, and inflammation changes

with short-term exposures to NO_2 provide limited evidence of plausible pathways by which risks of mortality may be increased, but no coherent picture is evident at this time (ISA, section 5.3.2.3).

b. Cardiovascular Effects

The ISA concluded that the available evidence on cardiovascular health effects following short-term exposure to NO_2 is inadequate to infer the presence or absence of a causal relationship at this time (ISA, section 5.3.2.2). Evidence from epidemiologic studies of heart rate variability, repolarization changes, and cardiac rhythm disorders among heart patients with ischemic cardiac disease are inconsistent (ISA, section 5.3.2.2). In most studies, associations with PM were found to be similar or stronger than associations with NO_2. Generally positive associations between ambient NO_2 concentrations and hospital admissions or emergency department visits for cardiovascular disease have been reported in single-pollutant models (ISA, section 5.3.2.2); however, most of these effect estimate values were diminished in multi-pollutant models that also contained CO and PM indices (ISA, section 5.3.2.2). Mechanistic evidence of a role for NO_2 in the development of cardiovascular diseases from studies of biomarkers of inflammation, cell adhesion, coagulation, and thrombosis is lacking (ISA, section 5.3.2.2). Furthermore, the effects of NO_2 on various hematological parameters in animals are inconsistent and, thus, provide little biological plausibility for effects of NO_2 on the cardiovascular system (ISA, section 5.3.2.2).

3. Health Effects With Long-Term Exposure to NO_2

a. Respiratory Morbidity

The ISA concluded that overall, the epidemiologic and experimental evidence is suggestive, but not sufficient, to infer a causal relationship between long-term NO_2 exposure and respiratory morbidity (ISA, section 5.3.2.4). The available database evaluating the relationship between respiratory illness in children and long-term exposures to NO_2 has increased since the 1996 review of the NO_2 NAAQS. A number of epidemiologic studies have examined the effects of long-term exposure to NO_2 and reported positive associations with decrements in lung function and partially irreversible decrements in lung function growth (ISA, section 3.4.1, Figures 3.4–1 and 3.4–2). Specifically, results from the California-based Children's Health Study, which evaluated NO_2 exposures in children over an 8-year period, demonstrated deficits in lung function growth (Gauderman *et al.*, 2004). This effect has also been observed in Mexico City, Mexico (Rojas-Martinez *et al.*, 2007a,b) and in Oslo, Norway (Oftedal *et al.*, 2008), with decrements ranging from 1 to 17.5 ml per 20-ppb increase in annual NO_2 concentration. Similar associations have been found for PM, O_3, and proximity to traffic (<500 m), though these studies did not report the results of co-pollutant models. The high correlation among traffic-related pollutants makes it difficult to accurately estimate independent effects in these long-term exposure studies (ISA, section 5.3.2.4). With regard to asthma incidence and long-term NO_2, two major cohort studies, the Children's Health Study (Gauderman *et al.*, 2005) and a birth cohort study in the Netherlands (Brauer *et al.*, 2007), observed significant associations. However, several other studies failed to find consistent associations between long-term NO_2 exposure and asthma outcomes (ISA, section 5.3.2.4). Similarly, epidemiologic studies conducted in the United States and Europe reported inconsistent results regarding an association between long-term exposure to NO_2 and respiratory symptoms (ISA, sections 3.4.3 and 5.3.2.4). While some positive associations were noted, a large number of symptom outcomes were examined and the results across specific outcomes were inconsistent (ISA, section 5.3.2.4).

Animal toxicological studies may provide biological plausibility for the chronic effects of NO_2 that have been observed in epidemiologic studies (ISA, sections 3.4.5 and 5.3.2.4). The main biochemical targets of NO_2 exposure appear to be antioxidants, membrane polyunsaturated fatty acids, and thiol groups. NO_2 effects include changes in oxidant/antioxidant homeostasis and chemical alterations of lipids and proteins. Lipid peroxidation has been observed at NO_2 exposures as low as 40 ppb for 9 months and at exposures of 1200 ppb for 1 week, suggesting lower effect thresholds with longer durations of exposure. Other studies showed decreases in formation of key arachidonic acid metabolites in alveolar macrophages following NO_2 exposures of 500 ppb. NO_2 has been shown to increase collagen synthesis rates at concentrations as low as 500 ppb. This could indicate increased total lung collagen, which is associated with pulmonary fibrosis, or increased collagen turnover, which is associated with remodeling of lung connective tissue. Morphological effects following chronic NO_2 exposures have been identified in animal studies that link to these increases in collagen synthesis and may provide plausibility for the deficits in lung function growth described in epidemiologic studies of long-term exposure to NO_2 (ISA, section 3.4.5).

b. Mortality

The ISA concluded that the epidemiologic evidence is inadequate to infer the presence or absence of a causal relationship between long-term exposure to NO_2 and mortality (ISA, section 5.3.2.6). In the United States and European cohort studies examining the relationship between long-term exposure to NO_2 and mortality, results have been inconsistent (ISA, section 5.3.2.6). Further, when associations were suggested, they were not specific to NO_2 but also implicated PM and other traffic indicators. The relatively high correlations reported between NO_2 and PM indices make it difficult to interpret these observed associations at this time (ISA, section 5.3.2.6).

c. Carcinogenic, Cardiovascular, and Reproductive/Developmental Effects

The ISA concluded that the available epidemiologic and toxicological evidence is inadequate to infer the presence or absence of a causal relationship for carcinogenic, cardiovascular, and reproductive and developmental effects related to long-term NO_2 exposure (ISA, section 5.3.2.5). Epidemiologic studies conducted in Europe have shown an association between long-term NO_2 exposure and increased incidence of cancer (ISA, section 5.3.2.5). However, the animal toxicological studies have provided no clear evidence that NO_2 acts as a carcinogen (ISA, section 5.3.2.5). The very limited epidemiologic and toxicological evidence do not suggest that long-term exposure to NO_2 has cardiovascular effects (ISA, section 5.3.2.5). The epidemiologic evidence is not consistent for associations between NO_2 exposure and fetal growth retardation; however, some evidence is accumulating for effects on preterm delivery (ISA, section 5.3.2.5). Scant animal evidence supports a weak association between NO_2 exposure and adverse birth outcomes and provides little mechanistic information or biological plausibility for the epidemiologic findings.

4. NO_2-Related Impacts on Public Health

Specific groups within the general population are likely at increased risk

for suffering adverse effects from NO_2 exposure. This could occur because they are affected by lower levels of NO_2 than the general population (susceptibility), because they experience a larger health impact than the general population to a given level of exposure (susceptibility), and/or because they are exposed to higher levels of NO_2 than the general population (vulnerability). The term susceptibility generally encompasses innate (*e.g.*, genetic or developmental) and/or acquired (*e.g.*, age or disease) factors that make individuals more likely to experience effects with exposure to pollutants. The severity of health effects experienced by a susceptible subgroup may be much greater than that experienced by the population at large. Factors that may influence susceptibility to the effects of air pollution include age (*e.g.*, infants, children, elderly); gender; race/ethnicity; genetic factors; and pre-existing disease/condition (*e.g.*, obesity, diabetes, respiratory disease, asthma, chronic obstructive pulmonary disease (COPD), cardiovascular disease, airway hyperresponsiveness, respiratory infection, adverse birth outcome) (ISA, sections 4.3.1, 4.3.5, and 5.3.2.8). In addition, certain groups may experience relatively high exposure to NO_2, thus forming a potentially vulnerable population (ISA, section 4.3.6). Factors that may influence exposures and/or susceptibility to air pollution include socioeconomic status (SES), education level, air conditioning use, proximity to roadways, geographic location, level of physical activity, and work environment (*e.g.*, indoor versus outdoor) (ISA, section 4.3.5). The ISA discussed factors that can confer susceptibility and/or vulnerability to air pollution with most of the discussion devoted to factors for which NO_2-specific evidence exists (ISA, section 4.3). These factors are discussed below.

a. Pre-Existing Disease

A number of health conditions have been found to put individuals at greater risk for adverse events following exposure to air pollution. In general, these include asthma, COPD, respiratory infection, cardiac conduction disorders, congestive heart failure (CHF), diabetes, past myocardial infarction (MI), obesity, coronary artery disease, low birth weight/prematurity, and hypertension (ISA, sections 4.3.1, 4.3.5, and 5.3.2.9). In addition to these conditions, epidemiologic evidence indicates that individuals with bronchial or airway hyperresponsiveness, as determined by methacholine provocation, may be at increased risk for experiencing respiratory symptoms (ISA, section 4.3.1). In considering NO_2 specifically, the ISA evaluated studies on asthmatics, individuals with cardiopulmonary disease, and diabetics (ISA, sections 4.3.1.1 and 4.3.1.2). These groups are discussed in more detail below.

Epidemiologic and controlled human exposure studies, supported by animal toxicology studies, have provided evidence for associations between NO_2 exposure and respiratory effects in asthmatics (ISA, section 4.3.1.1). The ISA found evidence from epidemiologic studies for an association between ambient NO_2 and children's hospital admissions, emergency department visits, and calls to doctors for asthma. Long-term NO_2 exposure was associated with aggravation of asthma effects that include symptoms, medication use, and lung function. Time-series studies demonstrated a relationship in children between hospital admissions or emergency department visits for asthma and ambient NO_2 levels, even after adjusting for co-pollutants such as PM and CO (ISA, section 4.3.1.1). Important evidence was available from epidemiologic studies of indoor NO_2 exposures. Recent studies have shown associations with asthma attacks and severity of virus-induced asthma (ISA, section 4.3.1.1). In addition, in controlled human exposure studies, airway hyperresponsiveness in asthmatics occurred following exposure to ambient or near-ambient NO_2 concentrations (ISA, sections 5.3.2.1–5.3.2.6). Compared to asthma, less evidence is available to support cardiovascular disease as a mediator of susceptibility to NO_2. However, recent epidemiologic studies report that individuals with preexisting conditions (*e.g.*, including diabetes, CHF, prior MI) may be at increased risk for adverse cardiac health events associated with ambient NO_2 concentrations (ISA, section 4.3.1.2). The small number of controlled human exposure and animal toxicological studies that have evaluated cardiovascular endpoints provide only limited supporting evidence for susceptibility to NO_2 in persons with cardiovascular disease (ISA, section 4.3.1.2).

b. Age

The ISA identified infants, children (*i.e.*, <18 years of age), and older adults (*i.e.*, >65 years of age) as groups that are potentially more susceptible than the general population to the health effects associated with ambient NO_2 concentrations (ISA, section 4.3.2). The ISA found evidence that associations of NO_2 with respiratory emergency department visits and hospitalizations were stronger among children and older adults, though not all studies had comparable findings on this issue (ISA, section 4.3.2). In addition, long-term exposure studies suggest effects in children that include impaired lung function growth, increased respiratory symptoms and infections, and onset of asthma (ISA, section 3.4 and 4.3.2). In some studies, associations between NO_2 and hospitalizations or emergency department visits for CVD have been observed in elderly populations. Among studies that observed positive associations between NO_2 and mortality, a comparison indicated that, in general, the elderly population was more susceptible than the non-elderly population to NO_2 effects (ISA, section 4.3.2).

c. Genetics

As noted in the ISA (section 4.3.4), genetic factors related to health outcomes and ambient pollutant exposures merit consideration. Several criteria should be satisfied in selecting and establishing useful links between polymorphisms in candidate genes and adverse respiratory effects. First, the candidate gene must be significantly involved in the pathogenesis of the adverse effect of interest. Second, polymorphisms in the gene must produce a functional change in either the protein product or in the level of expression of the protein. Third, in epidemiologic studies, the issue of confounding by other environmental exposures must be carefully considered (ISA, section 4.3.4). Investigation of genetic susceptibility to NO_2 effects has focused on the glutathione S-tranferase (GST) gene. Several GST genes have common, functionally-important alleles that affect host defense in the lung (ISA, section 4.3.4). GST genes are inducible by electrophilic species (*e.g.*, reactive oxygen species) and individuals with genotypes that result in enzymes with reduced or absent peroxidase activity are likely to have reduced defenses against oxidative insult. This could potentially result in increased susceptibility to inhaled oxidants and radicals. However, data on genetic susceptibility to NO_2 are only beginning to emerge and, while it remains plausible that there are genetic factors that can influence health responses to NO_2, the few available studies do not provide specific support for genetic susceptibility to NO_2 exposure (ISA, section 4.3.4).

d. Gender

As reported in the ISA, a limited number of NO_2 studies have stratified results by gender. The results of these studies were mixed, and the ISA did not

draw conclusions regarding the potential for gender to confer susceptibility to the effects of NO_2 (ISA, section 4.3.3).

e. Proximity to Roadways

Certain groups may experience relatively high exposure to NO_2, thus forming a potentially vulnerable population. The ISA included discussion of populations reported to experience increased NO_2 exposures on or near roadways (ISA, section 4.3.6). Large gradients in NO_X concentrations near roadways may lead to increased exposures for individuals residing, working, traveling, or attending school in the vicinity of roadways. Many studies find that indoor, personal, and outdoor NO_2 levels are strongly associated with proximity to traffic or to traffic density (ISA, section 4.3.6).

That adverse respiratory effects can be associated with proximity to roadways has been demonstrated in a number of studies. For example, Gauderman and colleagues (2007) reported reduced lung function growth in children who lived within 500 m of a freeway compared to children who lived at least 1500 m from a freeway. In a separate study, Gauderman and colleagues (2005) reported that the incidence of physician-diagnosed asthma increased with both increasing NO_2 concentrations outside the child's residence and decreasing distance between the child's residence and a major freeway.

In addition to those who live near major roadways, individuals who spend time commuting on major roadways can also be exposed to relatively higher concentrations of NO_2 than the ones reported at monitors away from the roads. Due to high air exchange rates, NO_2 concentrations inside a vehicle can rapidly approach ambient concentrations on the roadway during commuting (ISA, section 4.3.6). Mean in-vehicle NO_2 concentrations are often between 2 and 3 times higher than ambient levels measured at monitors located away from the road (ISA, section 4.3.6). Due to the potential for high peak exposures while driving, total personal exposure could be underestimated if exposures while commuting are not considered. Therefore, individuals with occupations that require them to be in traffic or close to traffic (*e.g.*, bus and taxi drivers, highway patrol officers, toll collectors) and individuals with long commutes could be exposed to relatively high levels of NO_2 compared to the ambient levels measured at fixed-site monitors located away from the roadway.

f. Socioeconomic Status

The ISA discussed evidence that SES modifies the effects of air pollution (section 4.3.6). Many recent studies examined modification by SES indicators on the association between mortality and PM or other indices such as traffic density, distance to roadway, or a general air pollution index (ISA, section 4.3.6). SES modification of NO_2 associations has been examined in fewer studies. However, in a study conducted in Seoul, South Korea, community-level SES indicators modified the association of air pollution with emergency department visits for asthma. Of the five criteria air pollutants evaluated, NO_2 showed the strongest association in lower SES districts compared to high SES districts (Kim *et al.*, 2007). In addition, Clougherty *et al.* (2007) evaluated exposure to violence (a potential surrogate for SES) as a modifier of the effect of traffic-related air pollutants, including NO_2, on childhood asthma. The authors reported an elevated risk of asthma with an increase in NO_2 exposure solely among children with above-median exposure to violence in their neighborhoods (ISA, section 4.3.6). Although these recent studies have evaluated the impact of SES on vulnerability to NO_2, they are too few in number to draw definitive conclusions (ISA, section 5.3.2.8).

g. Size of the At-Risk Population

The population potentially affected by NO_2 is large. A considerable fraction of the population resides, works, or attends school near major roadways, and these individuals are likely to have increased exposure to NO_2 (ISA, section 4.4). Based on data from the 2003 American Housing Survey, approximately 36 million individuals live within 300 feet (~90 meters) of a four-lane highway, railroad, or airport (ISA, section 4.4).[8] Furthermore, in California, 2.3% of schools with a total enrollment of more than 150,000 students were located within approximately 500 feet of high-traffic roads, with a higher proportion of non-white and economically disadvantaged students attending those schools (ISA, section 4.4). Of this population, asthmatics and members of other susceptible groups discussed above will have even greater risks of experiencing health effects related to NO_2 exposure. In the United States, approximately 10% of adults and 13% of children have been diagnosed with asthma, and 6% of adults have been diagnosed with COPD (ISA, section 4.4). The prevalence and severity of asthma is higher among certain ethnic or racial groups such as Puerto Ricans, American Indians, Alaskan Natives, and African Americans (ISA, section 4.4). A higher prevalence of asthma among persons of lower SES and an excess burden of asthma hospitalizations and mortality in minority and inner-city communities have been observed (ISA, section 4.4). In addition, based on U.S. census data from 2000, about 72.3 million (26%) of the U.S. population are under 18 years of age, 18.3 million (7.4%) are under 5 years of age, and 35 million (12%) are 65 years of age or older. Therefore, large portions of the U.S. population are in age groups that are likely at-risk for health effects associated with exposure to ambient NO_2. The size of the potentially at-risk population suggests that exposure to ambient NO_2 could have a significant impact on public health in the United States.

C. Human Exposure and Health Risk Characterization

To put judgments about NO_2-associated health effects into a broader public health context, EPA has drawn upon the results of the quantitative exposure and risk assessments. Judgments reflecting the nature of the evidence and the overall weight of the evidence are taken into consideration in these quantitative exposure and risk assessments, discussed below. These assessments provide estimates of the likelihood that asthmatic individuals would experience exposures of potential concern and estimates of the incidence of NO_2-associated respiratory emergency department visits under varying air quality scenarios (*e.g.*, just meeting the current or alternative standards), as well as characterizations of the kind and degree of uncertainties inherent in such estimates.

This section describes the approach taken in the REA to characterize NO_2-related exposures and health risks. Goals of the REA included estimating short-term exposures and potential human health risks associated with (1) recent levels of ambient NO_2; (2) NO_2 levels adjusted to simulate just meeting the current standard; and (3) NO_2 levels adjusted to simulate just meeting

[8] The most current American Housing Survey (*http://www.census.gov/hhes/www/housing/ahs/ahs.html*) is from 2007 and lists a higher fraction of housing units within the 300 foot boundary than do prior surveys. According to Table IA–6 from that report (*http://www.census.gov/hhes/www/housing/ahs/ahs07/tab1a–6.pdf*), out of 128,303,000 total housing units in the United States, 20,016,000 were reported by the surveyed occupant or landlord as being within 300 feet of a 4-or-more lane highway, railroad, or airport. That constitutes 15.613% of the total housing units in the U.S. Assuming equal distributions, with a current population of 306,330,199, that means that there would be 47.8 million people meeting the 300 foot criteria.

potential alternative standards. This section discusses the scientific evidence from the ISA that was used as the basis for the risk characterization (II.C.1), the approaches used in characterizing exposures and risks (II.C.2), and important uncertainties associated with these analyses (II.C.3). The results of the exposure and risk analyses, as they relate to the current and potential alternative standards, are discussed in subsequent sections of this proposal (sections II.E and II.F, respectively).

1. Evidence Base for the Risk Characterization

For purposes of the quantitative characterization of NO_2 health risks, the REA determined that it was appropriate to focus on endpoints for which the ISA concluded that the available evidence is sufficient to infer either a causal or a likely causal relationship. This was generally consistent with judgments made in other recent NAAQS reviews (*e.g.*, see EPA, 2005).

As noted above in section II.A, the only health effect category for which the evidence was judged in the ISA to be sufficient to infer either a causal or a likely causal relationship is respiratory morbidity following short-term NO_2 exposure. Therefore, for purposes of characterizing health risks associated with NO_2, the REA focused on respiratory morbidity endpoints that have been associated with short-term NO_2 exposures. Other health effects (*e.g.*, those associated with long-term exposures) are considered as part of the evidence-based evaluation of potential alternative standards (see section II.F.2). In evaluating the appropriateness of specific endpoints for use in the NO_2 risk characterization, the REA considered both epidemiologic and controlled human exposure studies.

When evaluating epidemiologic studies as to their appropriateness for use as the basis for a quantitative risk assessment, the REA considered several factors. First, the REA concluded that studies conducted in the United States are preferable to those conducted outside the United States given the potential for effect estimates to be impacted by factors such as the ambient pollutant mix, the placement of monitors, activity patterns of the population, and characteristics of the healthcare system. Second, the REA concluded that studies of ambient NO_2 are preferable to those of indoor NO_2, which focus on individuals exposed to NO_2 from indoor sources. These indoor sources can result in exposure patterns, NO_2 levels, and co-pollutants that are different from those typically associated with ambient NO_2. Therefore, although indoor studies made important contributions to the evidence base for causality judgments in the ISA, the preferred approach for conducting a quantitative risk assessment based on the epidemiologic literature to inform decisions regarding an ambient NO_2 standard is to consider studies of ambient NO_2. Third, the REA concluded that it was appropriate to focus on studies of emergency department visits and hospital admissions given the clear public health significance of these endpoints and the availability of baseline incidence data. Finally, the REA concluded that it was appropriate to focus on studies that evaluated NO_2 health effect associations using both single- and multi-pollutant models. Taking these factors into consideration, the epidemiology-based risk assessment in the REA focused on the study conducted in Atlanta, Georgia by Tolbert *et al.* (2007). This assessment is described in more detail in the REA (chapter 9).

In identifying health endpoints from controlled human exposure studies on which to focus the characterization of NO_2 health risks, the REA concluded that it was appropriate to focus on endpoints that occur at or near ambient levels of NO_2 and endpoints that may be important from a public health perspective. Controlled human exposure studies have addressed the consequences of short-term (*e.g.*, 30-minutes to several hours) NO_2 exposures for a number of health endpoints including airway responsiveness, host defense and immunity, inflammation, and lung function (ISA, section 3.1). With regard to the NO_2 levels at which different effects have been documented, the ISA concluded: (1) In asthmatics NO_2 may increase the allergen-induced airway inflammatory response at exposures as low as 260 ppb for 30 min (ISA, Figure 3.1–2), and NO_2 exposures between 200 and 300 ppb for 30 minutes or 100 ppb for 60-minutes can result in small, but significant, increases in nonspecific airway responsiveness (ISA, section 5.3.2.1); (2) limited evidence indicates that NO_2 may increase susceptibility to injury by subsequent viral challenge following exposures of 600–1500 ppb for 3 hours; (3) evidence exists for increased airway inflammation at NO_2 concentrations less than 2000 ppb; and (4) the direct effects of NO_2 on lung function in asthmatics have been inconsistent at exposure concentrations below 1000 ppb (ISA, section 5.3.2.1). Therefore, of the health effects caused by NO_2 in controlled human exposure studies, the only effect identified by the ISA to occur at or near ambient levels is increased airway responsiveness in asthmatics.

The REA concluded that airway responsiveness in the asthmatic population is an appropriate focus for the risk characterization for several reasons. First, the ISA concluded that ''persons with preexisting pulmonary conditions are likely at greater risk from ambient NO_2 exposures than the general public, with the most extensive evidence available for asthmatics as a potentially susceptible group'' (ISA, section 5.3.2.8). Second, when discussing the clinical significance of NO_2-related airway hyperresponsiveness in asthmatics, the ISA concluded that ''transient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control'' (ISA, sections 3.1.3 and 5.4). That this effect could have public health implications is suggested by the large size of the asthmatic population in the United States (ISA, Table 4.4–1). Third, NO_2 effects on airway responsiveness in asthmatics are part of the body of experimental evidence that provides plausibility and coherence for the effects observed on hospital admissions and emergency department visits in epidemiologic studies (ISA, section 5.3.2.1). As a result of these considerations, of the endpoints from controlled human exposure studies, the REA focused on airway responsiveness in asthmatics for purposes of quantifying risks associated with ambient NO_2 (*see* below).

Because many of the studies of airway responsiveness evaluated only a single level of NO_2 and because of methodological differences between the studies, the data are not sufficient to derive an exposure-response relationship in the range of interest. Therefore, the REA concluded that the most appropriate approach to characterizing risks based on the controlled human exposure evidence for airway responsiveness was to compare estimated NO_2 air quality and exposure levels with potential health effect benchmark levels. In this review, the term ''exposures of potential concern'' is defined as personal exposures to 1-hour ambient NO_2 concentrations at and above specific benchmark levels. Benchmark levels represent NO_2 exposure concentrations reported to increase airway responsiveness in most asthmatics, as discussed above in section II.B.1.d. Although the analysis of exposures of potential concern was conducted using discrete benchmark levels (*i.e.*, 100, 150, 200, 250, 300 ppb), EPA recognizes that there is no sharp

breakpoint within the continuum ranging from at and above 300 ppb down to 100 ppb. In considering the concept of exposures of potential concern, it is important to balance concerns about the potential for health effects and their severity with the increasing uncertainty associated with our understanding of the likelihood of such effects at lower NO_2 levels. Within the context of this continuum, estimates of exposures of potential concern at discrete benchmark levels provide some perspective on the potential public health impacts of NO_2-related health effects that have been demonstrated in controlled human exposure studies but cannot be evaluated in quantitative risk assessments (*i.e.*, increased airway responsiveness). They also help in understanding the extent to which such impacts could change by just meeting the current and potential alternative standards.

The NO_2-related increase in airway responsiveness is plausibly linked to the NO_2-associated morbidity reported in epidemiologic studies (*e.g.*, increased respiratory symptoms, emergency department visits and hospital admissions). However, estimates of the number of asthmatics likely to experience exposures of potential concern cannot be translated directly into quantitative estimates of the number of people likely to experience specific health effects, since sufficient information to draw such comparisons is not available. Due to individual variability in responsiveness, only a subset of asthmatics exposed at and above a specific benchmark level can be expected to experience health effects. The amount of weight to place on the estimates of exposures of potential concern at any of these benchmark levels depends in part on the weight of the scientific evidence concerning health effects associated with NO_2 exposures at and above that benchmark level. It also depends on judgments about the importance from a public health perspective of the health effects that are known or can reasonably be inferred to occur as a result of exposures at and above the benchmark level. Such public health policy judgments are embodied in the NAAQS standard setting criteria (*i.e.*, standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety).

2. Overview of Approaches

As noted above, the purpose of the assessments described in the REA was to characterize air quality, exposures, and health risks associated with recent ambient levels of NO_2, with NO_2 levels that could be associated with just meeting the current NO_2 NAAQS, and with NO_2 levels that could be associated with just meeting potential alternative standards. To characterize health risks, we employed three approaches in the REA. In the first approach, for each air quality scenario, NO_2 concentrations at fixed-site monitors and simulated concentrations on/near roadways were compared to potential health effect benchmark values derived from the controlled human exposure literature. In the second approach, modeled estimates of actual exposures in asthmatics were compared to potential health effect benchmarks. In the third approach, concentration-response relationships from an epidemiologic study were used in conjunction with baseline incidence data and recent or simulated ambient concentrations to estimate health impacts. An overview of the approaches to characterizing health risks is provided below and each approach has been described in more detail in the REA (chapters 6 through 9).

In the first approach, we compared ambient NO_2 concentrations with potential health effect benchmark levels for NO_2. The ambient NO_2 concentrations used in these analyses were based on those measured at monitors in the current NO_2 monitoring network. These monitored concentrations were compared to benchmark levels directly and were also used, in conjunction with literature-derived characterizations of the NO_2 concentration gradient around roadways, as the basis for estimating NO_2 concentrations on/near roadways. Scenario-driven air quality analyses were performed using ambient NO_2 concentrations for the years 1995 though 2006. With this approach, NO_2 air quality serves as a surrogate for exposure. All U.S. monitoring sites where NO_2 data have been collected, and that met completeness criteria (REA, chapter 7), were represented by this analysis. As such, the results generated were considered a broad characterization of national air quality and human exposures that might be associated with these concentrations. An advantage of this approach is its relative simplicity; however, there is uncertainty associated with the assumption that NO_2 air quality can serve as an adequate surrogate for total exposure to ambient NO_2. Actual exposures might be influenced by factors not considered by this approach, including small scale spatial variability in ambient NO_2 concentrations (which might not be captured by the network of fixed-site ambient monitors) and spatial/temporal variability in human activity patterns.

In the second approach, we used an inhalation exposure model to generate more realistic estimates of personal exposures in asthmatics (REA, chapter 8 for more detail on this assessment). This analysis estimated temporally and spatially variable ambient NO_2 concentrations and simulated human contact with these pollutant concentrations. The approach was designed to incorporate exposures that are not necessarily captured by the existing ambient monitoring data, including those that occur on or near roadways. AERMOD, an EPA dispersion model, was used to estimate 1-hour ambient NO_2 concentrations using emissions estimates from stationary and on-road mobile sources.[9] The Air Pollutants Exposure (APEX) model, an EPA human exposure model, was then used to estimate population exposures using the hourly census block level NO_2 concentrations estimated by AERMOD. A probabilistic approach was used to model individual exposures considering the time people spend in different microenvironments and the variable NO_2 concentrations that occur within these microenvironments across time, space, and microenvironment type. Estimates of personal exposure were compared to potential NO_2 health benchmark levels. This approach to assessing exposures was more resource intensive than using ambient levels as a surrogate for exposure; therefore, the final REA included the analysis of only one specific location in the U.S. (Atlanta MSA). Although the geographic scope of this analysis was restricted, the approach provided estimates of NO_2 exposures in asthmatics in Atlanta, particularly those exposures associated with important emission sources of NO_X, and the analysis served to complement the broad air quality characterization.

For the characterization of risks in both the air quality analysis and the exposure modeling analysis described above, the REA used a range of short-term potential health effect benchmarks. As noted above, the levels of potential benchmarks are based on NO_2 exposure levels that have been associated with increased airway responsiveness in asthmatics in controlled human exposure studies (ISA, section 5.3.2.1). Benchmark values of 100, 150, 200, 250, and 300 ppb were compared to both NO_2 air quality levels and to estimates of NO_2 exposure in asthmatics. When

[9] Estimated emissions from Hartsfield International Airport in Atlanta, a non-road mobile source, were also included in this analysis.

NO_2 air quality was used as a surrogate for exposure, the output of the analysis was an estimate of the number of times per year specific locations experience 1-hour levels of NO_2 that exceed a particular benchmark. When personal exposures were simulated, the output of the analysis was an estimate of the number of asthmatics at risk for experiencing daily maximum 1-hour levels of NO_2 of ambient origin that exceed a particular benchmark. An advantage of using the benchmark approach to characterize health risks is that the effects observed in controlled human exposure studies clearly result from NO_2 exposure. A disadvantage of this approach is that the magnitude of the NO_2 effect on airway responsiveness can vary considerably from individual to individual and not all asthmatics would be expected to respond to the same levels of NO_2 exposure. Therefore, the public health impacts of NO_2-induced airway hyperresponsiveness are difficult to quantify.

In the third approach, we estimated respiratory emergency department visits as a function of ambient levels of NO_2 measured at a fixed-site monitor representing ambient air quality for an urban area. In this approach, concentration-response functions from an epidemiologic study (Tolbert *et al.*, 2007) were used, in combination with baseline incidence data for respiratory emergency department visits in the Atlanta area and ambient NO_2 monitoring data, to estimate the impact on emergency department visits of ambient levels of NO_2. Compared to the risk characterization based on the air quality and exposure analyses described above, this approach to characterizing health risks has several advantages. For example, the public health significance of respiratory emergency department visits is less ambiguous, in terms of its impact on individuals, than is an increase of unknown magnitude in the airway response. In addition, the concentration-response relationship reflects real-world levels of NO_2 and co-pollutants present in ambient air. However, as noted previously, a disadvantage of this approach is the ambiguity and complexity associated with quantifying the contribution of NO_2 to emergency department visits relative to the contributions of co-occurring pollutants.

3. Key Limitations and Uncertainties

A number of key uncertainties should be considered when interpreting the results of these analyses. While the air quality, exposure, and quantitative risk analyses are each associated with unique uncertainties, they also share some uncertainties in common. Important uncertainties shared by these analyses, as well as uncertainties specifically associated with the air quality, exposure, and risk analyses, are discussed below.

In order to simulate just meeting the current annual standard and many of the alternative 1-hour standards analyzed, an adjustment (either upward or downward) of recent ambient NO_2 concentrations was required. As noted in the REA, an upward adjustment does not reflect a judgment that levels of NO_2 are likely to increase across the country or in any specific location under the current standard or any of the potential alternative standards. However, it does acknowledge that, under the current standard and some of the alternative standards evaluated, an increase in NO_2 concentrations would be permitted. The benefit of these air quality adjustments is that they can inform consideration of the current and alternative standards by providing estimates of health risks that could be associated with ambient air quality levels that just meet these standards. In adjusting air quality to simulate just meeting these standards, the analyses in the REA assumed that the overall shape of the distribution of NO_2 concentrations in an area would not change. While the REA concluded that this is a reasonable assumption in the absence of evidence supporting a different distribution, and while available analyses support this approach (Rizzo, 2008), the REA recognized this as an important uncertainty. It may be an especially important uncertainty for those scenarios where considerable adjustment is required to simulate just meeting one or more of the standards (REA, section 8.12).

In addition, simulation of just meeting different alternative standards was achieved by adjusting NO_2 concentrations at monitors in the current area-wide network. Therefore, resulting estimates of the potential public health implications of different decisions are most directly relevant to a standard focused specifically on the area-wide NO_2 concentrations that are the primary target of the current monitoring network. However, as discussed below (sections II.F.4.e and III), with this notice the Administrator is proposing to establish a standard focused specifically on the peak concentrations to which individuals can be exposed from on-road mobile source emissions on or near major roadways and to support such a standard with a monitoring network that includes monitors placed near major roadways. This proposed shift in the monitoring network introduces uncertainty in the extent to which the exposure and risk analyses presented in the REA can directly inform decisions on the proposed standard.

In addition to the general uncertainties discussed above, some uncertainties are specific to the air quality analyses. In order to estimate ambient NO_2 concentrations on or near roadways in the air quality analyses, the REA used empirically-derived relationships between ambient concentrations measured at fixed-site monitors in the current NO_2 monitoring network and on/near-road concentrations. The data used to develop the relationships were likely collected under different conditions (*e.g.*, different meteorological conditions which can affect important parameters in this relationship, such as the production of NO_2 from NO). The REA noted that the extent to which these conditions are representative of the times and places included in our analyses is unknown. Therefore, there is uncertainty in the degree to which the relationships used to estimate on/near-road NO_2 concentrations reflect the actual relationship in the locations and over the time periods of interest.

Potential health benchmark levels used in the air quality analyses were based largely on a meta-analysis (ISA, Table 3.1–3) of controlled human exposure studies of airway hyperresponsiveness. One important source of uncertainty with regard to this approach is that controlled human exposure studies have typically involved volunteers with mild asthma. Data are lacking for more severely affected asthmatics, who may be more susceptible (ISA, section 3.1.3.2). As a result, the potential health effect benchmarks could underestimate risks in populations with greater susceptibility. While approaches to classifying asthma severity differ, some estimates indicate that over half of asthmatics could be classified as moderate or severe (Fuhlbrigge *et al.*, 2002; Stout *et al.*, 2006). A second important source of uncertainty with regard to this approach is that the meta-analysis showed increased airway responsiveness in asthmatics at the lowest NO_2 level for which data were available (*i.e.* 100 ppb). Controlled human exposure studies have not evaluated the possibility of NO_2 effects on airway responsiveness in asthmatics at exposure concentrations below 100 ppb. A third important source of uncertainty associated with this approach is that the meta-analysis provided information on the direction of the NO_2-induced airway response, but not on the magnitude of the response.

Therefore, although the ISA did conclude that increased airway responsiveness associated with NO_2 exposure could increase symptoms and worsen asthma control (ISA, section 5.4), the full public health implications of benchmark exceedances are uncertain.

The Atlanta exposure assessment was also associated with a number of key uncertainties that should be considered when interpreting the results with regard to decisions on the standard. Some of these uncertainties, including those associated with benchmark levels, were shared with the air quality analyses. Additional uncertainties associated specifically with the Atlanta exposure assessment are discussed briefly below.

When compared to ambient measurement data, predicted upper percentile NO_2 concentrations may be 10–50% higher. Because these predicted concentrations are used as inputs for the exposure modeling, this suggests the possibility that the exposure assessment is over-predicting upper percentile NO_2 exposures. Other approaches used to evaluate exposure results (*i.e.*, comparison to personal exposure monitoring results and comparison of exposure-to-ambient concentration ratios with those identified in the ISA) have suggested that exposure estimates are reasonable. However, the possibility cannot be ruled out that benchmark exceedances are over-predicted in the Atlanta exposure analysis.

The exposure assessment was limited to Atlanta and the extent to which these results are representative of other locations in the U.S. is uncertain. The REA (section 8.11) concluded that the Atlanta exposure estimates are likely representative of other moderate to large urban areas. However, the REA also recognized that, given the greater proximity of the population to mobile sources in large urban areas such as Los Angeles, New York, and Chicago (*see* REA, Tables 8–14 and 8–15), the estimates of benchmark exceedances in Atlanta may be smaller than in these larger cities.

A number of key uncertainties should also be considered when interpreting the results of the Atlanta risk assessment with regard to decisions on the standard. Some of these, including the appropriateness of generalizing results from Atlanta, are shared with the Atlanta exposure assessment. Additional uncertainties associated specifically with the Atlanta risk assessment are discussed briefly below.

There is uncertainty about whether the association between NO_2 and emergency department visits actually reflects a causal relationship across the range of daily and hourly concentration levels in the epidemiologic studies. The ISA (section 5.4, p. 5–15) noted that when interpreting the NO_2 epidemiologic results, ''It is difficult to determine * * * the extent to which NO_2 is independently associated with respiratory effects or if NO_2 is a marker for the effects of another traffic-related pollutant or mix of pollutants (*see* section 5.2.2 for more details on exposure issues). A factor contributing to uncertainty in estimating the NO_2-related effect from epidemiologic studies is that NO_2 is a component of a complex air pollution mixture from traffic related sources that include CO and various forms of PM.'' This uncertainty should be considered when interpreting the quantitative NO_2 risk estimates based on the Atlanta epidemiologic study. However, in discussing these uncertainties, the ISA (section 5.4, p. 5–16) concluded that, ''Although this complicates the efforts to disentangle specific NO_2-related health effects, the evidence summarized in this assessment indicates that NO_2 associations generally remain robust in multi-pollutant models and supports a direct effect of short-term NO_2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS. The robustness of epidemiologic findings to adjustment for co-pollutants, coupled with data from animal and human experimental studies, support a determination that the relationship between NO_2 and respiratory morbidity is likely causal, while still recognizing the relationship between NO_2 and other traffic-related pollutants.''

A related uncertainty is that associated with the estimated NO_2 coefficient in the concentration-response function. This coefficient has been characterized by confidence intervals reflecting sample size. However, these confidence intervals do not reflect all of the uncertainties related to the concentration-response functions, such as whether or not the model used in the epidemiologic study is the correct model form. Concerning the possible role of co-pollutants in the Tolbert *et al.* (2007) study, single-pollutant models may produce overestimates of the NO_2 effects if some of those effects are really due in whole or part to one or more of the other pollutants. On the other hand, effect estimates based on multi-pollutant models can be uncertain, and can result in statistically non-significant estimates where a true relationship exists, if the co-pollutants included in the model are highly correlated with NO_2. As a result of these considerations, we report risk estimates based on both the single- and multi-pollutant models from Tolbert *et al.* (2007).

D. Considerations in Review of the Standard

This section presents the integrative synthesis of the evidence and information contained in the ISA and the REA with regard to the current and potential alternative standards. EPA notes that the final decision on retaining or revising the current primary NO_2 standard is a public health policy judgment to be made by the Administrator. This judgment will be informed by a recognition that the available health effects evidence reflects a continuum consisting of ambient levels of NO_2 at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. The Administrator's final decision will draw upon scientific information and analyses related to health effects, population exposures, and risks; judgments about the appropriate response to the range of uncertainties that are inherent in the scientific evidence and analyses; and comments received in response to this proposal.

1. Background on the Current Standard

The current standard, which is an annual average of 0.053 ppm (53 ppb), was retained by the Administrator in the most recent review in 1996 (61 FR 52854 (October 8, 1996)). The decision in that review to retain the annual standard was based on consideration of available scientific evidence for health effects associated with NO_2 and on air quality information. With regard to these considerations, the Administrator noted that ''a 0.053 ppm annual standard would keep annual NO_2 concentrations considerably below the long-term levels for which serious chronic effects have been observed in animals'' and that ''[r]etaining the existing standard would also provide protection against short-term peak NO_2 concentrations at the levels associated with mild changes in pulmonary function and airway responsiveness observed in controlled human studies'' (60 FR 52874, 52880 (Oct. 11, 1995)). As a result, the Administrator concluded that ''the existing annual primary standard appears to be both adequate and necessary to protect human health against both long- and short-term NO_2 exposures'' and that ''retaining the existing annual standard is consistent

with the scientific data assessed in the Criteria Document (EPA, 1993) and the Staff Paper (EPA, 1995) and with the advice and recommendations of CASAC'' (61 FR 52852 at 52854).

As noted previously, the 1993 AQCD concluded that there were two key health effects of greatest concern at ambient or near-ambient levels of NO_2: increased airway responsiveness in asthmatic individuals after short-term exposures and increased occurrence of respiratory illness in children with longer-term exposures. Evidence also was found for increased risk of emphysema, but this was of major concern only with exposures to levels of NO_2 much higher than then-current ambient concentrations. The evidence regarding airway responsiveness was drawn largely from controlled human exposure studies. The evidence for respiratory illness was drawn from epidemiologic studies that reported associations between respiratory symptoms and indoor exposures to NO_2 in people living in homes with gas stoves. The biological plausibility of the epidemiologic results was supported by toxicological studies that detected changes in lung host defenses following NO_2 exposure. Subpopulations considered potentially more susceptible to the effects of NO_2 included individuals with preexisting respiratory disease, children, and the elderly.

In that review, health risks were characterized by comparing ambient monitoring data, which were used as a surrogate for exposure, with potential health benchmark levels identified from controlled human exposure studies. At the time of the review, a meta-analysis of controlled human exposure studies indicated the possibility for adverse health effects due to short-term (*e.g.*, 1-hour) exposures between 200 ppb and 300 ppb NO_2. Therefore, the focus of the assessment was on the potential for short-term (*i.e.*, 1-hour) exposures to NO_2 levels above potential health benchmarks in this range. The assessment used monitoring data from the years 1988–1992 and screened for sites with one or more hourly exceedances of potential short-term health effect benchmarks. Predictive models were then constructed to relate the frequency of hourly concentrations above short-term health effect benchmarks to a range of annual average concentrations, including the current standard. Based on the results of this analysis, both CASAC (Wolff, 1995) and the Administrator (60 FR 52874) concluded that the minimal occurrence of short-term peak concentrations at or above a potential health effect benchmark of 200 ppb (1-hour average) indicated that the existing annual standard would provide adequate health protection against short-term exposures. This conclusion, combined with the conclusion that the current annual standard would maintain annual average levels well-below those associated with serious effects in animal toxicological studies, formed a large part of the basis for the decision in the 1996 review to retain the existing annual standard.

2. Approach for Reviewing the Need To Retain or Revise the Current Standard

The decision in the present review on whether the current annual standard is requisite to protect public health with an adequate margin of safety will be informed by a number of scientific studies and analyses that were not available in the 1996 review. Specifically, as discussed above (section II), a large number of epidemiologic studies have been published since the 1996 review. Many of these studies evaluate associations between NO_2 and adverse respiratory endpoints (*e.g.*, respiratory symptoms, emergency department visits, hospital admissions) in locations where annual average NO_2 concentrations are well-below the level allowed by the current standard (53 ppb). In addition, the meta-analysis of controlled human exposure studies has been updated for this review to include information on additional exposure concentrations. Finally, the REA described estimates of NO_2-associated health risks that could be present in locations that just meet the current annual standard. These types of risk estimates were not available in the last review. The approach for considering this scientific evidence and exposure/risk information is discussed below.

To evaluate whether the current primary NO_2 standard is adequate or whether consideration of revisions is appropriate, EPA is using an approach in this review that has been described in chapter 10 of the REA. The approach outlined in the REA builds upon the approaches used in reviews of other criteria pollutants, including the most recent reviews of the Pb, O_3, and PM NAAQS (EPA, 2007d; EPA, 2007e; EPA, 2005), and reflects the body of evidence and information that is currently available. As in other recent reviews, EPA's considerations will include the implications of placing more or less weight or emphasis on different aspects of the scientific evidence and the exposure/risk-based information, recognizing that the weight to be given to various elements of the evidence and exposure/risk information is part of the public health policy judgments that the Administrator will make in reaching decisions on the standard.

A series of general questions frames this approach to considering the scientific evidence and exposure-/risk-based information. First, EPA's consideration of the scientific evidence and exposure/risk information with regard to the adequacy of the current standard is framed by the following questions:

- To what extent does evidence that has become available since the last review reinforce or call into question evidence for NO_2-associated effects that were identified in the last review?
- To what extent has evidence for different health effects and/or sensitive populations become available since the last review?
- To what extent have uncertainties identified in the last review been reduced and/or have new uncertainties emerged?
- To what extent does evidence and exposure-/risk-based information that has become available since the last review reinforce or call into question any of the basic elements of the current standard?

To the extent that the available evidence and exposure-/risk-based information suggests it may be appropriate to consider revision of the current standard, EPA considers that evidence and information with regard to its support for consideration of a standard that is either more or less protective than the current standard. This evaluation is framed by the following questions:

- Is there evidence that associations, especially causal or likely causal associations, extend to ambient NO_2 concentrations as low as, or lower than, the concentrations that have previously been associated with health effects? If so, what are the important uncertainties associated with that evidence?
- Are exposures above benchmark levels and/or health risks estimated to occur in areas that meet the current standard? If so, are the estimated exposures and health risks important from a public health perspective? What are the important uncertainties associated with the estimated risks?

To the extent that there is support for consideration of a revised standard, EPA then considers the specific elements of the standard (indicator, averaging time, form, and level) within the context of the currently available information. In so doing, the Agency addresses the following questions:

- Does the evidence provide support for considering a different indicator for gaseous NO_X?
- Does the evidence provide support for considering different averaging times?
- What ranges of levels and forms of alternative standards are supported by the evidence, and what are the associated uncertainties and limitations?

• To what extent do specific averaging times, levels, and forms of alternative standards reduce the estimated exposures above benchmark levels and risks attributable to NO_2, and what are the uncertainties associated with the estimated exposure and risk reductions?

The questions outlined above have been addressed in the REA. The following sections present considerations regarding the adequacy of the current standard and potential alternative standards, as discussed in chapter 10 of the REA, in terms of indicator, averaging time, form, and level.

E. Adequacy of the Current Standard

In considering the adequacy of the current standard, the policy assessment chapter of the REA considered the scientific evidence assessed in the ISA and the quantitative exposure- and risk-based information presented in the REA. A summary of this evidence and information as well as CASAC recommendations and the Administrator's conclusions regarding the adequacy of the current standard are presented below.

1. Evidence-Based Considerations

As discussed in chapter 10 of the REA, evidence published since the last review generally has confirmed and extended the conclusions articulated in the 1993 AQCD (ISA, section 5.3.2). The epidemiologic evidence has grown substantially with the addition of field and panel studies, intervention studies, time-series studies of effects such as emergency department visits and hospital admissions, and a substantial number of studies evaluating mortality risk associated with short-term NO_2 exposures. As noted above, no epidemiologic studies were available in 1993 that assessed relationships between NO_2 and outcomes such as hospital admissions, emergency department visits, or mortality. In contrast, dozens of epidemiologic studies on such outcomes, conducted at recent and current ambient NO_2 concentrations, are now included in this evaluation (ISA, chapter 3). While not as marked as the growth in the epidemiologic literature, a number of recent toxicological and human clinical studies also provide insights into relationships between NO_2 exposure and health effects.

As an initial consideration with regard to the adequacy of the current standard, the REA noted that the evidence relating long-term (weeks to years) NO_2 exposures at current ambient concentrations to adverse health effects was judged in the ISA to be either ''suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ''inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4–5.3.2.6). In contrast, the evidence relating short-term (minutes to hours) NO_2 exposures to respiratory morbidity was judged to be ''sufficient to infer a likely causal relationship'' (ISA, section 5.3.2.1). This judgment was supported primarily by a large body of recent epidemiologic evidence that evaluated associations of short-term NO_2 concentrations with respiratory symptoms, emergency department visits, and hospital admissions. These conclusions from the ISA suggest that, at a minimum, consideration of the adequacy of the current annual standard should take into account the extent to which that standard provides protection against respiratory effects associated with short-term NO_2 exposures. As noted in the REA, such an emphasis on health endpoints for which evidence has been judged to be sufficient to infer a likely causal relationship would be consistent with other recent NAAQS reviews (*e.g.*, EPA, 2005; EPA, 2007d; EPA, 2007e).

In considering the NO_2 epidemiologic studies as they relate to the adequacy of the current standard, the REA noted that annual average NO_2 concentrations were below the level of the current annual NO_2 NAAQS in many of the locations where positive, and often statistically significant, associations with respiratory morbidity endpoints have been reported (ISA, section 5.4). As discussed previously, the ISA characterized that evidence for respiratory effects as consistent and coherent. The evidence is consistent in that associations are reported in studies conducted in numerous locations and with a variety of methodological approaches (ISA, section 5.3.2.1). It is coherent in the sense that the studies report associations with respiratory health outcomes that are logically linked together (ISA, section 5.3.2.1). The ISA noted that when the epidemiologic literature is considered as a whole, there are generally positive associations between NO_2 and respiratory symptoms, hospital admissions, and emergency department visits. A number of these associations are statistically significant, particularly the more precise effect estimates (ISA, section 5.3.2.1).

As discussed previously, the interpretation of these NO_2 epidemiologic studies is complicated by the fact that on-road vehicle exhaust emissions are a nearly ubiquitous source of combustion pollutant mixtures that include NO_2. In order to provide some perspective on the uncertainty related to the presence of co-pollutants, the ISA evaluated epidemiologic studies that employed multi-pollutant models, epidemiologic studies of indoor and personal NO_2 exposure, and experimental studies. Specifically, the ISA noted that a number of NO_2 epidemiologic studies have attempted to disentangle the effects of NO_2 from those of co-occurring pollutants by employing multi-pollutant models. When evaluated as a whole, NO_2 effect estimates in these models generally remained robust when co-pollutants were included. Therefore, despite uncertainties associated with separating the effects of NO_2 from those of co-occurring pollutants, the ISA (section 5.4, p. 5–16) concluded that ''the evidence summarized in this assessment indicates that NO_2 associations generally remain robust in multi-pollutant models and supports a direct effect of short-term NO_2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS.'' With regard to indoor studies, the ISA noted that these studies can test hypotheses related to NO_2 specifically (ISA, section 3.1.4.1). Although confounding by indoor combustion sources is a concern, indoor studies are not confounded by the same mix of co-pollutants present in the ambient air or by the contribution of NO_2 to the formation of secondary particles or O_3 (ISA, section 3.1.4.1). The ISA noted that the findings of indoor NO_2 studies are consistent with those of studies using ambient concentrations from central site monitors and concluded that indoor studies provide evidence of coherence for respiratory effects (ISA, section 3.1.4.1). With regard to experimental studies, the REA noted that they have the advantage of providing information on health effects that are specifically associated with exposure to NO_2 in the absence of co-pollutants. The ISA concluded that the NO_2 epidemiologic literature is supported by (1) evidence from controlled human exposure studies of airway hyperresponsiveness in asthmatics, (2) controlled human exposure and animal toxicological studies of impaired host-defense systems and increased risk of susceptibility to viral and bacterial infection, and (3) controlled human exposure and animal toxicological studies of airway inflammation (ISA, section 5.3.2.1 and 5.4).

In drawing broad conclusions regarding the evidence, the ISA

considered the epidemiologic and experimental evidence as well as the uncertainties associated with that evidence. When this evidence and its associated uncertainties are taken together, the ISA concluded that the results of epidemiologic and experimental studies form a plausible and coherent data set that supports a relationship between NO_2 exposures and respiratory endpoints, including respiratory symptoms and emergency department visits, at ambient concentrations that are present in areas that meet the current NO_2 NAAQS. Thus, taking into consideration the evidence discussed above, particularly the epidemiologic studies reporting NO_2-associated health effects in locations that meet the current standard, the REA concluded that the scientific evidence calls into question the adequacy of the current standard to protect public health.

2. Exposure- and Risk-Based Considerations

In addition to the evidence-based considerations described above, the REA considered the extent to which exposure- and risk-based information can inform decisions regarding the adequacy of the current annual NO_2 standard, taking into account key uncertainties associated with the estimated exposures and risks. As noted above, NO_2-associated health risks were characterized with three approaches. In the first, NO_2 air quality from locations across the country was used as a surrogate for exposure. In the second, exposures were estimated for all asthmatics and for asthmatic children considering time spent in different microenvironments in one urban area, Atlanta, GA. For both of these analyses, health risks were characterized by comparing estimates of air quality or exposure to potential health benchmark levels. Benchmark levels spanned the range of NO_2 concentrations that have been reported to increase airway responsiveness in asthmatics (*i.e.*, 100–300 ppb). In the third approach to characterizing NO_2-related health risks, occurrences of NO_2-related respiratory emergency department visits were estimated for Atlanta. This quantitative risk assessment was based on NO_2 concentration-response relationships identified in an epidemiologic study of air pollution-related emergency department visits in Atlanta. The results of each of these analyses are discussed in this section, specifically as they relate to the current standard.

When considering the Atlanta risk assessment results as they relate to the adequacy of the current standard, the REA noted that central estimates of incidence of NO_2-related respiratory emergency department visits in Atlanta ranged from approximately 8 to 9% of total respiratory-related emergency department visits per year (or 9,800–10,900 NO_2-related incidences) based on single pollutant models when air quality is adjusted upward to simulate a situation where Atlanta just meets the current standard. Central estimates of incidence of NO_2-related respiratory emergency department visits ranged from 2.9–7.7% of total respiratory-related emergency department visits per year (or 3,600–9,400 NO_2-related incidences) based on two-pollutant models. Inclusion of O_3 and/or PM_{10} in multi-pollutant models resulted in the inclusion of an estimate of zero NO_2-related respiratory emergency department visits within the 95% confidence intervals.

When considering the Atlanta exposure results as they relate to the adequacy of the current standard, the REA noted the number of days per year asthmatics could experience exposure to NO_2 concentrations greater than or equal to potential health benchmark levels, given air quality that is adjusted upward to simulate just meeting the current standard. If NO_2 concentrations were such that the Atlanta area just meets the current standard, nearly all asthmatics in Atlanta (>97%) would be estimated to experience six or more days per year with 1-hour NO_2 exposure concentrations greater than or equal to our highest benchmark level (300 ppb) (REA, Figure 8–22). Six days per year was the largest number of days specifically considered in the REA, but these results suggest that some asthmatics could experience 1-hour NO_2 exposure concentrations greater than or equal to 300 ppb on more than six days per year. In addition, more frequent exceedances would be expected for the lower benchmark levels.

When considering the air quality-based results as they relate to the adequacy of the current standard, the REA noted the number of benchmark exceedances estimated to occur in different locations given air quality that just meets that standard. In situations where annual NO_2 concentrations were adjusted upward to simulate just meeting the current standard, 1-hour NO_2 concentrations measured at fixed-site monitors in locations across the U.S. could exceed benchmark levels. Most locations were estimated to experience at least 50 days per year with 1-hour ambient NO_2 concentrations at fixed-site monitors in the current network greater than or equal to 100 ppb (Figures 7–2 and 7–3 in the REA) under this hypothetical scenario. Far fewer ambient exceedances were predicted for the higher benchmark levels. For example, only 5 areas were estimated to experience any days with 1-hour ambient NO_2 concentrations at fixed-site monitors greater than or equal to 300 ppb, and none of those locations were estimated to experience more than 2 such days per year, on average (REA, Appendix A).

However, on-road NO_2 concentrations were estimated in this analysis to be an average of 80% higher than concentrations at fixed-site monitors (though this relationship will vary across locations and with time). In the majority of locations evaluated, roadway exceedances of the 100 ppb benchmark level could occur on most days of the year when air quality is adjusted upward to simulate just meeting the current standard (Figure 7–6 in the REA). Even for higher benchmark levels, most locations were estimated to have exceedances on roadways. All locations evaluated except one (Boston) were estimated to experience on-road NO_2 concentrations greater than or equal to 300 ppb (REA, Appendix A). Four of these locations were estimated to experience an average of greater than 20 days per year with on-road NO_2 concentrations greater than or equal to 300 ppb (REA, Appendix A).

3. Summary of Considerations From the REA

As noted above, the policy assessment chapter of the REA considered the scientific evidence with regard to the current standard. This included consideration of causality judgments made in the ISA regarding the level of support for effects associated with short-term and long-term exposures, the epidemiologic evidence described in the ISA including associated uncertainties, the conclusions in the ISA regarding the robustness of this evidence, and the support provided for epidemiologic findings by experimental studies. The REA concluded that, given these considerations, particularly the evidence for NO_2-associated effects in locations that meet the current standard, the adequacy of the current standard to protect the public health is clearly called into question. This evidence provides support for consideration of an NO_2 standard that would provide increased health protection for at-risk groups, including asthmatics and individuals who spend time on or near major roadways, against health effects associated with short-term exposures ranging from increased asthma symptoms to respiratory-related emergency department visits and

hospital admissions, in addition to potential effects associated with long-term exposures.

In examining the exposure- and risk-based information with regard to the adequacy of the current annual NO_2 standard to protect the public health, the REA noted that estimated risks associated with air quality adjusted upward to simulate just meeting the current standard can reasonably be concluded to be important from a public health perspective. In particular, a large percentage (8–9%) of respiratory-related ED visits in Atlanta could be associated with short-term NO_2 exposures, most asthmatics in Atlanta could be exposed on multiple days per year to NO_2 concentrations at or above the highest benchmark evaluated, and most locations evaluated could experience on-/near-road NO_2 concentrations above benchmark levels on more than half of the days in a given year. Therefore, the REA noted that exposure- and risk-based results reinforce the scientific evidence in supporting the conclusion that consideration should be given to revising the current standard so as to provide increased public health protection, especially for at-risk groups, from NO_2-related adverse health effects associated with short-term, and potential long-term, exposures.

4. CASAC Views

With regard to the adequacy of the current standard, CASAC conclusions were consistent with the views expressed in the policy assessment chapter of the REA. CASAC agreed that the primary concern in this review is to protect against health effects that have been associated with short-term NO_2 exposures. CASAC also agreed that the current annual standard is not sufficient to protect public health against the types of exposures that could lead to these health effects. Given these considerations, and as noted in their letter to the EPA Administrator, ''CASAC concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised'' (Samet, 2008b). CASAC's views on how the standard should be revised are provided below within the context of discussions on the elements (*i.e.*, indicator, averaging time, form, level) of a new short-term standard.

5. Administrator's Conclusions Regarding Adequacy of the Current Standard

In considering the adequacy of the current NO_2 NAAQS, the Administrator has considered the conclusions of the ISA, the conclusions of the policy assessment chapter of the REA, and the views expressed by CASAC. In particular, the ISA concluded that the results of epidemiologic and experimental studies form a plausible and coherent data set that supports a likely causal relationship between short-term NO_2 exposures and adverse respiratory effects at ambient NO_2 concentrations that are present in locations meeting the current NO_2 NAAQS. With regard to the exposure and risk results, the REA concludes that central risk estimates suggest that the current standard could allow important adverse public health impacts.

Based on her consideration of these conclusions, as well as consideration of CASAC's conclusion that the current NO_2 NAAQS does not protect the public's health, the Administrator concludes that the current NO_2 standard does not provide the requisite degree of protection for public health against adverse effects associated with short-term exposures. In considering approaches to revising the current standard, the Administrator concludes that it is appropriate to consider setting a new short-term standard to supplement the current annual standard. The Administrator notes that such a short-term standard could provide increased public health protection, especially for members of at-risk groups, from effects described in both epidemiologic and controlled human exposure studies to be associated with short-term exposures to NO_2.

F. Conclusions on the Elements of a New Short-Term Standard and an Annual Standard

In considering alternative NO_2 primary NAAQS, the Administrator notes the need to protect at-risk individuals from short-term exposures to NO_2 air quality that could cause the types of respiratory morbidity effects reported in epidemiologic studies and the need to protect at-risk individuals from short-term exposure to NO_2 concentrations reported in controlled human exposure studies to increase airway responsiveness in asthmatics. Considerations with regard to potential alternative standards and the specific options being proposed are discussed in the following sections in terms of indicator, averaging time, form, and level (sections II.F.1–II.F.4).

1. Indicator

In past reviews, EPA has focused on NO_2 as the most appropriate indicator for ambient NO_X. In making a decision in the current review on the most appropriate indicator, the Administrator has considered the conclusions of the ISA and REA as well as the view expressed by CASAC. The REA noted that, while the presence of NO_X species other than NO_2 has been recognized, no alternative to NO_2 has been advanced as being a more appropriate surrogate. Controlled human exposure studies and animal toxicology studies provide specific evidence for health effects following exposure to NO_2. Epidemiologic studies also typically report levels of NO_2 though the degree to which monitored NO_2 reflects actual NO_2 levels, as opposed to NO_2 plus other gaseous NO_X, can vary (REA, section 2.2.3). In addition, because emissions that lead to the formation of NO_2 generally also lead to the formation of other NO_X oxidation products, measures leading to reductions in population exposures to NO_2 can generally be expected to lead to reductions in population exposures to other gaseous NO_X. Therefore, an NO_2 standard can also be expected to provide some degree of protection against potential health effects that may be independently associated with other gaseous NO_X even though such effects are not discernable from currently available studies indexed by NO_2 alone. Given these key points, the REA concluded that the evidence supports retaining NO_2 as the indicator. Consistent with this conclusion, the CASAC Panel recommended in its letter to the EPA Administrator that it ''concurs with retention of NO_2 as the indicator'' (Samet, 2008b). In light of the above considerations, the Administrator proposes to retain NO_2 as the indicator in the current review.

2. Averaging Time

The current annual averaging time for the NO_2 NAAQS was originally set in 1971, based on epidemiologic studies that supported a link between adverse respiratory effects and long-term exposure to low levels of NO_2. As noted above, that annual standard was retained in subsequent reviews in part because an air quality assessment conducted by EPA concluded that areas that meet the annual standard would be unlikely to experience short-term ambient peaks above concentrations that had been reported in a meta-analysis of controlled human exposure studies to increase airway responsiveness in asthmatics. In the current review, additional scientific evidence is available to inform a decision on averaging time. This includes the availability of a number of epidemiologic studies that have evaluated endpoints including respiratory symptoms, emergency

department visits, and hospital admissions as well as an updated meta-analysis of controlled human exposure studies of airway responsiveness in asthmatics.

In order to inform conclusions with regard to averaging time in this review, the REA considered judgments on the evidence from the ISA, results from experimental and epidemiologic studies, and an analysis of correlations between short- and long-term ambient NO_2 concentrations. These considerations are described in more detail below.

a. Short-Term Averaging Time

As described previously, the evidence relating short-term (minutes to hours) NO_2 exposures to respiratory morbidity was judged in the ISA to be ''sufficient to infer a likely causal relationship'' (ISA, section 5.3.2.1) while the evidence relating long-term (weeks to years) NO_2 exposures to adverse health effects was judged to be either ''suggestive but not sufficient to infer a causal relationship'' (respiratory morbidity) or ''inadequate to infer the presence or absence of a causal relationship'' (mortality, cancer, cardiovascular effects, reproductive/developmental effects) (ISA, sections 5.3.2.4–5.3.2.6). Thus, the REA concluded that these judgments most directly support an averaging time that focuses protection on short-term exposures to NO_2.

As in past reviews of the NO_2 NAAQS, it is instructive to evaluate the potential for a standard based on annual average NO_2 concentrations, as is the current standard, to provide protection against short-term NO_2 exposures. To this end, Table 10–1 in the REA reported the ratios of short-term to annual average NO_2 concentrations. Ratios of 1-hour daily maximum concentrations (98th and 99th percentile) [10] to annual average concentrations across 14 locations ranged from 2.5 to 8.7 while ratios of 24-hour average concentrations to annual average concentrations ranged from 1.6 to 3.8 (*see* Thompson, 2008 for more details). The REA concluded that the variability in these ratios across locations, particularly those for 1-hour concentrations, suggested that a standard based on annual average NO_2 concentrations would not likely be an effective or efficient approach to focus protection on short-term NO_2 exposures. For example, in an area with a relatively high ratio (*e.g.*, 8), the current annual standard (53 ppb) would be expected to allow 1-hour daily maximum NO_2 concentrations of about 400 ppb. In contrast, in an area with a relatively low ratio (*e.g.*, 3), the current standard would be expected to allow 1-hour daily maximum NO_2 concentrations of about 150 ppb. Thus, for purposes of protecting against the range of 1-hour NO_2 exposures, the REA noted that a standard based on annual average concentrations would likely require more control than necessary in some areas and less control than necessary in others, depending on the standard level selected.

In considering the level of support available for specific short-term averaging times, the policy assessment chapter of the REA noted evidence from both experimental and epidemiologic studies. Controlled human exposure studies and animal toxicological studies provide evidence that NO_2 exposures from less than 1-hour up to 3-hours can result in respiratory effects such as increased airway responsiveness and inflammation (ISA, section 5.3.2.7). Specifically, the ISA concluded that NO_2 exposures of 100 ppb for 1-hour (or 200 ppb to 300 ppb for 30-min) can result in small but significant increases in nonspecific airway responsiveness (ISA, section 5.3.2.1). In contrast, the epidemiologic literature provides support for short-term averaging times ranging from approximately 1-hour up to 24-hours (ISA, section 5.3.2.7). A number of epidemiologic studies have detected positive associations between respiratory morbidity and 1-hour (daily maximum) and/or 24-hour NO_2 concentrations. A few epidemiologic studies have considered both 1-hour and 24-hour averaging times, allowing comparisons to be made. The ISA reported that such comparisons in studies that evaluate asthma emergency department visits failed to reveal differences between effect estimates based on a 1-hour averaging time and those based on a 24-hour averaging time (ISA, section 5.3.2.7). Therefore, the ISA concluded that it is not possible, from the available epidemiologic evidence, to discern whether effects observed are attributable to average daily (or multi-day) concentrations (24-hour average) or high, peak exposures (1-hour maximum) (ISA, section 5.3.2.7).

As noted in the policy assessment chapter of the REA, given the above conclusions, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (*e.g.*, 1-h) while the epidemiologic evidence provides support for both 1-hour and 24-hour averaging times. At a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour daily maximum NO_2 concentrations. However, it is also important to consider the ability of a 1-hour (daily maximum) averaging time to protect against 24-hour average NO_2 concentrations. To this end, Table 10–2 in the REA presented correlations between 1-hour daily maximum NO_2 concentrations and 24-hour average NO_2 concentrations (98th and 99th percentile) across 14 locations (*see* Thompson, 2008 for more detail). Typical ratios ranged from 1.5 to 2.0, though one ratio (Las Vegas) was 3.1. These ratios were far less variable than those discussed above for annual average concentrations, suggesting that a standard based on 1-hour daily maximum NO_2 concentrations could also be effective at protecting against 24-hour NO_2 concentrations. The REA concluded that the scientific evidence, combined with the air quality correlations described above, support the appropriateness of a standard based on 1-hour daily maximum NO_2 concentrations to protect against health effects associated with short-term exposures.

b. Long-Term Averaging Time

While the REA concluded that the combination of the scientific evidence from the ISA and air quality analyses most directly support an averaging time that focuses protection on short-term exposures to NO_2, some evidence does support the need to also consider health effects potentially associated with long-term exposures. As noted above, the ISA judged the evidence relating long-term (weeks to years) NO_2 exposures to respiratory morbidity to be ''suggestive but not sufficient to infer a causal relationship.'' The available database supporting the relationship between respiratory illness in children and long-term exposures to NO_2 has increased since the 1996 review of the NO_2 NAAQS. Results from several studies, including the California-based Children's Health Study, have reported deficits in lung function growth (Gauderman *et al.*, 2004) in association with long-term exposure to NO_2. In addition, some studies have reported associations between asthma incidence and long-term NO_2. The plausibility of these associations is supported by some animal toxicological studies. Specifically, morphological effects following chronic NO_2 exposures have been identified in animal studies that

[10] As discussed below, 98th and 99th percentile forms were evaluated in the REA. A 99th percentile form corresponds approximately to the 4th highest 1-hour concentration in a year while a 98th percentile form corresponds approximately to the 7th or 8th highest 1-hour concentration in a year. A 4th highest concentration form has been used previously in the O_3 NAAQS while a 98th percentile form has been used previously in the $PM_{2.5}$ NAAQS.

link to these increases in collagen synthesis and may provide plausibility for the deficits in lung function growth described in epidemiologic studies of long-term exposure to NO_2 (ISA, section 3.4.5).

Therefore, though the evidence provides strong support for the need to protect against health effects associated with short-term NO_2 exposures, it may also be appropriate to consider the extent to which the NO_2 standard could protect against potential effects associated with long-term exposures. To address this issue, the REA estimated annual average NO_2 concentrations assuming different 1-hour standards were just met. For the locations evaluated, a 1-hour area-wide standard with a level at or below 100 ppb was estimated to be associated with annual average NO_2 concentrations below the level of the current annual standard (53 ppb) (REA, section 10.4.2). Therefore, it is possible that a 1-hour standard could also provide protection against potential effect associated with long-term exposures, depending on the level of the standard.

c. CASAC Views

CASAC agreed with the conclusions of the policy assessment chapter of the REA that a primary consideration of the NO_2 NAAQS should be the protection provided against health effects associated with short-term exposures. In their letter to the EPA Administrator, CASAC stated that they concur ''with having a short-term NAAQS primary standard for oxides of nitrogen and using the one-hour maximum NO_2 value.'' In addition, the letter noted that ''CASAC also recommends retaining the current standard based on the annual average.'' CASAC based this recommendation on the ''limited evidence related to potential long-term effects of NO_2 exposure and the lack of strong evidence of no effect.'' In addition, CASAC concluded that ''the findings of the REA do not provide assurance that a short-term standard based on the one-hour maximum will necessarily protect the population from long-term exposures at levels potentially leading to adverse health effects'' (Samet, 2008b).

d. Administrator's Conclusions on Averaging Time

In considering the most appropriate averaging time(s) for the NO_2 primary NAAQS, the Administrator notes the conclusions and judgments made in the ISA about available scientific evidence, conclusions from the REA, and CASAC recommendations discussed above. Based on these considerations, the Administrator proposes to set a new standard based on 1-hour daily maximum NO_2 concentrations. In addition, the Administrator notes that CASAC recommended retaining the current annual standard to account for the fact that some evidence suggests that long-term NO_2 exposures could cause adverse effects on respiratory health. Taking into account these considerations, in addition to proposing a new 1-hour NO_2 primary NAAQS to provide increased protection against effects associated with short-term exposures, the Administrator also proposes to retain an annual standard.

3. Form

When evaluating alternative forms in conjunction with specific levels, the REA considered the adequacy of the public health protection provided by the combination of level and form to be the foremost consideration. In addition, the REA recognized that it is desirable to have a form that is reasonably stable and insulated from the impacts of extreme meteorological events. As noted in the review of the O_3 NAAQS (EPA, 2007e), forms that call for averaging of concentrations over three years better reflect pollutant-associated health risks than forms based on expected exceedances. This is because such ''concentration-based'' forms give proportionally greater weight to periods of time when pollutant concentrations are well above the level of the standard than to times when the concentrations are just above the standard, while an expected exceedance form would give the same weight to periods of time with concentrations that just exceed the standard as to times when concentrations greatly exceed the standard. Averaging concentrations over three years also provides greater regulatory stability than a form based on allowing only a single expected exceedance in a year. Therefore, consistent with recent reviews of the O_3 and PM NAAQS, the REA focused on concentration-based forms averaged over 3 years.

In considering specific concentration-based forms, the REA focused on 98th and 99th percentile concentrations averaged over 3 years. With regard to these alternative forms, the REA noted that a 99th percentile form for a 1-hour daily maximum standard would correspond approximately to the 4th highest daily maximum concentration in a year (which is the form of the current O_3 NAAQS) while a 98th percentile form (which is the form of the current short-term $PM_{2.5}$ NAAQS) would correspond approximately to the 7th or 8th highest daily maximum concentration in a year (Table 10–4 in the REA; *see* Thompson, 2008 for methods). The REA concluded that either of these forms could provide an appropriate balance between limiting peak NO_2 concentrations and providing sufficient regulatory stability. This is consistent with judgments made in the 2006 review of the PM NAAQS (EPA, 2005).

When considering the extent to which exposure and risk analyses inform judgments on the form of the standard, the REA noted that a 99th percentile form could be appreciably more protective than a 98th percentile form (for the same standard level) in some locations, as shown by the results of air quality analyses. For example, a 99th percentile standard of 200 ppb was estimated to decrease the number of benchmark exceedances, relative to a 98th percentile form, by approximately 50–70% in Boston, Philadelphia, and Washington, DC (Table 10–5 in the REA). However, a 99th percentile form was estimated to decrease the number of benchmark exceedances by only approximately 10% in St. Louis, Detroit, and Las Vegas (Table 10–5 in the REA). For most locations analyzed, the difference was estimated to be between approximately 10 and 50% (Table 10–5 in the REA). With regard to the Atlanta exposure assessment, a 99th percentile form was estimated to decrease the number of days with 6 or more benchmark exceedances (for 300 ppb), relative to a 98th percentile form, by 5–35% depending on the standard level selected (REA Appendix B, table B–48). With regard to the Atlanta risk assessment, a 99th percentile form was estimated to be associated with approximately 6% to 8% fewer NO_2-related emergency department visits than a 98th percentile form, across the levels of the potential 1-hour standards examined.

When considering these results as they relate to the form of the standard, the REA noted that a decision on form must be made in conjunction with selection of a particular standard level. The primary emphasis in such a decision will be on the degree of public health protection provided by the combination of form and level.

CASAC agreed with the importance of considering the public health protection provided by the combination of form and level. In its letter to the EPA Administrator with regard to the final REA, the CASAC panel stated that it ''advises that EPA choose a health protective percentile appropriate for the level chosen for the one-hour standard.'' CASAC went on to recommend that a 98th percentile form would be

appropriate for a standard level at the lower boundary of the range evaluated (50 ppb, *see* below) but that a higher percentile should be considered for higher levels (Samet, 2008b).

When considering alternative forms, the Administrator notes the views expressed in the REA and the recommendations from CASAC, as described above. In particular, she notes that a 99th percentile (or 4th highest) form could be appreciably more protective in some locations than a 98th (or 7th or 8th highest) form. Given these considerations, and in light of the specific range proposed for level below, the Administrator proposes to adopt either a 99th percentile or a 4th highest form, averaged over 3 years. In addition, the Administrator notes that a 98th percentile form could be appropriate, particularly for standard levels at the low end of the range considered in the REA. Therefore, she also solicits comment on both 98th percentile and 7th or 8th highest forms.

4. Level

In assessing the level of the standard to propose, the Administrator has considered the broad range of scientific evidence assessed in the ISA, including the epidemiologic studies and controlled human exposure studies, as well as the results of exposure/risk analyses presented in the REA. In light of this body of evidence and analyses, she has determined that it is necessary to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects related to short-term (*i.e.*, 30 minutes to 24 hours) exposures to ambient NO_2. Such health effects have been associated with exposure to the distribution of short-term ambient NO_2 concentrations across an area. This distribution includes both the higher short-term (*i.e.*, peak) exposure concentrations that can occur on or near major roadways and the lower short-term exposure concentrations that can occur in areas not near major roadways. In considering the most appropriate approach to providing this protection, the Administrator is mindful of the extent to which the available evidence and analyses can inform a decision on standard level. Specifically, the range of proposed standard levels discussed below (section II.F.4.e) is informed by controlled human exposure and epidemiologic studies.

As discussed above (section II.B.1.d), controlled human exposure studies have reported associations between various levels of NO_2 exposures and increased airway responsiveness in asthmatics. These studies can inform an evaluation of the risks associated with exposure to specific NO_2 concentrations, regardless of where those exposures occur in an area. Controlled human exposure studies most directly inform consideration of the risks associated with peak short-term NO_2 exposure concentrations, such as those that can occur on or near major roadways. This is the case because NO_2 concentrations around major roadways could include concentrations within the range evaluated in the studies. Controlled human exposure studies have not been conducted at the lower concentrations of NO_2 typically expected in areas not near major roadways.

In addition, epidemiologic studies (section II.B.1.a and b) have reported associations between ambient NO_2 concentrations, measured at area-wide monitors in the current network, and increased respiratory symptoms, emergency department visits, and hospital admissions. Area-wide monitors in the urban areas in which these epidemiologic studies were conducted do not measure the full range of ambient NO_2 concentrations that can occur anywhere in the area, because they are not sited in locations with more localized peak concentrations. Thus, they do not measure the full range of ambient NO_2 concentrations that are likely responsible for the exposures linked to the NO_2-associated health effects reported in the studies. Rather, the area-wide NO_2 concentrations measured by these monitors are used as surrogates for the entire distribution of ambient NO_2 concentrations across the area, a distribution that includes NO_2 concentrations that are both higher and lower than the area-wide concentrations reported for the study locations. Specifically, this distribution of concentrations includes the higher short-term peak NO_2 concentrations that occur on or near major roadways and the lower short-term concentrations that occur away from roadways. Thus, the epidemiologic studies can inform an evaluation of the risks associated with the full range of exposures likely to occur across an area.

The available evidence and analyses support the importance of roadway-associated NO_2 exposures for public health. Specifically, the exposure assessment presented in the REA estimated that roadway-associated exposures account for the great majority of exposures to peak NO_2 concentrations (REA, Figures 8–17 and 8–18). In addition, the ISA (section 2.5.4) noted that in-vehicle NO_2 exposures could be 2–3 times higher than indicated by ambient monitors in the current area wide-oriented network. Millions of people in the U.S. live, work, and/or attend school near important sources of NO_2 such as major roadways (ISA, section 4.4) and ambient NO_2 concentrations in these locations are strongly associated with distance from major roads (*i.e.*, the closer to a major road, the higher the NO_2 concentration) (ISA, section 2.5.4). Therefore, these populations, which likely include a disproportionate number of individuals in groups with higher prevalence of asthma and higher hospitalization rates for asthma (*e.g.* ethnic or racial minorities and individuals of low socioeconomic status) (ISA, section 4.4), are likely exposed to NO_2 concentrations higher than those that occur away from major roadways.

Given the above considerations, the Administrator proposes to set a level for the 1-hour NO_2 primary NAAQS that reflects the maximum allowable NO_2 concentration anywhere in an area. This concentration is likely to occur on or near a major roadway. As discussed above (section II.A.2), monitoring studies suggest that NO_2 concentrations near roadways can be approximately 30 to 100% higher than concentrations in the same area but not near the road. This NO_2 concentration gradient around roadways is one factor considered by the Administrator in determining the appropriate standard level to propose. EPA proposes to set the level of the standard such that, when available information regarding the concentration gradient around roadways is considered, appropriate public health protection would be provided by limiting the higher short-term peak exposure concentrations expected to occur on and near major roadways, as well as the lower short-term exposure concentrations expected to occur away from those roadways.

The Administrator notes that this approach to setting the standard would provide a relatively high degree of confidence regarding the level of protection provided by the standard against peak exposures, such as those that can occur on or near major roadways. This is a particularly important consideration given the available information and the air quality and exposure analyses, discussed above in section II.F.4.b, which indicated that roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations. The Administrator concludes that the proposed approach would directly address the great majority of peak exposures and associated health effects. In addition, the range of standard levels proposed below (section II.F.4.e) would provide a reasonable degree of confidence that the

accompanying area-wide NO_2 concentrations would be maintained well below concentrations that have occurred in locations where epidemiologic studies have reported associations between ambient NO_2 concentrations and health endpoints such as increased respiratory symptoms, emergency department visits, and hospital admissions. Therefore, the Administrator proposes to set a standard level reflecting the maximum allowable NO_2 concentration anywhere in an area that, in combination with the proposed decisions on indicator, averaging time, and form, will protect public health with an adequate margin of safety against the array of NO_2-associated health effects.

The remainder of this section describes the considerations relevant to the Administrator's proposed decisions on standard levels for a new 1-hour standard and the annual standard. Specifically, with regard to a 1-hour standard evidence-based considerations drawn from the ISA and discussed in the policy-assessment chapter of the REA are discussed in section II.F.4.a. Exposure- and risk-based considerations for a 1-hour standard drawn from the analyses in the REA and discussed in the policy assessment chapter are discussed in section II.F.4.b. A summary of the considerations relating to a 1-hour standard from the policy assessment chapter of the REA is presented in section II.F.4.c and CASAC views expressed in the context of their comments on the final REA are presented in section II.F.4.d. The Administrator's proposed approach to setting a 1-hour standard and her conclusions regarding the level of such a standard are presented in section II.F.4.e. An alternative approach to setting a 1-hour standard is discussed in section II.E.4.f. Comment is solicited on both approaches. Finally, the Administrator's proposed conclusions on the level of the annual standard are presented in section II.E.4.g.

a. Evidence-Based Considerations

Evidence-based considerations take into account the full body of scientific evidence assessed in the ISA. When considering the extent to which this scientific evidence can inform a decision on the level of a 1-hour standard, the policy assessment chapter of the REA notes that NO_2 concentrations represent different measures of exposure when drawn from experimental versus epidemiologic studies. Concentrations of NO_2 tested in experimental studies, such as controlled human exposure studies, represent exposure concentrations in the breathing zone of the individual test subjects. In cases where controlled human exposure studies report effects, those effects are caused directly by exposure to a specified concentration of NO_2. In contrast, concentrations of NO_2 drawn from epidemiologic studies are often based on ambient monitoring data. In the case of key U.S. studies that have been specifically considered within the context of assessing the appropriate level for the standard, these monitors measure area-wide NO_2 concentrations that occur away from major roadways. NO_2 concentrations recorded at these ambient monitors are used as surrogates for the distribution of NO_2 exposures across the study area and over the time period of the study. As noted above, these monitors do not measure the full range of ambient NO_2 concentrations that can occur in an area and, thus, they do not measure the full range of ambient NO_2 concentrations that are likely responsible for the NO_2-associated health effects reported in the studies. Instead they capture one part of the distribution (the area-wide concentration) and this is used as a surrogate for the entire distribution, which includes peak roadway-associated concentrations. As noted in the REA, the interpretation of NO_2 concentrations from different types of studies is an important consideration for decisions on standard level. These implications are discussed in more detail below in section II.F.4.e.

In considering the epidemiologic evidence, the REA noted the ISA conclusion that epidemiologic studies provide the strongest support for the link between short-term NO_2 exposure and respiratory morbidity. In addition, epidemiologic studies provide evidence for the most serious NO_2-associated respiratory effects, including respiratory-related hospital admissions and emergency department visits. As noted above, these effects have been reported to be associated with area-wide NO_2 concentrations in key U.S. epidemiologic studies. Because area-wide NO_2 concentrations are used as surrogates for the distribution of NO_2 exposures across the study area and over the time period of the study (*see* above), the health effects reported in these epidemiologic studies are reasonably inferred to be associated with exposure to ambient NO_2 concentrations that are both higher and lower than the area-wide concentrations reported for the study locations. As noted above, this distribution of exposure concentrations includes both the higher short-term peak NO_2 concentrations that occur on or near major roadways and the lower short-term concentrations that occur away from roadways.

When evaluating the epidemiologic literature for its potential to inform the selection of an appropriate range of standard levels, the REA noted the ISA conclusion that NO_2 epidemiologic studies provide ''little evidence of any effect threshold'' (ISA, section 5.3.2.9, p. 5–15). In studies that have evaluated concentration-response relationships, those relationships appear linear within the observed range of data (ISA, section 5.3.2.9). Given this lack of an apparent threshold below which effects do not occur, an important consideration with regard to providing an adequate margin of safety is the extent to which it is appropriate for the range of proposed standard levels to extend below NO_2 concentrations that have been associated with health effects in these studies. For purposes of using the epidemiologic evidence to identify a range of standard levels for evaluation in the absence of an apparent threshold, the REA considered the range of NO_2 concentrations that have been monitored in locations, and during time periods, of key U.S. epidemiologic studies (ISA, Table 5.4–1).

Figures 4 and 5 below (REA, Figures 5–1 and 5–2) show standardized effect estimates from single pollutant models and the 99th and 98th percentiles of the 1-hour daily maximum NO_2 concentrations recorded at area-wide monitors in the locations, and during the time periods, of key U.S. studies. The peak NO_2 concentrations to which individuals were exposed on and/or near major roadways in these locations during the study periods would be expected to be substantially higher than the concentrations recorded at these area-wide monitors. The lowest area-wide 1-hour daily maximum concentrations, 53 (99th percentile) and 50 (98th percentile) ppb, were monitored in the location of the study by Delfino *et al.* (2002). This single study reported mixed results for respiratory symptoms with most reported NO_2 effect estimates being positive, and with some but not all positive effect estimates being statistically significant. A cluster of 5 studies (Ito *et al.*, 2007; Jaffe *et al.*, 2003; NYDOH, 2006; Peel *et al.*, 2005; Tolbert *et al.*, 2007) were conducted in locations with area-wide 1-hour daily maximum NO_2 concentrations ranging from 93 to 112 ppb (99th percentile) and from 85 to 94 ppb (98th percentile). In these studies, single pollutant models yielded generally positive and often statistically significant NO_2 effect estimates for respiratory-related emergency

department visits and hospital admissions in a variety of locations across the U.S. Of these 5 studies, 4 studies (Ito, 2007; NYDOH, 2006; Peel *et al.*, 2005; Tolbert *et al.*, 2007) also reported NO_2 effect estimates using multi-pollutant models, as discussed above (section II.B.1.a). In the study by Ito (2007), risk estimates were robust and remained statistically significant in multi-pollutant models that included $PM_{2.5}$, O_3, CO, and SO_2.[11] In the study by Peel *et al.* (2005), the authors reported that ''The estimates for NO_2 were generally not attenuated in multipollutant models, while the estimates for the other pollutants [PM_{10}, ozone, NO_2, and CO] suggested weaker or no associations in the multipollutant models.'' The quantitative results for these multi-pollutant models were not presented in this study. In the remaining 2 studies (NYDOH, 2006; Tolbert *et al.*, 2007), NO_2 effect estimates that were positive in single pollutant models remained positive but not statistically significant in multi-pollutant models.[12] Two additional studies which evaluated only single pollutant models (Linn *et al.*, 2000; Ostro *et al.*, 2001) reported positive and statistically significant NO_2 effect estimates in locations with appreciably higher area-wide 1-hour daily maximum NO_2 concentrations (*i.e.*, around 200 ppb).

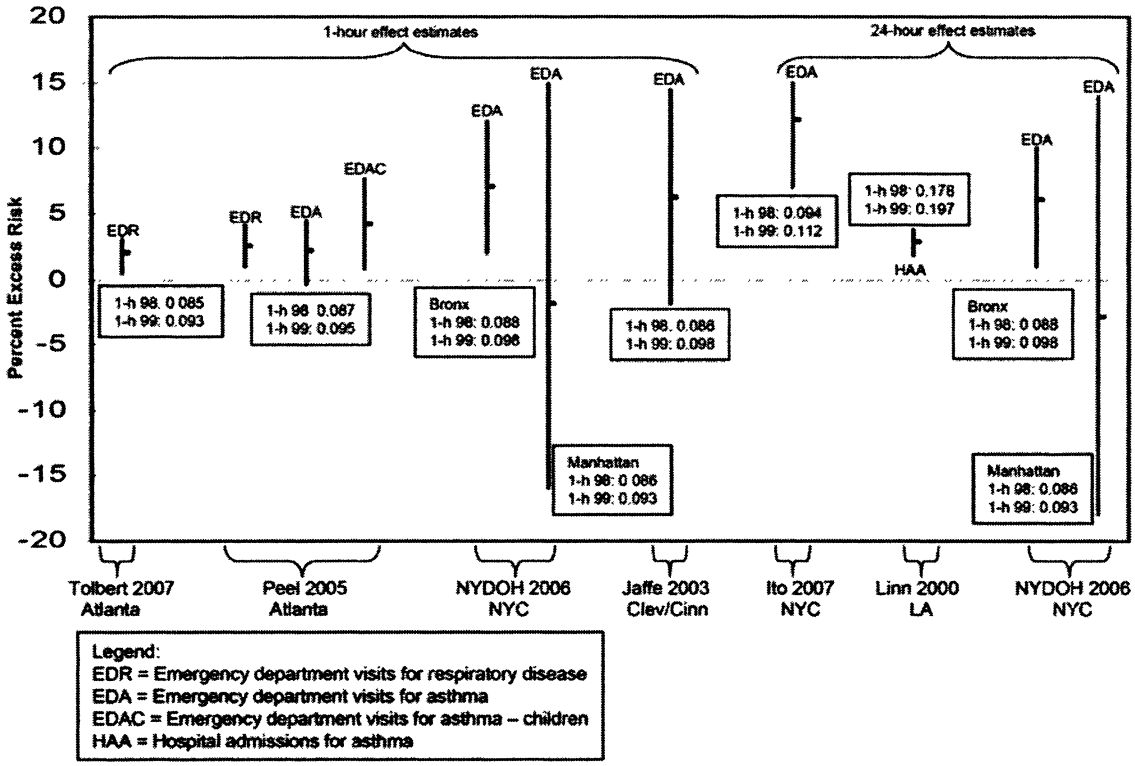


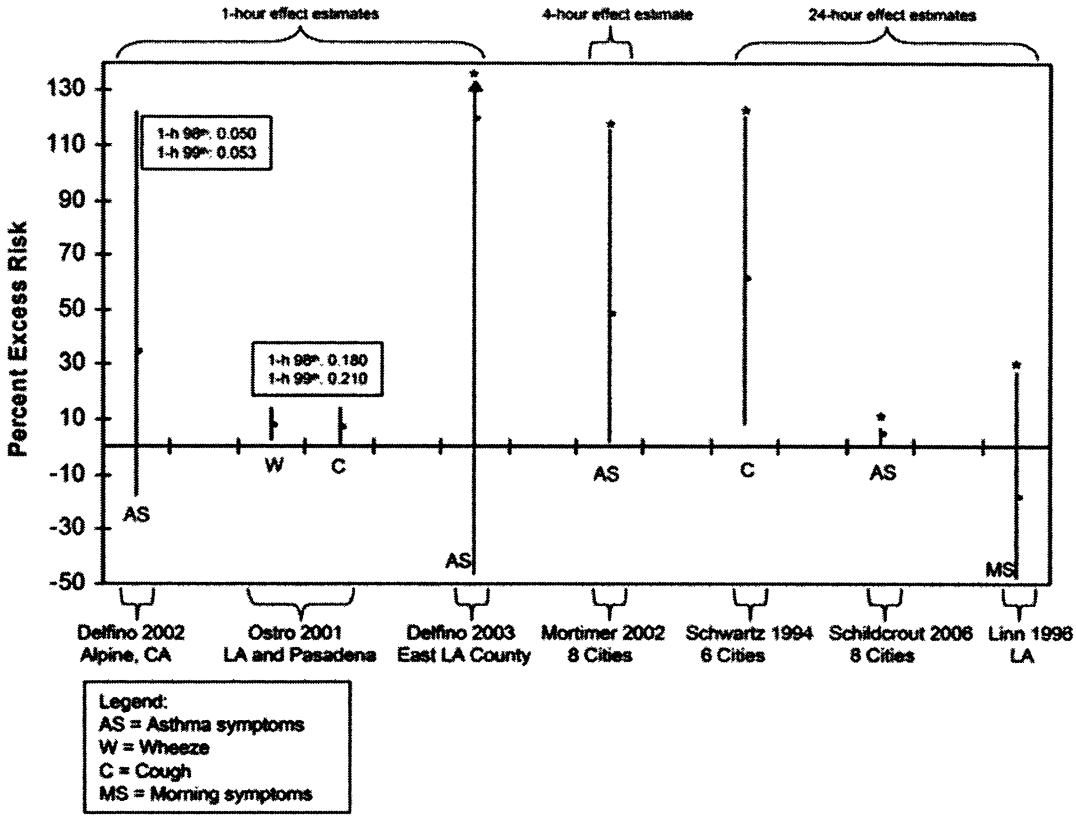
Figure 4. NO_2 effect estimates[13] (95% CI) for emergency department visits/hospital admissions and 1-hour daily maximum NO_2 concentrations (98th and 99th percentile values in boxes[14])

[11] In this study, multi-pollutant models were evaluated only for the warm months. Single pollutant effect estimates for NO_2 were statistically significant for the warm months, but not for the cold months.

[12] As discussed above in section II.B.1, the conclusion from the ISA that NO_2 effect estimates generally remain robust in multi-pollutant models is based on evaluation of the broader body of epidemiologic evidence which includes, but is not limited to, these U.S. studies (*e.g.*, see Figures 1–3 above and ISA, Figures 3.1–7, 3.1–10, and 3.1–11). Effect estimates from these U.S. studies were not included in the multi-pollutant figures in the ISA because the studies generally reported multi-pollutant model results only qualitatively. They generally did not report the quantitative information that would have been necessary to include the results in the ISA figures.

[13] Effect estimates presented in Figures 4 and 5 are from single pollutant models.

[14] Authors of relevant U.S. and Canadian studies were contacted and, for each study, air quality statistics were requested from the monitor that recorded the highest NO_2 concentrations. In cases where authors provided 1-hour daily maximum air quality statistics, this information is presented in Figures 4 and 5 (studies by Tolbert, Peel, NYDOH, Delfino). In four cases (studies by Ito, Jaffe, Linn, Ostro), we were not able to identify 1-hour NO_2 statistics from the information provided by the authors. In these cases, we evaluated monitored NO_2 concentrations reported to EPA's Air Quality System (AQS) for the location and time of the study. Figures 4 and 5 present the highest 98th/99th percentile 1-hour daily maximum NO_2 concentrations that correspond to each study location and time period. Prior to identifying potential alternative standards, we did not receive air quality information from any of the Canadian authors contacted and we were unable to reconstruct the air quality data sets for the Canadian studies. Therefore, for purposes of identifying levels of potential alternative standards, our analysis was based on these key U.S. studies. Note that the NO_2 concentrations reported in the study by Jaffe are labeled as 24-hour concentrations, but the author indicated in a personal communication (Jaffe, 2008) that they actually represent 1-hour daily maximum concentrations.



*We were not able to identify 1-hour 98th and 99th percentile NO2 concentrations for several of the U.S. respiratory symptom studies identified in table 5.4-1 of the ISA.

Figure 5. NO_2 effect estimates for respiratory symptoms and associated 1-hour daily maximum NO_2 levels (98th and 99th percentile values in boxes)

When evaluating the controlled human exposure literature for its potential to inform the selection of a range of appropriate standard levels for evaluation, the REA noted that available studies have addressed the consequences of short-term (*e.g.*, 30-minutes to several hours) NO_2 exposures for a number of health endpoints including increased airway responsiveness, reduced host defense and immunity, inflammation, and decreased lung function (ISA, section 3.1). In identifying health endpoints on which to focus for purposes of informing decisions about potential alternative standard levels, the REA concluded that it was appropriate to focus on those endpoints that occur at or near ambient levels of NO_2 and endpoints that are of potential public health significance. As described above in more detail (section II.C.1), the only endpoint to meet both of these criteria is increased airway responsiveness in asthmatics. The ISA concluded that NO_2 exposures between 200 and 300 ppb for 30 minutes and 100 ppb for 60-minutes can result in small but significant increases in nonspecific airway responsiveness (ISA, section 5.3.2.1) and that ''transient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control'' (ISA, sections 3.1.3 and 5.4). This effect could have important public health implications due to the large size of the asthmatic population in the United States (ISA, Table 4.4–1). In addition, NO_2 effects on airway responsiveness in asthmatics are part of the body of experimental evidence that provides plausibility and coherence for the observed NO_2-related increase in hospital admissions and emergency department visits in epidemiologic studies (ISA, section 5.3.2.1). For all of these reasons, the REA considered the extent to which results reported for the NO_2-associated increase in airway responsiveness in asthmatics could inform decisions on alternative standard levels.

With regard to controlled human exposure studies of airway responsiveness, the ISA and the REA discussed an update to a meta-analysis that was originally published by Folinsbee in 1992 and considered in the 1993 NO_X AQCD. The original analysis by Folinsbee (1992) included individual level data from 19 studies involving asthmatic volunteers. Folinsbee reported that 65% of resting asthmatics (57 of 88) exposed to NO_2 concentrations between 100 and 140 ppb experienced an increase in airway responsiveness. In addition, 76% (25 of 33) of resting asthmatics experienced increased airway responsiveness following exposure to NO_2 concentrations between 200 and 300 ppb. These results in resting asthmatics were statistically significant. Smaller, and statistically non-significant, percentages of exercising asthmatics experienced increased airway responsiveness following exposure to NO_2 concentrations (ISA, section 3.1.3.2). The reason for this difference is not known as the factors that predispose some asthmatics to NO_2 responsiveness are not understood (ISA, section 3.1.3.2).[15]

[15] When the asthmatic results were grouped together for all exposures, both at rest and during exercise, the percent of asthmatics with increased airway responsiveness decreased at the higher exposure concentrations. This result could be attributed to the lack of an effect in the asthmatics exposed during exercise.

The update of this meta-analysis presented in the ISA (Table 3.1–3) included one additional study of non-specific responsiveness and removed an allergen responsiveness study that was included in the original [16] (*see* ISA, section 3.1.3.2 for more discussion). While the updated analysis does not include new results at lower concentrations (100–250 ppb), we interpreted the results with a greater focus on 100 ppb due, in part, to the greater body of evidence available, including new epidemiologic evidence. Therefore, the updated analysis also reported results specifically for an NO_2 exposure concentration of 100 ppb. As with the original analysis by Folinsbee (1992), the updated meta-analysis reported that a larger percentage of resting asthmatics, as opposed to exercising asthmatics, experienced an NO_2-related increase in airway responsiveness. The updated analysis reported that, when exposed at rest, 66% (33 of 50) of asthmatics experienced an increase in airway responsiveness following exposure to 100 ppb NO_2, 67% (47 of 70) of asthmatics experienced an increase in airway responsiveness following exposure to NO_2 concentrations from 100 to 150 ppb, 75% (38 of 51) of asthmatics experienced an increase in airway responsiveness following exposure to NO_2 concentrations from 200 to 300 ppb, and 73% (24 of 33) of asthmatics experienced an increase in airway responsiveness following exposure to NO_2 concentrations above 300 ppb. The fraction of resting asthmatics experiencing an increase in airway responsiveness was statistically significant at each of these NO_2 concentrations.

Based on this evidence, we have identified exposure to NO_2 at a level of 100 ppb to be the lowest level at which effects have been observed in controlled human exposure studies, noting that it is also the lowest level tested in the studies used in the meta-analysis. There is no evidence from this meta-analysis, however, of a threshold below which NO_2-related effects do not occur.

b. Exposure- and Risk-Based Considerations

Chapters 7–9 of the REA estimated exposures and health risks associated with recent air quality and with air quality, as measured at monitors in the current area-wide network, which had been adjusted to simulate just meeting the current and potential alternative standards. The specific standard levels evaluated, for an area-wide standard based on the 3-year average of the 98th and 99th percentile 1-hour daily maximum NO_2 concentrations, were 50, 100, 150, and 200 ppb.

The results of the air quality, exposure, and risk analyses are presented below in Table 1. With regard to the air quality results, Table 1 presents the number of days per year that NO_2 concentrations on/near roads were estimated to equal or exceed the lowest and the highest health benchmarks evaluated (100 and 300 ppb). Compared to just meeting the current annual standard, exceedances estimated to be associated with just meeting 99th percentile 1-hour daily maximum area-wide standard levels of either 50 or 100 ppb were substantially lower. In contrast, exceedances estimated to be associated with 1-hour area-wide standards of 150 or 200 ppb were either similar to, or slightly higher than, those estimated for just meeting the current standard. Table 1 also presents the results of the Atlanta exposure and risk assessments. As is the case for the air quality analyses, NO_2 exposures and risks estimated to be associated with just meeting 1-hour area-wide standard levels of either 50 or 100 ppb were substantially lower than those associated with just meeting the current annual standard. Exposures and risks estimated to be associated with 1-hour area-wide standard levels of 150 or 200 ppb were somewhat lower than, or similar to, those estimated for just meeting the current annual standard.

TABLE 1—SUMMARY OF RESULTS OF THE EXPOSURE AND RISK ANALYSES PRESENTED IN THE REA

Air quality	Mean estimated number of days per year with 1-hour NO_2 concentrations on/near roads greater than or equal to benchmark levels (in location with largest number of estimate exceedances)		Mean percent of Atlanta asthmatics estimated to experience 6 or more days per year with 1-hour NO_2 exposure concentrations greater than or equal to benchmark levels (based on the year 2002)		Mean percent of total respiratory ED visits in Atlanta estimated to be related to NO_2 (based on the year 2007)	
	100 ppb benchmark	300 ppb benchmark	100 ppb benchmark (percent)	300 ppb benchmark (percent)	Single pollutant estimate	Multi-pollutant estimates*
Current annual standard	338	38	100	97	8.1	1.7–6.9
Potential Alternative Standards Evaluated in the REA						
99th 1-hour: 200 ppb	350	56	100	89	7.1	1.5–6.1
99th 1-hour: 150 ppb	337	13	100	57	5.4	1.1–4.6
99th 1-hour: 100 ppb	229	4	100	11	3.6	0.7–3.1
99th 1-hour: 50 ppb	13	1	57	0	1.8	0.4–1.6

* Ranges represent the range of risk estimates that result from including different co-pollutants in the model.

c. Summary of Considerations From the REA

The policy assessment chapter of the REA considered the scientific evidence and the exposure/risk information as they relate to considering alternative 1-hour NO_2 standards that could be judged to be requisite to protect public health with an adequate margin of safety. The conclusions of the REA were based, in large part, on scientific evidence (*i.e.*, key U.S. epidemiologic studies) and exposure/risk analyses that were based on the use of the available NO_2 air quality data from area-wide monitors, as discussed above in sections II.B and II.C. The implications of these conclusions for a standard level that reflects the maximum allowable concentration anywhere in an area (a

[16] The updated meta-analysis added a study that evaluated non-specific airway responsiveness following exposure to 260 ppb NO_2 and removed a study that evaluated allergen-induced airway responsiveness following exposure to 100 ppb NO_2.

concentration likely to occur near major roads) are discussed below in section II.F.4.e.

When considering an appropriate upper end of the range of 1-hour daily maximum standard levels supported by the scientific evidence, the REA noted the following:

• Positive and statistically significant associations were observed in several key U.S. epidemiologic studies in locations with area-wide 98th and 99th percentile 1-hour daily maximum NO_2 concentrations ranging from 85 to 112 ppb [17] (Peel *et al.*, 2005; NYDOH, 2006; Ito *et al.*, 2007; Tolbert *et al.*, 2007) (*see* Figure 4 above).

• The meta-analysis of airway responsiveness presented in the ISA reported increased airway responsiveness in most asthmatics (66% or 33 out of 50) following short-term exposures to 100 ppb NO_2, which was the lowest concentration for which such data were available. Although some uncertainties associated with this evidence, as described above, provide support for considering standard levels below 100 ppb (*i.e.*, studies have typically involved volunteers with mild asthma and data are lacking from more severely affected asthmatics, who may be more susceptible (ISA, p. 3–16)), other uncertainties (*i.e.*, the undetermined magnitude and clinical significance of the NO_2-associated increase in airway responsiveness) provide support for considering higher standard levels.

Given these considerations, the REA concluded that the scientific evidence provides support for a standard level up to 100 ppb. The REA also noted that, to the extent more emphasis is placed on the uncertainties associated with ascribing effects to NO_2 in the cluster of epidemiologic studies and on the magnitude and clinical significance of the NO_2-associated increase in airway responsiveness following exposure to NO_2, standard levels higher than 100 ppb could be considered. However, the strongest support was concluded to be for standard levels at or below 100 ppb.

When considering an appropriate lower end of a range of levels supported by the scientific evidence, the REA noted the following:

• The epidemiologic study by Delfino *et al.*, (2002) evaluated associations between short-term ambient NO_2 concentrations and respiratory symptoms in a location (Alpine, CA) where area-wide NO_2 concentrations were well below levels in other key U.S. epidemiologic studies. As noted above, this single study provides mixed evidence for NO_2-associated effects in a location with 99th and 98th percentile 1-hour daily maximum area-wide NO_2 concentrations of 53 and 50 ppb, respectively.

• The meta-analysis of controlled human exposure studies reported increased airway responsiveness in asthmatics at the lowest NO_2 concentration for which data were available (*i.e.*, 100 ppb). In identifying the specific lower level for the standard that could be reasonably supported by this controlled human exposure evidence, there are several reasons why it is appropriate to consider levels below 100 ppb. First, the meta-analysis did not provide information on the potential for an NO_2-induced increase in airway responsiveness at concentrations below 100 ppb, leaving open the possibility for effects following exposures to lower concentrations. Second, the studies included in the meta-analysis did not evaluate severe asthmatics and most of the subjects included in these studies were mild asthmatics. Asthmatics characterized as having more severe asthma may be more susceptible than mild asthmatics to the effects of NO_2 exposure (ISA, section 3.1.3.2).

Thus, the REA concluded that it was appropriate to base the lower end of the range of standard levels on NO_2 concentrations in the location of the epidemiologic study by Delfino and on providing increased protection relative to the lowest level at which increased airway responsiveness in asthmatics was reported in controlled human exposure studies. Given the mixed results reported in the Delfino study, the REA concluded that it was appropriate to consider standard levels approximately equal to, rather than below, those measured in the location of the study. Given these considerations, the REA concluded that the lower end of the range of levels that is reasonably supported by the scientific evidence is 50 ppb for a 1-hour standard that would protect public health with an adequate margin of safety.

In addition to these evidence-based considerations, the REA compared the health risks estimated to be associated with just meeting the current standard to those estimated to be associated with different 1-hour standards. As noted above (section II.C), the REA characterized NO_2-associated health risks by estimating the potential occurrence of ambient NO_2 concentrations greater than or equal to concentrations reported to increase airway responsiveness, exposures of asthmatics to NO_2 concentrations reported to increase airway responsiveness, and the incidence of NO_2-associated emergency department visits. Given the REA conclusion that the available evidence and information clearly call into question the adequacy of the current standard, the adequacy of alternative 1-hour standards would also be called into question if those standards were estimated to be associated with similar or higher risks. In considering the three analyses that characterized NO_2-associated health risks, the REA noted that just meeting 1-hour area-wide standard levels of 150 and 200 ppb was estimated to be associated with risks ranging from somewhat lower to slightly higher than those estimated for the just meeting the current standard. In contrast, just meeting 1-hour standard levels of 50 or 100 ppb, in conjunction with the current area-wide monitoring network, was estimated to result in appreciably lower health risks than the current standard. Given this, the REA concluded that the exposure/risk information reinforces the scientific evidence in supporting a standard level from 50 to 100 ppb.

d. CASAC Views

CASAC expressed their views in a letter to the EPA Administrator (Samet, 2008b) within the context of their review of the final REA, a review which focused primarily on the policy assessment chapter.[18] In drawing conclusions regarding the level of a short-term standard, CASAC considered the scientific evidence evaluated in the ISA, the exposure and risk results presented in the REA, and the evidence- and risk-based considerations presented in the policy assessment chapter of the REA. CASAC concurred with the conclusion from the policy assessment chapter that the strongest support is for standard levels between 50 and 100 ppb. Their letter noted that, ''CASAC firmly recommends that the upper end of the range not exceed 100 ppb.'' In considering the impact of margin of safety on standard level, CASAC noted that ''the intent of the Clean Air Act is to protect public health with an adequate margin of safety and consequently uncertainty should be considered as a reason to move towards the lower end of the range of levels and not to the upper.'' In addition, with regard to the NO_2 concentration gradient

[17] As noted above, the health effects reported in epidemiologic studies are reasonably inferred to be associated with exposure to ambient NO_2 concentrations that are both higher than and lower than the area-wide concentrations reported for the study location.

[18] Earlier CASAC letters focused on their review of the air quality, exposure, and risk analyses as presented in other chapters of the draft REA.

around roadways, CASAC noted that ''the highest exposures likely occur when individuals are near roadways.'' As a result they recommended that the Agency consider the implications of this exposure issue when interpreting the evidence and when considering the siting of regulatory monitors.

CASAC comments were offered within the context of their review of the final REA. As noted above, the conclusions from the policy assessment chapter of the final REA were based, in large part, on scientific evidence and exposure/risk information based on NO_2 air quality data from the current area-wide NO_2 monitoring network. Therefore, it is not clear the degree to which CASAC recommendations might differ for a standard level that reflects the maximum allowable NO_2 concentration anywhere in an area, including near major roads. As noted in section I.C above, we are specifically soliciting CASAC comment on the use of this approach and on the proposed range of levels for a standard set using this approach.

In drawing conclusions regarding the level of an annual standard, CASAC noted the scientific evidence assessed in the ISA. Specifically, CASAC concluded that while there is evidence supporting the link between long-term NO_2 exposure and adverse health effects, this evidence does not provide a strong quantitative basis for changing the level of the current annual standard. Therefore, with regard to the annual standard, CASAC recommended ''retaining the current level, as evidence has not been cited that would lead to either an increase or decrease'' (Samet, 2008b).

e. Administrator's Conclusions on Level for a 1-Hour Standard

In considering the appropriate level for an NO_2 standard based on the 3-year average of the 99th percentile (or 4th highest) 1-hour daily maximum NO_2 concentration, the Administrator has considered the broad body of scientific evidence and exposure/risk information. She draws from that evidence and information the need to protect at-risk individuals against the distribution of short-term ambient NO_2 exposure concentrations across an area and the array of health effects that have been linked to such NO_2 exposures.

Specifically, the Administrator has considered the extent to which a variety of levels, which would reflect the maximum allowable 1-hour NO_2 concentration anywhere in an area, would be expected to protect at-risk individuals against increased airway responsiveness, respiratory symptoms, and respiratory-related emergency department visits and hospital admissions. The Administrator notes that these health endpoints are logically linked together in that the evidence for increased airway responsiveness in asthmatics is part of the body of experimental evidence that the ISA recognized as supporting the plausibility of associations between ambient NO_2 and the respiratory morbidity endpoints (*i.e.*, respiratory symptoms, emergency department visits, and hospital admissions) reported in epidemiologic studies.

As noted above, NO_2 exposure patterns associated with respiratory morbidity in epidemiologic studies are reasonably expected to include short-term peak exposures on and/or near major roadways of a magnitude that has been reported to increase airway responsiveness in asthmatics. Therefore, to inform the identification of an appropriate range of standard levels to propose, the Administrator has considered the scientific evidence, the exposure/risk results, and information on the NO_2 concentration gradient around roadways.

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 NO_2 and respiratory morbidity. Despite the possibility that associations between health effects and NO_2 in epidemiologic studies may be confounded by the presence of co-occurring pollutants, particularly other traffic-related pollutants, the ISA concluded that NO_2 effect estimates remain robust in multi-pollutant models and that the evidence supports a direct effect of NO_2 exposures on respiratory morbidity, independent of associations with other traffic-related pollutants. Given this conclusion, along with conclusions from the ISA regarding the consistency and the coherence of results across the relatively large number of NO_2 epidemiologic studies (both indoor and outdoor) and the supporting evidence from experimental studies, the Administrator has judged it appropriate to place substantial weight on epidemiologic studies in identifying an appropriate range of levels to propose.
- Controlled human exposure studies report that short-term exposures to NO_2 can increase airway responsiveness in asthmatics. With regard to this evidence, the Administrator also has considered the uncertainties associated with the magnitude and the clinical relevance of the NO_2-associated increase in airway responsiveness, noting that this effect may or may not be clinically significant for any given asthmatic. However, given the potential public health importance of this effect, due to the large size of the asthmatic population in the U.S. and the possibility that the NO_2-associated increase in airway responsiveness could worsen asthma symptoms and decrease control of asthma, the Administrator judges that it is also appropriate to place weight on this evidence when identifying an appropriate range of levels to propose.
- The results of the risk and exposure analyses presented in the REA provide information on the potential public health implications of setting the standard at different levels. The Administrator acknowledges the uncertainties associated with these analyses which, as discussed in the REA, could result in either over- or underestimates of NO_2-associated health risks. However, she also notes that those uncertainties should be similar across different air quality simulations within the air quality, exposure, and risk analyses. Therefore, the Administrator judges that these analyses are potentially useful for considering the relative levels of public health protection that could be provided by specific standard levels.

After considering the scientific evidence and the exposure/risk information (*see* sections II.B, II.C, and II.F.4.a through II.F.4.c), as well as the available information on the NO_2 concentration gradient around roadways (section II.A.2), as they relate to a standard level reflecting the maximum allowable NO_2 concentration in an area, the Administrator concludes that the strongest support is for a standard level at or somewhat below 100 ppb. The Administrator's rationale in reaching this conclusion is provided below.

First, the Administrator notes that a standard level of 100 ppb or lower under the proposed approach would be expected to limit short-term peak NO_2 exposures to concentrations that have been reported to increase airway responsiveness in asthmatics. With regard to this, the Administrator specifically notes the following:

- The meta-analysis of controlled human exposure data in the ISA reported increased airway

responsiveness in asthmatics at rest following exposure at and above 100 ppb NO_2, the lowest NO_2 concentration for which airway responsiveness data are available in humans.

• This meta-analysis does not provide any evidence of a threshold below which effects do not occur. The studies included in the meta-analysis evaluated primarily mild asthmatics while more severely affected individuals could respond to lower concentrations. Given this, it is possible that exposure to NO_2 concentrations below 100 ppb could increase airway responsiveness in some asthmatics.

• However, the magnitude of the NO_2-induced increase in airway responsiveness, and its clinical implications, cannot be quantified from the meta-analysis. As noted previously, the NO_2-induced increase in airway responsiveness may or may not be clinically significant. Further, there was a lack of an effect in asthmatics exposed during exercise.

Given the above considerations, the Administrator concludes that the controlled human exposure studies of airway responsiveness provide support for limiting exposure to NO_2 concentrations at or somewhat below 100 ppb. While she acknowledges that exposure to lower concentrations could increase airway responsiveness in some asthmatics, the Administrator concludes that, given the uncertainties regarding the magnitude and the clinical significance of the NO_2-induced increase in airway responsiveness, the greatest support is for limiting exposures to 100 ppb.

Second, the Administrator notes that a standard level at or somewhat below 100 ppb under the proposed approach would be expected to maintain peak area-wide NO_2 concentrations considerably below peak area-wide concentrations measured in locations where multiple key U.S. epidemiologic studies have reported associations with emergency department visits and hospital admissions. With regard to this, the Administrator specifically notes that 5 key U.S. studies provide evidence for effects in locations where 99th percentile 1-hour daily maximum NO_2 concentrations measured at area-wide monitors ranged from 93 to 112 ppb. The Administrator notes that the study by Delfino provides mixed evidence for effects in a location with a 99th percentile 1-hour daily maximum NO_2 concentration, as measured by an area-wide monitor, of 53 ppb. In that study, most of the reported NO_2 effect estimates were positive, but not statistically significant. Focusing on these studies, the Administrator concludes that they provide support for limiting area-wide NO_2 concentrations to below 90 ppb (99th percentile) in order to provide protection against the reported effects. She also concludes that limiting area-wide concentrations to considerably below 90 ppb would be appropriate in order to provide an adequate margin of safety. Given the mixed results of the Delfino study, the Administrator concludes that it may not be necessary to maintain area-wide NO_2 concentrations at or below 50 ppb to provide protection against the effects reported in epidemiologic studies.

Given that NO_2 concentrations near roads may be 30 to 100% higher than concentrations away from roads (*see* section II.A.2), the Administrator notes that a standard level at or somewhat below 100 ppb under the proposed approach could limit area-wide NO_2 concentrations to well below 90 ppb (99th percentile). With regard to this, she specifically notes the following:

• If NO_2 concentrations near roads are 30% higher than concentrations away from roads, a standard level of 100 ppb could limit area-wide concentrations to approximately 75 ppb.

• If NO_2 concentrations near roads are 65% higher than concentrations away from roads (the mid-range of the 30% to 100% gradients), a standard level of 100 ppb could limit area-wide NO_2 concentrations to approximately 60 ppb.

• If NO_2 concentrations near roads are 100% higher than concentrations away from roads, a standard level of 100 ppb could limit area-wide concentrations to approximately 50 ppb.

Therefore, a standard level at or somewhat below 100 ppb under the proposed approach would be expected to maintain area-wide NO_2 concentrations well below 90 ppb across locations despite the expected variation in the NO_2 concentration gradient that can exist around roadways in different locations and over time. Such a standard level recognizes the substantial weight that the Administrator judges is appropriate to place on the cluster of key U.S. epidemiologic studies that reported positive, and often statistically significant, associations between NO_2 and emergency department visits and hospital admissions. This judgment takes into account the determinations in the ISA, based on a much broader body of evidence, that there is a likely causal association between exposure to NO_2 and these kinds of morbidity effects, and that there is no evidence of a threshold below which such effects would not occur.

As noted above, based on the Administrator's consideration of the controlled human exposure and epidemiologic evidence, she concludes that the strongest support is for a standard level reflecting the maximum allowable NO_2 concentration in an area at or somewhat below 100 ppb. In addition to these evidence-based considerations, the Administrator notes that a standard level of 100 ppb under the proposed approach would be consistent with the results of the exposure and risk analyses presented in the REA. As described in sections II.F.4.b and II.F.4.c above, the results of these analyses supported limiting area-wide NO_2 concentrations to between 50 and 100 ppb, which would be expected with a standard level at or below 100 ppb under the proposed approach. Given all of these considerations, the Administrator concludes that a standard level at or somewhat below 100 ppb under the proposed approach would be requisite to protect public health with an adequate margin of safety against the array of NO_2-associated health effects.

To the extent it is determined appropriate to emphasize the possibility that NO_2-induced airway responsiveness in asthmatics could occur following exposures below 100 ppb and/or the clinical significance of such increase in airway responsiveness, the Administrator notes that the evidence would support setting the standard level below 100 ppb. The Administrator also notes that a standard level below 100 ppb would be consistent with placing greater emphasis on the mixed results reported in the epidemiologic study by Delfino *et al.* (2002). Specifically, she notes that a standard level of 80 ppb would be expected to limit area-wide NO_2 concentrations to approximately 50 ppb (80 is 65% higher than 50) and that a standard level of 80 ppb would be expected to provide protection against exposure concentrations below those that have been reported to increase airway responsiveness in asthmatics.

For the reasons stated above, the Administrator proposes to set the level of a new 1-hour standard between 80 ppb and 100 ppb. In so doing, the Administrator proposes to place emphasis on reported findings from both epidemiologic studies and from controlled human exposure studies. In order to protect against NO_2-associated emergency department visits and hospital admissions reported in multiple key U.S. epidemiologic studies, and against reported NO_2-induced increases in airway responsiveness, the Administrator proposes to set the standard level no higher than 100 ppb. In addition, in light of the fact that the Administrator is considering, and soliciting comment

on, the appropriate weight to place on the potential risk of NO_2-associated effects in locations with relatively low area-wide NO_2 concentrations and on the significance of potential NO_2-induced increases in airway responsiveness in some asthmatics following exposures to concentrations below 100 ppb, the Administrator is proposing to set a standard level within a range that includes 100 ppb but is no lower than 80 ppb.

The Administrator solicits comment on the appropriateness of this proposed range of standard levels as well as on the approach she has used to identify the range. Specifically, the Administrator solicits comment on the following:

- The weight she has placed on the epidemiologic evidence, the controlled human exposure evidence, the exposure/risk information, and the uncertainties associated with each of these.
- Her use of available information on the NO_2 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, NO_2 air quality information, and the uncertainties associated with each.

With regard to the proposed range of standard levels, the Administrator notes that the proposed range is consistent with the recommendation by CASAC to set a standard level no higher than 100 ppb. However, much of the evidence and exposure/risk information that informed CASAC's advice was based on NO_2 concentrations measured at area-wide monitors in the current monitoring network. CASAC did not explicitly address whether or how the standard level should differ if it reflects the maximum allowable NO_2 concentration in a location (including near major roads) rather than the maximum allowable area-wide concentration.

The Administrator also solicits comment on setting a standard level above 100 ppb and up to 150 ppb. In so doing, the Administrator recognizes that there are uncertainties with the scientific evidence, such as that associated with the magnitude and clinical significance of the NO_2-induced increase in airway responsiveness in asthmatics and with attributing effects reported in epidemiologic studies specifically to NO_2 given the presence of co-occurring pollutants. The Administrator invites comment on the extent to which it is appropriate to emphasize these uncertainties in considering the standard level and on whether it would be appropriate to set a standard level as high as 150 ppb.

The Administrator notes that, in order to consider the potential implications of a standard level as high as 150 ppb, it is important to put such a standard in the context of potential ambient concentrations. A standard level of 150 ppb under the proposed approach could be associated with 1-hour area-wide NO_2 concentrations of approximately 90 ppb (150 is approximately 65% higher than 90), and potentially with concentrations ranging from 75 to 115 ppb (150 is approximately 100% higher than 75 and 30% higher than 115) depending on location.

The Administrator notes that a standard level as high as 150 ppb would place more emphasis on uncertainties associated with the scientific evidence. Specifically, a standard level of 150 ppb would emphasize the uncertainty associated with the magnitude and the clinical significance of the NO_2-induced increase in airway responsiveness in asthmatics and would be based on an assumption that NO_2-associated health effects reported in epidemiologic studies are due in large part to exposure to co-occurring pollutants, rather than exposure to NO_2. As noted above, the Administrator seeks comment on the extent to which it would be appropriate to emphasize these uncertainties in considering the standard level and the extent to which the scientific evidence would support levels up to 150 ppb.

In addition, the Administrator notes that a standard level lower than 80 ppb could be appropriate to the extent that near-road concentrations are determined to be closer to 30% higher than area-wide concentrations or to the extent that additional emphasis is placed on the possibility that exposure to NO_2 concentrations below 100 ppb could increase airway responsiveness in some asthmatics. Accordingly, the Administrator also solicits comment on standard levels as low as 65 ppb (30% higher than an area-wide concentration of 50 ppb).

f. Alternative Approach to Setting the 1-Hour Standard Level

As discussed above, the Administrator is proposing a standard level reflecting the maximum allowable NO_2 concentration anywhere in an area. However, for the reasons discussed below, EPA also solicits comment on an alternative approach to setting a 1-hour NO_2 standard. Under this alternative approach, the standard level would reflect the maximum allowable NO_2 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 NO_2 concentration anywhere in that area. In conjunction with soliciting comment on this alternative approach, EPA solicits comment on setting the level of such a standard within the range of 50 to 75 ppb. In addition, as with the proposed standard, EPA solicits comment on NO_2 as the indicator, a 1-hour (daily maximum) averaging time, and the 3-year average of the 99th percentile (or 4th highest) or 98th percentile (or the 7th or 8th highest) as the form.

With regard to the range of levels from 50 to 75 ppb, which would reflect maximum allowable area-wide NO_2 concentrations under this approach, the Administrator notes the following. First, a standard level within in this range would be expected to maintain area-wide NO_2 concentrations below peak 1-hour area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Second, she notes that standard levels from the lower end of this range would be expected to limit roadway-associated exposures to NO_2 concentrations that have been reported in controlled human exposure studies to increase airway responsiveness in asthmatics. A standard level of 50 ppb under this approach could limit near-road concentrations to between 65 and 100 ppb, given that near-road NO_2 concentrations can range from 30% to 100% higher than area-wide concentrations. Assuming the mid-point of the range of gradients (*i.e.*, that near-road concentrations are 65% higher than area-wide concentrations), a standard level of 50 ppb under this approach could limit near-road concentrations to approximately 80 ppb and a standard level of 60 ppb could limit near-road concentrations to approximately 100 ppb. Third, to the extent that relatively more emphasis is placed on the uncertainties regarding the magnitude and clinical significance of the NO_2-induced increase in airway responsiveness, the Administrator notes that a standard level from the upper end of the range could be determined to be appropriate. Finally, this approach would provide more confidence than the proposed approach regarding the degree to which a specific standard level would limit area-wide NO_2 concentrations but less confidence regarding the degree to which a specific

standard level would limit the peak NO_2 concentrations likely to occur near major roadways.

The Administrator recognizes that her proposed approach results from a comprehensive evaluation of alternative approaches to determining the level of the NO_2 primary NAAQS, but that these approaches have not previously been presented to CASAC, or other stakeholders, for their evaluation and public discussion. More specifically, the Administrator notes that much of the information included in the policy assessment chapter of the REA, which formed the foundation for CASAC's recommendations regarding standard level, was based on evaluation of data drawn from the current area wide-oriented monitoring network. Further, the Administrator notes that CASAC did not explicitly discuss in their recommendations whether and how the standard level should differ if that level reflects the maximum allowable NO_2 concentration anywhere in an area rather than the maximum allowable NO_2 concentration measured at an area-wide monitoring site. Given this, the Administrator recognizes the possibility that comments received on this proposal, particularly those received from CASAC, could provide important new information for consideration.

g. Level of the Annual Standard

With regard to the annual standard, the Administrator notes that the ISA concluded that the scientific evidence is suggestive but not sufficient to infer a causal relationship between long-term NO_2 exposure and respiratory morbidity. While some studies have reported associations between long-term NO_2 exposure and respiratory endpoints such as decrements in lung function growth (Gauderman *et al.*, 2004; Rojas-Martinez *et al.*, 2007a and b; Oftedal *et al.*, 2008), the ISA notes that the high correlation among traffic-related pollutants makes it difficult to accurately estimate independent effects in these long-term studies. CASAC recommended retaining an annual standard in order to provide protection against potential health effects associated with long-term exposures. They based this recommendation on ''the limited evidence related to potential long-term effects of NO_2 exposure and the lack of strong evidence of no effect'' (Samet, 2008b). With regard to the level of an annual standard, CASAC recommended retaining the current level as the evidence considered did not provide a basis for either increasing or decreasing it. Given these considerations, and recognizing that a new 1-hour standard level as proposed would also provide some degree of protection from long-term exposures, the Administrator proposes to take a cautious approach and retain the current annual standard. The Administrator solicits comment on this approach.

G. Summary of Proposed Decisions on the Primary Standard

For the reasons discussed above, and taking into account information and assessments presented in the ISA and REA as well as the advice and recommendations of CASAC, the Administrator proposes that the current annual standard is not requisite to protect public health with an adequate margin of safety. The Administrator proposes to establish a new short-term standard that will afford increased protection for asthmatics and other at-risk populations against an array of adverse respiratory health effects related to short-term NO_2 exposure. These effects include increased asthma symptoms, worsened control of asthma, an increase in respiratory illnesses and symptoms, and related serious indicators of respiratory morbidity including emergency department visits and hospital admissions for respiratory causes.

Specifically, the Administrator proposes to set a new short-term primary NO_2 standard, with a 1-hour (daily maximum) averaging time, a form defined as the 3-year average of the 99th percentile or the 4th highest daily maximum concentration. The level for the new standard is proposed to be within the range of 80 to 100 ppb, reflecting maximum allowable concentrations anywhere in an area. In conjunction with this proposed standard, the Administrator also solicits comment on levels as low as 65 ppb and as high as 150 ppb, and on alternative forms including the 3-year average of the 98th percentile or the 7th or 8th highest daily maximum concentration.

In addition, the Administrator also solicits comment on an alternative approach to setting a new 1-hour standard. Under this alternative, the NO_2 NAAQS would reflect the maximum allowable area-wide NO_2 concentration, which would be measured away from major roads. With regard to this approach, the Administrator solicits comment on a level within the range from 50 to 75 ppb and on the same alternative forms as noted above.

In addition to setting a new 1-hour standard, the Administrator proposes to retain the current annual standard. The current annual standard together with a new 1-hour standard would provide protection against health effects potentially associated with long-term exposures to NO_2. The Administrator solicits comment on this approach.

III. Proposed Amendments to Ambient Monitoring and Reporting Requirements

The EPA is proposing changes to the ambient air monitoring, reporting, and network design requirements for the NO_2 NAAQS. This section discusses the changes we are proposing which are intended to support the proposed 1-hour NAAQS and proposed retention of the current annual NAAQS in Section II. Ambient NO_2 monitoring data are used to determine whether an area is in violation of the NO_2 NAAQS. Ambient NO_2 monitoring data are collected by state, local, and Tribal monitoring agencies (''monitoring agencies'') in accordance with the monitoring requirements contained in 40 CFR parts 50, 53, and 58.

A. Monitoring Methods

To be used in a determination of compliance with the NO_2 NAAQS, NO_2 data must be collected using a Federal Reference Method (FRM) or a Federal Equivalent Method (FEM) analyzer. The current monitoring method in use by most State and local monitoring agencies is the gas-phase chemiluminescence FRM (40 CFR Part 50, Appendix F), which was implemented into the NO_2 monitoring network in the early 1980s. The current list of all approved FRMs and FEMs capable of providing ambient NO_2 data for use in attainment designations may be found on the EPA Web site (*http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf*). It must be noted, however, that due to the proposal of a new 1-hour NAAQS, wet chemical based FEMs would not be appropriate for use in determining compliance of the proposed 1-hour NAAQS, since such methods are incapable of providing hourly averaged data. Therefore, we propose that any NO_2 FRM or FEM used for making primary NAAQS decisions must be capable of providing hourly averaged concentration data. We propose to only allow FRM or FEMs capable of providing hourly averaged concentration data to be used to produce data for comparison to the NAAQS, and solicit comment on this proposed requirement.

The sum of nitric oxide (NO) and NO_2 is commonly called NO_X. Nitrogen oxides, technically the total reactive nitrogen oxide family, known as NO_Y, is defined as the sum of NO, NO_2, and the higher nitrogen oxides collectively

termed NO_Z. Important components of ambient NO_Z include nitrous acid (HNO_2), nitric acid (HNO_3), and the peroxyacetyl nitrates (PANs). However, NO_2 is the indicator for the nitrogen oxides NAAQS. In the ambient monitoring network, very nearly all measurements of NO_2 are collected by the chemiluminescence FRM. However, this technique directly measures only NO by the principle of gas-phase chemiluminescence induced by the reaction of NO with O_3 at low pressure. NO_2 concentrations are determined indirectly by the analyzer in two steps: (1) By first measuring the ambient NO concentration, and (2) determining total NO_X, including NO_2, by measuring a second NO concentration after reducing the NO_2 in the sample air stream to NO (most often through the use of a molybdenum oxide (MoO_X) substrate heated to between 300 °C and 400 °C in the sample flow path). The difference between the second concentration (NO plus the NO_2 reduced to NO) and the first concentration (ambient NO only) is reported as the NO_2 concentration.

One issue of note with the chemiluminescence FRM is that the reduction of NO_2 to NO on the MoO_X converter substrate is not specific to NO_2; hence, chemiluminescence method analyzers are subject to varying interferences produced by the presence in the air sample of the NO_Z species listed above and others occurring in trace amounts in ambient air. This interference is often termed a ''positive artifact'' in the reported NO_2 concentration since the presence of NO_Z results in an over-estimate in the reported measurement of the actual ambient NO_2 concentration. This interference by NO_Z compounds has long been known and evaluated (Fehsenfeld *et al.*, 1987; Nunnermacker *et al.*, 1998; Parrish and Fehsenfeld, 2000; McClenny *et al.*, 2002; U.S. Environmental Protection Agency, 1993, 2006a). The sensitivity of the chemiluminescence FRM to potential interference by individual NO_Z compounds is variable and depends in part on characteristics of individual monitors, such as the design of the instrument inlet, the temperature and composition of the reducing substrate, and the interactions of atmospheric species with the reducing substrate. Furthermore, the concentrations of NO_Z compounds in ambient air are variable with time and distance from the sources of NO and NO_2, chiefly the point source and both on-road and non-road mobile source combustion of fossil fuels. Nearer to these sources, the potential interference is lower than it is farther away because more of the measured nitrogen oxides are present as the emitted NO and quickly formed NO_2, rather than NO_Z. This is because oxidation to the NO_Z compounds from NO and NO_2 requires time and the presence of other atmospheric compounds like the hydroxyl radical.

Overall, as noted in the ISA, it appears that interference by NO_Z on chemiluminescence FRMs is not more than 10 percent of the reported NO_2 concentration during most or all of the day during winter (cold temperatures), but larger interference ranging up to 70 percent can be found during summer (warm temperatures) in the afternoon at sites away and downwind from strong emission sources. In general, the NO_Z interference in the reported NO_2 concentrations collected downwind of source areas and NO_2 concentrations collected in relatively remote areas away from concentrated point, area, or mobile sources is larger than the NO_Z interference in NO_2 measurements taken in urban cores or other areas with fresh NO_X emissions.

The chemiluminescence FRM is well established, comprising a large majority of the current operating network, and has served as the principal monitoring method in the NO_2 network for more than thirty years. Many of the epidemiologic studies referenced in the REA as the health basis for the proposed primary NO_2 NAAQS utilized ambient NO_2 data obtained from chemiluminescence FRMs, and subsequently, the uncertainties that may occur from the potential positive influence of NO_Z species on NO_2 values provided by the ambient FRM monitoring network are already reflected in those studies. Therefore, for purposes of comparing NO_2 monitoring data to the NO_2 NAAQS, the EPA believes that the chemiluminescence FRMs are appropriate for continued use under the current standard and under any of the options being considered for a new 1-hour averaged primary NO_2 NAAQS.

EPA is aware of the more recent development of an alternative method in determining NO_2 concentrations by chemiluminescence, specifically through the use of a photolytic converter, which uses specific wavelengths of ultraviolet light to reduce NO_2 to NO in lieu of the FRM's MoO_X substrate converter. The advantage of the photolytic-chemiluminescence method is that the photolytic converter is more specific to NO_2, as compared to a MoO_X substrate converter, and does not reduce many NO_Z species to NO (Ryerson *et al.*, 2000), reducing the potential influence of NO_Z concentrations on the reported NO_2 concentration. The photolytic-chemiluminescence method is currently deployed within certain research networks, but the EPA has not approved this method as an FRM or an FEM. If this technique is to be advanced to an FRM or FEM, the method may require additional research and development to ensure the stability of the photolytic converter rates in a variety of ambient conditions and monitor set-ups that might be experienced in the field and a consistent method of mathematically correcting for the known converter efficiencies.

EPA also recognizes that, although not widely used by state and local monitoring agencies, the existing FRM and FEM path-integrated optical remote sensing techniques, also known as open-path and remote sensing methods, which use spectrometers to detect pollutant concentrations by light absorption over an optical path length, are suitable for continued use in the ambient monitoring network as they can provide NO_2 measurements with reduced influences of NO_Z species on the reported NO_2 concentrations, relative to the chemiluminescence FRM. However, these methods do not provide point specific concentrations like those provided by chemiluminescence FRMs that are typically expected and seen in the monitoring network, and may be one of the reasons these methods are not more widely used.

In recognition of the existence of alternative methods that may be useful in the measurement of NO_2 for NAAQS compliance purposes, as well as other objectives, EPA solicits comment 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 U.S. at NO_2 monitoring sites.

B. Network Design

1. Background

The basic objectives of an ambient monitoring network, as noted in 40 CFR Part 58 Appendix D, include (1) providing air pollution data to the general public in a timely manner, (2) supporting compliance with ambient air quality standards and emissions strategy development, and (3) providing support for air pollution research. Section II.A.1 notes that there are currently no minimum monitoring requirements for NO_2 in 40 CFR part 58 Appendix D,

other than the requirement for EPA Regional Administrator approval before removing any existing monitors, and that any ongoing NO_2 monitoring must have at least one monitor sited to measure the maximum concentration of NO_2 in that area. As discussed in Section II.A.2, an analysis of the approximately 400 [19] monitors comprising the current NO_2 monitoring network (Watkins and Thompson, 2008) indicates that the most frequently stated monitor objectives for sites in the current NO_2 network are for the assessment of concentrations for general population exposure and maximum (highest) concentrations typically at the neighborhood and urban scales. Spatial scales are defined in 40 CFR Part 58 Appendix D, Section 1.2, where the scales of representativeness of most interest for the monitoring site types include:

1. *Microscale*—Defines the concentration in air volumes associated with area dimensions ranging from several meters up to about 100 meters.

2. *Middle scale*—Defines the concentration typical of areas up to several city blocks in size, with dimensions ranging from about 100 meters to 0.5 kilometers.

3. *Neighborhood scale*—Defines concentrations within some extended area of the city that has relatively uniform land use with dimensions in the 0.5 to 4.0 kilometers range.

4. *Urban scale*—Defines concentrations within an area of city-like dimensions, on the order of 4 to 50 kilometers. Within a city, the geographic placement of sources may result in there being no single site that can be said to represent air quality on an urban scale. The neighborhood and urban scales have the potential to overlap in applications that concern secondarily formed or homogeneously distributed air pollutants.

5. *Regional scale*—Defines usually a rural area of reasonably homogeneous geography without large sources, and extends from tens to hundreds of kilometers.

The ISA and REA indicate that one of the largest factors affecting ambient exposures to NO_2 above health benchmark concentrations are mobile source emissions, particularly at locations near major roads. Information in the ISA and the REA shows that concentrations of mobile source pollutants, including NO_2, typically display peak concentrations on or immediately adjacent to roads, producing a gradient in pollutant concentrations where concentrations decrease with increasing distance from roads (Section II.A.2 above, ISA sections 2.5.4 and 4.3.6 and Table 2.2–1; REA section 7.3.2 and Figures 8–17 and 8–18). In the ambient environment, NO_2 is largely a secondary pollutant resulting from the reaction of NO with available ozone (O_3), the concentrations of which depend on photochemical reactions of ambient hydrocarbons and prior (precursory) NO_X emissions. The ISA notes that the direct emission of NO_2 from mobile sources is estimated to be only a few percent of the total NO_X emissions for light-duty gasoline vehicles, and anywhere from less than 10 percent up to 70 percent of the total NO_X emission from heavy-duty diesel vehicles, depending on the engine, the use of emission control technologies such as catalyzed diesel particulate filters (CDPFs), and mode of vehicle operation.[20] However, since the rate of conversion of mobile source NO to NO_2 as described above is a generally rapid process, (*i.e.*, on the order of a minute (ISA Section 2.2.2)), NO_2 behaves like a primary pollutant in the near-road environment, exhibiting peak concentrations on or closely adjacent to roads. However, due to the secondary formation characteristic of NO_2, its rate of decay with increasing distance from a road can be slower than that of the other pollutants directly emitted from mobile sources including carbon monoxide (CO), ultrafine particulates, air toxics, and black carbon. Literature values indicate that the distance required for NO_2 concentrations to return to near area-wide or background concentrations away from major roadways can range up to 500 meters. The actual distance is variable, and highly dependent on topography, roadside features, meteorology, and the related photochemical reactivity conditions (Baldauf *et al.*, 2008; Beckerman *et al.*, 2007; Clements *et al.*, 2008; Gilbert *et al.* 2003; Hagler *et al.*, 2009; Rodes and Holland, 1980; Singer *et al.*, 2003; Zhou and Levy, 2007). Nonetheless, any efforts to measure peak ambient NO_2 concentrations from on-road mobile sources, or other mobile source pollutant of interest noted above, would be best served by monitoring as near as practicable to roadways of interest.

2. Proposed Changes

In conjunction with the proposed 1-hour NAAQS and the proposed retention of the current annual NAAQS, we propose a number of changes to the NO_2 monitoring network. As described above in Section II.F.4, we are proposing a 1-hour NO_2 NAAQS that reflects the maximum allowable NO_2 concentration in an area. However, the current network is not oriented to address peak concentrations, such as the on-road and near-road environment, but many sites may be situated to assess high concentrations at the neighborhood or larger spatial scales. The EPA is proposing a two-tier network design to monitor ambient concentrations of NO_2 and assess compliance with the NO_2 NAAQS. The two tiers would provide data for comparison with both the 1-hour and annual standards, and would be comprised of (1) monitoring in areas of expected maximum 1-hour concentrations and (2) monitoring to characterize areas with the highest expected NO_2 concentrations at the neighborhood and larger spatial scales, or ''area-wide'' scales. Because the maximum hourly NO_2 concentrations in many areas are expected to be due to on-road mobile emissions, the EPA believes that the first tier of the monitoring network should include a component requiring monitoring near major roads, where higher NO_2 concentrations have been identified and there are no significant monitoring efforts to address roadway exposures. The EPA recognizes that requiring a component of the ambient NO_2 monitoring network to characterize the peak NO_2 concentrations derived from on-road mobile sources, using monitors placed near major roadways (''near-road monitors''), will introduce new requirements for monitoring sites that, for a majority of the state and local monitoring networks, currently do not exist.[21] However, the monitoring of maximum hourly concentrations of NO_2, particularly in the near-road environment, is an essential component

[19] It should be noted that the ISA Section 2.4.1 references a different number of active monitors in the NO_2 network. The difference stems from how 'currently operating monitors' were defined when extracting data from AQS. The ISA only references SLAMS, NAMS, and PAMS sites with defined montoring objectives, while the Watkins and Thompson, 2008 value represents all NO_2 sites reporting data at any point during the year.

[20] The ISA references studies of heavy-duty diesel vehicles retrofitted with a CDPF in describing the range of NO_2 to NO_X ratios from diesel vehicles. These studies are based on vehicles equipped with CDPFs prior to 2009. However, as of January 1, 2009, EPA's National Clean Diesel Campaign requires that emission control devices included on its Verified Technologies List raise the fraction of NO_2 in exhaust NO_X from an engine no more than 20% above the baseline engine NO_2 to NO_X ratio. Retrofit technologies sold after January 1, 2009 that do not meet the NO_2 emission limit may not be installed or sold as EPA verified technologies.

[21] For purposes of the discussion, near-road NO_2 monitors are defined to be no greater than 50 meters from the nearest traffic lane of target road segments. The details of appropriately placing NO_2 monitors near roads are explained in Section III.2.a of this document.

of an ambient monitoring network designed to determine compliance with the proposed 1-hour NAAQS. In addition, the EPA recognizes that the establishment of near-road monitoring sites will produce certain other advantages, by providing a new data source for public health studies that will support future NAAQS reviews, allowing for the tracking of mobile source emission reductions progress, providing monitoring infrastructure that may be of use for mixtures of pollutants in a multi-pollutant paradigm, and supporting scientific studies of other mobile source pollutants like CO, ultrafine particulate matter, black carbon, and air toxics.

The second tier of the proposed network design, the area-wide monitoring component, is intended to characterize the highest concentrations of NO_2 typical or representative of neighborhood and larger spatial scales, to address the wider area impact of NO_2 sources on urban populations. Further, a requirement for the continuation of area-wide monitoring of NO_2 serves to maintain continuity in collecting area-wide data that have served to inform long-term pollutant concentration trends analysis and health and scientific research for more than thirty years.

We propose that state and, when appropriate, local air monitoring agencies provide a plan for deploying monitors in accordance with the following proposed network design by July 1, 2011. We also propose that the NO_2 network being proposed be physically established no later than January 1, 2013. Considering the proposed timeline and criteria presented in the network design, we solicit comment on whether state and local monitoring agencies should be required to deploy monitors sooner than January 1, 2013.

a. Monitoring in Areas of Expected Maximum Concentrations Near Major Roads

We are proposing to require monitoring in locations of expected maximum concentrations near major roads in larger urban areas, with minimum monitoring requirements triggered for metropolitan areas based on Core Based Statistical Area (CBSA) population thresholds and the traffic related metric annual average daily traffic (AADT). The U.S. Department of Transportation (U.S. DOT) Federal Highway Administration's Status of the Nation's Highways, Bridges, and Transit: 2006 Conditions and Performance document (*http://www.fhwa.dot.gov/policy/2006cpr/es02h.htm*) states that ''while urban mileage constitutes only 24.9 percent of total (US) mileage, these roads carried 64.1 percent of the 3 trillion vehicles miles (VMT) travelled in the United States in 2004.'' The document also states that ''urban interstate highways made up only 0.4 percent of total (US) mileage but carried 15.5 percent of total VMT.'' These statements indicate how much more traffic volume exists on roads in urban areas versus the more rural areas that have significant amounts mileage of the total public road inventory. Because the combination of increased mobile source emissions and increased urban population densities can lead to increased exposures and associated risks, urban areas are the appropriate areas to concentrate required near-road monitoring efforts. Therefore, we propose that one near-road NO_2 monitor be required in CBSAs with a population greater than or equal to 350,000 persons. This population threshold is proposed to provide the near-road monitoring component of the network an appropriate spatial extent across the country, given the limited availability of routine measurements in these environments. Based on 2007 Census Bureau statistics, this will result in approximately 142 sites in as many CBSAs.[22]

We also propose that a second near-road monitor be required in CBSAs with a population greater than or equal to 2,500,000 persons, or in any CBSAs with one or more road segments with an AADT count greater than or equal to 250,000. Based on 2007 Census Bureau statistics and data from the 2007 Highway Performance Monitoring System (HPMS) maintained by the U.S. DOT Federal Highway Administration (FHWA), this particular element of the minimum monitoring requirements will add approximately 23 sites to the approximate 142 near-road sites in CBSAs that already will have one near-road monitor required due to the 350,000 population threshold. Of the 23 additional sites, two sites are due to the 250,000 AADT threshold and are attributed to the Las Vegas, Nevada and Sacramento, California CBSAs. The 2,500,000 population threshold is proposed as a second threshold to allow for further characterization of larger urban areas that are more likely to have a greater number of major roads across a potentially larger geographic area, and a corresponding increase in potential for exposure. Of the approximate 1.66 million public road segments tracked in the HPMS, road segments of 250,000 AADT or greater make up the top 0.03 percent of the most traveled public road segments. The FHWA has also used this threshold on its Web site to give an indication of the most travelled urban highways in the country (*http://www.fhwa.dot.gov/policyinformation/tables/02.cfm*). We proposed to use HPMS-reported AADT as the traffic volume metric because AADT appears to be the most widely used traffic volume metric in the scientific literature, is widely available, and offers the most objective and consistent metric available to indicate traffic volumes across the country. These AADT data are typically available from local Metropolitan Planning Organizations (MPOs), state departments of transportation, and from the FHWA's HPMS. The FHWA also provides national guidance on the appropriate measurement and estimation of AADT for different road types in their HPMS Field Manual (*http://www.fhwa.dot.gov/ohim/hpmsmanl/hpms.cfm*). We are therefore proposing the 250,000 AADT threshold for requiring a near-road monitor because that threshold represents the highest traffic volume road segments in the country, which may correspond to the greatest potential for high exposures directly connected to motor vehicle emissions.

In summary, the combination of the above proposed minimum monitoring requirement thresholds for the near-road monitors as part of the ambient NO_2 monitoring network are anticipated to require approximately 165 near-road sites in 142 CBSAs. We solicit comment on the proposed CBSA population threshold values (*i.e.*, 350,000 and 2,500,000) and on the use of population thresholds both lower and higher than those proposed, the use of the traffic volume metric AADT, and the 250,000 AADT threshold in establishing the minimum number of required near-road sites for urban areas.

In choosing these population and traffic related thresholds for the minimum monitoring requirements, it should be noted that, based on 2007 Census Bureau statistics, the U.S. Virgin Islands and seven states (Delaware, Montana, North Dakota, South Dakota, Vermont, West Virginia, and Wyoming) currently would not have required near-road monitoring sites under this current proposal. Considering the relative lack of near-road monitoring data nationwide, the new level and averaging time of the NAAQS being proposed, and the desire to establish a spatially representative and protective network, we solicit comment on the inclusion or

[22] We also note that this population threshold corresponds to the minimum population level in which Air Quality Index (AQI) levels are required to be reported, as noted in 40 CFR Part 58 Subpart F.

exclusion of an additional or alternative monitoring requirement such that each state and territory would have at least one near-road monitoring site.

The EPA recognizes that in certain cases, there can be an area or areas of expected maximum hourly concentration in a CBSA due to a major stationary source or to the combination of multiple sources that could include point, area, and non-road source emissions in addition to on-road mobile source emissions. Such locations might be identified through data analysis, such as the evaluation of existing ambient data and/or emissions data, or through air quality modeling. An example of such a location might be away from roads and downwind of a stationary source or sources in situations where the required near-road monitors do not represent a location or locations of expected maximum hourly NO_2 concentrations in a CBSA. In these situations, where such locations are known, we propose that the Regional Administrator will have discretion to require monitoring above the minimum requirements as necessary to address situations where the required near-road monitors do not represent a location or locations where the expected maximum hourly NO_2 concentrations exist in a CBSA. The EPA also proposes to allow Regional Administrators the ability to require additional near-road monitoring sites to address situations where minimum monitoring requirements are not sufficient to meet monitoring objectives, such as a situation where there is a variety of exposure potential in an area due to variety in the amount or types of fleet mix, congestion patterns, terrain, or geographic areas within a CBSA. An example of requiring an additional near-road monitor might be a case where a particular community or neighborhood is significantly or uniquely affected by road emissions, but the site or area is not monitored even though the responsible State or local monitoring agency is fulfilling the minimum monitoring requirements.

In all cases, the Regional Administrator and the responsible State or local air monitoring agency should work together to design and/or maintain the most appropriate NO_2 network to service the variety of data needs for an area. We solicit comment on the proposal to allow Regional Administrators the discretion to require monitoring above the minimum requirements for any CBSA where required near-road monitors do not represent a location or locations where the expected maximum hourly NO_2 concentrations exist in a CBSA. We also solicit comment on the proposal to allow Regional Administrators to require additional near-road NO_2 monitoring stations above the minimum required in situations where the minimum monitoring requirements are not sufficient to meet monitoring objectives as noted above.

The new near-road monitoring sites that are to be part of the NO_2 ambient monitoring network will require specific site selection criteria to focus monitoring efforts on one or a few major roads in a given CBSA. The EPA anticipates that these near-road monitoring sites will likely be best characterized as microscale, mobile source oriented sites. We propose that monitoring agencies be required to select their near-road monitoring site location(s) to characterize the largest traffic volume segment(s) in the CBSA, determined by ranking all road segments by AADT, and identifying a location or locations adjacent to those top ranked AADT segments where motor vehicle emission-derived NO_2 concentrations are expected to be at a maximum. Where a state or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly NO_2 concentrations are expected to occur, the monitoring agency should consider taking into account the potential for population exposure in the criteria utilized to select the final site location.

We propose that near-road NO_2 monitoring stations must be sited so that the NO_2 monitor probe is no greater than 50 meters away, horizontally, from the outside nearest edge of the traffic lanes of the target road segment, and shall have no obstructions in the fetch between the monitor probe and roadway traffic such as noise barriers or vegetation higher than the monitor probe height. Baldauf *et al.* (2009) indicate that the NO_2 probe would ideally be situated between 10 and 20 meters from the nearest traffic lane. We are not proposing that the near-road NO_2 monitor be on the predominantly downwind side of the target roadway, however, we solicit comment on whether this requirement is necessary to ensure near-road NO_2 sites capture maximum expected hourly concentrations.

We propose that the monitor probe be located within 2 to 7 meters above the ground, as is required for microscale $PM_{2.5}$ sites. EPA recognizes that these near-road monitoring sites will be adjacent to a variety of road types, where some target roads will be on an even plane with the monitoring station, while others may be cut roads, (*i.e.*, below the plane of the monitoring station), or fill and open elevated roads, (*i.e.*, where the road plane is above the monitoring station). In any given case, it is most appropriate to place the NO_2 monitor probe as close to the plane of the target road segment as possible, while staying between 2 to 7 meters above the ground. In addition, we propose that monitor probe placement on noise barriers or buildings, where the inlet probe height is no less than 2 meters and no more than 7 meters above the target road, will be acceptable, so long as the inlet probe is at least 1 meter vertically or horizontally away (in the direction of the target road) from any supporting wall or structure, and the subsequent residence time of the pollutant in the sample line between the inlet probe and the analyzer does not exceed 20 seconds. Although a wall-mounted or noise barrier-mounted near-road monitor set-up is not ideal, it may allow for existing sites to be utilized as near-road monitoring stations if they also meet the site selection criterion described below.

As noted above, we are proposing a siting criterion for NO_2 monitor probe placement to be no greater than 50 meters away from the outside nearest edge of the traffic lanes of the target road segment. Based on a review of the scientific literature, as discussed in Section II.A and the background portion of this section, locations on or immediately adjacent to roads typically exhibit the peak concentrations for mobile source pollutants, therefore monitor probe placement at increasing distances from a road will correspondingly decrease the potential for sampling maximum concentrations of NO_2. In addition, monitor probe placement within 50 meters of a target road allows for increased probability of reading elevated concentrations from the mobile source emissions even when wind conditions cause the near-road monitoring site to be upwind of the target road. Research literature indicates that in certain cases, mobile source derived pollutant concentrations, including NO_2, can be detected upwind of roads, above background levels, due to a phenomenon called upwind meandering. Kalthoff *et al.* (2007) indicates that mobile source derived pollutants can meander upwind on the order of tens of meters, mainly due to vehicle induced turbulence, while Beckerman *et al.* (2008) note that near-road pollutant concentrations on the predominantly upwind side of their study sites dropped off to near background levels within the first 50 meters, but were above background in this short and variable upwind range, which could be due to, at least in part,

vehicle induced turbulence. This upwind meandering characteristic of pollutants in the near-road environment provides an additional basis for locating near-road sites within 50 meters of target road segments because of the increased opportunity to monitor mobile source derived NO_2 concentrations that, although not peak concentrations, are still elevated above background levels, in meteorological conditions where the site is upwind of the target road.

We solicit comment on the proposed near-road NO_2 monitor siting criteria presented here, particularly: (1) The requirement for monitoring agencies to select near-road NO_2 monitor sites by ranking all road segments in a given CBSA by AADT, (2) selecting a site adjacent to a top ranked AADT road segment where motor vehicle emission-derived NO_2 concentrations are expected to be at a maximum, (3) the consideration of population exposure as a selection criterion in situations where a state or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly NO_2 concentrations are expected to occur, (4) the requirement for near-road NO_2 monitor probes to be no greater than 50 meters in the horizontal from the outside nearest edge of the traffic lanes of the target road segment, and (5) the requirement for monitor probes to be between 2 to 7 meters above the ground, and when located on a wall or supporting structure, that the inlet probe be at least 1 meter vertically or horizontally away from any supporting wall or structure.

We also solicit comment on an alternative approach that would allow state and local agencies greater discretion in selecting monitoring locations to fulfill minimum monitoring requirements for measurements of expected maximum NO_2 concentrations in each CBSA. In this alternative approach, an NO_2 monitor would still be required in locations of expected maximum NO_2 concentrations in CBSAs with a population greater than or equal to 350,000 persons. An additional monitor would be required in CBSAs with a population greater than or equal to 2,500,000, or in any CBSAs with one or more road segments with an AADT count greater than or equal to 250,000. Under this approach, states would not be specifically required to place monitors near roads, but would have flexibility to place monitors at locations of expected maximum concentrations. However, if a location or locations of expected maximum concentration were near roads in a CBSA, we would expect the NO_2 monitor to be placed near those roads. Further, we solicit comment on alternative ways of considering population exposure, in concert with the identification of locations of maximum expected NO_2 concentrations, in determining where to place near-road NO_2 monitors. In suggesting an appropriate role for population exposure, we invite comment on how the suggested role would take into account the fact that NAAQS are designed to protect all of the public, including at-risk or sensitive sub-populations, which can include smaller sub-populations that may be exposed to higher concentrations. We also invite comment on how any suggested role would compare with EPA's historic practice of placing monitors at locations of maximum concentration at the appropriate spatial scale, reflecting consideration of the averaging time of the NAAQS.

In situations where open-path monitors are used at near-road NO_2 sites, we have not identified an appropriate path length for this microscale monitoring site. For the purpose of this proposal, we propose a path length range of 50 to 300 meters as an appropriate path length range for open-path near-road NO_2 monitors. The high end of this proposed range coincides with path lengths identified for other pollutants at the micro and middle-scales. We solicit comment on the appropriate path length for a near-road NO_2 open-path monitor.

During the near-road monitor site selection process, monitoring agencies may utilize forms of quantitative analysis, such as emissions and/or air quality modeling, data analysis, or saturation studies, to better evaluate which of their top ranked AADT road segments may exhibit the potential for creating the highest NO_2 concentrations that might be monitored in the CBSA. As an example, such an analysis might indicate that of the top ranked AADT road segments in a given area, those segments that are part of or adjacent to interchanges and toll plazas, that have higher ratios of heavy duty diesel traffic to light duty traffic, have a high fraction of rapidly accelerating or grade-climbing vehicles, or that are located in or near particular terrain or land features, may exhibit higher potential maximum NO_2 concentrations. In addition, top ranked AADT road segment analysis may allow the monitoring agencies to select a near-road monitoring site located in a more densely populated area or a location representing more vulnerable populations from a pool of otherwise similarly categorized site candidates. In CBSAs required to have two near-road monitoring sites, we propose that the second site be selected based on AADT ranking and expected maximum concentration, but differentiated from the first site by factors such as: Fleet mix, congestion patterns, terrain, or geographic area within the CBSA, or at minimum, selecting a site along a different road with a different route, interstate, or freeway designation. This differentiation is to avoid having the two sites characterize the same traffic when there are potentially other road segments with different traffic characteristics available that meet siting criteria for the second near-road monitor. We solicit comment on the factors and methods to be used to differentiate a second required near-road NO_2 monitoring site from the first such site in a given CBSA.

In further support of characterizing the peak NO_2 concentrations occurring in the near-road environment, the EPA proposes to require three-dimensional anemometry, providing wind vector data in the horizontal and vertical planes, along with temperature and relative humidity measurements, at all required near-road monitoring sites. Due to the near-road NO_2 site being a somewhat specialized microscale site, we propose that the meteorological measurement hardware would be required to be situated at the same height as the NO_2 monitor probe, as opposed to a standardized height, to aid in characterizing what NO_2 analyzers are measuring from the target road segments. The requirement of three-dimensional anemometry is to allow for the determination of the standard deviation of vertical wind velocities (σ_w). Venkatram *et al.* (2007) notes that σ_w is a key meteorological factor in governing the dispersion of on road pollutant emissions. Therefore, the measurement of three dimensional wind would serve to inform when the near-road site is relatively upwind or downwind of the target road, provide a method to potentially identify the magnitude of vehicle induced turbulence, permit calculation of σ_w in the near-road environment to provide a better understanding of the mixing of mobile source pollutants at the monitoring site and how site characteristics influence mixing, and, with the inclusion of temperature and relative humidity, provide basic meteorological data. We solicit comment on the proposed requirement for three-dimensional anemometry, the placement of the meteorological equipment at the same height of the NO_2 monitor probe height, and the requirement for meteorological

measurements in general at all required near-road monitoring sites.

b. Area-Wide Monitoring at Neighborhood and Larger Spatial Scales

As the second tier of the NO_2 ambient monitoring network, we are proposing a minimum number of monitors to characterize that area with highest expected NO_2 concentrations at the neighborhood and larger (area-wide) spatial scales. We are proposing to require one area-wide monitoring site in each CBSA with a population greater than or equal to 1,000,000, to be sited to represent an area of maximum concentration at the neighborhood or larger spatial scales. This minimum monitoring requirement is expected to trigger 52 monitoring sites in as many CBSAs. Many of these monitors are likely already in place as part of the approximately 400 NO_2 monitoring sites that are currently operating across the country. Further, the EPA proposes to allow any current photochemical assessment monitoring station (PAMS) sites that are situated to address the highest NO_2 concentrations in an urban area and sited at neighborhood or urban scales to satisfy this proposed area-wide monitoring requirement. While in many cases it may be found that these area-wide monitors may show lower concentrations than the maximum concentration near-road NO_2 monitors, data from these larger spatially representative sites would provide information on area-wide exposures from an individual or a group of point, area, on-road and/or non-road mobile sources. These area-wide monitoring data may also, when coupled with the near-road monitoring data, assist in the determination of spatial variation of NO_2 concentrations across a given area, and assist in providing insight to the gradients that exist between local near-road or stationary source derived concentration maxima and the area-wide concentration levels.

The EPA recognizes that the minimum number of area-wide monitors required in this proposal may be less than the total number of NO_2 monitoring sites needed to satisfy the multiple monitoring objectives that neighborhood and larger scale sites can serve. These additional monitoring objectives include ambient photochemical pollutant assessment, aiding in ozone forecasting, aiding in PM precursor analysis and PM forecasting, and characterization of point and area sources that may be impacting certain communities. We propose that EPA Regional Administrators have the discretion to require additional area-wide NO_2 monitoring sites above the minimum monitoring requirements where the minimum monitoring requirements for area-wide monitors are not sufficient to meet monitoring objectives. For example, the Regional Administrator may require additional NO_2 monitors in certain communities, both inside and outside of CBSAs, which are affected by an individual or group of sources but are not required to have an NO_2 monitor as part of the minimum monitoring requirements. The Regional Administrator and the responsible State or local air monitoring agency should work together to design and/or maintain the most appropriate NO_2 network to service the variety of data needs for an area.

We solicit comment on the proposed minimum monitoring requirement of approximately 52 monitors to characterize areas with highest expected NO_2 concentrations at the area-wide (neighborhood and larger) spatial scales in CBSAs with populations of 1,000,000 or more persons. We also solicit comment on the proposal that the Regional Administrator can require additional monitoring sites on a case-by-case basis, to address situations where the minimum monitoring requirements for area-wide monitoring sites are not sufficient for an area.

3. Solicitation for Comment on an Alternative Network Design

In conjunction with the solicitation of comment on an alternative NAAQS that is discussed in Section II.F.4, the complementary network design would not reflect peak NO_2 concentrations anywhere in an area. Instead, the alternative network design would rely on monitors sited at the neighborhood and larger spatially representative scales, which is identical to the second component of the two-tiered network design being proposed except for having different population thresholds for minimum required monitoring. The currently operating NO_2 network would likely satisfy a portion of this alternative network design, however the entire network would need to be assessed before state or local agencies could make such determinations. State and local agencies would have to determine what each currently operating site is actually assessing to identify if any given site represents the highest concentrations for a given CBSA at the neighborhood and larger spatial scales. We solicit comment on an alternative network design where near-road monitors are not specifically included in the minimum monitoring requirements, and only monitors sited at the neighborhood and larger spatial scales are required. In this alternative network design, minimum monitoring requirements would apply to CBSAs based on population thresholds, where one monitor would be required in CBSAs with populations of 350,000 or more persons and a second monitor would be required for CBSAs with populations of 1,000,000 or more persons. Based on 2007 U.S. Census Bureau statistics, we estimate that these population thresholds would require approximately 194 monitoring sites in 142 CBSAs. The first monitor required in any CBSA would be expected to be sited at the neighborhood or larger scale to characterize that area with highest expected NO_2 concentrations. Any second monitor required in a CBSA would be expected to characterize a separate area within the same CBSA, also with expected high NO_2 concentrations. All such monitor site locations are anticipated to be in areas of higher population densities of CBSAs and in, or adjacent to, urban cores. The alternative network design would allow the Regional Administrators to use their discretion to require monitoring above the minimum requirements to address community impacts from the variety of NO_2 emission sources. EPA expects that this network design will result in little or no progress being made in the development of long-term near-road monitoring capabilities due to the lack of specific network design requirements. EPA seeks comment on this alternative network design.

In addition to soliciting comment generally on this alternative area-wide monitoring approach, the Administrator specifically requests comment on the appropriate definition of area-wide NO_2 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 soliciting comment. Comparing NO_2 concentrations measured near major roadways to a level meant to reflect the maximum allowable NO_2 concentrations at neighborhood and larger spatially representative scales would have the effect of increasing the stringency of the standard beyond that intended. With regard to this specific request for comment, the Administrator notes that the definition of area-wide concentrations could include a provision requiring that they be monitored at a distance greater than or equal to some prescribed distance from the nearest roadway. The Administrator notes that, while it is clear that peak

roadway-associated NO_2 concentrations occur on or very near major roads, the point at which these concentrations return to area-wide concentrations comparable to the area-wide standard is less certain and may vary considerable by location. As discussed above (section II.A.2), the scientific literature suggests that concentrations can return to typical urban background concentrations within distances of up to 500 meters from roads, though the actual distance will vary with topography, roadside features, meteorology, and photochemical reactivity conditions. The REA notes that studies suggest the return to background concentrations can occur from within distances of up to 200 to 500 m from the roads. Therefore, the Administrator requests comment on the degree to which these distances (up to 200 m, and up to 500m) serve to further define the distance from major roads that would represent concentrations comparable to the alternative standard. Further, since roadways of various sizes and traffic volumes can affect nearby NO_2 concentrations and roadways are ubiquitous in urban areas, the Administrator notes that defining representative area-wide concentrations could require more than a uniform assumption of a single specific distance from a class of roadway. The Administrator notes that the approach to defining representative area-wide distances could include consideration of location-specific roadway traffic volume and location-specific roadway characteristics such as topography, presence of sound walls, vehicle mix, and traffic patterns, to adequately address the variability. Given these considerations, the Administrator solicits comment on how to define the minimum distance to the nearest major roadway such that measured concentrations at this distance (or farther) would represent area-wide NO_2 concentrations for comparison to the alternative standard.

C. Data Reporting

NO_2 chemiluminescence FRMs are continuous gas analyzers, producing updated data values on the order of every 20 seconds. Data values are typically aggregated into minute averages and then compiled into hourly averages for reporting purposes. State and local monitoring agencies are required to report hourly NO, NO_2, and NO_X data to AQS within 90 days of the end of each calendar quarter. Some agencies also voluntarily report their pre-validated data on an hourly basis to EPA's real time AIRNow data system, where the data may be used by air quality forecasters to assist in ozone forecasting. The EPA believes these data reporting procedures are appropriate to support the current NO_2 NAAQS and any options being considered for a revised primary NO_2 NAAQS.

As a part of the larger data quality performance requirements of the ambient monitoring program, we are proposing to develop data quality objectives (DQOs) for the proposed NO_2 network. The DQOs are meant to identify measurement uncertainty for a given pollutant method. We propose a goal for acceptable measurement uncertainty for NO_2 methods to be defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent. We solicit comment on the proposed goals for acceptable measurement uncertainty.

IV. Proposed Appendix S—Interpretation of the Primary NAAQS for Oxides of Nitrogen and Proposed Revisions to the Exceptional Events Rule

The EPA is proposing to add Appendix S, Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen, to 40 CFR part 50 in order to provide data handling procedures for the proposed NO_2 1-hour primary standard and for the existing NO_2 annual primary standard. The proposed Appendix S would detail the computations necessary for determining when the proposed 1-hour and existing annual primary NO_2 NAAQS are met. The proposed Appendix S also would address data reporting, data completeness considerations, and rounding conventions.

Two versions of the proposed Appendix S are printed at the end of this notice. The first applies to an annual primary standard and a 1-hour primary standard based on the annual 4th high value form, while the second applies to an annual primary standard and a 1-hour primary standard based on the 99th percentile daily value form. The discussion here addresses the first of these versions, followed by a brief description of the differences found in the second version.

Both versions of the proposed Appendix S are based on a near-roadway approach to the setting the level of the 1-hour standard and to siting monitors. As such, these versions place no geographical restrictions on which monitoring sites' concentration data can and will be compared to the standard when making nonattainment determinations and other findings related to attainment or violation of the standard. If the final rule adopts the area-wide approach on which section II.F.4.e of this notice invites comment, provisions would be added to section 2 of Appendix S to specify geographical criteria for determining which monitoring sites' data can and will be compared to the standard consistent with the area-wide approach as described in that section.

The EPA is proposing to amend and move the provisions of 40 CFR 50.11 related to data completeness for the existing annual primary standard to the new Appendix S, and to add provisions for the proposed 1-hour primary standard. Substantively, the proposed data handling procedures for the annual primary standard in Appendix S are the same as the existing provisions in 40 CFR 50.11 for that standard, except for a proposed addition of a cross-reference to the Exceptional Events Rule, a proposed addition of Administrator discretion to consider otherwise incomplete data complete, and a proposed provision addressing the possibility of there being multiple NO_2 monitors at one site. The proposed procedures for the 1-hour primary standard are entirely new.

The EPA is also proposing NO_2-specific changes to the deadlines, in 40 CFR 50.14, by which States must flag ambient air data that they believe have been affected by exceptional events and submit initial descriptions of those events, and the deadlines by which States must submit detailed justifications to support the exclusion of that data from EPA determinations of attainment or nonattainment with the NAAQS. The deadlines now contained in 40 CFR 50.14 are generic, and are not always appropriate for NO_2 given the anticipated schedule for the designations of areas under the proposed NO_2 NAAQS.

A. Background

The purpose of a data interpretation appendix in general is to provide the practical details on how to make a comparison between multi-day and possibly multi-monitor ambient air concentration data and the level of the NAAQS, so that determinations of compliance and violation are as objective as possible. Data interpretation guidelines also provide criteria for determining whether there are sufficient data to make a NAAQS level comparison at all.

The regulatory language for the current NO_2 NAAQS, originally adopted in 1977, contains data interpretation instructions only for the issue of data completeness. This situation contrasts

with the situations for ozone, $PM_{2.5}$, PM_{10}, and most recently Pb for which there are detailed data interpretation appendices in 40 CFR part 50 addressing more issues that can arise in comparing monitoring data to the NAAQS. EPA has used its experience drafting and applying these other data interpretation appendices to develop the proposed text for Appendix S.

An exceptional event is defined in 40 CFR 50.1 as an event that affects air quality, is not reasonably controllable or preventable, is an event caused by human activity that is unlikely to recur at a particular location or a natural event, and is determined by the Administrator in accordance with 40 CFR 50.14 to be an exceptional event. Air quality data that is determined to have been affected by an exceptional event under the procedural steps and substantive criteria specified in section 50.14 may be excluded from consideration when EPA makes a determination that an area is meeting or violating the associated NAAQS. The key procedural deadlines in section 50.14 are that a State must notify EPA that data have been affected by an event, *i.e.*, ''flag'' the data in the Air Quality Systems (AQS) database, and provide an initial description of the event by July 1 of the year after the data are collected, and that the State must submit the full justification for exclusion within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data, for example a designation action, is anticipated, the schedule is foreshortened and all information must be submitted to EPA no later than a year before the decision is to be made. This generic schedule presents problems when a NAAQS has been recently revised, as discussed below.

The REA did not address data interpretation details. However, the approach to data interpretation used in the REA, for example to report the number of cities which would violate possible 1-hour primary NAAQS, was generally consistent with the proposed data interpretation procedures.

B. Interpretation of the Primary NAAQS for Oxides of Nitrogen

The purpose of a data interpretation rule for the NO_2 NAAQS is to give effect to the form, level, averaging time, and indicator specified in the proposed regulatory text at 40 CFR 50.11, anticipating and resolving in advance various future situations that could occur. The proposed Appendix S provides common definitions and requirements that apply to both the annual and the 1-hour primary standards for NO_2. The common requirements concern how ambient data are to be reported, what ambient data are to be considered (including the issue of which of multiple monitors' data sets will be used when more than one monitor has operated at a site), and the applicability of the Exceptional Events Rule to the primary NO_2 NAAQS.

The proposed Appendix S also addresses several issues in ways which are specific to the individual primary NO_2 standards, as described below.

1. Annual Primary Standard

The proposed data interpretation provisions for the annual standard are consistent with the current instructions included along with the statement of the level and form of the standard in 40 CFR 53.11. These are the following: (1) At least 75% of the hours in the year must have reported concentration data. (2) The available hourly data are arithmetically averaged, and then rounded (not truncated) to whole parts per billion. (3) The design value is this rounded annual average concentration. (4) The design value is compared with the level of the annual primary standard (expressed in parts per billion).

It would be possible to introduce additional steps for the annual primary standard which in principle could make the design value a more reliable indicator of actual annual average concentration in cases where some monitoring data have been lost. For example, averaging within a calendar quarter first and then averaging across quarters could help compensate for uneven data capture across the year. For some aspects of the data interpretation procedures for some other pollutants, the current data interpretation appendices do contain such additional steps. The proposed provisions for the proposed 1-hour NO_2 standard (described immediately below) also incorporate some such features. However, we believe that such complexity is not needed to appropriately implement the annual primary standard, especially since no area presently comes close to violating the standard. EPA invites comment on whether the annual primary standard design value should be a weighted annual mean (*e.g.* averaging within calendar quarters before averaging across quarters), rather than the mean of all available hourly values.

2. 1-Hour Primary Standard Based on the Annual 4th High Value Form

With regard to data completeness for the proposed 1-hour primary standard, the proposed Appendix follows past EPA practice for other NAAQS pollutants by requiring that in general at least 75% of the monitoring data that should have resulted from following the planned monitoring schedule in a period must be available for the key air quality statistic from that period to be considered valid. For the proposed 1-hour primary NO_2 NAAQS, the key air quality statistics are the daily maximum 1-hour concentrations in three successive years. It is important that sampling within a day encompass the period when concentrations are likely to be highest and that all seasons of the year are well represented. Hence, the 75% requirement is proposed to be applied at the daily and quarterly levels. EPA invites comment on the proposed completeness requirements.

Recognizing that there may be years with incomplete data, the proposed text provides that a design value derived from incomplete data will nevertheless be considered valid in either of two situations.

First, if the design value calculated from at least four days of monitoring observations in each of these years exceeds the level of the 1-hour primary standard, it would be valid. This situation could arise if monitoring was intermittent but high NO_2 levels were measured on enough hours and days for the mean of the three annual 4th values to exceed the standard. In this situation, more complete monitoring could not possibly have indicated that the standard was actually met.

Second, we are proposing a diagnostic data substitution test which is intended to identify those cases with incomplete data in which it nevertheless is very likely, if not virtually certain, that the daily 1-hour design value would have been observed to be below the level of the NAAQS if monitoring data had been minimally complete.

The diagnostic test would be applied only if there is at least 50% data capture in each quarter of each year and if the 3-year mean of the observed annual 4th highest maximum hourly values in the incomplete data is below the NAAQS level. The test would substitute a high hypothetical concentration for as much of the missing data as needed to meet the 100% requirement in each quarter. The value that is substituted for the missing values is the highest daily maximum 1-hour observed in the same quarter, looking across all three years under evaluation. If the resulting 3-year design value is below the NAAQS, it is highly likely that the design value calculated from complete data would also have been below the NAAQS, so the original design value indicating compliance would be considered valid.

It should be noted that one outcome of applying the proposed substitution test is that a year with incomplete data may nevertheless be determined to not have a valid design value and thus to be unusable in making 1-hour primary NAAQS compliance determinations for that 3-year period. EPA invites comment on incorporating into the final rule the proposed substitution test.

Also, we are proposing that the Administrator have general discretion to use incomplete data based on case-specific factors, either at the request of a state or at her own initiative. Similar provisions exist already for some other NAAQS.

3. 1-Hour Primary Standard Based on the Annual 99th Percentile Daily Value Form

The second version of the proposed Appendix S appearing at the end of this notice contains proposed interpretation procedures for a 1-hour primary standard based on the 99th percentile daily value form. The 4th high daily value form and the 99th percentile daily value form would yield the same design value in a situation in which every hour and day of the year has reported monitoring data, since the 99th percentile of 365 daily values is the 4th highest value. However, the two forms diverge if data completeness is 82% or less, because in that case the 99th percentile value is the 3rd highest (or higher) value, to compensate for the lack of monitoring data on days when concentrations could also have been high.

Logically, provisions to address possible data incompleteness under the 99th percentile daily value form should be somewhat different from those for the 4th highest form. With a 4th highest form, incompleteness should not invalidate a design value that exceeds the standard, for reasons explained above. With the 99th percentile form, however, a design value exceeding the standard stemming from incomplete data should not automatically be considered valid, because concentrations on the unmonitored days could have been relatively low, such that the actual 99th percentile value for the year could have been lower, and the design value could have been below the standard. The second proposed version of Appendix S accordingly has somewhat different provisions for dealing with data incompleteness. One difference is the addition of another diagnostic test based on data substitution, which in some cases can validate a design value based on incomplete data that exceeds the standard.

The second version of the proposed Appendix S provides a table for determining which day's maximum 1-hour concentration will be used as the 99th percentile concentration for the year. The proposed table is similar to one used now for the 24-hour PM2.5 NAAQS, which is based on a 98th percentile form, but adjusted to reflect a 99th percentile form for the 1-hour primary NO_2 standard. The proposed Appendix S also provides instructions for rounding (not truncating) the average of three annual 99th percentile hourly concentrations before comparison to the level of the primary NAAQS.

C. Exceptional Events Information Submission Schedule

The Exceptional Events Rule at 40 CFR 50.14 contains generic deadlines for a state to submit to EPA specified information about exceptional events and associated air pollutant concentration data. A state must initially notify EPA that data has been affected by an event by July 1 of the year after the data are collected; this is done by flagging the data in AQS and providing an initial event description. The state must also, after notice and opportunity for public comment, submit a demonstration to justify any claim within 3 years after the quarter in which the data were collected. However, if a regulatory decision based on the data (for example, a designation action) is anticipated, the schedule to flag data in AQS and submit complete documentation to EPA for review is foreshortened, and all information must be submitted to EPA no later than one year before the decision is to be made.

These generic deadlines are suitable for the period after initial designations have been made under a NAAQS, when the decision that may depend on data exclusion is a redesignation from attainment to nonattainment or from nonattainment to attainment. However, these deadlines present problems with respect to initial designations under a newly revised NAAQS. One problem is that some of the deadlines, especially the deadlines for flagging some relevant data, may have already passed by the time the revised NAAQS is promulgated. Until the level and form of the NAAQS have been promulgated a state does not know whether the criteria for excluding data (which are tied to the level and form of the NAAQS) were met on a given day. The only way a state could guard against this possibility is to flag all data that could possibly be eligible for exclusion under a future NAAQS. This could result in flagging far more data than will eventually be eligible for exclusion. EPA believes this is an inefficient use of state and EPA resources, and is potentially confusing and misleading to the public and regulated entities. Another problem is that it may not be feasible for information on some exceptional events that may affect final designations to be collected and submitted to EPA at least one year in advance of the final designation decision. This could have the unintended consequence of EPA designating an area nonattainment as a result of uncontrollable natural or other qualified exceptional events.

When Section 50.14 was revised in March 2007, EPA was mindful that designations were needed under the recently revised $PM_{2.5}$ NAAQS, so exceptions to the generic deadline were included for $PM_{2.5}$. The EPA was also mindful that similar issues would arise for subsequent new or revised NAAQS. The Exceptional Events Rule at section 50.14(c)(2)(v) indicates ''when EPA sets a NAAQS for a new pollutant, or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging data for initial designation of areas for those NAAQS.''

For the specific case of NO_2, EPA anticipates that initial designations under the revised NAAQS may be made by January 22, 2012 based on air quality data from the years 2008–2010. (*See* Section VI below for more detailed discussion of the designation schedule and what data EPA intends to use.) If final designations are made by January 22, 2012, all events to be considered during the designations process must be flagged and fully documented by states one year prior to designations, by January 22, 2011. This date also coincides with the Clean Air Act deadline for Governors to submit to EPA their recommendations for designating all areas of their states.

EPA is proposing revisions to 40 CFR 50.14 to change submission dates for information supporting claimed exceptional events affecting NO_2 data. The proposed rule text at the end of this notice shows the changes that would apply if a revised NO_2 NAAQS is promulgated by January 22, 2010, and designations are made two years after promulgation of a NO_2 NAAQS revision. For air quality data collected in 2008, we propose to extend the generic July 1, 2009 deadline for flagging data (and providing a brief initial description of the event) to July 1, 2010. EPA believes this extension provides adequate time for states to review the impact of exceptional events from 2008 on the revised standard and notify EPA by flagging the relevant data in AQS. EPA is not proposing to change the generic deadline of January 22, 2011 for

submitting documentation to justify an NO_2-related exceptional event from 2008. We believe the generic deadline provides adequate time for states to develop and submit proper documentation.

For data collected in 2009, EPA does not believe it is necessary to change the generic deadline of July 1, 2010 for flagging data and providing initial event descriptions. Similarly, EPA does not believe it is necessary to change the generic deadline of January 22, 2011 for states to submit documentation to justify an NO_2-related exceptional event from 2009.

For data collected in 2010, EPA believes the designations deadline of January 22, 2011 for flagging data and providing initial event descriptions does not provide states with adequate time to review and identify potential exceptional events that occur in calendar year 2010, especially events that might occur late in the year. Therefore, EPA is proposing that states may flag and provide initial event descriptions for 2010 data no later than April 1, 2011. This affords states more than 2 additional months than would be provided under the generic schedule to review and identify exceptional events affecting 2010 NO_2 data. Similarly, EPA believes the designations schedule that would require states to submit detailed documentation to justify 2010 events claims by January 22, 2011 is not reasonable, because it would potentially preclude states from completing the required public review of the documentation prior to submitting to EPA. Therefore, EPA is proposing to extend this deadline to July 1, 2011. This would afford states more than 5 additional months than provided by the generic schedule to complete the required public review and submit full supporting documentation, yet would still allow EPA adequate time to review the documentation and develop its final plans for designations by January 22, 2012.

Table 2 below summarizes the proposed two year designation deadlines discussed in this section. If the promulgation date for a revised NO_2 NAAQS will occur on a different date than January 22, 2010, EPA will revise the final NO_2 exceptional event flagging and documentation submission deadlines accordingly, consistent with this proposal, to provide states with reasonably adequate opportunity to review, identify, and document exceptional events that may affect an area designation under a revised NAAQS. EPA invites comment on these proposed changes in the exceptional event flagging and documentation submission deadlines.

TABLE 2—SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW OR REVISED NAAQS

NAAQS pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
$PM_{2.5}$/24-Hr Standard (35 µg/m3) Promulgated October 17, 2006.	2004–2006	October 1, 2007 [a]	April 15, 2008.[a]
Ozone/8–Hr Standard (0.075 ppm) Promulgated March 12, 2008.	2005–2007	June 18, 2009 [b]	June 18, 2009.[b]
	2008	June 18, 2009[b]	June 18, 2009.[b]
	2009	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first [b].	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first.[b]
NO_2/1–Hour Standard (80–100 PPB, final level TBD).	2008	July 1, 2010 [b]	January 22, 2011.
	2009	July 1, 2010	January 22, 2011.
	2010	April 1, 2011 [b]	July 1, 2011.[b]

[a] These dates are unchanged from those published in the original rulemaking, and are shown in this table for informational purposes.
[b] Indicates change from general schedule in 40 CFR 50.14.
NOTE: EPA notes that the table of revised deadlines *only* applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

V. Clean Air Act Implementation Requirements

This section of the preamble discusses the Clean Air Act (CAA) requirements that states and emissions sources must address when implementing new or revised NO_2 NAAQS based on the structure outlined in the CAA and existing rules.[23] EPA may provide additional guidance in the future, as necessary, to assist states and emissions sources to comply with the CAA requirements for implementing new or revised NO_2 NAAQS.

The CAA assigns important roles to EPA, states, and, in specified circumstances, Tribal governments to achieve the NAAQS. States have the primary responsibility for developing and implementing State Implementation Plans (SIPs) that contain state measures necessary to achieve the air quality standards in each area. EPA provides assistance to states by providing technical tools, assistance, and guidance, including information on the potential control measures that may assist in helping areas attain the standards.

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once they have been established by EPA. Under section 110 of the CAA, 42 U.S.C. 7410, and related provisions, states are required to submit, for EPA approval, SIPs that provide for the attainment and maintenance of such standards through control programs directed at sources of NO_2 emissions. If a state fails to adopt and implement the required SIPs by the time periods provided in the CAA, the EPA has responsibility under the CAA to adopt a Federal Implementation Plan (FIP) to assure that areas attain the NAAQS in an expeditious manner.

The states, in conjunction with EPA, also administer the prevention of significant deterioration (PSD) program for NO_2. *See* sections 160–169 of the CAA. In addition, Federal programs provide for nationwide reductions in emissions of NO_2 and other air pollutants under Title II of the Act, 42

[23] Since EPA is proposing to retain the annual standard without revision, the discussion in this section relates to implementation of the proposed 1-hour standard, rather than the annual standard.

U.S.C. 7521–7574, which involves controls for automobiles, trucks, buses, motorcycles, nonroad engines, and aircraft emissions; the new source performance standards (NSPS) for stationary sources under section 111 of the CAA, 42 U.S.C. 7411; and the national emission standards for hazardous air pollutants for stationary sources under section 112 of the CAA, 42 U.S.C. 7412.

CAA Section 301(d) authorizes EPA to treat eligible Indian Tribes in the same manner as states (TAS) under the CAA and requires EPA to promulgate regulations specifying the provisions of the statute for which such treatment is appropriate. EPA has promulgated these regulations—known as the Tribal Authority Rule or TAR—at 40 CFR Part 49. *See* 63 FR 7254 (February 12, 1998). The TAR establishes the process for Indian Tribes to seek TAS eligibility and sets forth the CAA functions for which TAS will be available. Under the TAR, eligible Tribes may seek approval for all CAA and regulatory purposes other than a small number of functions enumerated at section 49.4. Implementation plans under section 110 are included within the scope of CAA functions for which eligible Tribes may obtain approval. Section 110(o) also specifically describes Tribal roles in submitting implementation plans. Eligible Indian Tribes may thus submit implementation plans covering their reservations and other areas under their jurisdiction.

Under the CAA and TAR, Tribes are not, however, required to apply for TAS or implement any CAA program. In promulgating the TAR EPA explicitly determined that it was not appropriate to treat Tribes similarly to states for purposes of, among other things, specific plan submittal and implementation deadlines for NAAQS-related requirements. 40 CFR 49.4(a). In addition, where Tribes do seek approval of CAA programs, including section 110 implementation plans, the TAR provides flexibility and allows them to submit partial program elements, so long as such elements are reasonably severable—*i.e.*, ''not integrally related to program elements that are not included in the plan submittal, and are consistent with applicable statutory and regulatory requirements''. 40 CFR 49.7.

To date, very few Tribes have sought TAS for purposes of section 110 implementation plans. However, some Tribes may be interested in pursuing such plans to implement today's proposed standard. As noted above, such Tribes may seek approval of partial, reasonably severable plan elements, or they may seek to implement all relevant components of an air quality program for purposes of meeting the requirements of the Act. In several sections of this preamble, EPA describes the various roles and requirements states will address in implementing today's proposed standard. Such references to states are generally intended to include eligible Indian Tribes to the extent consistent with the flexibility provided to Tribes under the TAR. Where Tribes do not seek TAS for section 110 implementation plans, EPA will promulgate Federal implementation plans as ''necessary or appropriate to protect air quality.'' 40 CFR 49.11(a)

EPA also notes that some Tribes operate air quality monitoring networks in their areas. For such monitors to be used to measure attainment with this primary NAAQS for NO_2, the criteria and procedures identified in this rule would apply.

A. Designations

After EPA establishes or revises a NAAQS, the CAA requires EPA and the states to begin taking steps to ensure that the new or revised NAAQS are met. The first step is to identify areas of the country that do not meet the new or revised NAAQS. The CAA defines EPA's authority to designate areas that do not meet a new or revised NAAQS. Section 107(d)(1) provides that, ''By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised NAAQS for any pollutant under section 109, the Governor of each state shall * * * submit to the Administrator a list of all areas (or portions thereof) in the state'' that designates those areas as nonattainment, attainment, or unclassifiable. Section 107(d)(1)(B)(i) further provides, ''Upon promulgation or revision of a NAAQS, the Administrator shall promulgate the designations of all areas (or portions thereof) * * * as expeditiously as practicable, but in no case later than 2 years from the date of promulgation. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations. ''The term ''promulgation'' has been interpreted by the courts to be signature and dissemination of a rule. By no later than 120 days prior to promulgating designations, EPA is required to notify states of any intended modifications to their boundaries as EPA may deem necessary. States then have an opportunity to comment on EPA's tentative decision. Whether or not a state provides a recommendation, EPA must promulgate the designation that it deems appropriate.

Thus, following promulgation of the revised NO_2 NAAQS in January 2010, EPA must promulgate initial designations by January 2012 (2 years after promulgation of the revised NAAQS), or, by January 2013 in the event that the Administrator has insufficient information to promulgate initial designations within 2 years. In the case of the NO_2 NAAQS, in today's action EPA is proposing new NO_2 monitor siting rules that focus on roadways. EPA anticipates that it will require up to 3 years to get a new monitoring network in place, plus an additional 3 years of monitoring thereafter in order to determine compliance with the revised standard. This means that a full set of air quality data from the new network will not be available until approximately 2016. Since data from the new network will not be available prior to the CAA designation deadlines even if EPA takes an additional year, EPA intends to complete initial designations in 2012 using air quality data from the current NO_2 monitoring network in place, using NO_2 monitoring data from the years 2008–2010.

Accordingly, Governors will be required to submit their initial designation recommendations to EPA no later than January 2011. If the Administrator intends to modify any state area recommendation, EPA will notify the Governor no later than 120 days prior to initial designations in January 2012. States that believe the Administrator's modification is inappropriate will have an opportunity to demonstrate why they believe their recommendation is more appropriate before designations are promulgated in January 2012. As explained below in more detail, we intend to designate areas under the current NO_2 monitoring network as ''unclassifiable'' or ''nonattainment'' based on the data set for 2008–2010.

We intend to designate areas that do not show violations of the revised NO_2 NAAQS as ''unclassifiable'' since the existing area-wide monitoring network does not fully satisfy the near roadway-oriented NO_2 monitoring requirements proposed in this notice. Because there are no monitors in the current NO_2 network that meet the proposed definition of ''near-roadway,'' monitoring data that does not indicate a violation of the NAAQS would not provide a sufficient basis for concluding that an area is meeting the revised NO_2 NAAQS. Rather, an area-wide monitor may record concentrations that are below the revised NO_2 NAAQS because it is not sited where concentrations in the area are highest. Thus, we do not

believe the current monitoring network provides information that supports designating an area as ''attainment'' with today's proposed standards.

The EPA anticipates that areas designated as ''unclassifiable'' in January 2012 will remain so until a new NO_2 monitoring network is deployed and 3 years of monitoring data have been collected. Once the NO_2 monitors are placed in locations meeting the proposed near-roadway siting requirements and monitoring data become available, the Agency could subsequently redesignate areas as ''nonattainment'' or ''attainment'' under section 107(d)(3).

In January 2012 we intend to designate as ''nonattainment'' areas that show violations of the revised standard under the current monitoring network. As discussed above, the current monitoring network may not record NO_2 concentrations near roadways where NO_2 concentrations are highest. We thus anticipate that any area showing violations of the revised NO_2 standard based on the current monitoring network will continue to show violations when monitors are placed in near-roadway locations.

In summary, as required by section 107(d)(1)(A)(i) of the CAA, in January 2012 the EPA must designate as ''nonattainment'' any areas with monitors within the existing network that report violations of the revised NO_2 NAAQS. All other areas not indicating a violation of the revised NO_2 NAAQS will be designated as ''unclassifiable.'' While the CAA provides the Agency an additional third year from promulgation of a NAAQS to complete designations in the event that there is insufficient information to make NAAQS compliance determinations, we anticipate that delaying designations for this additional year would not result in significant additional data that would allow EPA to designate areas that would otherwise be designated ''unclassifiable.'' Once a near-roadway network has been deployed and 3 years of air quality data has been collected, we anticipate redesignating unclassifiable areas as ''attainment'' or ''nonattainment'' where additional data from the new network provides a basis for such a designation.

EPA is also taking comment on the area-wide approach discussed in section II.F.4.e above. If this approach is finalized, we anticipate designating areas as either ''attainment,'' ''nonattainment'' or ''unclassifiable'' in 2012, based on air quality data for years 2008–2010. Unlike the near-roadway approach, we would expect to have sufficient data to designate some areas showing no violations of the revised NAAQS as ''attainment'' rather than ''unclassifiable.'' As required by CAA section 107(d), we would expect to designate areas with violating monitors and nearby areas, including those with major roadways that contribute to such violations, as ''nonattainment.'' Any areas which EPA cannot classify on the basis of available information as meeting or not meeting the revised NAAQS would be designated as ''unclassifiable.''

B. Classifications

Section 172(a)(1)(A) of the CAA authorizes EPA to classify areas designated as nonattainment for the purpose of applying an attainment date pursuant to section 172(a)(2), or for other reasons. In determining the appropriate classification, EPA may consider such factors as the severity of the nonattainment problem and the availability and feasibility of pollution control measures (see section 172(a)(1)(A) of the CAA). The EPA may classify NO_2 nonattainment areas, but is not required to do so. The primary reason to establish classifications is to set different deadlines for each class of nonattainment area to complete the planning process and to provide for different attainment dates based upon the severity of the nonattainment problem for the affected area. However, the CAA separately establishes specific planning and attainment deadlines in sections 191 and 192: 18 months for the submittal of an attainment plan and as expeditiously as possible but no later than 5 years for areas to attain standard. EPA believes that classifications are unnecessary in light of these relatively short deadlines. Therefore, EPA is not proposing to establish classifications for a revised NO_2 NAAQS.

C. Attainment Dates

The maximum deadline date by which an area is required to attain the NO_2 NAAQS is determined from the effective date of the nonattainment designation for the affected area. For areas designated nonattainment for the revised NO_2 NAAQS, SIPs must provide for attainment of the NAAQS as expeditiously as practicable, but no later than 5 years from the date of the nonattainment designation for the area (see section 192(a) of the CAA). The EPA will determine whether an area has demonstrated attainment of the NO_2 NAAQS by evaluating air quality monitoring data consistent with the form of the NO_2 NAAQS if revised, which will be codified at 40 CFR part 50, Appendix F.

1. Attaining the NAAQS

In order for an area to be redesignated as attainment, the state must comply with the five requirements as provided under section 107(d)(3)(E) of the CAA. This section requires that:

—EPA must have determined that the area has met the NO_2 NAAQS;
—EPA has fully approved the state's implementation plan;
—the improvement in air quality in the affected area is due to permanent and enforceable reductions in emissions;
—EPA has fully approved a maintenance plan for the area; and
—The state(s) containing the area have met all applicable requirements under section 110 and part D.

2. Consequences of Failing To Attain by the Statutory Attainment Date

Any NO_2 nonattainment area that fails to attain by its statutory attainment date would be subject to the requirements of sections 179(c) and (d) of the CAA. EPA is required to make a finding of failure to attain no later than 6 months after the specified attainment date and publish a notice in the **Federal Register**. The state would be required to submit an implementation plan revision, no later than one year following the effective date of the **Federal Register** notice making the determination of the area's failure to attain, which demonstrates that the standard will be attained as expeditiously as practicable, but no later than 5 years from the effective date of EPA's finding that the area failed to attain. In addition, section 179(d)(2) provides that the SIP revision must include any specific additional measures as may be reasonably prescribed by EPA, including ''all measures that can be feasibly implemented in the area in light of technological achievability, costs, and any nonair quality and other air quality-related health and environmental impacts.''

D. Section 110(a)(2) NAAQS Infrastructure Requirements

Section 110(a)(2) of the CAA requires all states to develop and maintain a solid air quality management infrastructure, including enforceable emission limitations, an ambient monitoring program, an enforcement program, air quality modeling, and adequate personnel, resources, and legal authority. Section 110(a)(2)(D) also requires state plans to prohibit emissions from within the state which contribute significantly to nonattainment or maintenance areas in any other State, or which interfere with programs under part C to prevent

significant deterioration of air quality or to achieve reasonable progress toward the national visibility goal for Federal class I areas (national parks and wilderness areas).

Under section 110(a)(1) and (2) of the CAA, all states are required to submit SIPs to EPA which demonstrate that basic program elements have been addressed within 3 years of the promulgation of any new or revised NAAQS. Subsections (A) through (M) of section 110(a)(2) listed below, set forth the elements that a State's program must contain in the SIP.[24] The list of section 110(a)(2) NAAQS implementation requirements are the following:

- *Ambient air quality monitoring/data system:* Section 110(a)(2)(B) requires SIPs to provide for setting up and operating ambient air quality monitors, collecting and analyzing data and making these data available to EPA upon request.
- *Program for enforcement of control measures:* Section 110(a)(2)(C) requires SIPs to include a program providing for enforcement of measures and regulation and permitting of new/modified sources.
- *Interstate transport:* Section 110(a)(2)(D) requires SIPs to include provisions prohibiting any source or other type of emissions activity in the state from contributing significantly to nonattainment in another state or from interfering with measures required to prevent significant deterioration of air quality or to protect visibility.
- *Adequate resources:* Section 110(a)(2)(E) requires states to provide assurances of adequate funding, personnel and legal authority for implementation of their SIPs.
- *Stationary source monitoring system:* Section 110(a)(2)(F) requires states to establish a system to monitor emissions from stationary sources and to submit periodic emissions reports to EPA.
- *Emergency power:* Section 110(a)(2)(G) requires states to include contingency plans, and adequate authority to implement them, for emergency episodes in their SIPs.
- *Provisions for SIP revision due to NAAQS changes or findings of inadequacies:* Section 110(a)(2)(H) requires states to provide for revisions of their SIPs in response to changes in the NAAQS, availability of improved methods for attaining the NAAQS, or in response to an EPA finding that the SIP is inadequate.
- *Consultation with local and Federal government officials:* Section 110(a)(2)(J) requires states to meet applicable local and Federal government consultation requirements when developing SIP and reviewing preconstruction permits.
- *Public notification of NAAQS exceedances:* Section 110(a)(2)(J) requires states to adopt measures to notify the public of instances or areas in which a NAAQS is exceeded.
- *PSD and visibility protection:* Section 110(a)(2)(J) also requires states to adopt emissions limitations, and such other measures, as may be necessary to prevent significant deterioration of air quality in attainment areas and protect visibility in Federal Class I areas in accordance with the requirements of CAA Title I, part C.
- *Air quality modeling/data:* Section 110(a)(2)(K) requires that SIPs provide for performing air quality modeling for predicting effects on air quality of emissions of any NAAQS pollutant and submission of data to EPA upon request.
- *Permitting fees:* Section 110(a)(2)(L) requires the SIP to include requirements for each major stationary source to pay permitting fees to cover the cost of reviewing, approving, implementing and enforcing a permit.
- *Consultation/participation by affected local government:* Section 110(a)(2)(M) requires states to provide for consultation and participation by local political subdivisions affected by the SIP.

E. Attainment Planning Requirements

1. Nonattainment Area SIPs

Any state containing an area designated as nonattainment with respect to the NO_2 NAAQS must develop for submission a SIP meeting the requirements of part D, Title I, of the CAA, providing for attainment by the applicable statutory attainment date (*see* sections 191(a) and 192(a) of the CAA). As indicated in section 191(a) all components of the NO_2 part D SIP must be submitted within 18 months of the effective date of an area's designation as nonattainment.

Section 172 of the CAA includes general requirements for all designated nonattainment areas. Section 172(c)(1) requires that each nonattainment area plan ''provide for the implementation of all reasonably available control measures (RACM) as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of Reasonably Available Control Technology (RACT)), and shall provide for attainment of the national primary ambient air quality standards.'' States are required to implement RACM and RACT in order to attain ''as expeditiously as practicable''.

Section 172(c) requires states with nonattainment areas to submit a SIP for these areas which contain an attainment demonstration which shows that the affected area will attain the standard by the applicable statutory attainment date. The State must also show that the area will attain the standards as expeditiously as practicable, and it must include an analysis of whether implementation of reasonably available measures will advance the attainment date for the area.

Part D SIPs must also provide for reasonable further progress (RFP) (*see* section 172(c)(2) of the CAA). The CAA defines RFP as ''such annual incremental reductions in emissions of the relevant air pollution as are required by part D, or may reasonably be required by the Administrator for the purpose of ensuring attainment of the applicable NAAQS by the applicable attainment date.'' (*See* section 171 of the CAA) Historically, for some pollutants, RFP has been met by showing annual incremental emission reductions sufficient to maintain generally linear progress toward attainment by the applicable attainment date.

All NO_2 nonattainment area SIPs must include contingency measures which must be implemented in the event that an area fails to meet RFP or fails to attain the standards by its attainment date. (*See* section 172(c)(9)) These contingency measures must be fully adopted rules or control measures that take effect without further action by the state or the Administrator. The EPA interprets this requirement to mean that the contingency measures must be implemented with only minimal further action by the state or the affected sources with no additional rulemaking actions such as public hearings or legislative review.

Emission inventories are also critical for the efforts of State, local, and Federal agencies to attain and maintain the NAAQS that EPA has established for criteria pollutants including NO_2. Section 191(a) in conjunction with section 172(c) requires that areas designated as nonattainment for NO_2 submit an emission inventory to EPA no later than 18 months after designation as nonattainment. In the case of NO_2, sections 191(a) and 172(c) also require that states submit periodic emission

[24] Two elements identified in section 110(a)(2) are not listed below because, as EPA interprets the CAA, SIPs incorporating any necessary local nonattainment area controls would not be due within 3 years, but rather are due at the time the nonattainment area planning requirements are due. These elements are: (1) Emission limits and other control measures, section 110(a)(2)(A), and (2) Provisions for meeting part D, section 110(a)(2)(I), which requires areas designated as nonattainment to meet the applicable nonattainment planning requirements of part D, title I of the CAA.

inventories for nonattainment areas. The periodic inventory must include emissions of NO_2 for point, nonpoint, mobile (on-road and non-road), and area sources.

2. New Source Review and Prevention of Significant Deterioration Requirements

The Prevention of Significant Deterioration (PSD) and nonattainment New Source Review (NSR) programs contained in parts C and D of Title I of the CAA govern preconstruction review of any new or modified major stationary sources of air pollutants regulated under the CAA as well as any precursors to the formation of that pollutant when identified for regulation by the Administrator.[25] The EPA rules addressing these programs can be found at 40 CFR 51.165, 51.166, 52.21, 52.24, and part 51, appendix S. States which have areas designated as nonattainment for the NO_2 NAAQS must submit, as a part of the SIP due 18 months after an area is designated as nonattainment, provisions requiring permits for the construction and operation of new or modified stationary sources anywhere in the nonattainment area. SIPs that address the PSD requirements related to attainment areas are due no later than 3 years after the promulgation of a revised NAAQS for NO_2.

The NSR program is composed of three different permit programs:

- Prevention of Significant Deterioration (PSD).
- Nonattainment NSR (NA NSR).
- Minor NSR.

The PSD program applies when a major source, that is located in an area that is designated as attainment or unclassifiable for any criteria pollutant, is constructed, or undergoes a major modification.[26] The nonattainment NSR program applies on a pollutant-specific basis when a major source constructs or modifies in an area that is designated as nonattainment for that pollutant. The minor NSR program addresses both major and minor sources that undergo construction or modification activities that do not qualify as major, and it applies, as necessary to ensure attainment, regardless of the designation of the area in which a source is located.

The PSD requirements include but are not limited to the following:

- Installation of Best Available Control Technology (BACT);
- Air quality monitoring and modeling analyses to ensure that a project's emissions will not cause or contribute to a violation of any NAAQS or maximum allowable pollutant increase (PSD increment);
- Notification of Federal Land Manager of nearby Class I areas; and
- Public comment on permit.

Nonattainment NSR requirements include but are not limited to:

- Installation of Lowest Achievable Emissions Rate (LAER) control technology;
- Offsetting new emissions with creditable emissions reductions;
- A certification that all major sources owned and operated in the state by the same owner are in compliance with all applicable requirements under the CAA;
- An alternative siting analysis demonstrating that the benefits of a proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification; and
- Public comment on the permit.

Minor NSR programs must meet the statutory requirements in section 110(a)(2)(C) of the CAA which requires ''* * * regulation of the modification and construction of any stationary source * * * as necessary to ensure that the [NAAQS] are achieved.'' Areas which are newly designated as nonattainment for the NO_2 NAAQS as a result of any changes made to the NAAQS will be required to adopt a nonattainment NSR program to address major sources of NO_2 where the program does not currently exist for the NO_2 NAAQS and may need to amend their minor source program as well. Prior to adoption of the SIP revision addressing major source nonattainment NSR for NO_2 nonattainment areas, the requirements of 40 CFR part 51, appendix S will apply.

3. General Conformity

Section 176(c) of the CAA, as amended (42 U.S.C. 7401 *et seq.*), requires that all Federal actions conform to an applicable implementation plan developed pursuant to section 110 and part D of the CAA. The EPA rules, developed under the authority of section 176(c) of the CAA, prescribe the criteria and procedures for demonstrating and assuring conformity of Federal actions to a SIP. Each Federal agency must determine that any actions covered by the general conformity rule conform to the applicable SIP before the action is taken. The criteria and procedures for conformity apply only in nonattainment areas and those areas redesignated attainment since 1990 (''maintenance areas'') with respect to the criteria pollutants under the CAA:[27] Carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), particulate matter ($PM_{2.5}$ and PM_{10}), and sulfur dioxide (SO2). The general conformity rules apply one year following the effective date of designations for any new or revised NAAQS.

The general conformity determination examines the impacts of direct and indirect emissions related to Federal actions. The general conformity rule provides several options to satisfy air quality criteria, such as modeling or offsets, and requires the Federal action to also meet any applicable SIP requirements and emissions milestones. The general conformity rule also requires that notices of draft and final general conformity determinations be provided directly to air quality regulatory agencies and to the public by publication in a local newspaper.

4. Transportation Conformity

Transportation conformity is required under CAA section 176(c) (42 U.S.C. 7506(c)) to ensure that transportation plans, transportation improvement programs (TIPs) and Federally supported highway and transit projects will not cause new air quality violations, worsen existing violations, or delay timely attainment of the relevant NAAQS or interim reductions and milestones. Transportation conformity applies to areas that are designated nonattainment and maintenance for transportation-related criteria pollutants: carbon monoxide (CO), ozone (O3), nitrogen dioxide (NO_2), and particulate matter ($PM_{2.5}$ and PM_{10}). Transportation conformity for a revised NO_2 NAAQS does not apply until one year after the effective date of a nonattainment designation. (*See* CAA section 176(c)(6) and 40 CFR 93.102(d)).

EPA's Transportation Conformity Rule (40 CFR Part 51, Subpart T, and Part 93, Subpart A establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not proposing changes to the Transportation Conformity rule in this proposed rulemaking. However, in the future, EPA will review the need to conduct a

[25] The terms ''major'' and ''minor'' define the size of a stationary source, for applicability purposes, in terms of an annual emissions rate (tons per year, tpy) for a pollutant. Generally, a minor source is any source that is not ''major.'' ''Major'' is defined by the applicable regulations—PSD or nonattainment NSR.

[26] In addition, the PSD program applies to non-criteria pollutants subject to regulation under the Act, except those pollutants regulated under section 112 and pollutants subject to regulation only under section 211(o).

[27] Criteria pollutants are those pollutants for which EPA has established a NAAQS under section 109 of the CAA.

rulemaking to establish any new or revised transportation conformity tests that would apply under a revision to the NO_2 NAAQS for transportation plans, TIPs, and applicable highway and transit projects.

VI. Communication of Public Health Information

Information on the public health implications of ambient concentrations of criteria pollutants is currently made available primarily through EPA's Air Quality Index (AQI) program. The current Air Quality Index has been in use since its inception in 1999 (64 FR 42530). It provides accurate, timely, and easily understandable information about daily levels of pollution (40 CFR 58.50). The AQI establishes a nationally uniform system of indexing pollution levels for NO_2, carbon monoxide, ozone, particulate matter and sulfur dioxide. The AQI converts pollutant concentrations in a community's air to a number on a scale from 0 to 500. Reported AQI values enable the public to know whether air pollution levels in a particular location are characterized as good (0–50), moderate (51–100), unhealthy for sensitive groups (101–150), unhealthy (151–200), very unhealthy (201–300), or hazardous (300–500). The AQI index value of 100 typically corresponds to the level of the short-term NAAQS for each pollutant. An AQI value greater than 100 means that a pollutant is in one of the unhealthy categories (*i.e.*, unhealthy for sensitive groups, unhealthy, very unhealthy, or hazardous) on a given day; an AQI value at or below 100 means that a pollutant concentration is in one of the satisfactory categories (*i.e.*, moderate or good). Decisions about the pollutant concentrations at which to set the various AQI breakpoints, that delineate the various AQI categories, draw directly from the underlying health information that supports the NAAQS review.

The Agency recognizes the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS. Therefore EPA proposes to finalize conforming changes to the AQI, in connection with the Agency's final decision on the NO_2 NAAQS if revisions to the primary standard are promulgated. Currently, no AQI breakpoints are identified below an AQI value of 200 since there is no short-term NO_2 NAAQS. Therefore, if a short-term NO_2 NAAQS is promulgated, conforming changes would include setting the 100 level of the AQI at the same level as the revised primary NO_2 NAAQS and also setting the other AQI breakpoints at the lower end of the AQI scale (*i.e.*, AQI values of 50 and 150). EPA does not propose to change breakpoints at the higher end of the AQI scale (from 200 to 500), which would apply to state contingency plans or the Significant Harm Level (40 CFR 51.16), because the information from this review does not inform decisions about breakpoints at those higher levels.

With regard to an AQI value of 50, the breakpoint between the good and moderate categories, historically this value is set at the level of the annual NAAQS, if there is one, or one-half the level of the short-term NAAQS in the absence of an annual NAAQS (63 FR 67823, Dec. 12, 1998). Taking into consideration this practice, EPA is proposing to set the AQI value of 50 to be between 0.040 and 0.053 ppm NO_2, 1-hour average. EPA anticipates that figures towards the lower end of this range would be appropriate if the standard is set towards the lower end of the proposed range for the standard (*e.g.* 80 ppb), while figures towards the higher end of the range would be more appropriate for standards set at the higher end of the range for the standard (*e.g.*, 100 ppb). EPA solicits comments on this range for an AQI of 50, and the appropriate basis for selecting an AQI of 50 both within this range and, in light of EPA's solicitation of comment on standard levels below 80 ppb and above 100 ppb, above or below this range.

With regard to an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, historically values between the short-term standard and an AQI value of 500 are set at levels that are approximately equidistant between the AQI values of 100 and 500 unless there is health evidence that suggests a specific level would be appropriate (63 FR 67829, Dec. 12, 1998). For an AQI value of 150, the range of 0.360 to 0.370 ppm NO_2, 1-hour average, represents the midpoint between the proposed range for the short-term standard and the level of an AQI value of 200 (0.64 ppm NO_2, 1-hour average). Therefore, EPA is proposing to set the AQI value of 150 to be between 0.360 and 0.370 ppm NO_2, 1-hour average.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), this action is an ''economically significant regulatory action'' because it is likely to have an annual effect on the economy of $100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action. In addition, EPA prepared a Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in developing this proposed rule.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by EPA for these proposed revisions to part 58 has been assigned EPA ICR number 2358.01.

The information collected under 40 CFR part 53 (*e.g.*, test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). We do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with NO_2 FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 2358.01). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The proposed amendments would revise the technical requirements for NO_2 monitoring sites, require the siting and operation of additional NO_2 ambient air monitors, and the reporting of the collected ambient NO_2 monitoring

data to EPA's Air Quality System (AQS). The annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) is $3,616,487. Burden is defined at 5 CFR 1320.3(b). State, local, and Tribal entities are eligible for State assistance grants provided by the Federal government under the CAA which can be used for monitors and related activities.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA–HQ–OAR–2006–0922. Submit any comments related to the ICR to EPA and OMB. *See* **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after July 15, 2009, a comment to OMB is best assured of having its full effect if OMB receives it by August 14, 2009. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of NO_2 in ambient air as required by section 109 of the CAA. *American Trucking Assn's* v. *EPA*, 175 F. 3d 1027, 1044–45 (D.C. cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the proposed amendments to 40 CFR part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Unless otherwise prohibited by law, under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is required under section 202, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and to adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This action is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. The revisions to the NO_2 NAAQS impose no enforceable duty on any State, local or Tribal governments or the private sector. The expected costs associated with the monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed $100 million in the aggregate for any year. Furthermore, as indicated previously, in setting a NAAQS, EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the Clean Air Act prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the NO_2 NAAQS.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the NO_2 NAAQS. In this proposed rule, EPA is merely providing an interpretation of those requirements. However, even if this rule did establish an independent obligation for States to submit SIPs, it is questionable whether an obligation to submit a SIP revision would constitute a Federal mandate in any case. The obligation for a State to submit a SIP that arises out of section 110 and section 191 of the CAA is not legally enforceable by a court of law, and at most is a condition for continued receipt of highway funds. Therefore, it is possible to view an action requiring such a submittal as not creating any enforceable duty within the meaning of 2 U.S.C. 658 for purposes of the UMRA. Even if it did, the duty could be viewed as falling within the exception for a condition of Federal assistance under 2 U.S.C. 658.

EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments. Therefore, this rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

This proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, this rule does not impact CAA section 107 which establishes that the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or Tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

However, EPA recognizes that States will have a substantial interest in this rule and any corresponding revisions to associated air quality surveillance requirements, 40 CFR part 58. Therefore, in the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.'' This proposed rule does not have Tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal government and Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Tribes. The rule does not alter the relationship between the Federal government and Tribes as established in the CAA and the TAR. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, this rule does not infringe existing Tribal authorities to regulate air quality under their own programs or under programs submitted to EPA for approval. Furthermore, this rule does not affect the flexibility afforded to Tribes in seeking to implement CAA programs consistent with the TAR, nor does it impose any new obligation on Tribes to adopt or implement any NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on Tribal governments. Thus, Executive Order 13175 does not apply to this rule. However, EPA recognizes that Tribes may be interested in this rule and any corresponding revisions to associated air quality surveillance requirements. Therefore, in the spirit of Executive Order 13175, and consistent with EPA policy to promote communications between EPA and Tribes, EPA specifically solicits additional comment on this proposed rule from Tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks

This action is subject to Executive Order (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and we believe that the environmental health risk addressed by this action has a disproportionate effect on children. The proposed rule will establish uniform national ambient air quality standards for NO_2; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. The protection offered by these standards may be especially important for asthmatics, including asthmatic children, because respiratory effects in asthmatics are among the most sensitive health endpoints for NO_2 exposure. Because asthmatic children are considered a sensitive population, we have evaluated the potential health effects of exposure to NO_2 pollution among asthmatic children. These effects and the size of the population affected are discussed in chapters 3 and 4 of the ISA; chapters 3, 4, and 8 of the REA, and sections II.A through II.E of this preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This rule is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this rule is to establish revised NAAQS for NO_2. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking involves technical standards with regard to ambient monitoring of NO_2. The use of this voluntary consensus standard would be impractical because the

analysis method does not provide for the method detection limits necessary to adequately characterize ambient NO_2 concentrations for the purpose of determining compliance with the proposed revisions to the NO_2 NAAQS.

EPA welcomes comments on this aspect of the proposed rule, and specifically invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in the regulation.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health effects on any population, including any minority or low-income population. The proposed rule will establish uniform national standards for NO_2 in ambient air. EPA solicits comment on environmental justice issues related to the proposed revision of the NO_2 NAAQS.

References

Baldauf, R, Watkins N, Heist D, Bailey C, Rowley P, Shores R. (2009). Near-road air quality monitoring: Factors affecting network design and interpreation of data. *Air Qual. Atmos. Health.* 2:1–9.

Barck, C, Sandström T, Lundahl J, Halldén G, Svartengren M, Strand V, Rak S, Bylin G. (2002). Ambient level of NO_2 augments the inflammatory response to inhaled allergen in asthmatics. *Respir Med.* 96:907–917.

Barck, C, Lundahl J, Halldén G, Bylin G. (2005). Brief exposures to NO_2 augment the allergic inflammation in asthmatics. *Environ Res.* 97:58–66.

Beckerman, B, Jerrett M, Brook JR, Verma DK, Arain MA, Finkelstein MM. (2008). Correlation of nitrogen dioxide with other traffic pollutants near a major expressway. *Atmos Environ.* 42:275–290.

Brauer, M, Hoek G, Smit HA, De Jongste JC, Gerritsen J, Postma DS, Kerkhof M, Brunekreef B. (2007). Air pollution and development of asthma, allergy and infections in a birth cohort. *Eur. Respir. J.* 29:879–888.

Chauhan, AJ, Inskip HM, Linaker CH, Smith S, Schreiber J, Johnston SL, Holgate ST (2003). Personal exposure to nitrogen dioxide (NO_2) and the severity of virus-induced asthma in children. *Lancet* 361:1939–1944.

Clements, A, Yuling J, Fraser MP, Yifang Z, Pudota J, DenBleyker A, Michel E, Collins DR, McDonald-Buller E, Allen DT. (2008). Air Pollutant Concentrations near Texas Roadways: Chemical Transformation of Pollutants. *Proceedings of the 101st Air & Waste Management Annual Conference,* Portland, OR.

Clougherty, JE, Levy JI, Kubzansky LD, Ryan PB, Suglia SF, Canner MJ, and Wright RJ. (2007). Synergistic effects of traffic-related air pollution and exposure to violence on urban asthma etiology. *Environ. Health Perspect.* 115:1140–1146.

Delfino, RJ, Zeiger RS, Seltzer JM, Street DH, McLaren CE. (2002). Association of asthma symptoms with peak particulate air pollution and effect modification by anti-inflammatory medication use. *Environ. Health Perspect.* 110:A607–A617.

EPA. (1993). Air Quality Criteria Document for the Oxides of Nitrogen. National Center for Environmental Assessment, Research Triangle Park, NC. EPA–600/8–91/049F. Available at: *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=40179.*

EPA. (1995). Review of the National Ambient Air Quality Standards for Nitrogen Dioxide: Assessment of Scientific and Technical Information. OAQPS Staff Paper. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA–452/R–95–005. September 1995.

EPA. (2005). Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available at: *http://www.epa.gov/ttn/naaqs/standards/pm/data/pmstaffpaper_20051221.pdf.*

EPA. (2007a). Plan for Review of the Primary National Ambient Air Quality Standard for Nitrogen Dioxide. Available at: *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_pd.html.*

EPA. (2007b). Nitrogen Dioxide Health Assessment Plan: Scope and Methods for Exposure and Risk Assessment. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available at: *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_pd.html.*

EPA. (2007d). Review of the National Ambient Air Quality Standards for Pb: Policy Assessment of Scientific and Technical Information. OAQPS Staff paper. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA–452/R–07–013. Available at: *http://www.epa.gov/ttn/naaqs/standards/pb/data/20071101_pb_staff.pdf.*

EPA. (2007e). Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information. OAQPS Staff paper. Office of Air Quality Planning and Standards, Research Triangle Park, NC. EPA–452/R–07–007a. Available at: *http://epa.gov/ttn/naaqs/standards/ozone/s_o3_cr_sp.html.*

EPA. (2008a). ISA for Oxides of Nitrogen—Health Criteria. National Center for Environmental Assessment, Research Triangle Park, NC. Available at: *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=194645.*

EPA. (2008b). Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard. Office of Air Quality Planning and Standards, Research Triangle Park, NC.

Fehsenfeld, FC, Dickerson RR, Hubler G, Luke WT, Nunnermacker LJ, Williams EJ, Roberts JM, Calvert JG, Curran CM, Delany AC, Eubank CS, Fahey DW, Fried A, Gandrud BW, Langford AO, Murphy PC, Norton RB, Pickering KE, Ridley BA. (1987) A ground-based intercomparison of NO, NO_X, and NOy measurement techniques. J. Geophys. Res. [Atmos.] 92: 14,710–14,722.

Folinsbee, LJ. (1992). Does nitrogen dioxide exposure increase airways responsiveness? *Toxicol Ind Health.* 8:273–283.

Frampton, MW, Boscia J, Roberts NJ, Azadniv M, Torres A, Cox C, Morrow PE, Nichols J, Chalupa D, Frasier LM, Gibb FR, Speers DM, Tsai Y, Utell MJ. (2002) Nitrogen dioxide exposure: effects on airway and blood cells. *Am. J. Physiol.* 282:L155–L165.

Fuhlbrigge, AL, Adams RJ, Guilbert TW, Grant E, Lozano P, Janson SL, Martinez F, Weiss KB, Weiss ST. (2002). The burden of asthma in the United States: level and distribution are dependent on interpretation of the national asthma education and prevention program guidelines. *Am J Respir Crit Care Med.* 166:1044–1049.

Gauderman, W J, Avol E, Gilliland F, Vora H, Thomas D, Berhane K, McConnell R, Kuenzli N, Lurmann F, Rappaport E, Margolis H, Bates D, Peters J. (2004). The effect of air pollution on lung development from 10 to 18 years of age. *N. Engl. J. Med.* 351:1057–1067.

Gauderman, WJ, Avol E, Lurmann F, Kuenzli N, Gilliland F, Peters J, McConnell R. (2005). Childhood asthma and exposure to traffic and nitrogen dioxide. *Epidemiology* 16:737–743.

Gilbert, NL, Woodhouse S, Stieb DM, Brook JR. (2003). Ambient nitrogen dioxide and distance from a major highway. *Sci. Total Environ.* 312:43–6.

Henderson, R. (2008). Letter to EPA Administrator Stephen Johnson: ''Clean Air Scientific Advisory Committee (CASAC) Comments and Recommendations Concerning the Proposed Rule for the Revision of the

National Ambient Air Quality Standards (NAAQS) for NO_2.'' EPA-CASAC–08–016, July 18.

Ito, K, Thurston, GD, Silverman, RA. (2007). Characterization of PM2.5, gaseous pollutants, and meteorological interactions in the context of time-series health effects models. *J. of Expos. Science and Environ. Epidemiology.* 17:S45–S60.

Jaffe, DH, Singer ME, Rimm AA. (2003). Air pollution and emergency department visits for asthma among Ohio Medicaid recipients, 1991–1996. *Environ. Res.* 91:21–28.

Janssen, NAH., van Vliet PHN, Asrts F, Harssema H, Brunekreef B. (2001). Assessment of exposure to traffic related air pollution of children attending schools near motorways. *Atmos. Environ.* 35:3875–3884.

Kalthoff, N, Baumer D, Corsmeier U, Kohler M, Vogel B. (2005). Vehicle-induced turbulence near a motorway, *Atmospheric Environment* 39:5737–5749.

Kim, S-Y, O'Neill M, Lee J-T, Cho Y, Kim J, and Kim H. (2007). Air pollution, socioeconomic position, and emergency hospital visits for asthma in Seoul, Korea. *Int. Arch. Occup. Environ. Health* 80:701–710.

Linn, WS, Szlachcic Y, Gong H, Kinney PL, Berhane KT. (2000). Air pollution and daily hospital admissions in metropolitan Los Angeles. *Environ. Health Perspect.* 108:427–434.

McClenny, WA, Williams EJ, Cohen RC, Stutz J. (2002). Preparing to measure the effects of the NOX SIP Call—methods for ambient air monitoring of NO, NO_2, NOY, and individual NOZ species. *J. Air Waste Manage. Assoc.* 52:542–562.

McCurdy, TR. (1994). Analysis of high 1 hour NO_2 values and associated annual averages using 1988–1992 data. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available in Docket A–93–06.

Mortimer, KM, Neas LM, Dockery DW, Redline S, Tager IB. (2002). The effect of air pollution on inner-city children with asthma. *Eur Respir J.* 19:699–705.

National Heart, Lung, and Blood Institute (NHLBI). (2007) Expert panel report 3: guidelines for the diagnosis and management of asthma. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Asthma Education and Prevention Program; NIH Publication No. 07–4051.

New York Department of Health. (2006). A study of ambient air contaminants and asthma in New York City, Final Report Part B: Air contaminants and emergency department visits for asthma in the Bronx and Manhattan. Prepared for: The U.S. Department of Health and Human Services, Agency for Toxic Substance and Disease Registry.

Nunnermacker, LJ, Imre D, Daum PH, Kleinman L, Lee YN, Lee JH, Springston SR, Newman L, Weinstein-Lloyd J, Luke WT, Banta R, Alvarez R, Senff C, Sillman S, Holdren M, Keigley GW, Zhou X. (1998). Characterization of the Nashville urban plume on July 3 and July 18, 1995. *J. Geophys. Res. [Atmos.]* 103:28,129–28,148.

Oftedal, B, Brunekreef B, Nystad W, Madsen C, Walker SE, Nafstad P. (2008). Residential outdoor air pollution and lung function in schoolchildren. *Epidemiology* 19:129–137.

Ostro, B, Lipsett M, Mann J, Braxton-Owens H, White M. (2001). Air pollution and exacerbation of asthma in African-American children in Los Angeles. *Epidemiology* 12:200–208.

Parrish, DD, Fehsenfeld FC. (2000). Methods for gas-phase measurements of ozone, ozone precursors and aerosol precursors. *Atmos. Environ.* 34:1921–1957.

Peacock, M. (2008). Letter to CASAC chair Rogene Henderson. September 8.

Peacock, M. (2006). Letter to EPA Assistant Administrator Dr. George Gray: ''Process for Reviewing National Ambient Air Quality Standards.'' December 7.

Peel, JL, Tolbert PE, Klein M, Metzger KB, Flanders WD, Knox T, Mulholland JA, Ryan PB, Frumkin H. (2005). Ambient air pollution and respiratory emergency department visits. *Epidemiology.* 16:164–174.

Pilotto, LS, Douglas RM, Attewell RG, Wilson SR (1997) Respiratory effects associated with indoor nitrogen dioxide exposure in children. Int. J. Epidemiol. 26: 788–796.

Pilotto, LS, Nitschke M, Smith BJ, Pisaniello D, Ruffin RE, McElroy HJ, Martin J, Hiller JE. (2004). Randomized controlled trial of unflued gas heater replacement on respiratory health of asthmatic schoolchildren. *Int J Epidemiol.* 33:208–214.

Rizzo (2008). Investigation of how distributions of hourly nitrogen dioxide concentrations have changed over time in six cities. Nitrogen Dioxide NAAQS Review Docket (EPA–HQ–OAR–2006–092_2). Available at *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_rea.html.*

Rodes, CE and Holland DM. (1981). Variations of NO, NO_2, and O_3 concentrations downwind of a Los Angeles Freeway. *Atmos. Environ.* 15:243–250.

Roorda-Knape, MC, Janssen NAH, De Hartog JJ, Van Vliet PHN, Harssema H, Brunekreef B. (1998). Air pollution from traffic in city districts near major motorways. *Atmos. Environ.* 32:1921–1930.

Rojas-Martinez, R, Perez-Padilla R, Olaiz-Fernandez G, Mendoza-Alvarado L, Moreno-Macias H, Fortoul T, McDonnell W, Loomis D, Romieu I. (2007a) Lung function growth in children with long-term exposure to air pollutants in Mexico City. *Am. J. Respir. Crit. Care Med.* 176:377–384.

Rojas-Martinez, R, Perez-Padilla R, Olaiz-Fernandez G, Mendoza-Alvarado L, Moreno-Macias H, Fortoul T, McDonnell W, Loomis D, Romieu I. (2007b) Lung function growth in children with long-term exposure to air pollutants in Mexico City. Online data supplement. Available: *http://ajrccm.atsjournals.org/cgi/data/176/4/377/DC1/1* [3 October, 2007].

Ryerson, TB, Williams EJ, Fehsenfeld FC. (2000). An efficient photolysis system for fast-response NO_2 measurements. *J. Geophys. Res. [Atmos.]* 105:26,447–26,461.

Samet, J. (2008a). Letter to EPA Administrator Stephen Johnson: ''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.*'' EPA-CASAC–08–021, September 24.

Samet, J. (2008b). Letter to EPA Administrator Stephen Johnson: ''Clean Air Scientific Advisory Committee's (CASAC) Review Comments on EPA's *Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard.*'' EPA-CASAC–09–003, December 16.

Schildcrout, JS, Sheppard L, Lumley T, Slaughter JC, Koenig JQ, Shapiro GG. (2006). Ambient air pollution and asthma exacerbations in children: an eight-city analysis. *Am J Epidemiol.* 164:505–517.

Schwartz, J, Dockery DW, Neas LM, Wypij D, Ware JH, Spengler JD, Koutrakis P, Speizer FE, Ferris BG, Jr. (1994). Acute effects of summer air pollution on respiratory symptom reporting in children. *Am J Respir Crit Care Med.* 150:1234–1242.

Singer, B, Hodgson A, Hotchi T, Kim J. (2004). Passive measurement of nitrogen oxides to assess traffic-related pollutant exposure for the East Bay Children's Respiratory Health Study. *Atmos Environ.* 38:393–403.

Stout, JW, Visness CM, Enright P, Lamm, C, Shapiro G, Gan, VN, Adams K, Mitchell HE. (2006). Classification of asthma severity in children. *Arch Pediatr Adolesc Med.* 160:844–850.

Strand, V, Rak S, Svartengren M, Bylin G. (1997). Nitrogen dioxide exposure enhances asthmatic reaction to inhaled allergen in subjects with asthma. *Am J Respir Crit Care Med.* 155:881–887.

Strand, V, Svartengren M, Rak S, Barck C, Bylin G. (1998). Repeated exposure to an ambient level of NO_2 enhances asthmatic response to nonsymptomatic allergen dose. *Eur Respir J.* 12:6–12.

Thompson, R. (2008). Nitrogen Dioxide (NO_2) Descriptive Statistics Tables. Memo to the NO_2 NAAQS docket. Available at *http://www.epa.gov/ttn/naaqs/standards/nox/s_nox_cr_rea.html.*

Tolbert, PE, Klein M, Peel JL, Sarnat SE, Sarnat JA. (2007). Multipollutant modeling issues in a study of ambient air quality and emergency department visits in Atlanta. *J. Exposure Sci. Environ. Epidemiol.* 17(Suppl. 2s): S29–S35.

Venkatram, A, Isakov V, Thoma E, Baldauf RW. (2007). Analysis of air quality data near roadways using a dispersion model. *Atmos. Environ.* 41:9481–9497.

Watkins, N. and Thompson, R. (2008). NO_X Network Review and Background. Memo to the NO_2 NAAQS docket.

Wolff, GT. (1995). Letter to EPA Administrator Carol Browner: ''CASAC Review of the Staff Paper for the Review of the National Ambient Air Quality Standards for Nitrogen Dioxide: Assessment of Scientific and Technical Information.'' EPA–SAB–CASAC–LTR–95–004, August 22.

Zhou, Y and Levy JI. (2007). Factors influencing the spatial extent of mobile source air pollution impacts: a meta-analysis. *BMC Public Health.* 7:89.

List of Subjects

40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

40 CFR Part 58

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 26, 2009.

Lisa P. Jackson,

Administrator.

For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 50—NATIONAL PRIMARY AMBIENT AIR QUALITY STANDARDS

1. The authority citation for part 50 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart A—General Provisions

2. Section 50.11 is revised to read as follows:

§ 50.11 National primary and secondary ambient air quality standards for oxides of nitrogen (nitrogen dioxide).

(a) The level of the national primary annual ambient air quality standard for oxides of nitrogen is 53 parts per billion (ppb, which is 1 part in 1,000,000,000), annual average concentration, measured in the ambient air as nitrogen dioxide.

(b) The level of the national primary 1-hour ambient air quality standard for oxides of nitrogen is (80–100) ppb, 1-hour average concentration, measured in the ambient air as nitrogen dioxide.

(c) The level of the national secondary ambient air quality standard for nitrogen dioxide is 0.053 parts per million (100 micrograms per cubic meter), annual arithmetic mean concentration.

(d) The levels of the standards shall be measured by:

(1) A reference method based on appendix F to this part; or

(2) By a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter.

(e) The annual primary standard is met when the annual average concentration in a calendar year is less than or equal to 53 ppb, as determined in accordance with Appendix S of this part for the annual standard.

(f) The 1-hour primary standard is met when the three-year average of the annual (99th percentile)(fourth highest) of the daily maximum 1-hour average concentration is less than or equal to (80–100) ppb, as determined in accordance with Appendix S of this part for the 1-hour standard.

(g) The secondary standard is attained when the annual arithmetic mean concentration in a calendar year is less than or equal to 0.053 ppm, rounded to three decimal places (fractional parts equal to or greater than 0.0005 ppm must be rounded up). To demonstrate attainment, an annual mean must be based upon hourly data that are at least 75 percent complete or upon data derived from manual methods that are at least 75 percent complete for the scheduled sampling days in each calendar quarter.

3. Section 50.14 is amended by revising paragraph (c)(2)(vi) to read as follows:

§ 50.14 Treatment of air quality monitoring data influenced by exceptional events.

* * * * *

(c) * * *

(2) * * *

(vi) When EPA sets a NAAQS for a new pollutant or revises the NAAQS for an existing pollutant, it may revise or set a new schedule for flagging exceptional event data, providing initial data descriptions and providing detailed data documentation in AQS for the initial designations of areas for those NAAQS: Table 1 provides the schedule for submission of flags with initial descriptions in AQS and detailed documentation and the schedule shall apply for those data which will or may influence the initial designation of areas for those NAAQS. EPA anticipates revising Table 1 as necessary to accommodate revised data submission schedules for new or revised NAAQS.

TABLE 1—TO PARAGRAPH (C)(2)(VI): SCHEDULE FOR EXCEPTIONAL EVENT FLAGGING AND DOCUMENTATION SUBMISSION FOR DATA TO BE USED IN DESIGNATIONS DECISIONS FOR NEW OR REVISED NAAQS

NAAQS pollutant/standard/(level)/promulgation date	Air quality data collected for calendar year	Event flagging & initial description deadline	Detailed documentation submission deadline
$PM_{2.5}$/24-Hr Standard (35μg/m^3) Promulgated October 17, 2006.	2004–2006	October 1, 2007 [a]	April 15, 2008. [a]
Ozone/8-Hr Standard (0.075 ppm) Promulgated March 12, 2008.	2005–2007	June 18, 2009 [b]	June 18, 2009.[b]
	2008	June 18, 2009 [b]	June 18, 2009.[b]
	2009	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first. [b]	60 Days after the end of the calendar quarter in which the event occurred or February 5, 2010, whichever date occurs first.[b]
NO_2/1-Hour Standard (80–100 ppb, final level TBD).	2008	July 1, 2010 [b]	January 22, 2011.
	2009	July 1, 2010	January 22, 2011.
	2010	April 1, 2011 [b]	July 1, 2011.[b]

[a] These dates are unchanged from those published in the original rulemaking, and are shown in this table for informational purposes.

[b] Indicates change from general schedule in 40 CFR 50.14.

Note: EPA notes that the table of revised deadlines *only* applies to data EPA will use to establish the final initial designations for new or revised NAAQS. The general schedule applies for all other purposes, most notably, for data used by EPA for redesignations to attainment.

* * * * *

4. Appendix S is added to read as follows:

Option 1 for Appendix S to Part 50:

Appendix S to Part 50—Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen (Nitrogen Dioxide) (1-Hour Primary Standard Based on the 4th Highest Daily Maximum Value Form)

1. General

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary national ambient air quality standards for oxides of nitrogen as measured by nitrogen dioxide (''NO_2 NAAQS'') specified in § 50.11 are met. Nitrogen dioxide (NO_2) is measured in the ambient air by a Federal reference method (FRM) based on appendix F to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported NO_2 concentrations and the levels of the NO_2 NAAQS are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, is determined by the requirements and process deadlines specified in §§ 50.1, 50.14 and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual mean refers to the annual average of all of the 1-hour concentration values as defined in section 5.1 of this appendix.

Daily maximum 1-hour values for NO_2 refers to the maximum 1-hour NO_2 concentration values measured from midnight to midnight (local standard time) that are used in NAAQS computations.

Design values are the metrics (*i.e.*, statistics) that are compared to the NAAQS levels to determine compliance, calculated as specified in section 5 of this appendix. The design values for the primary NAAQS are:

(1) The annual mean value for a monitoring site for one year (referred to as the ''annual primary standard design value'').

(2) The 3-year average of annual 4th highest daily maximum 1-hour values for a monitoring site (referred to as the ''1-hour primary standard design value'').

Annual 4th highest daily maximum 1-hour value refers to the 4th highest daily 1-hour maximum value at a site in a particular year.

Quarter refers to a calendar quarter.

Year refers to a calendar year.

2. Requirements for Data Used for Comparisons With the NO_2 NAAQS and Data Reporting Considerations

(a) All valid FRM/FEM NO_2 hourly data required to be submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Multi-hour average concentration values collected by wet chemistry methods shall not be used.

(b) When two or more NO_2 monitors are operated at a site, the state may in advance designate one of them as the primary monitor. If the state has not made this designation in advance, the Administrator will make the designation, either in advance or retrospectively. Design values will be developed using only the data from the primary monitor, if this results in a valid design value. If data from the primary monitor do not allow the development of a valid design value, data solely from the other monitor(s) will be used in turn to develop a valid design value, if this results in a valid design value. If there are three or more monitors, the order for such comparison of the other monitors will be determined by the Administrator. The Administrator may combine data from different monitors in different years for the purpose of developing a valid 1-hour primary standard design value, if a valid design value cannot be developed solely with the data from a single monitor. However, data from two or more monitors in the same year at the same site will not be combined in an attempt to meet data completeness requirements, except if one monitor has physically replaced another instrument permanently, in which case the two instruments will be considered to be the same monitor, or if the state has switched the designation of the primary monitor from one instrument to another during the year.

(c) Hourly NO_2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

3. Comparisons With the NO_2 NAAQS

3.1 The Annual Primary NO_2 NAAQS

(a) The annual primary NO_2 NAAQS is met at a site when the valid annual primary standard design value is less than or equal to 53 parts per billion (ppb).

(b) An annual primary standard design value is valid when at least 75 percent of the hours in the year are reported.

(c) An annual primary standard design value based on data that do not meet the completeness criteria stated in 3.1(b) may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(d) The procedures for calculating the annual primary standard design values are given in section 5.1 of this appendix.

3.2 The 1-Hour Primary NO_2 NAAQS

(a) The 1-hour primary NO_2 NAAQS is met at a site when the valid 1-hour primary standard design value is less than or equal to [80–100] parts per billion (ppb).

(b) An NO_2 1-hour primary standard design value is valid if it encompasses three consecutive calendar years of complete data. A year meets data completeness requirements when all 4 quarters are complete. A quarter is complete when at least 75 percent of the sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values are reported.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 3.2(b) of this appendix and thus would normally not be useable for the calculation of a valid 3-year 1-hour primary standard design value, the 3-year 1-hour primary standard design value shall nevertheless be considered valid if either of the following conditions is true.

(i) If there are at least four days in each of the 3 years that have at least one reported hourly value, and the resulting 3-year 1-hour primary standard design value exceeds the 1-hour primary NAAQS. In this situation, more complete data capture could not possibly have resulted in a design value below the 1-hour primary NAAQS.

(ii)(A) A 1-hour primary standard design value that is below the level of the NAAQS can be validated if the substitution test in section 3.2(c)(ii)(B) results in a ''test design value'' that is below the level of the NAAQS. The test substitutes actual ''high'' reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the calendar quarter) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true under-NAAQS-level status for that 3-year period; the result of this data substitution test (the ''test design value,'' as defined in section 3.2(c)(ii)(B)), is not considered the actual design value. For this test, substitution is permitted only if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. However, maximum 1-hour values from days with less than 75 percent of the hours reported shall also be considered in identifying the high value to be used for substitution.

(B) *The substitution test is as follows:* Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture; if any quarter has less than 50 percent data capture then this substitution test cannot be used. Identify for each quarter (*e.g.*, January–March) the highest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days in the quarter period shall be considered when identifying this highest value, including days with less than 75 percent data capture. If after substituting the highest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 100 percent complete, the procedure in section 5.2 yields a recalculated 3-year 1-hour standard ''test design value'' below the level of the standard, then the 1-hour primary

standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been met in that 3-year period. As noted in section 3.2(c)(i), in such a case, the 3-year design value based on the data actually reported, not the ''test design value'', shall be used as the valid design value.

(d) A 1-hour primary standard design value based on data that do not meet the completeness criteria stated in section 3.2(b) and also do not satisfy section 3.2(c), may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures for calculating the 1-hour primary standard design values are given in section 5.2 of this appendix.

4. Rounding Conventions

4.1 Rounding Conventions for the Annual Primary NO_2 NAAQS

(a) Hourly NO_2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) The annual primary standard design value is calculated pursuant to section 5.1 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.2 Rounding Conventions for the 1-Hour Primary NO_2 NAAQS

(a) Hourly NO_2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) Daily maximum 1-hour values, including the annual 4th highest of those daily values, are not rounded.

(c) The 1-hour primary standard design value is calculated pursuant to section 5.2 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

5. Calculation Procedures for the Primary NO_2 NAAQS

5.1 Calculation Procedures for the Annual Primary NO_2 NAAQS

(a) When the data for a site and year meet the data completeness requirements in section 3.1(b) of this appendix, or if the Administrator exercises the discretionary authority in section 3.1(c), the annual mean is simply the arithmetic average of all of the reported 1-hour values.

(b) The annual primary standard design value for a site is the valid annual mean rounded according to the conventions in section 4.1.

5.2 Calculation Procedures for the 1-Hour Primary NO_2 NAAQS

(a) When the data for a particular site and year meet the data completeness requirements in section 3.2(b), or if one of the conditions of section 3.2(c) is met, or if the Administrator exercises the discretionary authority in section 3.2(d), calculation of the 4th highest daily 1-hour maximum is accomplished as follows.

(i) For each year, select from each day the highest hourly value. All daily maximum 1-hour values from all days in the quarter period shall be considered at this step, including days with less than 75 percent data capture.

(ii) For each year, order these daily values and take the 4th highest.

(iii) The 1-hour primary standard design value for a site is mean of the three annual 4th highest values, rounded according to the conventions in section 4.2.

Option 2 for Appendix S to Part 50:

Appendix S to Part 50—Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen (Nitrogen Dioxide) (1-Hour Primary Standard Based on the 99th Percentile Form)

1. General

(a) This appendix explains the data handling conventions and computations necessary for determining when the primary national ambient air quality standards for oxides of nitrogen as measured by nitrogen dioxide (''NO_2 NAAQS'') specified in § 50.11 are met. Nitrogen dioxide (NO_2) is measured in the ambient air by a Federal reference method (FRM) based on appendix F to this part or by a Federal equivalent method (FEM) designated in accordance with part 53 of this chapter. Data handling and computation procedures to be used in making comparisons between reported NO_2 concentrations and the levels of the NO_2 NAAQS are specified in the following sections.

(b) Whether to exclude, retain, or make adjustments to the data affected by exceptional events, including natural events, is determined by the requirements and process deadlines specified in §§ 50.1, 50.14 and 51.930 of this chapter.

(c) The terms used in this appendix are defined as follows:

Annual mean refers to the annual average of all of the 1-hour concentration values as defined in section 5.1 of this appendix.

Daily maximum 1-hour values for NO_2 refers to the maximum 1-hour NO_2 concentration values measured from midnight to midnight (local standard time) that are used in NAAQS computations.

Design values are the metrics (*i.e.*, statistics) that are compared to the NAAQS levels to determine compliance, calculated as specified in section 5 of this appendix. The design values for the primary NAAQS are:

(1) The annual mean value for a monitoring site for one year (referred to as the ''annual primary standard design value'').

(2) The 3-year average of annual 99th percentile daily maximum 1-hour values for a monitoring site (referred to as the ''1-hour primary standard design value'').

99th percentile daily maximum 1-hour value is the value below which nominally 99 percent of all daily maximum 1-hour concentration values fall, using the ranking and selection method specified in section 5.2 of this appendix.

Quarter refers to a calendar quarter.

Year refers to a calendar year.

2. Requirements for Data Used for Comparisons With the NO_2 NAAQS and Data Reporting Considerations

(a) All valid FRM/FEM NO_2 hourly data required to be submitted to EPA's Air Quality System (AQS), or otherwise available to EPA, meeting the requirements of part 58 of this chapter including appendices A, C, and E shall be used in design value calculations. Multi-hour average concentration values collected by wet chemistry methods shall not be used.

(b) When two or more NO_2 monitors are operated at a site, the state may in advance designate one of them as the primary monitor. If the state has not made this designation, the Administrator will make the designation, either in advance or retrospectively. Design values will be developed using only the data from the primary monitor, if this results in a valid design value. If data from the primary monitor do not allow the development of a valid design value, data solely from the other monitor(s) will be used in turn to develop a valid design value, if this results in a valid design value. If there are three or more monitors, the order for such comparison of the other monitors will be determined by the Administrator. The Administrator may combine data from different monitors in different years for the purpose of developing a valid 1-hour primary standard design value, if a valid design value cannot be developed solely with the data from a single monitor. However, data from two or more monitors in the same year at the same site will not be combined in an attempt to meet data completeness requirements, except if one monitor has physically replaced another instrument permanently, in which case the two instruments will be considered to be the same monitor, or if the state has switched the designation of the primary monitor from one instrument to another during the year.

(c) Hourly NO_2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

3. Comparisons With the NO_2 NAAQS

3.1 The Annual Primary NO_2 NAAQS

(a) The annual primary NO_2 NAAQS is met at a site when the valid annual primary standard design value is less than or equal to 53 parts per billion (ppb).

(b) An annual primary standard design value is valid when at least 75 percent of the hours in the year are reported.

(c) An annual primary standard design value based on data that do not meet the completeness criteria stated in section 3.1(b) may also be considered valid with the approval of, or at the initiative of, the

Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(d) The procedures for calculating the annual primary standard design values are given in section 5.1 of this appendix.

3.2 The 1-Hour Primary NO_2 NAAQS

(a) The 1-hour primary NO_2 NAAQS is met at a site when the valid 1-hour primary standard design value is less than or equal to [80–100] parts per billion (ppb).

(b) An NO_2 1-hour primary standard design value is valid if it encompasses three consecutive calendar years of complete data. A year meets data completeness requirements when all 4 quarters are complete. A quarter is complete when at least 75 percent of the sampling days for each quarter have complete data. A sampling day has complete data if 75 percent of the hourly concentration values are reported.

(c) In the case of one, two, or three years that do not meet the completeness requirements of section 3.2(b) of this appendix and thus would normally not be useable for the calculation of a valid 3-year 1-hour primary standard design value, the 3-year 1-hour primary standard design value shall nevertheless be considered valid if one of the following conditions is true.

(i) At least 75 percent of the days in each quarter of each of three consecutive years have at least one reported hourly value, and the design value calculated according to the procedures specified in section 5.2 is above the level of the primary 1-hour standard.

(ii)(A) A 1-hour primary standard design value that is below the level of the NAAQS can be validated if the substitution test in section 3.2(c)(ii)(B) results in a ''test design value'' that is below the level of the NAAQS. The test substitutes actual ''high'' reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same calendar quarter) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true under-NAAQS-level status for that 3-year period; the result of this data substitution test (the ''test design value'', as defined in section 3.2(c)(ii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. However, maximum 1-hour values from days with less than 75 percent of the hours reported shall also be considered in identifying the high value to be used for substitution.

(B) *The substitution test is as follows:* Data substitution will be performed in all quarter periods that have less than 75 percent data capture but at least 50 percent data capture; if any quarter has less than 50 percent data capture then this substitution test cannot be used. Identify for each quarter (*e.g.*, January–March) the highest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days in the quarter period shall be considered when identifying this highest value, including days with less than 75 percent data capture. If after substituting the highest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 100 percent complete, the procedure in section 5.2 yields a recalculated 3-year 1-hour standard ''test design value'' below the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been met in that 3-year period. As noted in section 3.2(c)(i), in such a case, the 3-year design value based on the data actually reported, not the ''test design value'', shall be used as the valid design value.

(iii)(A) A 1-hour primary standard design value that is above the level of the NAAQS can be validated if the substitution test in section 3.2(c)(iii)(B) results in a ''test design value'' that is above the level of the NAAQS. The test substitutes actual ''low'' reported daily maximum 1-hour values from the same site at about the same time of the year (specifically, in the same three months of the calendar) for unknown values that were not successfully measured. Note that the test is merely diagnostic in nature, intended to confirm that there is a very high likelihood that the original design value (the one with less than 75 percent data capture of hours by day and of days by quarter) reflects the true above-NAAQS-level status for that 3-year period; the result of this data substitution test (the ''test design value,'' as defined in section 3.2(c)(iii)(B)) is not considered the actual design value. For this test, substitution is permitted only if there are a minimum number of available daily data points from which to identify the low quarter-specific daily maximum 1-hour values, specifically if there are at least 200 days across the three matching quarters of the three years under consideration (which is about 75 percent of all possible daily values in those three quarters) for which 75 percent of the hours in the day have reported concentrations. Only days with at least 75 percent of the hours reported shall be considered in identifying the low value to be used for substitution.

(B) *The substitution test is as follows:* Data substitution will be performed in all quarter periods that have less than 75 percent data capture. Identify for each quarter (*e.g.*, January–March) the lowest reported daily maximum 1-hour value for that quarter, looking across those three months of all three years under consideration. All daily maximum 1-hour values from all days with at least 75 percent capture in the quarter period shall be considered when identifying this lowest value. If after substituting the lowest reported daily maximum 1-hour value for a quarter for as much of the missing daily data in the matching deficient quarter(s) as is needed to make them 75 percent complete, the procedure in section 5.2 yields a recalculated 3-year 1-hour standard ''test design value'' above the level of the standard, then the 1-hour primary standard design value is deemed to have passed the diagnostic test and is valid, and the level of the standard is deemed to have been exceeded in that 3-year period. As noted in section 3.2(c)(i), in such a case, the 3-year design value based on the data actually reported, not the ''test design value'', shall be used as the valid design value.

(d) A 1-hour primary standard design value based on data that do not meet the completeness criteria stated in 3.2(b) and also do not satisfy section 3.2(c), may also be considered valid with the approval of, or at the initiative of, the Administrator, who may consider factors such as monitoring site closures/moves, monitoring diligence, the consistency and levels of the valid concentration measurements that are available, and nearby concentrations in determining whether to use such data.

(e) The procedures for calculating the 1-hour primary standard design values are given in section 5.2 of this appendix.

4. Rounding Conventions

4.1 Rounding Conventions for the Annual Primary NO_2 NAAQS

(a) Hourly NO_2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) The annual primary standard design value is calculated pursuant to section 5.1 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

4.2 Rounding Conventions for the 1-Hour Primary NO_2 NAAQS

(a) Hourly NO_2 measurement data shall be reported to AQS in units of parts per billion (ppb), to at most one place after the decimal, with additional digits to the right being truncated with no further rounding.

(b) Daily maximum 1-hour values and therefore the annual 4th highest of those daily values are not rounded.

(c) The 1-hour primary standard design value is calculated pursuant to section 5.2 and then rounded to the nearest whole number or 1 ppb (decimals 0.5 and greater are rounded up to the nearest whole number, and any decimal lower than 0.5 is rounded down to the nearest whole number).

5. Calculation Procedures for the Primary NO_2 NAAQS

5.1 Procedures for the Annual Primary NO_2 NAAQS

(a) When the data for a site and year meet the data completeness requirements in section 3.1(b) of this appendix, or if the Administrator exercises the discretionary authority in section 3.1(c), the annual mean is simply the arithmetic average of all of the reported 1-hour values.

(b) The annual primary standard design value for a site is the valid annual mean rounded according to the conventions in section 4.1.

5.2 Calculation Procedures for the 1-Hour Primary NO_2 NAAQS

(a) *Procedure for identifying annual 99th percentile values.* When the data for a particular site and year meet the data completeness requirements in section 3.2(b), or if one of the conditions of section 3.2(c) is met, or if the Administrator exercises the discretionary authority in section 3.2(d), identification of annual 99th percentile values will be based on the number of days with at least 75 percent of the hourly values reported.

(i) For the year, from only the days with at least 75 percent of the hourly values reported, select from each day the highest hourly value.

(ii) Sort all the valid daily values from a particular site and year by descending value. (For example: (x[1], x[2], x[3], * * *, x[n]). In this case, x[1] is the largest number and x[n] is the smallest value.) The 99th percentile is determined from this sorted series of daily values which is ordered from the highest to the lowest number. Using the left column of Table 1, determine the appropriate range (*i.e.*, row) for the annual number of days with valid data for year y (cn_y). The corresponding ''n'' value in the right column identifies the rank of the annual 99th percentile value in the descending sorted list of daily site values for year y. Thus, $P_{0.99,\ y}$= the nth largest value.

TABLE 1—TO SECTION 5.2(A)(II)

Annual number of days with valid data for year ''y'' (cn_y)	$P_{0.99,\ y}$ is the nth maximum value of the year, where n is the listed number
1–100	1
101–200	2
201–300	3
301–366	4

(b) The 1-hour primary standard design value for a site is mean of the three annual 4th highest values, rounded according to the conventions in section 4.2.

PART 58—AMBIENT AIR QUALITY SURVEILLANCE

5. The authority citation for part 58 continues to read as follows:

Authority: 42 U.S.C. 7403, 7410, 7601(a), 7611, and 7619.

Subpart A [AMENDED]

6. Section 58.1 is amended by adding definitions for ''AADP'' and ''Near-road NO_2 Monitor'' in alphabetical order to read as follows:

§ 58.1 Definitions.

* * * * *

AADT means the annual average daily traffic.

* * * * *

Near-road NO_2 Monitor means any NO_2 monitor meeting the specifications in 4.3.2 of Appendix D and paragraphs 2, 4(b), 6.1, and 6.4 of Appendix E of this part.

* * * * *

Subpart B [AMENDED]

7. Section 58.10, is amended by adding paragraphs (a)(5) and (b)(12) to read as follows:

§ 58.10 Annual monitoring network plan and periodic network assessment.

(a) * * *

(5) A plan for establishing NO_2 monitoring sites in accordance with the requirements of appendix D to this part shall be submitted to the Administrator by July 1, 2011. The plan shall provide for all required stations to be operational by January 1, 2013.

* * * * *

(b) * * *

(12) The identification of required NO_2 monitors as either near-road or area-wide sites in accordance with Appendix D, Section 4.3 of this part.

* * * * *

8. Section 58.13 is amended by adding paragraph (c) to read as follows:

§ 58.13 Monitoring network completion.

* * * * *

(c) The network of NO_2 monitors must be physically established no later than January 1, 2013, and at that time, must be operating under all of the requirements of this part, including the requirements of appendices A, C, D, E, and G to this part.

9. Section 58.16 is amended by revising paragraph (a) to read as follows:

§ 58.16 Data submittal and archiving requirements.

(a) The State, or where appropriate, local agency, shall report to the Administrator, via AQS all ambient air quality data and associated quality assurance data for SO_2; CO; O_3; NO_2; NO; NO_Y; NO_X; Pb-TSP mass concentration; Pb-PM_{10} mass concentration; PM_{10} mass concentration; $PM_{2.5}$ mass concentration; for filter-based $PM_{2.5}$FRM/FEM the field blank mass, sampler-generated average daily temperature, and sampler-generated average daily pressure; chemically speciated $PM_{2.5}$ mass concentration data; $PM_{10-2.5}$ mass concentration; chemically speciated $PM_{10-2.5}$ mass concentration data; meteorological data from NCore, PAMS, and near-road NO_2 monitoring sites; average daily temperature and average daily pressure for Pb sites if not already reported from sampler generated records; and metadata records and information specified by the AQS Data Coding Manual (*http://www.epa.gov/ttn/airs/airsaqs/manuals/manuals.htm*). The State, or where appropriate, local agency, may report site specific meteorological measurements generated by onsite equipment (meteorological instruments, or sampler generated) or measurements from the nearest airport reporting ambient pressure and temperature. Such air quality data and information must be submitted directly to the AQS via electronic transmission on the specified quarterly schedule described in paragraph (b) of this section.

* * * * *

10. Appendix A to Part 58 is amended as by adding section 2.3.1.5 to read as follows:

Appendix A to Part 58—Quality Assurance Requirements for SLAMS, SPMs and PSD Air Monitoring

* * * * *

2.3.1.5 Measurement Uncertainty for NO_2. The goal for acceptable measurement uncertainty is defined for precision as an upper 90 percent confidence limit for the coefficient of variation (CV) of 15 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

* * * * *

11. Appendix C to Part 58 is amended as by adding section 2.1.1 to read as follows:

Appendix C to Part 58—Ambient Air Quality Monitoring Methodology

* * * * *

2.1.1 Any NO_2 FRM or FEM used for making primary NAAQS decisions must be capable of providing hourly averaged concentration data.

* * * * *

12. Appendix D to Part 58 is amended by revising section 4.3 to read as follows:

Appendix D to Part 58—Network Design Criteria for Ambient Air Quality Monitoring

* * * * *

4.3 Nitrogen Dioxide (NO_2) Design Criteria

4.3.1 *General Requirements.* (a) State and, where appropriate, local agencies must operate a minimum number of required NO_2 monitoring sites as described below.

4.3.2 *Requirement for Near-road NO_2 Monitors.* (a) Within the NO_2 network, there must be one microscale near-road NO_2 monitoring station in each CBSA with a population of 350,000 or more persons to monitor a location of expected maximum hourly concentrations sited near a major road with high AADT counts as specified in

paragraph 4.3.2(a)(1) of this appendix. An additional near-road NO_2 monitoring station is required for any CBSA with a population of 2,500,000 persons or more, or in any CBSA with a population of 350,000 or more persons that has one or more roadway segments with 250,000 or greater AADT counts to monitor a second location of expected maximum hourly concentrations. CBSA populations shall be based on the latest available census figures.

(1) The near-road NO_2 monitoring stations shall be selected by ranking all road segments within a CBSA by AADT and then identifying a location or locations adjacent to those highest ranked road segments where maximum hourly NO_2 concentrations are expected to be highest and siting criteria can be met in accordance with appendix E of this part. Where a state or local air monitoring agency identifies multiple acceptable candidate sites where maximum hourly NO_2 concentrations are expected to occur, the monitoring agency should consider taking into account the potential for population exposure in the criteria utilized to select the final site location. Where one CBSA is required to have two near-road NO_2 monitoring stations, the sites shall be differentiated from each other by one or more of the following factors: fleet mix; congestion patterns; terrain; geographic area within the CBSA; or different route, interstate, or freeway designation.

(b) Measurements at required near-road NO_2 monitor sites must include at a minimum: NO, NO_2, NO_X, wind vector data in the horizontal and vertical planes, ambient temperature, and ambient relative humidity.

4.3.3 *Requirement for Area-wide NO_2 Monitoring.* (a) Within the NO_2 network, there must be one monitoring station in each CBSA with a population of 1,000,000 or more persons to monitor a location of expected highest NO_2 concentrations representing the neighborhood or larger spatial scales. PAMS sites collecting NO_2 data that are situated in an area of expected high NO_2 concentrations at the neighborhood or larger spatial scale may be used to satisfy this minimum monitoring requirement when the NO_2 monitor is operated year round. Emission inventories and meteorological analysis should be used to identify the appropriate locations within a CBSA for locating required area-wide NO_2 monitoring stations. CBSA populations shall be based on the latest available census figures.

4.3.4 *Regional Administrator Required Monitoring.* (a) The Regional Administrator may require additional NO_2 monitoring stations above the minimum requirements to monitor in locations away from roads, or sites that do not meet near-road NO_2 monitor siting criteria noted in appendix E of this part, where required near-road monitors do not represent a location or locations where the expected maximum hourly NO_2 concentrations exist in a CBSA. The Regional Administrator may also require additional near-road NO_2 monitoring stations above the minimum required in situations where the minimum monitoring requirements are not sufficient to meet monitoring objectives, and may consider additional locations of expected high NO_2 concentrations and the variety of exposure potential due to increased variety in amount or types of fleet mix, congestion patterns, terrain, or geographic areas within a CBSA. The Regional Administrator and the responsible State or local air monitoring agency should work together to design and/or maintain the most appropriate NO_2 network to service the variety of data needs for an area.

(b) The Regional Administrator may require additional NO_2 monitoring stations for area-wide NO_2 monitors at the neighborhood and larger spatial scales above the minimum monitoring requirements where the minimum monitoring requirements are not sufficient to meet monitoring objectives for an area, such as supporting photochemical pollutant assessment, air quality forecasting, PM precursor analysis, and characterizing impacts of NO_2 sources on certain communities. The Regional Administrator and the responsible State or local air monitoring agency should work together to design and/or maintain the most appropriate NO_2 network to service the variety of data needs for an area.

4.3.5 *NO_2 Monitoring Spatial Scales.* (a) The most important spatial scale for near-road NO_2 monitoring stations to effectively characterize the maximum expected hourly NO_2 concentration due to mobile source emissions on major roadways is the microscale. The most important spatial scales for other monitoring stations characterizing maximum expected hourly NO_2 concentrations are the microscale and middle scale. The most important spatial scale for area-wide monitoring of high NO_2 concentrations is the neighborhood scale.

(1) *Microscale*—This scale would typify areas in close proximity to major roadways or point and area sources. Emissions from roadways result in high ground level NO_2 concentrations at the microscale, where concentration gradients generally exhibit a marked decrease with increasing downwind distance from major roads. As noted in appendix E of this part, near-road NO_2 monitoring stations are required to be within 50 meters of target road segments in order to measure expected peak concentrations. Emissions from stationary point and area sources, and non-road sources may, under certain plume conditions, result in high ground level concentrations at the microscale. The microscale typically represents an area impacted by the plume with dimensions extending up to approximately 100 meters.

(2) *Middle scale*—This scale generally represents air quality levels in areas up to several city blocks in size with dimensions on the order of approximately 100 meters to 500 meters. The middle scale may include locations of expected maximum hourly concentrations due to proximity to major NO_2 point, area, and/or non-road sources.

(3) *Neighborhood scale*—The neighborhood scale would characterize air quality conditions throughout some relatively uniform land use areas with dimensions in the 0.5 to 4.0 kilometer range. Emissions from stationary point and area sources may, under certain plume conditions, result in high NO_2 concentrations at the neighborhood scale. Where a neighborhood site is located away from immediate NO_2 sources, the site may be useful in representing typical air quality values for a larger residential area, and therefore suitable for population exposure and trends analyses.

(4) *Urban scale*—Measurements in this scale would be used to estimate concentrations over large portions of an urban area with dimensions from 4 to 50 kilometers. Such measurements would be useful for assessing trends in area-wide air quality, and hence, the effectiveness of large-scale air pollution control strategies. Urban scale sites may also support other monitoring objectives of the NO_2 monitoring network identified in paragraph 4.3.4 above.

4.3.6 NO_y *Monitoring.* (a) NO/NO_y measurements are included within the NCore multipollutant site requirements and the PAMS program. These NO/NO_y measurements will produce conservative estimates for NO_2 that can be used to ensure tracking continued compliance with the NO_2 NAAQS. NO/NO_y monitors are used at these sites because it is important to collect data on total reactive nitrogen species for understanding O_3 photochemistry.

* * * * *

13. Section Appendix E to part 58 is amended as follows:

a. By revising section 2.

b. By adding paragraph (d) to section 4.

c. By revising section 6.1.

d. By adding section 6.4.

e. By revising section 11 including Table E–4.

Appendix E to Part 58—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

2. Horizontal and Vertical Placement

The probe or at least 80 percent of the monitoring path must be located between 2 and 15 meters above ground level for all ozone and sulfur dioxide monitoring sites, and for neighborhood or larger spatial scale Pb, PM_{10}, $PM_{10-2.5}$, $PM_{2.5}$, NO_2 and carbon monoxide sites. Middle scale $PM_{10-2.5}$ sites are required to have sampler inlets between 2 and 7 meters above ground level. Microscale Pb, PM_{10}, $PM_{10-2.5}$ and $PM_{2.5}$ sites are required to have sampler inlets between 2 and 7 meters above ground level. Microscale near-road NO_2 monitoring sites are required to have sampler inlets between 2 and 7 meters above ground level. The inlet probes for microscale carbon monoxide monitors that are being used to measure concentrations near roadways must be 3±½ meters above ground level. The probe or at least 90 percent of the monitoring path must be at least 1 meter vertically or horizontally away from any supporting structure, walls, parapets, penthouses, etc., and away from dusty or dirty areas. If the probe or a significant portion of the monitoring path is located near the side of a building or wall, then it should be located on the windward side of the building relative to the prevailing wind direction during the season of highest

concentration potential for the pollutant being measured.

* * * * *

4. Spacing From Obstructions

* * * * *

(d) For near-road NO_2 monitoring stations, the monitor probe shall have an unobstructed air flow, where no obstacles exist at or above the height of the monitor probe, between the monitor probe and the outside nearest edge of the traffic lanes of the target road segment.

* * * * *

6. * * *

6.1 *Spacing for Ozone Probes and Monitoring Paths.* In siting an O_3 analyzer, it is important to minimize destructive interferences form sources of NO, since NO readily reacts with O_3. Table E–1 of this appendix provides the required minimum separation distances between a roadway and a probe or, where applicable, at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling site having a point analyzer probe located closer to a roadway than allowed by the Table E–1 requirements should be classified as microscale or middle scale, rather than neighborhood or urban scale, since the measurements from such a site would more closely represent the middle scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference from automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined from Table E–1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

* * * * *

6.4 Spacing for Nitrogen Dioxide (NO_2) Probes and Monitoring Paths (a) In siting near-road NO_2 monitors as required in paragraph 4.3.2 of appendix D of this part, the monitor probe shall be as near as practicable to the outside nearest edge of the traffic lanes of the target road segment; but shall not be located at a distance greater than 50 meters, in the horizontal, from the outside nearest edge of the traffic lanes of the target road segment.

(b) In siting NO_2 monitors for neighborhood and larger scale monitoring, it is important to minimize near-road influences. Table E–1 of this appendix provides the required minimum separation distances between a roadway and a probe or, where applicable, at least 90 percent of a monitoring path for various ranges of daily roadway traffic. A sampling site having a point analyzer probe located closer to a roadway than allowed by the Table E–1 requirements should be classified as microscale or middle scale rather than neighborhood or urban scale. If an open path analyzer is used at a site, the monitoring path(s) must not cross over a roadway with an average daily traffic count of 10,000 vehicles per day or more. For those situations where a monitoring path crosses a roadway with fewer than 10,000 vehicles per day, monitoring agencies must consider the entire segment of the monitoring path in the area of potential atmospheric interference form automobile emissions. Therefore, this calculation must include the length of the monitoring path over the roadway plus any segments of the monitoring path that lie in the area between the roadway and minimum separation distance, as determined from Table E–1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

* * * * *

11. Summary

Table E–4 of this appendix presents a summary of the general requirements for probe and monitoring path siting criteria with respect to distances and heights. It is apparent from Table E–4 that different elevation distances above the ground are shown for the various pollutants. The discussion in this appendix for each of the pollutants describes reasons for elevating the monitor, probe, or monitoring path. The differences in the specified range of heights are based on the vertical concentration gradients. For CO and near-road NO_2 monitors, the gradients in the vertical direction are very large for the microscale, so a small range of heights are used. The upper limit of 15 meters is specified for the consistency between pollutants and to allow the use of a single manifold or monitoring path for monitoring more than one pollutant.

TABLE E–4 OF APPENDIX E TO PART 58—SUMMARY OF PROBE AND MONITORING PATH SITING CRITERIA

Pollutant	Scale (maximum monitoring path length, meters)	Height from ground to probe, inlet or 80% of monitoring path [1]	Horizontal and vertical distance from supporting structures [2] to probe, inlet or 90% of monitoring path [1] (meters)	Distance from trees to probe, inlet or 90% of monitoring path [1] (meters)	Distance from roadways to probe, inlet or monitoring path [1] (meters)
SO_2 [3, 4, 5, 6]	Middle (300 m) Neighborhood Urban, and Regional (1 km).	2–15	> 1	> 10	N/A.
CO [4, 5, 7]	Micro, middle (300 m) Neighborhood (1 km).	3½: 2–15	> 1	> 10	2–10; *see* Table E–2 of this appendix for middle and neighborhood scales.
O_3 [3, 4, 5]	Middle (300 m) Neighborhood, Urban, and Regional (1 km).	2–15	> 1	> 10	*See* Table E–1 of this appendix for all scales.
NO_2 [3,4,5]	Micro (Near-road [50–300])	2–7 (micro)	> 1	> 10	≤ 50 meters for near-road microscale.
	Middle (300m)	2–15 (all other scales).			
	Neighborhood, Urban, and Regional (1 km).				*See* Table E–1 of this appendix for all other scales.
Ozone precursors (for PAMS) [3, 4, 5].	Neighborhood and Urban (1 km)	2–15	> 1	> 10	*See* Table E–4 of this appendix for all scales.
PM,Pb [3, 4, 5, 6, 8]	Micro: Middle, Neighborhood, Urban and Regional.	2–7 (micro); 2–7 (middle $PM_{10-2.5}$); 2–15 (all other scales).	> 2 (all scales, horizontal distance only).	> 10 (all scales)	2–10 (micro); *see* Figure E–1 of this appendix for all other scales.

N/A—Not applicable.

[1] Monitoring path for open path analyzers is applicable only to middle or neighborhood scale CO monitoring, middle, neighborhood, urban, and regional scale NO_2 monitoring, and all applicable scales for monitoring SO_2,O_3, and O_3 precursors.

[2] When probe is located on a rooftop, this separation distance is in reference to walls, parapets, or penthouses located on roof.

[3] Should be > 20 meters from the dripline of tree(s) and must be 10 meters from the dripline when the tree(s) act as an obstruction.

[4] Distance from sampler, probe, or 90% of monitoring path to obstacle, such as a building, must be at least twice the height the obstacle protrudes above the sampler, probe, or monitoring path. Sites not meeting this criterion may be classified as middle scale (*see* text).
[5] Must have unrestricted airflow 270 degrees around the probe or sampler; 180 degrees if the probe is on the side of a building or a wall.
[6] The probe, sampler, or monitoring path should be away from minor sources, such as furnace or incineration flues. The separation distance is dependent on the height of the minor source's emission point (such as a flue), the type of fuel or waste burned, and the quality of the fuel (sulfur, ash, or lead content). This criterion is designed to avoid undue influences from minor sources.
[7] For microscale CO monitoring sites, the probe must be > 10 meters from a street intersection and preferably at a midblock location.
[8] Collocated monitors must be within 4 meters of each other and at least 2 meters apart for flow rates greater than 200 liters/min or at least 1 meter apart for samplers having flow rates less than 200 liters/min to preclude airflow interference.

* * * * *

14. Appendix G to Part 58 is amended by revising section 9 and table 2 to read as follows:

Appendix G to Part 58—Uniform Air Quality Index (AQI) and Daily Reporting

* * * * *

9. How Does the AQI Relate to Air Pollution Levels?

For each pollutant, the AQI transforms ambient concentrations to a scale from 0 to 500. The AQI is keyed as appropriate to the national ambient air quality standards (NAAQS) for each pollutant. In most cases, the index value of 100 is associated with the numerical level of the short-term (*i.e.*, averaging time of 24-hours or less) standard for each pollutant. The index value of 50 is associated with one of the following: The numerical level of the annual standard for a pollutant, if there is one; one-half the level of the short-term standard for the pollutant; or the level at which it is appropriate to begin to provide guidance on cautionary language. Higher categories of the index are based on increasingly serious health effects that affect increasing proportions of the population. An index value is calculated each day for each pollutant (as described in section 12 of this appendix), unless that pollutant is specifically excluded (*see* section 8 of this appendix). The pollutant with the highest index value for the day is the ''critical'' pollutant, and must be included in the daily AQI report. As a result, the AQI for any given day is equal to the index value of the critical pollutant for that day. For the purposes of reporting the AQI, the indexes for PM_{10} and $PM_{2.5}$ are to be considered separately.

* * * * *

TABLE 2—BREAKPOINTS FOR THE AQI

These breakpoints							Equal these AQI's	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ (μg/m³)	PM_{10} (μg/m³)	CO (ppm)	SO_2 (ppm)	NO_2 (ppm) 1-hour	AQI	Category
0.000–0.059	.....	0.0–15.4	0–54	0.0–4.4	0.000–0.034	0–(0.040–0.053)	0–50	Good.
0.060–0.075	.....	15.5–40.4	55–154	4.5–9.4	0.035–0.144	(0.041–0.054)–(0.080–0.100)	51–100	Moderate.
0.076–0.095	0.125–0.164	40.5–65.4	155–254	9.5–12.4	0.145–0.224	(0.081–0.101)–(0.360–0.370)	101–150	Unhealthy for Sensitive Groups.
0.096–0.115	0.165–0.204	[3] 65.5–150.4	255–354	12.5–15.4	0.225–0.304	(0.361–0.371)–0.64	151–200	Unhealthy.
0.116–0.374	0.205–0.404	[3] 150.5–250.4	355–424	15.5–30.4	0.305–0.604	0.65–1.24	201–300	Very Unhealthy.
([2])	0.405–0.504	[3] 250.5–350.4	425–504	30.5–40.4	0.605–0.804	1.25–1.64	301–400	Hazardous.
([2])	0.505–0.604	[3] 350.5–500.4	505–604	40.5–50.4	0.805–1.004	1.65–2.04	401–500	Hazardous.

[1] Areas are generally required to report the AQI based on 8-hour ozone values. However, there are a small number of areas where an AQI based on 1-hour ozone values would be more precautionary. In these cases, in addition to calculating the 8-hour ozone index value, the 1-hour ozone index value may be calculated, and the maximum of the two values reported.
[2] 8-hour O_3 values do not define higher AQI values (≥301). AQI values of 301 or greater are calculated with 1-hour O_3 concentrations.
[3] If a different SHL for $PM_{2.5}$ is promulgated, these numbers will change accordingly.

[FR Doc. E9–15944 Filed 7–14–09; 8:45 am]

BILLING CODE 6560–50–P