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Primary National Ambient Air Quality Standards for Nitrogen Dioxide; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 50 and 58

[EPA–HQ–OAR–2006–0922; FRL 9107–9]

RIN 2060–AO19

Primary National Ambient Air Quality Standards for Nitrogen Dioxide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final 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 is making revisions to the primary NO_2 NAAQS in order to provide requisite protection of public health. Specifically, EPA is establishing a new 1-hour standard at a level of 100 ppb, based on the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations, to supplement the existing annual standard. EPA is also establishing requirements for an NO_2 monitoring network that will include monitors at locations where maximum NO_2 concentrations are expected to occur, including within 50 meters of major roadways, as well as monitors sited to measure the area-wide NO_2 concentrations that occur more broadly across communities.

DATES: This final rule is effective on April 12, 2010.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2006–0922. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *e.g.*, confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *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.

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I. Background

A. Summary of Revisions to the NO_2 Primary NAAQS

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 is making revisions to the primary NO_2 NAAQS in order to provide requisite protection of public health as appropriate under section 109 of the Clean Air Act (Act or CAA). Specifically, EPA is supplementing the existing annual standard for NO_2 of 53 parts per billion (ppb) by establishing a new short-term standard based on the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum concentrations. EPA is setting the level of this new standard at 100 ppb. EPA is making changes in data handling conventions for NO_2 by adding provisions for this new 1-hour primary standard. EPA is also establishing requirements for an NO_2 monitoring network. These new provisions require monitors at locations where maximum NO_2 concentrations are expected to occur, including within 50 meters of major roadways, as well as monitors sited to measure the area-wide NO_2 concentrations that occur more broadly across communities. EPA is making conforming changes to the air quality index (AQI).

B. Legislative Requirements

Two sections of the 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 [her] 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).[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."[2] 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 welfare from any known or anticipated adverse effects associated with the presence of such pollutant in the ambient air."[3] 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 (DC Cir 1980), *cert. denied*, 449 U.S.

[1] EPA notes that as the promulgation of a NAAQS is identified in section 307(d)(1) of the Clean Air Act, all of the provisions of this rulemaking are subject to the requirements of section 307(d) of the Clean Air Act.

[2] 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).

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

1042 (1980); *American Petroleum Institute* v. *Costle,* 665 F.2d 1176, 1186 (DC 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.

C. 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. With the revisions to the NO_2 NAAQS that result from this review, however, some areas could be classified as non-attainment. Certain States will 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).[4]

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 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.

D. 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 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 is not intended to address 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

[4] 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.

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, 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 policy assessment chapter of the final REA focused on the information that is most pertinent to evaluating the basic elements of national ambient air quality standards: Indicator, averaging time, form,[5] 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. In accordance with this schedule, the Administrator signed a notice of proposed rulemaking on June 26, 2009 (FR 74 34404). This action presents the Administrator's final decisions on the primary NO_2 standard.

E. Summary of Proposed Revisions to the NO_2 Primary NAAQS

For the reasons discussed in the preamble of the proposal for the NO_2 primary NAAQS (74 FR 34404), EPA proposed to make revisions to the primary NO_2 NAAQS and to make related revisions for NO_2 data handling conventions in order to provide requisite protection of public health. EPA also proposed to make corresponding changes to the AQI for NO_2. Specifically, EPA proposed to supplement the current annual standard by establishing a new short-term NO_2 standard that would reflect the maximum allowable NO_2 concentration anywhere in an area. EPA proposed that this new short-term standard would be based on the 3-year average of the 99th percentile (or 4th highest) of the yearly distribution of 1-hour daily maximum NO_2 concentrations and solicited comment on using the 3-year average of the 98th percentile (or 7th or 8th highest) of the yearly distribution of 1-hour daily maximum NO_2 concentrations. EPA proposed to set the level of this new 1-hour standard within the range of 80 to 100 ppb and solicited comment on standard levels as low as 65 ppb and as high as 150 ppb. EPA proposed to specify the level of the standard to the nearest ppb. EPA also proposed to establish requirements for an NO_2 monitoring network at locations where maximum NO_2 concentrations are expected to occur, including monitors within 50 meters of major roadways, as well as area-wide monitors sited to measure the NO_2 concentrations that can occur more broadly across communities. EPA also solicited comment on the alternative approach of setting a 1-hour standard that would reflect the allowable area-wide NO_2 concentration.

F. Organization and Approach to Final NO_2 Primary NAAQS Decisions

This action presents the Administrator's final decisions regarding the need to revise the current NO_2 primary NAAQS. Revisions to the primary NAAQS for NO_2, and the rationale supporting those revisions, are described below in section II. Requirements for the NO_2 ambient monitoring network are described in section III. Related requirements for data completeness, data handling, data reporting, rounding conventions, and exceptional events are described in section IV. Implementation of the revised NO_2 primary NAAQS is discussed in sections V and VI. Communication of public health information through the AQI is discussed in section VII and a discussion of statutory and executive order reviews is provided in section VIII.

Today's final decisions are based on a thorough review in the ISA of scientific information on known and potential human health effects associated with exposure to NO_2 in the air. These final decisions also take into account: (1) Assessments in the REA of the most policy-relevant information in the ISA as well as quantitative exposure and risk analyses based on that information; (2) CASAC Panel advice and recommendations, as reflected in its letters to the Administrator and its public discussions of the ISA, the REA, and the notice of proposed rulemaking; (3) public comments received during the development of ISA and REA; and (4) public comments received on the proposed rulemaking.

Some commenters have referred to and discussed individual scientific analyses on the health effects of NO_2 that were not included in the ISA (EPA, 2008a) ("new studies"). In considering

[5] 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.

and responding to comments for which such "new studies" were cited in support, EPA has provisionally considered the cited studies in the context of the findings of the ISA.

As in prior NAAQS reviews, EPA is basing its decision in this review on studies and related information included in the ISA and staff's policy assessment, which have undergone CASAC and public review. In this NO_2 NAAQS review, staff's policy assessment was presented in the form of a policy assessment chapter of the REA (EPA, 2008b). The studies assessed in the ISA and REA, and the integration of the scientific evidence presented in them, have undergone extensive critical review by EPA, CASAC, and the public. The rigor of that review makes these studies, and their integrative assessment, the most reliable source of scientific information on which to base decisions on the NAAQS, decisions that all parties recognize as of great import. NAAQS decisions can have profound impacts on public health and welfare, and NAAQS decisions should be based on studies that have been rigorously assessed in an integrative manner not only by EPA but also by the statutorily mandated independent advisory committee, as well as the public review that accompanies this process. EPA's provisional consideration of "new studies" did not and could not provide that kind of in-depth critical review.

This decision is consistent with EPA's practice in prior NAAQS reviews and its interpretation of the requirements of the CAA. Since the 1970 amendments, the EPA has taken the view that NAAQS decisions are to be based on scientific studies and related information that have been assessed as a part of the pertinent air quality criteria, and has consistently followed this approach. This longstanding interpretation was strengthened by new legislative requirements enacted in 1977, which added section 109(d)(2) of the Act concerning CASAC review of air quality criteria. *See* 71 FR 61144, 61148 (October 17, 2006) (final decision on review of PM NAAQS) for a detailed discussion of this issue and EPA's past practice.

As discussed in EPA's 1993 decision not to revise the NAAQS for ozone (O_3), "new studies" may sometimes be of such significance that it is appropriate to delay a decision on revision of a NAAQS and to supplement the pertinent air quality criteria so the studies can be taken into account (58 FR at 13013–13014, March 9, 1993). In the present case, EPA's provisional consideration of "new studies" concludes that, taken in context, the "new" information and findings do not materially change any of the broad scientific conclusions regarding the health effects of NO_2 made in the air quality criteria. For this reason, reopening the air quality criteria review would not be warranted even if there were time to do so under the court order governing the schedule for this rulemaking.

Accordingly, EPA is basing the final decisions in this review on the studies and related information included in the NO_2 air quality criteria that have undergone CASAC and public review. EPA will consider the "new studies" for purposes of decision-making in the next periodic review of the NO_2 NAAQS, which will provide the opportunity to fully assess these studies through a more rigorous review process involving EPA, CASAC, and the public. Further discussion of these "new studies" can be found below, in section II.E, and in the Response to Comments document.

II. Rationale for Final Decisions on the NO_2 Primary Standard

This section presents the rationale for the Administrator's decision to revise the existing NO_2 primary standard by supplementing the current annual standard with a new 1-hour standard. 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 summarized below in section II.B, 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. This rationale also draws upon the results of quantitative exposure and risk assessments, summarized below in section II.C.

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 provides background information that informed the Administrator's decisions on the primary standard and discusses the rationale for those decisions. Section II.A presents a discussion of NO_2 air quality. 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 results. Section II.D summarizes the approach that was 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–II.G discuss the Administrator's decisions regarding the adequacy of the current standard, elements of a new 1-hour standard, and retention of the current annual standard, respectively, taking into consideration public comments on the proposed decisions. Section II.H summarizes the Administrator's 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.[6] 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

[6] 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 Watkins and Thompson (2008) considered all NO_2 sites reporting data at any point during the year. Based on this approach, Watkins and Thompson (2008) also noted that the size of the NO_2 monitoring network has remained relatively stable since the early 1980s.

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 O_3 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, O_3 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, estimates presented in the REA suggest that on/near roadway NO_2 concentrations could be approximately 80% (REA, section 7.3.2) higher on average across locations than concentrations away from roadways and that roadway-associated environments could be responsible for the 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 to near area-wide ambient levels, or typical upwind urban background levels, within a few hundred meters downwind. While such a concentration gradient is present on almost all roads, the characteristics of the gradient, including the distance from the road that a mobile source pollutant signature can be differentiated from background concentrations, are heavily dependent on factors such as 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, 1981; 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, 1981; 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, 1981; 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 (discussed in 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 summarized below and discussed more fully in section II.B of the proposal notice, 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. This body of evidence focuses the current review on NO_2-related respiratory effects at lower ambient and exposure concentrations than considered in the previous review.

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

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, and 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.

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 widespread source of combustion pollutant mixtures that include NO_X and are an important contributor to NO_2 levels in near-road locations. Although the presence of other pollutants from vehicle exhaust emissions 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). The plausibility and coherence of these effects are also supported by epidemiologic studies of indoor NO_2 as well as experimental (*i.e.*, toxicological 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.

The epidemiologic and experimental studies encompass a number of respiratory-related health endpoints, including emergency department visits and hospitalizations, respiratory symptoms, airway hyperresponsiveness, airway inflammation, and lung function. The findings relevant to these endpoints, which provide the rationale to support the judgment of a likely causal relationship, are described in more detail in section II.B.1 of the proposal.

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 United States 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 ISA concluded that 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 (*see* section II.B.3 of the proposal for a more detailed discussion). 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). While 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 high correlation among traffic-related pollutants in epidemiologic studies makes it difficult to accurately estimate independent effects (ISA, section 5.3.2.4).

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 or 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 susceptibility and vulnerability 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 include pre-existing disease (*e.g.*, asthma), age (*i.e.*, infants, children, older adults), genetic factors, gender, socioeconomic status, and proximity to roadways (*see* section II.B.4 in proposal for more detailed discussion of these factors).

As discussed in more detail in the proposal (section II.B.4), 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).[7] 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 (approximately 22.2 million people in 2005) 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 United States census data from 2000, about 72.3 million (26%) of the United States 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 United States 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. As discussed more fully in section II.C of the proposal, this section summarizes 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 potential alternative standards.

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.

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. As described in more detail in the proposal (section II.C.1), the characterization of NO_2-associated health risks was based on an epidemiology study conducted in Atlanta, Georgia by Tolbert *et al.* (2007) and a meta-analysis of controlled human exposure studies of NO_2 and airway responsiveness in asthmatics (ISA, Table 3.1–3).[8]

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, the REA employed three approaches. 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 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 in the proposal (section II.C.2) and each approach, along with its limitations and uncertainties (*see* proposal, section II.C.3) has been described in more detail in the REA (chapters 6 through 9).

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. In interpreting these results within the context of the current revisions to the NO_2 primary NAAQS (*see* below), we note that simulation of different standard levels was based on adjusting NO_2 concentrations at available area-wide monitors. Therefore, the standard levels referred to above reflect the allowable area-wide NO_2 concentrations, not the maximum allowable concentrations. As a consequence, the maximum concentrations in an area that just meets one of these standard levels would be expected to be higher than the standard level. For example, given that near-road

[7] 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 1A–6 from that report (*http://www.census.gov/hhes/www/housing/ahs/ahs07/tab1a-6.pdf*), out of 128,203,000 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.

[8] The study by Tolbert *et al.* (2007) reported positive associations between 1-hour ambient NO_2 concentrations and respiratory-related emergency department visits. The meta-analysis was included in the ISA and reported that short-term exposures to NO_2 concentrations at or above 100 ppb increased airway responsiveness in most asthmatics.

NO_2 concentrations can be 30% to 100% higher than area-wide concentrations (*see* section II.E.2), an area-wide concentration of 50 ppb could correspond to near-road concentrations from 65 to 100 ppb.

Key results of the air quality, exposure, and risk analyses were presented in the policy assessment chapter of the REA and summarized in the proposal (Table 1 in proposal). In considering these results, the policy assessment chapter of the REA concluded that the risks estimated to be associated with just meeting the current annual standard can be judged important from a public health perspective. The results for specific 1-hour standard levels estimate that limiting the 98th/99th percentile of the distribution of 1-hour daily maximum NO_2 concentrations measured at area-wide monitors to 50 or 100 ppb could substantially reduce exposures to ambient NO_2 and associated health risks (compared to just meeting the current standard). In contrast, limiting these area-wide NO_2 concentrations to 150 or 200 ppb is estimated to result in similar, or in some cases higher, NO_2-associated exposures and health risks than just meeting the current standard. The pattern of results was similar for standards just meeting either the 98th or the 99th percentile 1-hour daily maximum area-wide standards (REA, Chapters 7, 8, and 9).

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

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 has been 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 decisions 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 from CASAC and the public.

To evaluate whether the current primary NO_2 standard is requisite or whether consideration of revisions is appropriate, EPA has used an approach in this review that was described in the policy assessment chapter of the REA. This approach builds upon those used in reviews of other criteria pollutants, including the most recent reviews of the Pb, O_3, and PM NAAQS (EPA, 2007c; EPA, 2007d; EPA, 2005), and reflects the body of evidence and information that is currently available. As in other recent reviews, EPA's considerations included 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 framed 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 has been 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 has been 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 has addressed 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 proposal, and in this final rulemaking. The following sections present the rationale for proposed decisions, discussion of public comments, and the Administrator's conclusions on the adequacy of the current standard and potential alternative standards in terms of indicator, averaging time, form, and level.

E. Adequacy of the Current Standard

This section discusses considerations related to the decision as to whether the current NO_2 primary NAAQS is requisite to protect public health with an adequate margin of safety. Specifically, section II.E.1 provides an overview of the rationale supporting the Administrator's conclusion in the proposal that the current standard alone does not provide adequate public health protection; section II.E.2 discusses comments received on the adequacy of the current standard; and section II.E.3 discusses the Administrator's final decision on whether the current NO_2 primary NAAQS is requisite to protect public health with an adequate margin of safety.

1. Rationale for Proposed Decision

In reaching a conclusion regarding the adequacy of the current NO_2 NAAQS in the proposal (section II.E.5), the Administrator considered the scientific evidence assessed in the ISA and the conclusions of the ISA, the exposure and risk information presented in the REA and the conclusions of the policy assessment chapter of the REA, and the views expressed by CASAC. These considerations are discussed in detail in the proposal (II.E.) and are summarized in this section. In the proposal, the

Administrator noted the following in considering the adequacy of the current standard:

- 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 respiratory-related hospital admissions and emergency department visits, at ambient concentrations that are present in areas that meet the current NO_2 NAAQS (ISA, section 5.4).
- The policy assessment chapter of the REA concluded that risks estimated to be associated with air quality adjusted upward to simulate just meeting the current standard can reasonably be judged important from a public health perspective (REA, section 10.3.3).
- The policy assessment chapter of the REA concluded that exposure- and risk-based results reinforce the scientific evidence in supporting the conclusion that consideration should be given to revising the current NO_2 NAAQS 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 (REA, section 10.3.3).
- CASAC agreed that the current annual standard alone is not sufficient to protect public health against the types of exposures that could lead to these health effects. Specifically, in their letter to the Administrator on the final REA, they stated that "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).

Based on these considerations (discussed in more detail in the proposal, section II.E), the Administrator concluded in the proposal that the current NO_2 primary NAAQS is not requisite to protect public health with an adequate margin of safety against adverse respiratory effects associated with short-term exposures. In considering approaches to revising the current standard, the Administrator concluded that it is appropriate to consider setting a new short-term standard in addition to retaining the current annual standard. The Administrator noted 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.

2. Comments on the Adequacy of the Current Standard

This section discusses comments received from CASAC and public commenters on the proposal that either supported or opposed the Administrator's proposed decision to revise the current NO_2 primary NAAQS. Comments on the adequacy of the current standard that focused on the scientific and/or the exposure/risk basis for the Administrator's proposed conclusions are discussed in sections II.E.2.a-II.E.2.c. Comments on the epidemiologic evidence are considered in section II.E.2.a. Comments on the controlled human exposure evidence are considered in section II.E.2.b. Comments on human exposure and health risk assessments are considered in section II.E.2.c. To the extent these comments on the evidence and information are also used to justify commenters' conclusions on decisions related to indicator, averaging time, level, or form, they are noted in the appropriate sections below (II.F.1–II.F.4).

In their comments on the proposal (Samet, 2009), CASAC reiterated their support for the need to revise the current annual NO_2 NAAQS in order to increase public health protection. As noted above, in its letter to the Administrator on the final REA (Samet, 2008b) CASAC stated that it "concurs with EPA's judgment that the current NAAQS does not protect the public's health and that it should be revised." In supporting adoption of a more stringent NAAQS for NO_2, CASAC considered the assessment of the scientific evidence presented in the ISA, the results of assessments presented in the REA, and the conclusions of the policy assessment chapter of the REA. As such, CASAC's rationale for revising the current standard was consistent with the Administrator's rationale as discussed in the proposal.

Many public commenters agreed with CASAC that, based on the available information, the current NO_2 standard is not requisite to protect public health with an adequate margin of safety and that revisions to the standard are appropriate. Among those calling for revisions to the standard were environmental groups (*e.g.*, Clean Air Council (CAC), Earth Justice (EJ), Environmental Defense Fund (EDF), Natural Resources Defense Council (NRDC), Group Against Smog and Pollution (GASP)); medical/public health organizations (*e.g.*, American Lung Association (ALA), American Medical Association (AMA), American Thoracic Society (ATS), National Association for the Medical Direction of Respiratory Care (NAMDRC), National Association of Cardiovascular and Pulmonary Rehabilitation (NACPR), American College of Chest Physicians (ACCP)); a large number of State agencies and organizations (*e.g.*, National Association of Clean Air Agencies (NACAA), Northeast States for Coordinated Air Use Management (NESCAUM), and State or local agencies in CA, IA, IL, MI, MO, NC, NM, NY, TX, VA, WI); Tribes (*e.g.*, National Tribal Air Association (NTAA), Fond du Lac Band of Lake Superior Chippewa (Fond du Lac)), and a number of individual commenters. These commenters concluded that the current NO_2 standard needs to be revised and that a more stringent standard is needed to protect the health of sensitive population groups. In supporting the need to adopt a more stringent NAAQS for NO_2, these commenters often referenced the conclusions of CASAC and relied on the evidence and information presented in the proposal. As such, similar to CASAC, the rationale offered by these commenters was consistent with that presented in the proposal to support the Administrator's proposed decision to revise the current NO_2 NAAQS.

Some industry commenters (*e.g.*, Alliance of Automobile Manufacturers (AAM), American Petroleum Institute (API), Interstate Natural Gas Association of America (INGAA), Utility Air Regulatory Group (UARG)) and one State commenter (IN Department of Environmental Management) expressed support for retaining the current annual standard alone. In supporting this view, these commenters generally concluded that the current standard is requisite to protect public health with an adequate margin of safety and that the available evidence is not sufficient to support revision of the standard. For example, UARG stated that "EPA has failed to demonstrate that the present NO_2 NAAQS is no longer at the level requisite to protect public health with an adequate margin of safety." In addition, INGAA stated that

"* * * EPA should be compelled to retain the current standard and defer a decision on a new short-term standard until the science is more clearly defined."

In support of their views, these commenters provided specific comments on the epidemiologic and controlled human exposure evidence as discussed below. In responding to these specific comments, we note that the Administrator relied in the proposal on the evidence, information and judgments contained in the ISA and the

REA (including the policy assessment chapter) as well as on the advice of CASAC. In considering the evidence, information, and judgments of the ISA and the REA, the Agency notes that these documents have been reviewed extensively by CASAC and have been discussed by CASAC at multiple public meetings (*see* section I.D). In their letter to the Administrator regarding the second draft ISA (Henderson, 2008), CASAC noted the following:

> Panel members concur with the primary conclusions reached in the ISA with regard to health risks that are associated with NO_2 exposure. In particular, the Panel agrees with the conclusion that the current scientific evidence is "sufficient to infer a likely causal relationship between short-term NO_2 exposure and adverse effects on the respiratory system." The strongest evidence in support of this conclusion comes from epidemiology studies that show generally positive associations between NO_2 and respiratory symptoms, hospitalizations or emergency department visits, as summarized in Figure 5.3.1."

Similarly, in their letter to the Administrator on the final REA (Samet, 2008b), CASAC noted the following:

> Overall, CASAC found this version of the REA satisfactory in its approach to moving from the scientific foundation developed in the Integrated Science Assessment (ISA) to setting out evidence-based options for the NAAQS. The REA provides the needed bridge from the evidence presented in the ISA to a characterization of the exposures and the associated risks with different profiles of exposure. It draws on toxicological and epidemiological evidence and addresses risk to an identified susceptible population, people with asthmatic conditions. EPA has also systematically described uncertainties associated with the risk assessments. We commend EPA for developing a succinct and thoughtfully developed synthesis in chapter 10. This summary chapter represents a long-needed and transparent model for linking a substantial body of scientific evidence to the four elements of the NAAQS.

Therefore, in discussing comments on the interpretation of the scientific evidence and exposure/risk information, we note that CASAC has endorsed the approaches and conclusions of the ISA and the REA. These approaches and conclusions are discussed below in more detail, within the context of specific public comments.

a. Comments on EPA's Interpretation of the Epidemiologic Evidence

Several industry groups (*e.g.*, API, National Mining Association (NMA), American Chemistry Council (ACC), AAM, Annapolis Center for Science-Based Public Policy (ACSBPP), Engine Manufacturers Association (EMA), ExxonMobil (Exxon), National Association of Manufacturers (NAM)) commented that, given the presence of numerous co-pollutants in the air, epidemiologic studies do not support the contention that NO_2 itself is causing health effects.

While EPA has recognized that multiple factors can contribute to the etiology of respiratory disease and that more than one air pollutant could independently impact respiratory health, we continue to judge, as discussed in the ISA, that the available evidence supports the conclusion that there is an independent effect of NO_2 on respiratory morbidity. In reaching this judgment, we recognize that a major methodological issue affecting NO_2 epidemiologic studies concerns the evaluation of the extent to which other air pollutants may confound or modify NO_2-related effect estimates. The use of multipollutant regression models is the most common approach for controlling potential confounding by co-pollutants in epidemiologic studies. The issues related to confounding and the evidence of potential confounding by co-pollutants has been thoroughly reviewed in the ISA (*see* Figures 3.1–10 and 3.1–11) and in previous assessments (*e.g.*, the criteria document for PM) (EPA, 2004). NO_2 risk estimates for respiratory morbidity endpoints, in general, were not sensitive to the inclusion of co-pollutants, including particulate and gaseous pollutants. As observed in Figures 3.1–10 and 3.1–11 in the ISA, relative risks for hospital admissions or emergency department visits are generally unchanged, nor is their interpretation modified, upon inclusion of PM or gaseous co-pollutants in the models. Similarly, associations between short-term NO_2 exposure and asthma symptoms are generally robust to adjustment for co-pollutants in multipollutant models, as shown in Figures 3.1–5 and 3.1–7 of the ISA. These results, in conjunction with the results of a randomized intervention study evaluating respiratory effects of indoor exposure to NO_2 (ISA, section 3.1.4.1), led to the conclusion that the effect of NO_2 on respiratory health outcomes is robust and independent of the effects of other ambient co-pollutants.

In addition, experimental studies conducted in animals and humans provide support for the plausibility of the associations reported in epidemiologic studies. These controlled human exposure and animal toxicological studies have reported effects of NO_2 on immune system function, lung host defense, airway inflammation, and airway responsiveness (ISA, section 5.4). These experimental study results support an independent contribution of NO_2 to the respiratory health effects reported in epidemiologic studies (ISA Section 5.4).

In considering the entire body of evidence, including epidemiologic and experimental studies, the ISA (section 5.4, p. 5–16) concluded the following:

> Although this [presence of co-pollutants] 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.

Comments on specific epidemiologic studies are discussed below.

The National Association of Manufacturers (NAM) commented that the final REA relied on an epidemiologic study (Delfino *et al.* 2002) not critically reviewed in the final ISA. Contrary to NAM's contention, the study by Delfino *et al.* (2002) was critically reviewed by EPA staff and pertinent information was extracted from the study. The respiratory health effects of NO_2 on asthma reported in this study are included in Figure 5.3–1, Table 5.4–1, and Annex Table AX6.3–2 of the ISA. While NAM comments on the narrative discussion of this study in the final ISA, their contention that EPA scientists did not critically analyze the study while preparing the final ISA is incorrect. The inclusion of the study in the figures and tables in this ISA, as well as inclusion in the 2004 PM AQCD, indicate critical analysis of the study that was implemented throughout the review process. The narrative discussion in the ISA focused on multicity studies (specifically those by Schwartz *et al.* 1994, Mortimer *et al.* 2002 and Schildcrout *et al.* 2006), which provide substantial epidemiologic evidence for the respiratory health effects of NO_2 on asthma among children.

Additional comments from NAM contend that EPA's interpretation of three individual epidemiologic studies (*e.g.* Krewski *et al.* 2000; Schildcrout *et al.* 2006; Mortimer *et al.* 2002) is inconsistent across different NAAQS reviews. The NAM comments on all three studies are discussed below.

NAM stated the following regarding the study by Krewski *et al:*

> In the Final ISA, EPA cites the Krewski, *et al.* (2000) study as evidence of a significant

association between NO_2 exposure and mortality. Although EPA acknowledges that exposure to NO_2 was "highly correlated" with other pollutants, including $PM_{2.5}$ and SO_2, EPA does not consider the analysis of the respective contributions of single pollutants in the same study that EPA included in its prior Staff Paper for Particulate Matter. In that document, EPA stated: "In single-pollutant models, none of the gaseous co-pollutants was significantly associated with mortality except SO_2." If EPA has not altered its scientific views concerning this study as expressed in the PM Staff Paper, it is entirely inappropriate for EPA to suggest that the Krewski, *et al.* (2000) study provides any evidence of an association between NO_2 exposure and mortality.

In these comments, NAM fails to recognize that the report from Krewski *et al.* (2000) contains a reanalysis of two cohort studies, the Harvard Six Cities and the American Cancer Society (ACS) studies. The characterization in the NO_X ISA of the study by Krewski *et al.* (2000), referenced by NAM in their comments, refers to the reanalysis of the Harvard Six Cities Study. As stated in the NO_X ISA (p. 3–74):

Krewski *et al.* (2000) conducted a sensitivity analysis of the Harvard Six Cities study and examined associations between gaseous pollutants (*i.e.*, O_3, NO_2, SO_2, CO) and mortality. NO_2 showed risk estimates similar to those for $PM_{2.5}$ per "low to high" range increment with total (1.15 [95% CI: 1.04, 1.27] per 10-ppb increase), cardiopulmonary (1.17 [95% CI: 1.02, 1.34]), and lung cancer (1.09 [95% CI: 0.76, 1.57]) deaths; however, in this dataset NO_2 was highly correlated with $PM_{2.5}$ (r = 0.78), SO_4^{2-} (r = 0.78), and SO_2 (r = 0.84).

In contrast, the characterization in the PM Staff Paper (EPA, 2005) of the study by Krewski *et al.* (2000), referenced by NAM in their comments, refers to the results of the ACS study. Therefore, NAM appears to have confused the conclusions on the results of the reanalysis of the Harvard Six Cities Study in the NO_X ISA with the conclusions on the results of the reanalysis of the ACS study in the PM Staff Paper.

Further, in considering the reanalysis of the ACS study by Krewski *et al.* (2000), the NO_X ISA observed that "NO_2 showed no associations with mortality outcomes" (ISA, p. 3–74). This statement is consistent with the interpretation of that reanalysis as discussed in the PM Staff Paper. Thus, there is no inconsistency in the interpretation of the results of the study by Krewski *et al.* (2000) in the PM Staff Paper (EPA, 2005) and the NO_X ISA (EPA, 2008a).

NAM also commented that EPA has relied on a study by Schildcrout *et al.* (2006) in the NO_X ISA but declined to rely on the same study for the previous review of the O_3 NAAQS. NAM made the following comment regarding the study by Schildcrout *et al:*

Another example of how EPA has reached different scientific conclusions in the Final ISA than in prior NAAQS documents is provided by the Schildcrout, *et al.* (2006) study. In the Final ISA, EPA includes an extensive discussion of this study of asthmatic children and the relationship purportedly found in this study between NO_2 and various respiratory symptoms. In contrast, as part of the NAAQS review for ozone, EPA expressly declined to rely on this same study because of specific limitations in the study design. Among the limitations EPA cites were the fact that the Schildcrout, *et al.* (2006) study included "children in which the severity of their asthma was not clearly identified," and the use of a study population that was "not comparable to other large multi-city studies." EPA must explain why it chose to discount the value of the Schildcrout, *et al.* (2006) study when evaluating the effects of ozone, but has relied on it extensively in the Final ISA for NO_2.

The study by Schildcrout *et al.* (2006) appeared in the peer-review literature too late to be considered in the 2006 O_3 AQCD; however, this study was included in the O_3 Provisional Assessment. The purpose of the Provisional Assessment was to determine if new literature materially changed any of the broad scientific conclusions regarding the health effects of O_3 exposure as stated in the 2006 O_3 AQCD. EPA concluded that, taken in context, the "new" information and findings did not materially change any of the broad scientific conclusions regarding the health effects of O_3 exposure made in the O_3 AQCD. Therefore, NAM's contention that EPA "declined" to rely on the Schildcrout study for the O_3 review because of limitations in study design is not correct.

The observations NAM draws from the O_3 Provisional Assessment regarding severity of asthma and the study population do not indicate limitations that resulted in EPA "discounting" the study results. Rather, these observations were intended to put the study in perspective for purposes of interpreting the results within the context of the larger body of O_3 health effects evidence. These observations were drawn from comments submitted by Dr. Schildcrout regarding the interpretation of the results of his study in the decision to revise the ozone standards (*see* docket ID EPA–HQ–OAR–2005–0172–6991). The results of this study are being fully considered in the ongoing review of the ozone NAAQS.

Finally, NAM contends that EPA reached differing scientific conclusions on the use of self-reported peak expiratory flow (PEF) depending on regulatory context, particularly in the large multi-city trial by Mortimer *et al.* (2002). We disagree with this contention. EPA consistently examines clinical measurements of lung function, which include PEF, forced expiratory flow in 1 second (FEV_1), forced vital capacity (FVC), maximal midexpiratory flow (MMEF), maximal expiratory flow at 50% (MEF_{50}), maximal expiratory flow at 25% (MEF_{25}), and forced expiratory flow at 25 to 75% of FVC (FEF_{25-75}). Evidence for all of these clinical measurements is considered before drawing a conclusion related to the association of lung function with a criteria pollutant. In different reviews, there may be more evidence from one of these clinical measurements than another. In the previous review of the O_3 NAAQS, EPA identified statistically significant associations between increased ozone levels and morning PEF, which remained significant even when concentrations exceeding 0.08 ppm were excluded from the analysis (Mortimer *et al.* 2002). EPA considered this evidence, along with evidence of other clinical measurements of changes in lung function, in drawing conclusions on the relationship between ozone and lung function. Using a similar approach to weigh the evidence pertinent to lung function, including studies that produced no statistically significant results for PEF, the NO_X ISA (section 3.1.5.3) states:

In summary, epidemiologic studies using data from supervised lung function measurements (spirometry or peak flow meters) report small decrements in lung function (Hoek and Brunekreef, 1994; Linn *et al.*, 1996; Moshammer *et al.*, 2006; Peacock *et al.*, 2003; Schindler *et al.*, 2001). No significant associations were reported in any studies using unsupervised, self-administered peak flow [PEF] measurements with portable devices.

The evaluation of the evidence in the NO_X ISA is consistent with the way the evidence from multiple clinical measures of lung function was used in the review of the O_3 NAAQS.

b. Comments on EPA's Interpretation of the Controlled Human Exposure Evidence

A number of industry groups (*e.g.*, AAM, ACC, API, Dow Chemical Company (Dow), EMA, NAM, UARG) disagreed with EPA's reliance on a meta-analysis of controlled human exposure studies of airway responsiveness in asthmatics. Based on this meta-analysis (ISA, Table 3.1–3 for results), the ISA concluded that "small but significant increases in nonspecific airway hyperresponsiveness were observed * * * at 0.1 ppm NO_2 for 60-min exposures in asthmatics" (ISA, p. 5–11). Industry groups raised a number of objections to this analysis and the way in which it has been used in the current review.

Several of these industry groups concluded that, in relying on this analysis, EPA has inappropriately relied on a new unpublished meta-analysis that has not been peer-reviewed, was not reviewed by CASAC, and was not conducted in a transparent manner. For example, as part of a Request for Correction submitted under EPA's Information Quality Guidelines, NAM stated that "EPA's substantial reliance on an unpublished assessment described as a "meta-analysis" of the relation between NO_2 exposure and changes in airway responsiveness violates EPA Guidelines requiring "transparency about data and methods."

EPA disagrees with this characterization of the updated meta-analysis included in the final ISA. As described in the ISA (p. 3–16), this meta-analysis is based on an earlier analysis by Folinsbee (1992) that has been subject to peer-review, that was published in a scientific journal (*Toxicol Ind Health.* 8:1–11, 1992), and that was reviewed by CASAC as part of the previous review of the NO_2 NAAQS (EPA, 1993, Table 15–10). The updates to this earlier analysis did not include substantive changes to the approach. As discussed in the final ISA (p. 3–16), the changes made to the analysis were to remove the results of one allergen study and add results from a non-specific responsiveness study, which focused the meta-analysis on non-specific airway responsiveness, and to discuss results for an additional exposure concentration (*i.e.*, 100 ppb). The information needed to reproduce this meta-analysis is provided in the ISA (Tables 3.1–2 and 3.1–3, including footnotes).

While the ISA meta-analysis reports findings on airway responsiveness in asthmatics following exposure to 100 ppb NO_2, a concentration not specifically discussed in the findings of the original report by Folinsbee (1992), this does not constitute a substantive change to that original analysis. For exposures at rest, four of the studies included in the analysis by Folinsbee evaluated the effects of exposure to 100 ppb NO_2. In that original meta-analysis, these studies were grouped with another study that evaluated exposures to 140 ppb NO_2. When analyzed together, exposures to NO_2 concentrations of 100 ppb and 140 ppb (grouped together in the manuscript and described as less than 0.2 ppm) increased airway responsiveness in 65% of resting asthmatics ($p < 0.01$). Therefore, reporting results at 100 ppb NO_2 in the ISA meta-analysis reflects a change in the way the data are presented and does not reflect a substantive change to the study. This change in presentation allows specific consideration of the potential for exposures to 100 ppb NO_2 to increase airway responsiveness, rather than grouping results at 100 ppb with results at other exposure concentrations.

In addition, the updated meta-analysis was considered by CASAC during their review of the REA (REA, Table 4–5 reports the results of the updated meta-analysis), which based part of the assessment of NO_2-associated health risks on the results of the meta-analysis. In their letter to the Administrator on the final REA (Samet, 2008b), CASAC stated that "[t]he evidence reviewed in the REA indicates that adverse health effects have been documented in clinical studies of persons with asthma at 100 ppb" and that "CASAC firmly recommends that the upper end of the range [of standard levels] not exceed 100 ppb, given the findings of the REA." In addition, in their comments on the proposal, CASAC reiterated this advice in their statement that "the level of the one-hour NO_2 standard should be within the range of 80–100 ppb and not above 100 ppb." These statements indicate that CASAC did specifically consider the results of the updated meta-analysis and that they used those results to inform their recommendations on the range of standard levels supported by the scientific evidence.

In summary, we note the following:

- The original meta-analysis was published in a peer-reviewed journal and was reviewed by CASAC in the previous review of the NO_2 NAAQS.
- The updated meta-analysis does not include substantive changes to the methodology of this original analysis.
- The changes that were made are clearly described in the ISA.
- CASAC specifically reviewed and considered the ISA meta-analysis in making recommendations regarding the range of standard levels supported by the science.

Many of these same industry groups also referred in their comments to a recent meta-analysis of controlled human exposure studies evaluating the airway response in asthmatics following NO_2 exposure (Goodman *et al.*, 2009). These groups generally recommended that EPA rely on this meta-analysis and on the authors' conclusions with regard to NO_2 and airway responsiveness. Specific comments based on the manuscript by Goodman *et al.*, as well as EPA's responses, are discussed below in more detail.[9]

Industry commenters generally claimed that the meta-analysis by Goodman *et al.* supports the conclusion that no adverse effects occur following exposures up to 600 ppb NO_2. However, Table 4 of the Goodman study reports that 64% (95% Confidence Interval: 58%, 71%) of resting asthmatics exposed to NO_2 experienced an increase in airway responsiveness. Furthermore, Figure 2a of this manuscript reports that for exposures < 0.2 ppm, the fraction affected is 0.61 (95% CI: 0.52, 0.70) while for exposures of 0.2 ppm to < 0.3 ppm, the fraction affected is 0.66 (95% CI: 0.59, 0.74). These findings are consistent with those reported in the meta-analysis by Folinsbee and in the updated meta-analysis that was included in the final ISA.

Also based on the meta-analysis by Goodman *et al.* (2009), several industry commenters concluded that NO_2-induced airway hyperresponsiveness is not adverse and, therefore, should not be considered in setting standards. The basis for this comment appears to be the conclusions reached by Goodman *et al.* that there is no dose-response relationship for NO_2 and that the magnitude of any NO_2 effect on airway responsiveness is too small to be considered adverse.

Due to differences in study protocols in the NO_2-airway response literature (ISA, section 3.1.3), EPA disagrees with the approach taken in the Goodman study to use existing data to attempt to evaluate the presence of a dose-response relationship and to determine the magnitude of the NO_2 response. Examples of differences in the study protocols include the NO_2 exposure method (*i.e.*, mouthpiece versus chamber), subject activity level (*i.e.*, rest versus exercise) during NO_2 exposure, choice of airway challenge agent, and physiological endpoint used to quantify airway responses. Goodman *et al.* (2009) also recognized heterogeneity among studies as a limitation in their analyses.

As a result of these differences, EPA judged it appropriate in the ISA meta-analysis to assess only the fraction of asthmatics experiencing increased or decreased airway responsiveness

[9] EPA considers the Goodman study to be a "new study" on which, as discussed above in section 1.B, it would not be appropriate to base a standard in the absence of thorough CASAC and public review of the study and its methodology. However, as discussed below, EPA has considered the study in the context of responding to public comments on the proposal and has concluded it does not provide a basis to materially change any of the broad scientific conclusions regarding the health effects of NO_2 made in the air quality criteria.

following NO_2 exposure. We have acknowledged in the REA, the proposal, and in this final rulemaking that there is uncertainty with regard to the magnitude and the clinical-significance of NO_2-induced increases in airway responsiveness (*see* sections II.C.3 and II.F.4.a in the proposed rulemaking as well as II.F.3 in this final rulemaking). The REA stated the following (p. 302):

> [O]ne of the important uncertainties associated with these [NO_2-induced airway hyperresponsiveness] results is that, because the 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. This limitation makes it particularly difficult to quantify the public health implications of these results.

While we acknowledge this uncertainty, EPA disagrees with the conclusion that the NO_2-induced increase in airway responsiveness in asthmatics exposed to NO_2 concentrations up to 600 ppb is not adverse and should not be considered in setting standards. Specifically, we note that the ISA concluded that "[t]ransient increases in airway responsiveness following NO_2 exposure have the potential to increase symptoms and worsen asthma control" (ISA, section 5.4). The uncertainty over the adversity of the response reported in controlled human exposure studies does not mean that the NO_2-induced increase in airway responsiveness is not adverse. Rather, it means that there is a risk of adversity, especially for asthmatics with more than mild asthma, but that this risk cannot be fully characterized based on existing studies. The studies of NO_2 and airway responsiveness included in the meta-analysis have generally evaluated mild asthmatics, rather than more severely affected asthmatics who could be more susceptible to the NO_2-induced increase in airway responsiveness (ISA, section 3.1.3.2). Given that this is the case, and given the large percentage of asthmatics that experienced an NO_2-induced increase in airway responsiveness in the studies and the large size of the asthmatic population in the United States, the REA concluded that it is appropriate to consider NO_2-induced airway hyperresponsiveness in characterizing NO_2-associated health risks (REA, section 10.3.2). As noted above, CASAC endorsed this conclusion in their letters to the Administrator on the final REA and on the proposal (Samet, 2008b; Samet, 2009).

c. Comments on EPA's Characterization of NO_2-Associated Exposures and Health Risks

Several commenters discussed the analyses of NO_2-associated exposures and health risks presented in the REA. As in past reviews (EPA 2005, 2007c, 2007d), EPA has estimated allowable risks associated with the current standard and potential alternative standards to inform judgments on the public health risks that could exist under different standard options. Some industry commenters (*e.g.*, API, NMA) concluded that the Administrator should consider modeled exposures and risks associated with actual NO_2 air quality rather than with NO_2 concentrations adjusted to simulate just meeting the current annual standard or potential alternative 1-hour standards. These commenters pointed out that such simulations require large adjustments to air quality and are highly uncertain and that NAAQS are intended to address actual, rather than highly improbable, risks to health.

We disagree with these commenters that exposure- and risk-related considerations in the NAAQS review should rely only on unadjusted air quality. In considering whether the current standard is requisite to protect public health with an adequate margin of safety, air quality adjustments allow estimates of NO_2-related exposures and health risks that could exist in areas that just meet that standard. That is, these adjustments allow consideration of exposures and risks that would be permissible under the current standard. Therefore, such adjustments are clearly useful to inform a decision on the issue before EPA (*i.e.*, the adequacy of the level of public health protection associated with allowable NO_2 air quality under the standard). Similarly, air quality adjustments to simulate different potential alternative standards provide information on exposures and risks that would be permissible under these alternatives.[10] As noted above, in their letter to the Administrator on the final REA (Samet, 2008b), CASAC concluded that "The REA provides the needed bridge from the evidence presented in the ISA to a characterization of the exposures and the associated risks with different profiles of exposure."

We agree that there are uncertainties inherent in air quality adjustments. These uncertainties are discussed thoroughly in the REA (sections 7.4, 8.12, 9.6, and 10.3.2.1) and in the proposed rule (section II.C.3). For example, the policy assessment chapter of the REA (section 10.3.2.1) noted the following regarding adjustment of NO_2 concentrations:

> In order to simulate just meeting the current annual standard and many of the alternative 1-h standards analyzed, an upward adjustment of recent ambient NO_2 concentrations was required. We note that this adjustment does not reflect a judgment that levels of NO_2 are likely to increase under the current standard or any of the potential alternative standards under consideration. Rather, these adjustments reflect the fact that the current standard, as well as some of the alternatives under consideration, could allow for such increases in ambient NO_2 concentrations. In adjusting air quality to simulate just meeting these standards, we have assumed that the overall shape of the distribution of NO_2 concentrations would not change. While we believe this is a reasonable assumption in the absence of evidence supporting a different distribution and we note that available analyses support this approach (Rizzo, 2008), we recognize this as an important uncertainty. It may be an especially important uncertainty for those scenarios where considerable upward adjustment is required to simulate just meeting one or more of the standards.

These air quality adjustments are not meant to imply an expectation that NO_2 concentrations will increase broadly across the United States or in any given area (REA, section 10.3.2.1). Rather, as noted above, they are meant to estimate NO_2-related exposures and health risks that would be permitted under the current and potential alternative standards. Such estimates can inform decisions on whether the current standard, or particular potential alternative standards, provide the requisite protection of public health.

3. Conclusions Regarding the Adequacy of the Current Standard

In considering the adequacy of the current standard, the Administrator has considered the scientific evidence assessed in the ISA, the exposure and risk results presented in the REA, the conclusions of the policy assessment chapter of the REA, and comments from CASAC and the public. These considerations are described below.

In considering the scientific evidence as it relates to the adequacy of the current standard, the Administrator notes that the epidemiologic evidence has grown substantially since the last review with the addition of field and panel studies, intervention studies, and time-series studies of effects such as emergency department visits and hospital admissions associated with

[10] Once EPA determines whether to retain or revise the current standard, the actual air quality levels in various areas of the country are clearly relevant under the NAAQS implementation provisions for the Act, such as the provision for designation of areas based on whether or not they attain the required NAAQS.

short-term NO_2 exposures. No epidemiologic studies were available in 1993 assessing relationships between NO_2 and outcomes such as hospital admissions or emergency department visits. 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).

As an initial consideration with regard to the adequacy of the current standard, the Administrator notes 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 conclusion was supported primarily by a large body of recent epidemiologic studies that evaluated associations of short-term NO_2 concentrations with respiratory symptoms, emergency department visits, and hospital admissions. Given these conclusions from the ISA, the Administrator judges 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.

In considering the NO_2 epidemiologic studies as they relate to the adequacy of the current standard, the Administrator notes 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 in the proposal (II.E.1) and above, the Administrator acknowledges that 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. She notes that, 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 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). Given the above consideration of the evidence, particularly the epidemiologic studies reporting NO_2-associated health effects in locations that meet the current standard, the Administrator agrees with the conclusion in the policy assessment chapter of the REA that the scientific evidence calls into question the adequacy of the current standard to protect public health.

In addition to the evidence-based considerations described above, the Administrator has considered the extent to which exposure- and risk-based information can inform decisions regarding the adequacy of the current annual NO_2 standard. While she acknowledges the uncertainties associated with adjusting air quality in these analyses, she judges that such analyses are appropriate for consideration in this review of the NO_2 primary NAAQS. In reaching this conclusion she notes the considerations discussed above, particularly the endorsement by CASAC of the REA and its characterization of NO_2-associated exposures and health risks.

In considering the exposure- and risk-based information with regard to the adequacy of the current annual NO_2 standard to protect the public health, the Administrator notes the conclusion in the policy assessment chapter of the REA that risks estimated to be 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 300 ppb, and most locations evaluated could experience on-/near-road NO_2 concentrations above 100 ppb on more than half of the days in a given year. Therefore, after considering the results of the exposure and risk analyses presented in the REA the Administrator agrees with the conclusion of the policy assessment chapter of the REA 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.

In reaching a conclusion on the adequacy of the current standard, the Administrator has also considered advice received from CASAC. In their comments on the final 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. 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).

Based on the considerations discussed above, the Administrator concludes that the current NO_2 primary NAAQS alone is not requisite to protect public health with an adequate margin of safety. Accordingly, she concludes that the NO_2 primary standard should be revised in order to provide increased public health protection against respiratory effects associated with short-term exposures, particularly for susceptible populations such as asthmatics, children, and older adults. In considering approaches to revising the current standard, the Administrator concludes that it is appropriate to consider setting a new short-term standard (*see* below). 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. Elements of a New Short-Term Standard

In considering a revised 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. The Administrator's considerations with regard to her decisions are discussed in the following sections in terms of indicator (II.F.1), averaging time (II.F.2), level (II.F.3), and form (II.F.4).

1. Indicator

a. Rationale for Proposed Decision

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 considered the conclusions of the ISA and the policy assessment chapter of the REA as well as the view expressed by CASAC. The policy assessment chapter of 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 assessed in the ISA 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 policy assessment chapter of the REA concluded that the evidence supports retaining NO_2 as the indicator. Consistent with this conclusion, the CASAC Panel stated 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 proposed to retain NO_2 as the indicator in the current review.

b. Comments on Indicator

A relatively small number of comments directly addressed the issue of the indicator for the standard (CASAC, Dow, API, AAM, and the Missouri Department of Natural Resources Air Pollution Control Program (MODNR)). All of these commenters endorsed the proposal to continue to use NO_2 as the indicator for ambient NO_X.

c. Conclusions on Indicator

Based on the available information discussed above, and consistent with the views of CASAC and other commenters, the Administrator concludes that it is appropriate to continue to use NO_2 as the indicator for a standard that is intended to address effects associated with exposure to NO_2, alone or in combination with other gaseous NO_X. In so doing, the Administrator recognizes that measures leading to reductions in population exposures to NO_2 will also reduce exposures to other nitrogen oxides.

2. Averaging Time

This section discusses considerations related to the averaging time of the NO_2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding averaging time (II.F.2.a; *see* section II.F.2 of the proposal for more detail), discusses comments related to averaging time (II.F.2.b), and presents the Administrator's final conclusions regarding averaging time (II.F.2.c).

a. Rationale for Proposed Decision

In considering the most appropriate averaging time for the NO_2 primary NAAQS, the Administrator noted in the proposal the conclusions and judgments made in the ISA about available scientific evidence, air quality correlations discussed in the REA, conclusions of the policy assessment chapter of the REA, and CASAC recommendations (section II.F.2 in the proposal). Specifically, she noted the following:

- Experimental studies in humans and animals have reported respiratory effects following NO_2 exposures lasting from less than 1-hour up to several hours. Epidemiologic studies have reported associations between respiratory effects and both 1 hour and 24-hour NO_2 concentrations. Therefore, the experimental evidence provides support for an averaging time of shorter duration than 24 hours (*e.g.*, 1 hour) 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 NO_2 concentrations.
- Air quality correlations presented in the policy assessment chapter of the REA illustrated the relatively high degree of variability in the ratios of annual average to short-term NO_2 concentrations (REA, Table 10–2). This

variability suggests 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 exposures.

- These air quality correlations (REA, Table 10–1) suggested 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 policy assessment chapter of the REA concluded that the scientific evidence, combined with the air quality correlations, 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.
- CASAC concurred "with having a short-term NAAQS primary standard for oxides of nitrogen and using the one-hour maximum NO_2 value" (Samet, 2008b).

Based on these considerations, the Administrator proposed to set a new standard based on 1-hour daily maximum NO_2 concentrations.

b. Comments on averaging time

As discussed above, CASAC endorsed the establishment of a new standard with a 1-hour averaging time. CASAC stated the following in their comments on the proposal (Samet, 2009):

> In reviewing the REA, CASAC supported a short-term standard for NO_2 and in reviewing the proposal, CASAC supports the proposed one-hour averaging time in EPA's proposed rule.

The supporting rationale offered by CASAC in support of a new 1-hour standard was generally the same as that put forward in the final REA and the proposal. Specifically, that rationale considered the available scientific evidence, which supports a link between 1-hour NO_2 concentrations and adverse respiratory effects, and air quality information presented in the REA, which suggests that a 1-hour standard can protect against effects linked to short-term NO_2 exposures while an annual standard would not be an effective or efficient approach to protecting against these effects.

A large number of public commenters also endorsed the establishment of a new standard with a 1-hour averaging time. These included a number of State agencies and organizations (*e.g.*, NACAA, NESCAUM and agencies in CA, IL, NM, TX, VA); environmental, medical, and public health organizations (*e.g.*, ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC); and most individual commenters. The supporting rationales offered by these commenters often acknowledged the recommendations of CASAC and the Administrator's rationale as discussed in the proposal.

Though many industry commenters recommended not revising the current annual standard (as discussed above in section II.E.2), several of these groups did conclude that if a short-term standard were to be set, a 1-hour averaging time would be appropriate (*e.g.*, Colorado Petroleum Association (CPA), Dow, NAM, Petroleum Association of Wyoming (PAW), Utah Petroleum Association (UPA)). As discussed above, industry commenters who disagreed with setting a new 1-hour standard generally based this conclusion on their interpretation of the scientific evidence and their conclusion that this evidence does not support the need to revise the current annual standard. These comments, and EPA's responses, are discussed in more detail above (section II.E) and in the Response to Comments document.

c. Conclusions on Averaging Time

In considering the most appropriate averaging time for the NO_2 primary NAAQS, the Administrator notes the available scientific evidence as assessed in the ISA, the air quality analyses presented in the REA, the conclusions of the policy assessment chapter of the REA, CASAC recommendations, and public comments received. These considerations are described below.

When considering averaging time, the Administrator notes that 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 Administrator concludes 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, the Administrator notes that 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, the Administrator notes that 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 [11]) 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 policy assessment chapter of 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 Administrator notes that the policy assessment chapter of the REA considered 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

[11] 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.

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. The Administrator concludes that, at a minimum, this suggests that a primary concern with regard to averaging time is the level of protection provided against 1-hour NO_2 concentrations. However, she also notes that it is important to consider the ability of a 1-hour averaging time to protect against 24-hour average NO_2 concentrations. To this end, the Administrator notes that 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.

Based on these considerations, the Administrator concludes that a standard with a 1-hour averaging time can effectively limit short-term (*i.e.*, 1- to 24-hours) exposures that have been linked to adverse respiratory effects. This conclusion is based on the observations summarized above and in more detail in the proposal, particularly that: (1) The 1-hour averaging time has been directly associated with respiratory effects in both epidemiologic and experimental studies and that (2) results from air quality analyses suggest that a 1-hour standard could also effectively control 24-hour NO_2 concentrations. In addition, the Administrator notes the support provided for a 1-hour averaging time in comments from CASAC, States, environmental groups, and medical/public health groups. The Administrator notes that arguments offered by some industry groups against setting a 1-hour NO_2 standard generally focus on commenters' conclusions regarding uncertainties in the scientific evidence. As discussed in more detail above (section II.E.2), the Administrator disagrees with the conclusions of these commenters regarding the appropriate interpretation of the scientific evidence and associated uncertainties. Given these considerations, the Administrator judges that it is appropriate to set a new NO_2 standard with a 1-hour averaging time.

3. Form

This section discusses considerations related to the form of the 1-hour NO_2 primary NAAQS. Specifically, this section summarizes the rationale for the Administrator's proposed decision regarding form (II.F.4.a; *see* section II.F.3 of the proposal for more detail), discusses comments related to form (II.F.4.b), and presents the Administrator's final conclusions regarding form (II.F.4.c).

a. Rationale For Proposed Decision

When considering alternative forms in the proposal, the Administrator noted the conclusions in the policy assessment chapter of the REA. Specifically, she noted the conclusion that the adequacy of the public health protection provided by the combination of standard level and form should be the foremost consideration. With regard to this, she noted that concentration-based forms can better reflect pollutant-associated health risks than forms based on expected exceedances. This is the case because concentration-based forms give proportionally greater weight to years when pollutant concentrations are well above the level of the standard than to years when the concentrations are just above the standard, while an expected exceedance form would give the same weight to years with concentrations that just exceed the standard as to years when concentrations greatly exceed the standard. The Administrator also recognized the conclusion in the policy assessment chapter of the REA that it is desirable from a public health perspective to have a form that is reasonably stable and insulated from the impacts of extreme meteorological events. With regard to this, she noted that a form that calls for averaging concentrations over three years would provide greater regulatory stability than a form based on a single year of concentrations. Therefore, consistent with recent reviews of the O_3 and PM NAAQS, the proposal focused on concentration-based forms averaged over 3 years, as evaluated in the REA.

In considering specific concentration-based forms, the REA focused on 98th and 99th percentile concentrations averaged over 3 years. This focus on the upper percentiles of the distribution is appropriate given the reliance, in part, on NO_2 health evidence from experimental studies, which provide information on specific exposure concentrations that are linked to specific health effects. 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 (REA, Table 10–4; *see* Thompson, 2008 for methods).

Consideration in the REA of an appropriate form for a 1-hour standard was based on analyses of standard levels that reflected the allowable area-wide NO_2 concentration, not the maximum allowable concentration. Therefore, in their review of the final REA, CASAC did not have the opportunity to comment on the appropriateness of specific forms in conjunction with a standard level that reflects the maximum allowable NO_2 concentration anywhere in an area. Given this, when considering alternative forms for the 1-hour standard in the proposal, the Administrator judged that it was appropriate to consider both forms evaluated in the REA (*i.e.*, 98th and 99th percentiles). Therefore, she proposed to adopt either a 99th percentile or a 4th highest form, averaged over 3 years, and she solicited comment on both 98th percentile and 7th or 8th highest forms.

b. CASAC and Public Comments on Form

In their letter to the Administrator, CASAC discussed the issue of form within the context of the proposed approach of setting a 1-hour standard level that reflects the maximum allowable NO_2 concentration anywhere in an area. CASAC recommended that, for such a standard, EPA adopt a form based on the 3-year average of the 98th percentile of the distribution of 1-hour daily maximum NO_2 concentrations. Specifically, they stated the following in their comments on the proposal (Samet, 2009):

> The 98th percentile is preferred by CASAC for the form, given the likely instability of measurements at the upper range and the absence of data from the proposed two-tier approach.

As indicated in their letter, CASAC concluded that the potential instability in higher percentile NO_2 concentrations near major roads argues for a 98th, rather than a 99th, percentile form. Several State organizations and agencies (*e.g.*, NESCAUM and agencies in IN, NC, SD, VA) and industry groups (*e.g.*, AAM, ACC, API, AirQuality Research and Logistics (AQRL), CPA, Dow, ExxonMobil, IPAMS, PAW, UPA) also recommended a 98th percentile form in order to provide regulatory stability. In contrast, a small number of State and local agencies (*e.g.*, in MO and TX), several environmental organizations (*e.g.*, EDF, EJ, GASP, NRDC), and medical/public health organizations (*e.g.*, ALA, ATS) recommended either a 99th percentile form or a more stringent form (*e.g.*, no exceedance) to further limit the occurrence of NO_2 concentrations that exceed the standard level in locations that attain the standard.

c. Conclusions On Form

The Administrator recognizes that there is not a clear health basis for selecting one specific form over another. She also recognizes that the analyses of different forms in the REA are most directly relevant to a standard that reflects NO_2 concentrations permitted to occur broadly across a community, rather than the maximum concentration that can occur anywhere in the area. In contrast, as discussed below (section II.F.4.c), the Administrator has judged it appropriate to set a new 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area. In light of this, the Administrator places particular emphasis on the comments received on form from CASAC relating to a 1-hour standard level that reflects the maximum allowable NO_2 concentration anywhere in an area. In particular, the Administrator notes that CASAC recommended a 98th percentile form averaged over 3 years for such a standard, given the potential for instability in the higher percentile concentrations around major roadways.

In considering this recommendation, the Administrator recognizes that the public health protection provided by the 1-hour NO_2 standard is based on the approach used to set the standard and the level of the standard (*see* below), in conjunction with the form of the standard. Given that the Administrator is setting a standard that reflects the maximum allowable NO_2 concentration anywhere in an area, rather than a standard that reflects the allowable area-wide NO_2 concentration, she agrees with CASAC that an appropriate consideration with regard to form is the extent to which specific statistics could be unstable at locations where maximum NO_2 concentrations are expected, such as near major roads. When considering alternative forms for the standard, the Administrator notes that an unstable form could result in areas shifting in and out of attainment, potentially disrupting ongoing air quality planning without achieving public health goals. Given the limited available information on the variability in peak NO_2 concentrations near important sources of NO_2 such as major roadways, and given the recommendation from CASAC that the potential for instability in the 99th percentile concentration is cause for supporting a 98th percentile form, the Administrator judges it appropriate to set the form based on the 3-year average of the 98th percentile of the annual distribution of 1-hour daily maximum NO_2 concentrations.

4. Level

As discussed below and in more detail in the proposal (section II.F.4), the Administrator has considered two different approaches to setting the 1-hour NO_2 primary NAAQS. In the proposal, each of these approaches was linked with a different range of standard levels. Specifically, the Administrator proposed to set a 1-hour standard reflecting the maximum allowable NO_2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. The Administrator also solicited comment on the alternative approach of setting a standard that reflects the allowable area-wide NO_2 concentration and setting the standard level from 50 to 75 ppb. This section summarizes the rationale for the Administrator's proposed approach and range of standard levels (II.F.3.a), describes the alternative approach and range of standard levels (II.F.3.b), discusses comments related to each approach and range of standard levels (II.F.3.c), and presents the Administrator's final conclusions regarding the approach and level (II.F.3.d).

a. Rationale For Proposed Decisions on Approach and Level

In assessing the most appropriate approach to setting the 1-hour standard and the most appropriate range of standard levels to propose, the Administrator considered the broad body of scientific evidence assessed in the ISA, including epidemiologic and controlled human exposure studies, as well as the results of exposure/risk analyses presented in the REA. In light of the body of available evidence and analyses, as described above, the Administrator concluded in the proposal that it is necessary to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term (*i.e.*, 30 minutes to 24 hours) exposures to NO_2. Such health effects have been associated with exposure to the distribution of short-term ambient NO_2 concentrations across an area, including higher short-term (*i.e.*, peak) exposure concentrations, such as those that can occur on or near major roadways and near other sources of NO_2, as well as the lower short-term exposure concentrations that can occur in areas not near major roadways or other sources of NO_2. The Administrator's proposed decisions on approach and level, as discussed in detail in the proposal (section II.F.4), are outlined below.

In considering a standard-setting approach, the Administrator was mindful in the proposal that the available evidence and analyses from the ISA and REA support the public health importance of roadway-associated NO_2 exposures. The exposure assessment described in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations (REA, Figures 8–17, 8–18). The ISA concluded (section 4.3.6) that NO_2 concentrations in heavy traffic or on freeways "can be twice the residential outdoor or residential/arterial road level." In considering the potential variability in the NO_2 concentration gradient, the proposal noted that available monitoring studies suggest that NO_2 concentrations could be 30 to 100% higher than those in the same area but away from the road.[12]

[12] In addition, the air quality analyses presented in the REA estimated that on-road NO_2 concentrations are about 80% higher on average than concentrations away from the road (REA, section 7.3.2) and that NO_2 monitors within 20 m

Continued

The Administrator also considered that millions of people in the United States live, work, and/or attend school near important sources of NO_2 such as major roadways (ISA, section 4.4), and that ambient NO_2 concentrations in these locations vary depending on the 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 that are higher than those occurring away from major roadways.

Given the above considerations, the Administrator proposed an approach to setting the 1-hour NO_2 primary NAAQS whereby the standard would reflect the maximum allowable NO_2 concentration anywhere in an area. In many locations, this concentration is likely to occur on or near a major roadway. EPA proposed to set the level of the standard such that, when available information regarding the concentration gradient around roads 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 concluded that this approach to setting the 1-hour NO_2 NAAQS would be expected to protect public health against exposure to the distribution of short-term NO_2 concentrations across an area and would provide a relatively high degree of confidence regarding the protection provided against peak exposures to higher NO_2 concentrations, such as those that can occur around major roadways. The remainder of this section discusses the proposed range of standard levels.

In considering the appropriate range of levels to propose for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area, the Administrator considered the broad body of scientific evidence and exposure/risk information as well as available information on the relationship between NO_2 concentrations near roads and those away from roads. Specifically, she considered the extent to which a variety of levels would be expected to protect at-risk individuals against increased airway responsiveness, respiratory symptoms, and respiratory-related emergency department visits and hospital admissions.

After considering the scientific evidence and the exposure/risk information (*see* sections II.B, II.C, and II.F.4.a.1 through II.F.4.a.3 in the proposal), as well as the available information on the NO_2 concentration gradient around roadways (section II.A.2 above and in the proposal), the Administrator concluded that the strongest support is for a standard level at or somewhat below 100 ppb. The Administrator's rationale in reaching this proposed conclusion is provided below.

The Administrator noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to limit short-term NO_2 exposures to concentrations that have been reported to increase airway responsiveness in asthmatics (*i.e.*, at or above 100 ppb). While she acknowledged that exposure to NO_2 concentrations below 100 ppb could potentially increase airway responsiveness in some asthmatics, the Administrator also noted uncertainties regarding the magnitude and the clinical significance of the NO_2-induced increase in airway responsiveness, as discussed in the policy assessment chapter of the REA (section 10.3.2.1, discussed in section II.F.4.e in the proposal). Given these uncertainties, the Administrator concluded in the proposal that controlled human exposure studies provide support for limiting exposures at or somewhat below 100 ppb NO_2.

The Administrator also noted that a standard level at or somewhat below 100 ppb in conjunction with the proposed approach would be expected to maintain peak area-wide NO_2 concentrations considerably below those measured in locations where key U.S. epidemiologic studies have reported associations with more serious respiratory effects, as indicated by increased emergency department visits and hospital admissions. Specifically, the Administrator noted that 5 key U.S. studies provide evidence for such associations in locations where the 99th percentile of the distribution of 1-hour daily maximum NO_2 concentrations measured at area-wide monitors ranged from 93 to 112 ppb (Ito *et al.*, 2007; Jaffe *et al.*, 2003; Peel *et al.*, 2005; Tolbert *et al.*, 2007; and a study by the New York State Department of Health, 2006).[13] The Administrator concluded that these studies provide support for a 1-hour standard that limits the 99th percentile of the distribution of 1-hour daily maximum area-wide NO_2 concentrations to below 90 ppb (corresponds to a 98th percentile concentration of 85 ppb), and that limiting area-wide concentrations to considerably below 90 ppb would be appropriate in order to provide an adequate margin of safety. The Administrator noted that, based on available information about the NO_2 concentration gradient around roads, a standard level at or somewhat below 100 ppb set in conjunction with the proposed approach would be expected to accomplish this. Specifically, she noted that given available information regarding NO_2 concentration gradients around roads (*see* section II.A.2), a standard level at or below 100 ppb (with either a 99th or 98th percentile form) would be expected to limit peak area-wide NO_2 concentrations to approximately 75 ppb or below.[14] Therefore, the Administrator concluded 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 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.

The Administrator also noted that a study by Delfino provides mixed evidence for effects in a location with area-wide 98th and 99th percentile 1-hour daily maximum NO_2 concentrations of 50 and 53 ppb, respectively. In that study, NO_2 effect estimates were positive, but some reported 95% confidence limits for the odds ratio (OR) that included values less than 1.00. Given the mixed results of the Delfino study, the Administrator concluded 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.

In addition to these evidence-based considerations, the Administrator noted that a standard level at or somewhat below 100 ppb under the proposed approach would be consistent with the

of roads measure NO_2 concentrations that are, on average across locations, 40% higher than concentrations measured by monitors at least 100 m from the road (REA, compare Tables 7–11 and 7–13).

[13] The 98th percentile concentrations in these study locations ranged from 85 to 94 ppb.

[14] For a standard of 100 ppb, area-wide concentrations would be expected to range from approximately 50 ppb (assuming near-road concentrations are 100% higher than area-wide concentrations) to 75 ppb (assuming near-road concentrations are 30% higher than area-wide concentrations).

results of the exposure and risk analyses presented in the REA. As discussed in section II.C of the proposal, the results of these analyses provide support for setting a standard that limits 1-hour area-wide NO_2 concentrations to between 50 and 100 ppb. As described above, a standard level of 100 ppb that reflects the maximum allowable NO_2 concentration would be expected to maintain area-wide NO_2 concentrations at or below approximately 75 ppb. Given all of these considerations, the Administrator concluded in the proposal that a standard level at or somewhat below 100 ppb (with a 99th percentile form), in conjunction with 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.

In addition to the considerations discussed above, which support setting a standard level at or somewhat below 100 ppb, the Administrator also considered the extent to which available evidence could support standard levels below 100 ppb. The Administrator concluded that the evidence could support setting the standard level below 100 ppb to the extent the following were emphasized:

- The possibility that an NO_2-induced increase in airway responsiveness could occur in asthmatics following exposures to concentrations below 100 ppb and/or the possibility that such an increase could be clinically significant.
- The mixed results reported in the study by Delfino *et al.* (2002) of an association between respiratory symptoms and the relatively low ambient NO_2 concentrations measured in the study area.

Specifically, she noted that a standard level of 80 ppb (99th percentile form), in conjunction with the proposed approach, could limit area-wide NO_2 concentrations to 50 ppb [15] and would be expected to limit exposure concentrations to below those that have been reported to increase airway responsiveness in asthmatics. For the reasons stated above, the Administrator proposed to set the level of a new 1-hour standard between 80 ppb and 100 ppb.

[15] This conclusion assumes that near-road NO_2 concentrations are 65% higher than area-wide concentrations, reflecting the mid-point in the range of 30 to 100%. Based on available information suggesting that near-road concentrations can be 30 to 100% higher than area-wide concentrations, a standard level of 80 ppb could limit area-wide concentrations to between 40 and 60 ppb.

b. Rationale for the Alternative Approach and Range of Levels

As described above, the Administrator proposed to set a 1-hour NO_2 NAAQS reflecting the maximum allowable NO_2 concentration anywhere in an area and to set the level of such a standard from 80 to 100 ppb. However, prior to the proposal, the approach of setting a 1-hour NO_2 NAAQS that reflects the maximum allowable NO_2 concentration anywhere in an area had not been discussed by EPA in the REA or considered by CASAC. Rather, the potential alternative standards discussed in the REA, and reviewed by CASAC, reflected allowable area-wide NO_2 concentrations (*i.e.*, concentrations that occur broadly across communities).

Given this, the Administrator noted in the proposal that comments received on the approach to setting the 1-hour standard (*i.e.*, from CASAC and from members of the public) could provide important new information for consideration. Therefore, the Administrator also solicited comment on the alternative approach of setting a 1-hour NO_2 primary NAAQS that would reflect the allowable area-wide NO_2 concentration, analogous to the standards evaluated in the REA, and with a level set within the range of 50 to 75 ppb. In discussing this alternative approach with a standard level from 50 to 75 ppb, the Administrator noted the following in the proposal:

- Such a standard 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.
- Standard levels from the lower end of the 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. Specifically, a standard level of 50 ppb under this approach could limit near-road concentrations to between approximately 65 and 100 ppb, depending on the relationship between near-road NO_2 concentrations and area-wide concentrations.
- This alternative approach would provide relatively more confidence regarding the degree to which a specific standard level would limit area-wide NO_2 concentrations and less confidence regarding the degree to which a specific standard level would limit the peak NO_2 concentrations likely to occur near major roadways.

c. Comments on Approach and Level

In the proposal, each approach to setting the 1-hour standard, and each range of standard levels, was linked to different requirements for the design of the NO_2 monitoring network. Specifically, in conjunction with the proposed approach (*i.e.*, standard reflects the maximum allowable NO_2 concentration anywhere in an area and the level is set within the range of 80 to 100 ppb), the Administrator proposed to establish a 2-tiered monitoring network that would include monitors sited to measure the maximum NO_2 concentrations anywhere in an area, including near major roadways, and monitors sited to measure maximum area-wide NO_2 concentrations. In conjunction with the alternative approach (*i.e.*, standard reflects the allowable area-wide NO_2 concentration and the level is set within the range of 50 to 75 ppb), the Administrator solicited comment on a monitoring network that would only include area-wide NO_2 monitors. Because of these linkages in the proposal, most commenters combined their comments on the approach to setting a 1-hour standard and on the standard level with their comments on the monitoring requirements. In this section, we discuss comments from CASAC and public commenters on the approach to setting a 1-hour standard and on the standard level. Comments on the monitoring network are also discussed in this section to the extent they indicate a preference for either the proposed or alternative approach to setting the 1-hour standard. More specific comments on monitor placement and network design are discussed below in section III.B.2 and in the Response to Comments document. EPA responses to technical comments on the scientific evidence and the exposure/response information are discussed above in section II.E.2 and in the Response to Comments document. The Administrator's response to commenters' views on the approach to setting the 1-hour standard and on the standard level is embodied in the discussed in section II.F.4.d.

i. CASAC Comments on the Approach to Setting the Standard

A majority of CASAC and CASAC Panel members [16] favored the proposed approach of setting a 1-hour standard that reflects the maximum allowable

[16] CASAC members were also part of the CASAC Panel for the NO_2 NAAQS review (i.e., the Oxides of Nitrogen Primary National Ambient Air Quality Standards Panel). Therefore, references to the CASAC Panel include both CASAC members and Panel members.

NO_2 concentration anywhere in an area and linking such a standard with a 2-tiered monitoring network that would include both near-road and area-wide monitors, though CASAC did not reach consensus on this approach. Specifically, in their letter to the Administrator (Samet, 2009), CASAC stated the following:

There was a split view on the two approaches among both CASAC and CASAC panel members with a majority of each favoring the Agency's proposed two-tiered monitoring network because they thought this approach would be more effective in limiting near-roadway exposures that may reach levels in the range at which some individuals with asthma may be adversely affected. Other members acknowledged the need for research and development of near-road monitoring data for criteria pollutants in general but favored retention of EPA's current area-wide monitoring for NO_2 regulatory purposes, due to the lack of epidemiological data based on near-roadway exposure measurements and issues related to implementing a near-road monitoring system for NO_2.

Thus, the recommendation of the majority of CASAC Panel members was based on their conclusion that the proposed approach would be more effective than the alternative at limiting near-roadway exposures to NO_2 concentrations that could adversely affect asthmatics. In addition, these CASAC Panel members noted important uncertainties with the alternative approach. Specifically, they stated the following (Samet, 2009):

Panel members also supported the proposed two-tiered approach because basing regulations on area-wide monitoring alone was problematic. Such an approach would require EPA to embed uncertainties and assumptions about the relationship between area-wide and road-side monitoring into the area-wide standard.

A minority of CASAC Panel members expressed support for the alternative approach of setting a 1-hour standard that reflects the allowable area-wide NO_2 concentration. These CASAC Panel members concluded that there would be important uncertainties associated with the proposed approach. Specifically, they noted that the key U.S. NO_2 epidemiologic studies relied upon area-wide NO_2 concentrations. In their view, the use of area-wide concentrations in these studies introduces uncertainty into the selection of a standard level for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area and that is linked with a requirement to place monitors near major roads. As a result of this uncertainty, CASAC Panel members who favored the alternative approach noted that "it would be better to set the standard on the same area-wide monitoring basis as employed in the epidemiologic studies upon which it [the standard] now relies" (Samet, 2009). These CASAC Panel members also strongly supported obtaining monitoring data near major roads, while recognizing uncertainties associated with identifying appropriate monitoring sites near roads (*see* section III.B.2 and the Response to Comments document for more discussion of CASAC's monitoring comments).

ii. Public Comments on the Approach to Setting the Standard

Consistent with the views expressed by the majority of CASAC members, a number of commenters concluded that the most appropriate approach would be to set a 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area and to couple that standard with a requirement that monitors be placed in locations where maximum concentrations are expected, including near major roads. This view was expressed by some State and local agencies (*e.g.*, in CA, IA, NY, TX, WA, WI), by a number of environmental organizations (*e.g.*, CAC, EDF, EJ, GASP, NRDC), by the ALA, and individual commenters. Several additional medical and public health organizations (ACCP, AMA, ATS, NADRC, NACPR) did not explicitly express a recommendation regarding the approach though these organizations did recommend that, in setting a 1-hour standard, particular attention should be paid to NO_X concentrations around major roadways. In support of their recommendation to adopt the proposed approach and to focus monitoring around major roads, these commenters generally concluded that a primary consideration should be the extent to which the NO_2 NAAQS protects at-risk populations that live and/or attend school near important sources of NO_2 such as major roads. As such, these comments supported the rationale in the proposal for setting a 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area.

A number of State commenters expressed the view that area-wide monitors should be used for attainment/non-attainment determinations (*e.g.*, NACAA, NESCAUM and agencies in IL, IN, MI, MS, NC, NM, SC). One State commenter (NESCAUM) agreed with EPA concerns about near-road exposures but concluded that it is premature to establish a large near-road monitoring network at this time due to uncertainty regarding the relationship between near-road and area-wide NO_2 concentrations and the variability in that relationship. NESCAUM recommended that EPA work with States to establish a targeted monitoring program in select urban areas to gather data that would inform future modifications to the monitoring network, but that "[t]he existing area-wide monitoring network should be used to identify initial nonattainment areas." Other State commenters also concluded that the most appropriate approach would be to base non-attainment determinations only on area-wide monitors. Based on their monitoring comments, many of these commenters appeared to support setting a 1-hour standard that reflects the allowable area-wide NO_2 concentration. State concerns with the proposed approach often included uncertainties associated with identifying and accessing appropriate monitor sites near major roads, as well as concerns related to implementation and cost to States (as discussed further in the Response to Comments document, the Administrator may not consider cost of implementation in decisions on a NAAQS).

One commenter (AAM) concluded that the focus of the proposed approach on NO_2 concentrations around major roadways is not justified because the REA and the proposal overstate the extent to which NO_2 concentrations near roads are higher than NO_2 concentrations farther away from the road. This conclusion is based on an analysis of 42 existing NO_2 monitors in 6 locations. Comparing NO_2 concentrations measured by these monitors, some of which are closer to roads and others of which are farther from roads, AAM concluded that "roadside monitors are not measuring high NO_2 concentrations."

We agree that there is uncertainty associated with estimates of roadway-associated NO_2 concentrations (*see* REA, sections 7.4.6 and 8.4.8.3 for detailed discussion of these uncertainties) and in identifying locations where maximum concentrations are expected to occur. However, we note that the Administrator's conclusions regarding the relationship between NO_2 concentrations near roads and those away from roads rely on multiple lines of scientific evidence and information. Specifically, the Administrator relied in the proposal on the following in drawing conclusions regarding the distribution of NO_2 concentrations across areas:

• Monitoring studies discussed in the ISA and REA that were designed to characterize the NO_2 concentration gradient around roads, which indicated that NO_2 concentrations near roads can be approximately 30 to 100% higher than concentrations away from the road in the same area.

- Air quality and exposure analyses presented in the REA which estimate that, on average across locations, NO_2 concentrations on roads could be 80% higher than those away from roads and that roadway-associated exposures account for the majority of exposures to NO_2 concentrations at or above 100 ppb.

In contrast, the existing NO_2 monitoring network, which was the basis for the analysis submitted by AAM, was not designed to characterize the spatial gradients in NO_2 concentrations surrounding roadways. Rather, concentrations of NO_2 measured by existing monitors are likely to reflect contributions from a combination of mobile and stationary sources, with one or the other dominating depending on the proximity of these sources to the monitors. Therefore, we conclude that the analysis submitted by AAM, which does not consider other relevant lines of evidence and information, does not appropriately characterize the relationship between NO_2 concentrations near roads and those away from roads. (*See* the Response to Comments document for a more detailed discussion of AAM comments.)

In addition, we note that, although the Administrator concluded in the proposal that maximum NO_2 concentrations in many areas are likely to occur around major roads, she also recognized that maximum concentrations can occur elsewhere in an area. For this reason, she proposed to set a 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area, regardless of where that maximum concentration occurs.[17] Therefore, the proposed approach to setting the standard would be expected to limit the maximum NO_2 concentrations anywhere in an area even if in some areas, as is contended by AAM, those maximum NO_2 concentrations do not occur near roads.

iii. CASAC Comments on Standard Level

In commenting on the proposal, CASAC discussed both the proposed range of standard levels (*i.e.*, 80–100 ppb) and the alternative range of standard levels (*i.e.*, 50–75 ppb). CASAC did express the consensus conclusion that if the Agency finalizes a 1-hour standard in accordance with the proposed approach (*i.e.*, standard level reflects the maximum allowable NO_2 concentration anywhere in an area), then it is appropriate to consider the proposed range of standard levels from 80 to 100 ppb. Specifically, the CASAC letter to the Administrator on the proposal (Samet, 2009) stated the following with regard to the proposed approach:

> [T]he level of the one-hour NO_2 standard should be within the range of 80–100 ppb and not above 100 ppb. In its letter of December 2, 2008, CASAC strongly voiced a consensus view that the upper end of the range should not exceed 100 ppb, based on evidence of risk at that concentration. The lower limit of 80 ppb was viewed as reasonable by CASAC; selection of a value lower than 80 ppb would represent a policy judgment based on uncertainty and the degree of public health protection sought, given the limited health-based evidence at concentrations below 100 ppb.

CASAC also recommended that this level be employed with a 98th percentile form, in order to promote the stability of the standard (*see* above for discussion of form).

iv. Public Comments on Standard Level

A number of State and local agencies and organizations expressed support for setting the level of the 1-hour NO_2 standard within the proposed range of 80 to 100 ppb. While some State and local agencies (*e.g.*, in CA, IA, MI, NY, TX) made this recommendation in conjunction with a recommendation to focus monitoring near major roads and other important sources of NO_2, a number of State commenters (*e.g.*, NACAA, NESCAUM and agencies in IL, NC, NM, TX, VA) recommended a standard level from 80 to 100 ppb in conjunction with a recommendation that only area-wide monitors be deployed for purposes of determining attainment with the standard. Based on these monitoring comments, these State commenters appear to favor an approach where a standard level from 80 to 100 ppb would reflect the allowable area-wide NO_2 concentration. As discussed above (and in more detail in section III.B.2 and the Response to Comments document), State commenters often based these recommendations on uncertainties associated with designing an appropriate national near-road monitoring network.

A number of environmental organizations (*e.g.*, CAC, EDF, EJ, GASP, NRDC) and medical/public health organizations (*e.g.*, ACCP, ALA, AMA, ATS, NACPR, NAMDRC) supported setting a standard level below 80 ppb for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area. Several of these groups recommended a standard level of 50 ppb. This recommendation was typically based on the commenters' interpretation of the epidemiologic and controlled human exposure evidence, as described below.

Some of these commenters noted that the 98th percentile area-wide NO_2 concentration was below 80 ppb in the location of a single key U.S. epidemiologic study (*i.e.*, 50 ppb in study by Delfino). Given this, commenters concluded that the standard level should be set at 50 ppb. Their comments on the monitoring network generally favored a requirement to place monitors near major roads and, therefore, these commenters appeared to favor a standard level as low as 50 ppb and to recommend that such a standard level reflect the maximum allowable NO_2 concentration anywhere in an area. In their comments, the ALA, EDF, EJ, and NRDC stated the following:

> Considering the Delfino study alone on EPA's terms, that is, focusing on the 98th percentile of the 1-hour daily maximum concentrations, EPA reports a concentration of 50 ppb where asthma symptoms were observed. Based primarily on this study, EPA concluded in the REA that it was appropriate to set the lower end of the range at 50 ppb, which corresponded to the lowest-observed effects level of airway hyperresponsiveness in asthmatics. To provide the strongest public health protection, we therefore urge the level of the standard be set at 50 ppb.

In some cases, the same commenters also appeared to recommend setting a standard level below 50 ppb because mean area-wide NO_2 concentrations reported in locations of key U.S. epidemiologic studies are below this concentration. Specifically, with regard to the key U.S. epidemiologic studies, these commenters (*e.g.*, ALA, EDF, EJ, NRDC) stated the following:

> These studies clearly identify adverse health effects such as emergency room visits and hospital admissions for respiratory causes at concentrations currently occurring in the United States. Mean concentrations for all but two of these studies are about or below 50 ppb, suggesting that the standard must be set below this level to allow for a margin of safety.

The Administrator's consideration of the Delfino study as it relates to a decision on standard level is discussed below (section II.F.4.d). Regarding the recommendation to set the level below 50 ppb based on mean area-wide NO_2 concentrations in epidemiologic study

[17] To measure maximum concentrations, the Administrator proposed monitoring provisions that would require monitors within 50 meters of major roads and to allow the Regional Administrator to require additional monitors in situations where maximum concentrations would be expected to occur in locations other than near major roads (*e.g.*, due to the influence of multiple smaller roads and/or stationary sources).

locations, we note that the Administrator proposed to set a standard that reflects the maximum allowable NO_2 concentration anywhere in an area and to set the form of that standard at the upper end of the distribution of 1-hour daily maximum NO_2 concentrations.[18] As described in the proposal, such a standard, with a level from the proposed range of 80 to 100 ppb, would be expected to maintain peak area-wide NO_2 concentrations below the peak area-wide concentrations measured in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Because reducing NO_X emissions to meet a 98th percentile NO_2 standard should lower the distribution of NO_2 concentrations, including the mean, a standard that limits the 98th percentile of the distribution of 1-hour daily maximum concentrations would also be expected to limit mean concentrations. Therefore, although we acknowledge that the relationship between peak and mean NO_2 concentrations will likely vary across locations and over time, if peak area-wide NO_2 concentrations are maintained below those in key epidemiologic study locations, mean area-wide NO_2 concentrations would also be expected to be maintained below the mean area-wide concentrations in those locations (*see* ISA, figure 2.4–13 for information on the relationship between peak and mean NO_2 concentrations).

As discussed above (section, II.E.2), a number of industry groups did not support setting a new 1-hour NO_2 standard. However, several of these groups (*e.g.*, AAM, Dow, NAM, NPRA) also concluded that, if EPA does choose to set a new 1-hour standard, the level of that standard should be above 100 ppb. As a basis for this recommendation, these groups emphasized uncertainties in the scientific evidence. Specifically, as discussed in more detail above (section II.E.2), these commenters typically concluded that available epidemiologic studies do not support the conclusion that NO_2 causes reported health effects. This was based on their assertion that the presence of co-pollutants in the ambient air precludes the identification of a specific NO_2 contribution to reported effects. As a result, these commenters recommended that a 1-hour standard should be based on the controlled human exposure evidence and that, in considering that evidence, EPA should rely on the meta-analysis of NO_2 airway responsiveness studies conducted by Goodman *et al.*, (2009) rather than the meta-analysis included in the final ISA. As described above, they concluded that in relying on the ISA meta-analysis, EPA has inappropriately relied on a new unpublished meta-analysis that has not been peer-reviewed, was not reviewed by CASAC, and was not conducted in a transparent manner. EPA recognizes the uncertainties in the scientific evidence that are discussed by these industry commenters; however, we strongly disagree with their conclusions regarding the implications of these uncertainties for decisions on the NO_2 NAAQS. These comments, and EPA's responses, are discussed in detail above (section II.E.2) and in the Response to Comments document and are summarized briefly below.

As noted in section II.E.2, we agree that the presence of co-pollutants in the ambient air complicates the interpretation of epidemiologic studies; however, our conclusions regarding causality are based on consideration of the broad body of epidemiologic studies (including those employing multi-pollutant models) as well as animal toxicological and controlled human exposure studies. The ISA concluded that this body of evidence "supports a direct effect of short-term NO_2 exposure on respiratory morbidity at ambient concentrations below the current NAAQS level" (ISA, p. 5–16). In addition, the ISA (p. 5–15) concluded the following:

> [T]he strongest evidence for an association between NO_2 exposure and adverse human health effects comes from epidemiologic studies of respiratory symptoms and ED visits and hospital admissions. These new findings were based on numerous studies, including panel and field studies, multipollutant studies that control for the effects of other pollutants, and studies conducted in areas where the whole distribution of ambient 24-h avg NO_2 concentrations was below the current NAAQS level of 0.053 ppm (53 ppb) (annual average).

Given that epidemiologic studies provide the strongest support for an association between NO_2 and respiratory morbidity, and that a number of these studies controlled for the presence of other pollutants with multi-pollutant models (in which NO_2 effect estimates remained robust), we disagree that NO_2 epidemiologic studies should not be used to inform a decision on the level of the 1-hour NO_2 standard.

In addition, we agree that uncertainty exists regarding the extent to which the NO_2-induced increase in airway responsiveness is adverse (REA, section 10.3.2.1); however, as discussed in detail above (section II.E.2), we disagree with the conclusion by many industry commenters that this effect is not adverse in asthmatics following exposures from 100 to 600 ppb NO_2. Specifically, we do not agree that the approach taken in the study by Goodman *et al.* (2009), which was used by many industry commenters to support their conclusions, was appropriate. The authors of the Goodman study used data from existing NO_2 studies to characterize the dose-response relationship of NO_2 and airway responsiveness and to calculate the magnitude of the NO_2 effect. Given the protocol differences in existing studies of NO_2 and airway responsiveness, we do not agree that it is appropriate to base such an analysis on these studies.

The Administrator's consideration of these uncertainties, within the context of setting a standard level, is discussed in the next section.

d. Conclusions on Approach and Standard Level

Having carefully considered the public comments on the appropriate approach and level for a 1-hour NO_2 standard, as discussed above, the Administrator believes the fundamental conclusions reached in the ISA and REA remain valid. In considering the approach, the Administrator continues to place primary emphasis on the conclusions of the ISA and the analyses of the REA, both of which focus attention on the importance of roadways in contributing to peak NO_2 exposures, given that roadway-associated exposures can dominate personal exposures to NO_2. In considering the level at which the 1-hour primary NO_2 standard should be set, the Administrator continues to place primary emphasis on the body of scientific evidence assessed in the ISA, as summarized above in section II.B, while viewing the results of exposure and risk analyses, discussed above in section II.C, as providing information in support of her decision.

With regard to her decision on the approach to setting the 1-hour standard, the Administrator continues to judge it appropriate to provide increased public health protection for at-risk individuals against an array of adverse respiratory health effects linked with short-term exposures to NO_2, where such health effects have been associated with exposure to the distribution of short-term ambient NO_2 concentrations across

[18] As discussed above, the Administrator has selected the 98th percentile as the form for the new 1-hour NO_2 standard.

an area. In protecting public health against exposure to the distribution of short-term NO_2 concentrations across an area, the Administrator is placing emphasis on providing a relatively high degree of confidence regarding the protection provided against exposures to peak concentrations of NO_2, such as those that can occur around major roadways. Available evidence and information suggest that roadways account for the majority of exposures to peak NO_2 concentrations and, therefore, are important contributors to NO_2-associated public health risks. In reaching this conclusion, the Administrator notes the following:

- Mobile sources account for the majority of NO_X emissions (ISA, Table 2.2–1).
- The ISA stated that NO_2 concentrations in heavy traffic or on freeways "can be twice the residential outdoor or residential/arterial road level," that "exposure in traffic can dominate personal exposure to NO_2," and that "NO_2 levels are strongly associated with distance from major roads (*i.e.*, the closer to a major road, the higher the NO_2 concentration)" (ISA, sections 2.5.4, 4.3.6).
- The exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations (REA, Figures 8–17, 8–18).
- Monitoring studies suggest that NO_2 concentrations near roads can be considerably higher than those in the same area but away from roads (*e.g.*, by 30–100%, *see* section II.A.2).
- In their comments on the approach to setting the 1-hour NO_2 standard, the majority of CASAC Panel members emphasized the importance of setting a standard that limits roadway-associated exposures to NO_2 concentrations that could adversely affect asthmatics. These CASAC Panel members favored the proposed approach, including its focus on roads.

In addition, the Administrator notes that a considerable fraction of the population resides, works, or attends school near major roadways or other sources of NO_2 and that these populations 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).[19] 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 (ISA, section 4.4). Of this population, which likely includes a disproportionate number of individuals in groups with a 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), asthmatics and members of other susceptible groups (*e.g.*, children, elderly) will have the greatest 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).

In considering the approach to setting the 1-hour standard, the Administrator also notes that concerns with the proposed approach expressed by the minority of CASAC Panel members included concern with the uncertainty in the relationship between near-road and area-wide NO_2 concentrations, given that U.S. epidemiologic studies have been based on concentrations measured at area-wide monitors. However, as discussed by the majority of CASAC Panel members, a similar uncertainty would be involved in setting a standard with the alternative approach (Samet, 2009). The Administrator agrees with the majority of CASAC Panel members and concludes that uncertainty in the relationship between near-road and area-wide NO_2 concentrations should be considered regardless of the approach selected to set the standard. She recognizes that this uncertainty can and should be taken into consideration when considering the level of the standard.

In drawing conclusions on the approach, the Administrator has considered the extent to which each approach, in conjunction with the ranges of standard levels discussed in the proposal, would be expected to limit the distribution of NO_2 concentrations across an area and, therefore, would be expected to protect against risks associated with NO_2 exposures. Specifically, she has considered the extent to which a standard set with each approach would be expected to limit maximum NO_2 concentrations and area-wide NO_2 concentrations.

With regard to expected maximum concentrations, the Administrator notes the following:

- A standard reflecting the maximum allowable NO_2 concentration anywhere in an area would provide a relatively high degree of confidence regarding the level of protection provided against peak exposures, such as those that can occur on or near major roadways. A standard level from anywhere within the proposed range (*i.e.*, 80 to 100 ppb) would be expected to limit exposures to NO_2 concentrations reported to increase airway responsiveness in asthmatics.
- A standard reflecting the allowable area-wide NO_2 concentration would not provide a high degree of confidence regarding the extent to which maximum NO_2 concentrations would be limited. Maximum NO_2 concentrations would be expected to be controlled to varying degrees across locations and over time depending on the NO_2 concentration gradient around roads. Given the expected variability in gradients across locations and over time, most standard levels within the range considered in the proposal with this option (*i.e.*, 50 to 75 ppb) would not be expected to consistently limit the occurrence of NO_2 concentrations that have been reported to increase airway responsiveness in asthmatics.

With regard to expected area-wide concentrations, the Administrator notes the following:

- The extent to which a standard reflecting the maximum allowable NO_2 concentration anywhere in an area would be expected to limit area-wide NO_2 concentrations would vary across locations, *e.g.*, depending on the NO_2 concentration gradient around roads. However, in conjunction with a standard level from anywhere within the proposed range (*i.e.*, 80–100 ppb), such an approach would be expected to maintain area-wide NO_2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO_2 and respiratory-related hospital admissions and emergency department visits (based on available information regarding the NO_2 concentration gradient around roads as discussed below).
- A standard reflecting the maximum allowable area-wide NO_2 concentration would provide a relatively high degree of certainty regarding the extent to which area-wide NO_2 concentrations are limited. In conjunction with a standard level from anywhere within the range of

[19] 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. According to Table 1A–6 from that report (*http://www.census.gov/hhes/www/housing/ahs/ahs07/tab1a-6.pdf*), out of 128.2 million total housing units in the United States, about 20 million 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 15.6% of the total housing units in the U.S. Assuming equal distributions, with a current population of 306.3 million, that means that there would be 47.8 million people meeting the 300 foot criteria.

levels discussed in the proposal (*i.e.*, 50–75 ppb) with this alternative approach, such a standard would be expected to maintain area-wide NO_2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO_2 and respiratory-related hospital admissions and emergency department visits.

Given the above considerations, the Administrator concludes that both approaches, in conjunction with appropriate standard levels, would be expected to maintain area-wide NO_2 concentrations below those measured in locations where key U.S. epidemiologic studies have reported associations between ambient NO_2 and respiratory-related hospital admissions and emergency department visits. In contrast, the Administrator concludes that only a standard reflecting the maximum allowable NO_2 concentration anywhere in an area, in conjunction with an appropriate standard level, would be expected to consistently limit exposures, across locations and over time, to NO_2 concentrations reported to increase airway responsiveness in asthmatics. After considering the evidence and uncertainties, and the advice of the CASAC Panel, the Administrator judges that the most appropriate approach to setting a 1-hour standard to protect against the distribution of short-term NO_2 concentrations across an area, including the higher concentrations that can occur around roads and result in elevated exposure concentrations, is to set a standard that reflects the maximum allowable NO_2 concentration anywhere in an area.

In considering the level of a 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area, the Administrator notes that there is no bright line clearly directing the choice of level. Rather, the choice of what is appropriate is a public health policy judgment entrusted to the Administrator. This judgment must include consideration of the strengths and limitations of the evidence and the appropriate inferences to be drawn from the evidence and the exposure and risk assessments. Specifically, the Administrator notes the following:

- Controlled human exposure studies have reported that various NO_2 exposure concentrations increased airway responsiveness in mostly mild asthmatics (section II above and II.B.1.d in proposal). 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. Because concentrations evaluated in controlled human exposure studies are at the high end of the distribution of ambient NO_2 concentrations (ISA, section 5.3.2.1), these studies most directly inform consideration of the risks associated with exposure to peak short-term NO_2 concentrations.
- Epidemiologic studies (section II.B.1.a and b) conducted in the United States 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 are not sited in locations where localized peak concentrations are likely to occur. Thus, they do not measure the full range of ambient NO_2 concentrations across the area. Rather, the area-wide NO_2 concentrations measured by these monitors are used as surrogates for the distribution of ambient NO_2 concentrations across the area, a distribution that includes NO_2 concentrations both higher than (*e.g.*, around major roadways) and lower than the area-wide concentrations measured in study locations. Epidemiologic studies evaluate whether area-wide NO_2 concentrations are associated with the risk of respiratory morbidity. Available information on NO_2 concentration gradients around roadways can inform estimates of the relationship between the area-wide NO_2 concentrations measured in epidemiologic study locations and the higher NO_2 concentrations likely to have occurred around roads in those locations, which can then inform the decision on the level of a standard reflecting the maximum allowable NO_2 concentration anywhere in an area.
- The risk and exposure analyses presented in the REA provide information on the potential public health implications of setting standards that limit area-wide NO_2 concentrations to specific levels. While 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, she judges that these analyses are informative for considering the relative levels of public health protection that could be provided by different standards.

The Administrator's consideration of the controlled human exposure evidence, epidemiologic evidence, and exposure/risk information are discussed below specifically with regard to a decision on the level of a standard that reflects the maximum allowable NO_2 concentration anywhere in an area.

In considering the potential for controlled human exposure studies of NO_2 and airway responsiveness to inform a decision on standard level, the Administrator notes the following:

- NO_2-induced increases in airway responsiveness, as reported in controlled human exposure studies, are logically linked to the adverse respiratory effects that have been reported in NO_2 epidemiologic studies.
- The meta-analysis of controlled human exposure data in the ISA reported increased airway responsiveness in a large percentage of asthmatics at rest following exposures 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. Therefore, it is possible that exposure to NO_2 concentrations below 100 ppb could increase airway responsiveness in some asthmatics.

In considering the evidence, the Administrator recognizes that the NO_2-induced increases in airway responsiveness reported for exposures to NO_2 concentrations at or above 100 ppb could be adverse for some asthmatics. However, she also notes that important uncertainties exist with regard to the extent to which NO_2-induced increases in airway responsiveness are adverse. Specifically, she notes the following with regard to these uncertainties:

- The magnitude of the NO_2-induced increase in airway responsiveness, and the extent to which it is adverse, cannot be quantified from the ISA meta-analysis (REA, section 10.3.2.1).
- The NO_2-induced increase in airway responsiveness in resting asthmatics was typically not accompanied by increased respiratory symptoms, even following exposures to NO_2 concentrations well above 100 ppb (ISA, section 3.1.3.3).
- The increase in airway responsiveness that was reported for resting asthmatics was not present in exercising asthmatics (ISA, Table 3.1–3).

Taking into consideration all of the above, the Administrator concludes that existing evidence supports the conclusion that the NO_2-induced increase in airway responsiveness at or above 100 ppb presents a risk of adverse effects for some asthmatics, especially those with more serious (*i.e.*, more than mild) asthma. The Administrator notes that the risks associated with increased airway responsiveness cannot be fully characterized by these studies, and thus she is not able to determine whether the increased airway responsiveness experienced by asthmatics in these studies is an adverse health effect. However, based on these studies the Administrator concludes that asthmatics, particularly those suffering from more severe asthma, warrant protection from the risk of adverse effects associated with the NO_2-induced increase in airway responsiveness. Therefore, the Administrator concludes that the controlled human exposure evidence supports setting a standard level no higher than 100 ppb to reflect a cautious approach to the uncertainty regarding the adversity of the effect. However, those uncertainties lead her to also conclude that this evidence does not support setting a standard level lower than 100 ppb.

In considering the more serious health effects reported in NO_2 epidemiologic studies, as they relate to the level of a standard that reflects the maximum allowable NO_2 concentration anywhere in an area, the Administrator notes the following:

• A cluster of 5 key U.S. epidemiologic studies (Ito *et al.*, 2007; Jaffe *et al.*, 2003; Peel *et al.*, 2005; Tolbert *et al.*, 2007; and a study by the New York State Department of Health, 2006) provide evidence for associations between NO_2 and respiratory-related emergency department visits and hospital admissions in locations where 98th percentile 1-hour daily maximum NO_2 concentrations measured at area-wide monitors ranged from 85 to 94 ppb. The Administrator judges it appropriate to place substantial weight on this cluster of key U.S. epidemiologic studies in selecting a standard level, as they are a group of studies that reported positive, and often statistically significant, associations between NO_2 and respiratory morbidity in multiple cities across the United States.[20]

• A single study (Delfino *et al.*, 2002) provides mixed evidence for NO_2 effects (*i.e.*, respiratory symptoms) in a location with a 98th percentile 1-hour daily maximum NO_2 concentration, as measured by an area-wide monitor, of 50 ppb. In that study, most of the reported NO_2 effect estimates were positive, but not statistically significant. Given the variability in the NO_2 effect estimates in this study, as well as the lack of studies in other locations with similarly low NO_2 concentrations, the Administrator judges it appropriate to place limited weight on this study, compared to the cluster of 5 studies as noted above.

Given these considerations, the Administrator concludes that the epidemiologic evidence provides strong support for setting a standard that limits the 98th percentile of the distribution of 1-hour daily maximum area-wide NO_2 concentrations to below 85 ppb. 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 the types of respiratory morbidity effects reported in these studies. Given the considerations discussed above, the Administrator judges that it is not necessary, based on existing evidence, to set a standard that maintains peak area-wide NO_2 concentrations to below 50 ppb.

In considering specific standard levels supported by the epidemiologic evidence, the Administrator notes that a level of 100 ppb, for a standard reflecting the maximum allowable NO_2 concentration anywhere in the area, would be expected to maintain area-wide NO_2 concentrations well below 85 ppb, which is the lowest 98th percentile concentration in the cluster of 5 studies. With regard to this, she specifically notes the following:

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

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

The Administrator has also considered the NO_2 exposure and risk information within the context of the above conclusions on standard level. Specifically, she notes that the results of exposure and risk analyses were interpreted as providing support for limiting area-wide NO_2 concentrations to no higher than 100 ppb. Specifically, these analyses estimated that a standard that limits area-wide NO_2 concentrations to approximately 100 ppb or below would be expected to result in important reductions in respiratory risks, relative to the level of risk permitted by the current annual standard alone. As discussed above, a standard reflecting the maximum allowable NO_2 concentration with a level of 100 ppb would be expected to maintain area-wide NO_2 concentrations to within a range of approximately 50 to 75 ppb. Given this, the Administrator concludes that a standard level of 100 ppb is consistent with conclusions based on the NO_2 exposure and risk information.

Finally, the Administrator notes that a standard level of 100 ppb is consistent with the consensus recommendation of CASAC.

Given the above considerations and the comments received on the proposal, the Administrator determines that the appropriate judgment, based on the entire body of evidence and information available in this review, and the related uncertainties, is a standard level of 100 ppb (for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area). She concludes that such a standard, with the averaging time and form discussed above, will provide a significant increase in public health protection compared to that provided by the current annual standard alone and would be expected to protect against the respiratory effects that have been linked with NO_2 exposures in both controlled human exposure and epidemiologic studies. Specifically, she concludes that such a standard will limit exposures at and above 100 ppb for the vast majority of people, including those in at-risk groups, and will maintain maximum area-wide NO_2 concentrations well below those in locations where key U.S. epidemiologic studies have reported that ambient NO_2 is associated with clearly adverse respiratory health effects, as indicated by increased hospital admissions and emergency department visits.

In setting the standard level at 100 ppb rather than a lower level, the Administrator notes that a 1-hour standard with a level lower than 100 ppb would only result in significant further public health protection if, in fact, there is a continuum of serious, adverse health risks caused by exposure to NO_2 concentrations below 100 ppb and/or associated with area-wide NO_2 concentrations well-below those in locations where key U.S. epidemiologic studies have reported associations with respiratory-related emergency department visits and hospital admissions. Based on the available evidence, the Administrator does not believe that such assumptions are warranted. Taking into account the uncertainties that remain in interpreting the evidence from available controlled human exposure and epidemiologic studies, the Administrator notes that the likelihood of obtaining benefits to public health with a standard set below

[20] Some of these studies also included susceptible and vulnerable populations (*e.g.*, children in Peel *et al.* (2005); poor and minority populations in Ito *et al.*, 2007).

100 ppb decreases, while the likelihood of requiring reductions in ambient concentrations that go beyond those that are needed to protect public health increases.

Therefore, the Administrator judges that a standard reflecting the maximum allowable NO_2 concentration anywhere in an area set at 100 ppb is sufficient to protect public health with an adequate margin of safety, including the health of at-risk populations, from adverse respiratory effects that have been linked to short-term exposures to NO_2 and for which the evidence supports a likely causal relationship with NO_2 exposures. The Administrator does not believe that a lower standard level is needed to provide this degree of protection. These conclusions by the Administrator appropriately consider the requirement for a standard that is neither more nor less stringent than necessary for this purpose and recognizes that the CAA does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that reduces risk sufficiently so as to protect the public health with an adequate margin of safety.

G. Annual Standard

In the proposal, the Administrator noted that some evidence supports a link between long-term exposures to NO_2 and adverse respiratory effects and that CASAC recommended in their comments prior to the proposal that, in addition to setting a new 1-hour standard to increase public health protection, the current annual standard be retained. CASAC's recommendation was based on the scientific evidence and on their conclusion that a 1-hour standard might not provide adequate protection against exposure to long-term NO_2 concentrations (Samet, 2008b).

With regard to an annual standard, CASAC and a large number of public commenters (*e.g.*, NACAA, NESCAUM; agencies from States including CA, IN, MO, NC, NY, SC, TX, VA; Tribal organizations including Fon du Lac and the National Tribal Air Organization; environmental/medical/public health groups including ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC) agreed with the proposed decision to maintain an annual standard, though their recommendations with regard to the level of that annual standard differed (*see* below).

As noted above, CASAC recommended "retaining the current standard based on the annual average" based on the "limited evidence related to potential long-term effects of NO_2 exposure and the lack of strong evidence of no effect" and 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). A number of State agencies and organizations also recommended maintaining the current level of the annual standard (*i.e.*, 53 ppb). This recommendation was based on the conclusion that, while some evidence supports a link between long-term NO_2 exposures and adverse respiratory effects, that evidence is not sufficient to support a standard level either higher or lower than the current level. In addition, a number of industry groups (*e.g.*, AAM, API, Dow, INGAA, UARG) recommended retaining the level of the current annual standard but, as described above, did so within the context of a recommendation that EPA should not set a new 1-hour standard.

In contrast, some environmental organizations and medical/public health organizations as well as a small number of States (*e.g.*, ALA, EDF, EJ, NRDC, and organizations in CA) recommended setting a lower level for the annual standard. These commenters generally supported their recommendation by pointing to the State of California's annual standard of 30 ppb and to studies where long-term ambient NO_2 concentrations have been associated with adverse respiratory effects such as impairments in lung function growth.

As discussed above (II.B.3), the evidence relating long-term NO_2 exposures 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 the case of respiratory morbidity, the ISA (section 5.3.2.4) concluded that "The high correlation among traffic-related pollutants made it difficult to accurately estimate the independent effects in these long-term exposure studies." Given these uncertainties associated with the role of long-term NO_2 exposures in causing the reported effects, the Administrator concluded in the proposal that, consistent with the CASAC recommendation, existing evidence is not sufficient to justify setting an annual standard with either a higher or lower level than the current standard. Commenters have not submitted any new analyses or information that would change this conclusion. Therefore, the Administrator does not agree with the commenters who recommended a lower level for the annual standard.

The Administrator judges that her conclusions in the proposal regarding the annual standard remain appropriate. Specifically, she continues to agree with the conclusion that, though some evidence does support the need to limit long-term exposures to NO_2, the existing evidence for adverse health effects following long-term NO_2 exposures does not support either increasing or decreasing the level of the annual standard. In light of this and considering the recommendation from CASAC to retain the current level of the annual standard, the Administrator judges it appropriate to maintain the level of the annual standard at 53 ppb.

H. Summary of Final Decisions on the Primary NO_2 Standard

For the reasons discussed above, and taking into account information and assessments presented in the ISA and REA, the advice and recommendations of the CASAC, and public comments, the Administrator has decided to revise the existing primary NO_2 standard. Specifically, the Administrator has determined that the current annual standard by itself is not requisite to protect public health with an adequate margin of safety. In order to provide protection for asthmatics and other at-risk populations against an array of adverse respiratory health effects related to short-term NO_2 exposure, the Administrator is establishing a short-term NO_2 standard defined by the 3-year average of the 98th percentile of the yearly distribution of 1-hour daily maximum NO_2 concentrations. She is setting the level of this standard at 100 ppb, which is to reflect the maximum allowable NO_2 concentration anywhere in an area. In addition to setting a new 1-hour standard, the Administrator retains the current annual standard with a level of 53 ppb. The new 1-hour standard, in combination with the annual standard, will provide protection for susceptible groups against adverse respiratory health effects associated with short-term exposures to NO_2 and effects potentially associated with long-term exposures to NO_2.

III. Amendments to Ambient Monitoring and Reporting Requirements

The EPA is finalizing several changes to the ambient air monitoring, reporting, and network design requirements for the NO_2 NAAQS. This section discusses the changes we are finalizing which are intended to support the proposed 1-

hour NAAQS and retention of the current annual NAAQS as discussed 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

We are finalizing the proposed changes regarding the NO_2 Federal Reference Method (FRM) or Federal Equivalent Method (FEM) analyzers. Specifically, we are continuing to use the NO_2 chemiluminescence FRM and are finalizing the requirement that any NO_2 FRM or FEM used for making primary NAAQS decisions must be capable of providing hourly averaged concentration data. The following paragraphs provide background and rationale for the continued use of the chemiluminescence FRM and the decision to finalize the proposed changes.

1. Chemiluminescence FRM and Alternative Methods

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. EPA did not propose to discontinue using the chemiluminescence FRM, although we received some comments from industry (Alliance of Automobile Manufacturers, Edison Electric, and the National Petrochemical and Refiners Association) raising concerns about using a method that is subject to known interferences from certain species of oxides of nitrogen known as NO_Z. Important components of ambient NO_Z include nitrous acid (HNO_2), nitric acid (HNO_3), and the peroxyacetyl nitrates (PANs).

The issue of concern in public comments is that the reduction of NO_2 to NO on the MoO_X converter substrate used in chemiluminescence FRMs 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). Further, as noted in the ISA (ISA Section 2.3), 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.

The EPA acknowledges that the NO_Z interference in the reported NO_2 concentrations collected well downwind of NO_X source areas and in relatively remote areas away from concentrated point, area, or mobile sources is significantly larger than the NO_Z interference in NO_2 measurements taken in urban cores or other areas with fresh NO_X emissions. To meet the primary objective of monitoring maximum NO_2 concentrations in an area, the EPA is requiring NO_2 monitors to be placed in locations of the expected highest concentrations, not in relatively remote areas away from NO_X sources. The required monitors resulting from the network design discussed below in Section III.B will require monitors to be placed near fresh NO_X sources or in areas of dense NO_X emissions, where NO_2 concentrations are expected to be at a maximum, and interference from NO_Z species is at a minimum. Therefore, EPA believes that the positive artifact issue, although present, is small, relative to the actual NO_2 being measured. As a result EPA believes the chemiluminescence FRM is suitable for continued use in the ambient NO_2 monitoring network, as the potential positive bias from NO_Z species is not significant enough to discontinue using the chemiluminescence FRM.

EPA also received support from some industry groups (*e.g.* Savannah River Nuclear Solutions, Teledyne API, and the Utility Air Regulatory Groups) and States (*e.g.*, MODEQ and NCDENR) to further the development of alternative methods in determining NO_2 concentrations. Such alternative methods include the photolytic-chemiluminescence method and cavity ring-down spectroscopy. As a result, EPA will continue working with commercial and industrial vendors, to identify and evaluate such new technologies. These efforts may include field testing instruments and further characterizing methods in a laboratory setting to assess their potential as future reference or equivalent methods, and their role in more directly measuring NO_2.

2. Allowable FRM and FEMs for Comparison to the NAAQS

The current CFR language does not prohibit the use of any particular NO_2 FRM or FEM to be used in comparison to the standard.[21] There are designated wet chemical methods that are only able to report ambient concentration values averaged across multiple hours. With the establishment of a 1-hour NAAQS, any FRM or FEM which is a wet chemical based method would not be appropriate for use in determining compliance of the 1-hour NAAQS because they are unable to report hourly data. EPA addressed this issue by proposing and finalizing that only those methods capable of providing 1-hour measurements will be comparable to the NAAQS.

a. Proposed Changes to FRM and FEMs That May Be Compared to the NAAQS

EPA proposed that only those FRMs or FEMs that are capable of providing hourly averaged concentration data may be used for comparison to the NAAQS.

b. Comments

EPA received comments from some State and industry groups (*e.g.* Missouri, North Carolina, and Air Quality Research and Logistics) supporting the proposed approach to only allowing those FRMs or FEMs that are capable of providing hourly averaged concentration data may be used for comparison to both the annual and 1-hour NAAQS, and did not receive any public comments that objected to the proposed approach.

c. Decisions on Allowable FRM and FEMs for Comparison to the NAAQS

Accordingly, EPA is finalizing the proposed changes to 40 CFR Part 58 Appendix C to allow only data from FRM or FEMs that are capable of providing hourly data to be used for comparison to both the annual and 1-hour NAAQS.

B. Network Design

With the establishment of a 1-hour NO_2 NAAQS intended to limit exposure to maximum concentrations that may occur anywhere in an area, EPA recognizes that the data from the current NO_2 network is inadequate to fully assess compliance with the revised

[21] A list of approved FRM and FEMs is maintained by EPA's Office of Research and Development, and can be found at: *http://www.epa.gov/ttn/amtic/files/ambient/criteria/reference-equivalent-methods-list.pdf.*

NAAQS. As a result, EPA is promulgating new NO_2 network design requirements. The following sections provide background, rationale, and details for the final changes to the NO_2 network design requirements.

1. Two-Tiered Network Design

A two-tiered monitoring network is appropriate for the NO_2 NAAQS because one tier (the near-road network) reflects the much higher NO_2 concentrations that occur near-road and the second-tier (area-wide) characterizes the NO_2 concentrations that occur in a larger area such as neighborhood or urban areas. The ISA (Section 2.5.4 and 4.3.6) stated that NO_2 concentrations in heavy traffic or on freeways "can be twice the residential outdoor or residential/arterial road level," that "exposure in traffic can dominate personal exposure to NO_2," and that "NO_2 levels are strongly associated with distance from major roads (*i.e.*, the closer to a major road, the higher the NO_2 concentration)." The exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations (REA, Figures 8–17, 8–18). Monitoring studies suggest that NO_2 concentrations near roads can be considerably higher than those in the same area but away from the road (*e.g.*, by 30–100%, *see* section II.A.2), where pollutants typically display peak concentrations on or immediately adjacent to roads, producing a gradient in pollutant concentrations where concentrations decrease with increasing distance from roads. Since the intent of the revised NAAQS is to limit exposure to peak NO_2 concentrations that occur anywhere in an area, monitors intended to measure the maximum allowable NO_2 concentration in an area should include measurements of the peak concentrations that occur on and near roads due to on-road mobile sources. The first tier of the network design, which focuses monitoring near highly trafficked roads in urban areas where peak NO_2 concentrations are likely to occur, is intended to measure maximum concentrations anywhere in an area, particularly those due to on-road mobile sources since roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations. The basis for the second tier of the network design is to measure the highest area-wide concentrations to characterize the wider area impact of a variety of NO_2 sources on urban populations. Area-wide monitoring of NO_2 also serves to maintain continuity in collecting data to inform long-term pollutant concentration trends analysis and support ongoing health and scientific research.

This section discusses the two-tier network design approach compared to the alternative network design which was also presented for comment in conjunction with a solicitation for comment on an alternative NAAQS. The alternative network design concept was based entirely on requiring only monitors that would be considered area-wide, while not requiring any near-road monitoring sites. The details of the two-tier network design, including how many monitors are required, where they are to be located, and the related siting criteria are discussed in subsequent sections.

a. Proposed Two-Tier Network Design

EPA proposed a two-tier network design composed of (1) near-road monitors which would be placed in locations of expected maximum 1-hour NO_2 concentrations near heavily trafficked roads in urban areas and (2) monitors located to characterize areas with the highest expected NO_2 concentrations at the neighborhood and larger spatial scales (also referred to as "area-wide" monitors). As an alternative, and in conjunction with a solicitation for comment on an alternative NAAQS, EPA solicited comment on a network comprised of only area-wide monitors.

b. Comments

EPA received many comments on the overall two-tier network design, with those who made statements with a relatively clear position on the issue generally falling into four categories: (1) Those who support the adoption of the proposed two-tier design approach, (2) those who support the adoption of the two-tier concept, but with modifications, (3) those who only supported the adoption of the alternative network design, and (4) those who encourage EPA to commit to further research of the near-road environment by monitoring near-roads, but not to use near-road data for regulatory purposes, and therefore support the alternative network design in which EPA solicited comment on a network design composed only of area-wide monitors.

Those commenters who generally supported the proposed two-tier network, included CASAC (while there was not a consensus, a majority were in support of the proposed network design), public health organizations (*e.g.*, AACPR, ACCP, AMA, ATA, and NAMDRC), several State groups (*e.g.*, the New York City Law Department and the Metropolitan Washington Air Quality Committee), and some industry commenters (*e.g.*, American Chemistry Council, The Clean Energy Group, and Dow Chemical).

Those commenters who supported the adoption of the two-tier network design concept, but suggested modifications to the actual design included some health and environmental organizations (*e.g.*, ALA, EDF, EJ, and the NRDC), some States (*e.g.*, California, the Central Pennsylvania Clean Air Board, Harris County (Texas), Iowa, New York, San Joaquin Air Pollution Control District, Spokane Regional Clean Air Agency (SRCAA), the Texas Commission on Environmental Quality, and Wisconsin), and some industry commenters, including the American Petroleum Institute and the Utility Air Regulatory Group, who are cited by other industry commenters. We believe that although these commenters made suggestions to modify the proposed two-tier network design, they are indicating that it is an acceptable approach. Their comments and suggestions are discussed in greater detail in the following sections.

Those commenters who only supported the adoption of the alternative network design included State and industry groups (*e.g.*, Indiana Department of Environmental Management, the New York Department of Transportation (NYSDOT), Alliance of Automobile Manufacturers, and the Engine Manufacturers Association). These commenters typically made comments on the two-tier network design, but did not do so in a way that clearly supported near-road research.

EPA received comments from some States or State organizations (*e.g.*, National Association of Clean Air Agencies (NACAA), the Northeast States for Coordinated Air Use Management (NESCAUM), and 10 other individual States or State groups) and industry commenters (*e.g.*, Consumers Energy, Edison Electric, and the National Association of Manufacturers) that encouraged EPA to further research the near-road environment, opposing use of near-road monitoring data for regulatory purposes, and supported the adoption of the alternative network design for regulatory purposes. For example, with regard to implementing the two-tier network design that includes near-road regulatory monitoring, NACAA stated that "* * * a major new network—particularly one that is inherently complicated and untried—should not be rolled out without the benefit of an effective near-road monitoring research program that can address many of the relevant data questions, and inform the specific siting requirements of the rule." The NAM stated that "conducting such a near road [research] monitoring program would allow EPA to collect necessary data that can be used to better understand the health impacts associated with short term NO_2 exposures."

The EPA notes that the existing scientific research referenced in the proposal and throughout this final rule show that there are on- and near-road peaks of NO_2 concentrations, relative to upwind or background levels, which exist due to on-road mobile source emissions. This research, as a body of evidence, also identifies the multiple local factors that affect how, where, and when peak NO_2 concentrations occur on or near a particular road segment. These factors include traffic volume, fleet mix, roadway design, congestion patterns, terrain, and meteorology. The EPA and States have access to such data typically through Federal, State, and/or local departments of transportation or other government organizations, and, as a result, are in a position to implement a near-roar monitoring network that is intended to measure maximum expected NO_2 concentrations resulting from on-road mobile source emissions. Further, EPA notes that near-road monitoring is not a new objective for the ambient air monitoring community as near-road carbon monoxide monitoring has been a part of ongoing, long-term, routine networks for nearly three decades. As a result, there is experience within EPA (both OAR and ORD) and State and local agencies on conducting ambient monitoring near-roads. In addition, EPA intends to develop guidance with input from all stakeholders to assist with implementation of the monitoring requirements, which is discussed in section III.B.5. EPA believes that the existing science and research provide a sufficient base of information to require a near-road monitoring network and that the collective experience that exists in the ambient monitoring community will allow for successful implementation of that network. EPA also believes that through adherence of requirements for near-road site selection and siting criteria discussed in sections III.B.6 and III.B.7, respectively, that the two-tier network design will provide a network that has a reasonable degree of similarity across the country where the required near-road monitors are targeting the maximum NO_2 concentrations in an area attributable to on-road mobile sources.

Some industry commenters (*e.g.*, Engine Manufacturers Association, the South Carolina Chamber of Commerce, and the South Carolina Manufacturers Alliance) who supported the adoption of the alternative network design suggested that monitoring in the near-road environment would not be indicative of exposure for general populations, and that EPA should not focus on the near-road environment when requiring monitoring. For example, the South Carolina Chamber of Commerce and the South Carolina Manufacturers Alliance both state that "it appears the proposed monitoring network will result in a collection of microscale data, which is not at all representative of air quality relevant to population exposure."

The EPA notes that the intent of a near-road monitoring is to support the revised NAAQS by assessing peak NO_2 concentrations that may occur anywhere in an area. EPA recognizes that there is variability in the properties (such as traffic counts, fleet mix, and localized features) among the road segments that may exist in an area, but on the whole, roads are ubiquitous, particularly in urban environments. Consequently, a substantial fraction of the population is potentially exposed to relatively higher concentrations of NO_2 that can occur in the near-road environment. The 2007 American Housing Survey (*http://www.census.gov/hhes/www/housing/ahs/ahs07/ahs07.html*) estimates that over 20 million housing units are within 300 feet (91 meters) of a 4-lane highway, airport, or railroad. Using the same survey, and considering that the average number of residential occupants in a housing unit is approximately 2.25, it is estimated that at least 45 million American citizens live near 4-lane highways, airports, or railroads. Although that survey includes airports and railroads, roads are the most pervasive of the three, indicating that a significant amount of the general population live near roads. Furthermore, the 2008 American Time Use Survey (*http://www.bls.gov/tus/*) reported that the average U.S. civilian spent over 70 minutes traveling per day. Accordingly, EPA concludes that monitors near major roads will address a component of exposure for a significant portion of the general population that would otherwise not be addressed.

The majority of State commenters, regardless of their position on the proposed network design, along with some industry commenters, observed that there was a need for funding the monitoring network. These comments urged EPA to provide the resources needed to implement and operate the required monitoring network. EPA notes that it has historically funded part of the cost of the installation and operation of monitors used to satisfy Federal monitoring requirements. EPA understands these concerns, although the CAA requirements from which this final rule derives (CAA sections 110, 310(a) and 319) are not contingent on EPA providing funding to States to assist in meeting monitoring requirements. However, EPA intends to work with NACAA and the State and local air agencies in identifying available State and Tribal Air Grant (STAG) funds and consider the increased resource needs that may be needed to plan, implement, and operate this revised set of minimum requirements.

c. Conclusions Regarding the Two-Tier Network Design

The EPA believes that requiring near-road monitors in urban areas as part of the network design are necessary to protect against risks associated with exposures to peak concentrations of NO_2 anywhere in an area. The combination of increased mobile source emissions and increased urban population densities can lead to increased exposures and associated risks, therefore urban areas are the appropriate areas to concentrate required near-road monitoring efforts. The EPA also recognizes the need to have monitors in neighborhood and larger spatial scale locations away from roads that represent area-wide concentrations. These types of monitors serve multiple important monitoring objectives including comparison to the NAAQS, photochemical pollutant assessment, ozone forecasting, characterization of point and area source impacts, and by providing historical trends data for current and future epidemiological health research. In some situations, when coupled with data from near-road monitors, area-wide monitors may also assist in the determination of spatial variation of NO_2 concentrations across a given area and provide insight to the gradients that exist between near-road or stationary source oriented concentrations and area-wide concentration levels.

After considering the scientific data and the public comments regarding the proposed network design, the Administrator concludes that a two-tier network design composed of (1) near-road monitors which would be placed in locations of expected maximum 1-hour NO_2 concentrations near heavily trafficked roads in urban areas and (2) monitors located to characterize areas with the maximum expected NO_2 concentrations at the neighborhood and larger spatial scales (also referred to as "area-wide" monitors) are needed to implement the 1-hour NO_2 NAAQS and support the annual NAAQS. The details of this two-tier network design are discussed in the following eight sections.

2. First Tier (Near-Road Monitoring Component) of the NO_2 Network Design

This section provides background, rationale, and details for the final changes to the first tier of the two-tier NO_2 network design. In particular, this section will focus on the thresholds that trigger monitoring requirements. Near-road site selection and siting criteria details will be discussed in subsequent sections.

a. Proposed First Tier (Near-Road Monitoring Component) of the Network Design

EPA proposed that the first tier of the two-tier NO_2 monitoring network design focus monitors in locations of expected maximum 1-hour concentrations near major roads in urban areas. As noted in the previous section, the exposure assessment presented in the REA estimated that roadway-associated exposures account for the majority of exposures to peak NO_2 concentrations (REA, Figures 8–17, 8–18). Since the combination of increased mobile source emissions and increased urban population densities leads to increased exposures and associated risks, the Administrator judges that urban areas are the appropriate areas in which to concentrate required near-road monitoring efforts. Therefore, we proposed that a minimum of one near-road NO_2 monitor be required in Core Based Statistical Areas (CBSAs) with a population greater than or equal to 350,000 persons. Based on 2008 Census Bureau statistics, EPA estimated this would result in approximately 143 monitoring sites in as many CBSAs.

We also proposed 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 Annual Average Daily Traffic (AADT) count greater than or equal to 250,000. Based on 2008 Census Bureau statistics and data from the 2007 Highway Performance Monitoring System (HPMS) maintained by the U.S. Department of Transportation (DOT) Federal Highway Administration (FHWA), this particular element of the minimum monitoring requirements would have added approximately 24 [22] sites to the approximate 143 near-road sites in CBSAs that already would have had one near-road monitor required due to the 350,000 population threshold. Overall, the first tier of the proposed network design was estimated to require 167 near-road sites in 143 CBSAs.

b. Comments

The EPA received comments from some industry and public health organizations (*e.g.* Dow Chemical, ATS, and the AMA) supporting the proposed approach to use population thresholds for triggering minimum near-road monitoring requirements. For example, Dow Chemical Company stated that "Dow comments that the proposed population thresholds are reasonable for implementation of the new network design and that we don't see a need to establish a threshold lower than 350,000 people for the lower bound."

The EPA received comments from some States and State groups suggesting that a combination of population and AADT counts or just AADT counts should be used to trigger minimum near-road monitoring requirements. For example, the San Joaquin Air Pollution Control District in California suggested that we modify minimum monitoring requirements so that one near-road NO_2 monitor is required for any CBSA with a population of 350,000 people which also had one or more road segments with AADT counts of 125,000 or more. In another example, Harris County Public Health and Environmental Services (HCPHES) suggested that "* * * rather than specifying population limits for the monitoring, HCPHES supports a metric like the Annual Average Daily Traffic (AADT) as a threshold for requiring a near-road monitor. An initial focus on an AADT in excess of 250,000 is acceptable as a starting point but EPA should revisit that level and consider lowering it to 100,000 in five years." AASHTO [23] and NYDOT [23] suggested that EPA could set a threshold at 140,000 AADT for requiring near-road monitors rather than using population thresholds.

EPA is finalizing the population-only threshold approach to trigger near-road monitoring, as the first step in the process of establishing the first-tier of near-road monitors, and for identifying the appropriate number and locations for siting these monitors. EPA believes that the uncertainty in defining specific national AADT counts is too great to support use in this first step of the alternative approaches suggested by the commenters. EPA notes that, in general, roads with higher AADT counts have relatively higher amounts of mobile source emissions, leading to an increased potential for relatively higher on-road and roadside NO_2 concentrations. This concept is supported, for example, by Gilbert *et al.*, 2007, who state that the NO_2 concentrations analyzed in their study are significantly associated with traffic counts. In part, these suggestions by commenters to include AADT counts as part of, or independently as, a threshold for requiring monitors appears to be aimed at increasing the focus of the near-road network to locations where NO_2 concentrations are expected to be highest. However these suggestions would also, in effect, reduce the size of the required network compared to the network that EPA had proposed. The differences in fleet mix, roadway design, congestion patterns, terrain, and local meteorology amongst road segments that may have identical AADTs are quite variable and affect the NO_2 concentrations on and near those segments. The available data and related technical and scientific quantification of what particular AADT count might be expected to contribute to some specific NO_2 concentration is insufficient to establish a specific, nationally applicable AADT count threshold that could be used as part of a population-AADT combination, or a distinct AADT count, to require all near-road monitors. Therefore, EPA chose not to utilize a population-AADT or an AADT-only threshold to trigger all minimally required near-road monitoring because of the lack of a quantitative, nationally applicable relationship between a certain AADT threshold and an expected NO_2 concentration. Instead, EPA is finalizing the proposed population-only threshold approach to trigger a minimum of one monitor in a CBSA. In larger CBSAs, EPA does require, at a minimum, a second monitor based on either an AADT count of 250,000 or a population threshold of 2,500,00 or more persons in a CBSA as described more fully below. EPA believes this approach for siting near-road monitoring provides a greater degree of certainty in covering a large segment of the total population (66%, which is explained below) and will provide data on exposure from geographically and spatially diverse areas where a larger number of people

[22] Of the 24 additional sites, 22 are estimated to be triggered due to a population of 2,500,000 while 2 (Las Vegas, NV and Sacramento, CA) are estimated to be triggered by the presence of one or more road segments with 250,000 AADT since they do not have a population of 2,500,000 people.

[23] AASHTO, NESCAUM, and NYDOT did not support the two-tier network design; however they provided suggestions on how the network design might be modified if the EPA were to finalize requirements for near-road monitors. In the case of AASHTO and NYDOT, their suggestions were made with the suggestion that EPA use a separate rulemaking process to require monitors.

are likely to be exposed to peak NO_2 concentrations.

Some commenters (*e.g.*, AASHTO,[23] NESCAUM,[23] NYDEC, NYDOT [23]) suggested focusing multiple near-road monitors only in relatively larger CBSAs than those which were proposed. For example, NYDEC suggested that EPA require, at minimum, two near-road monitors in any CBSA of 2,500,000 people or more, but not in CBSAs below that population threshold. In their comments, they point out the variety of near-road environments that exist in the larger CBSAs such as New York City.

EPA notes that the larger CBSAs, such as those with a population of 2,500,000 or more persons, 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 in different settings (evidenced in the U.S. Department of Transportation (U.S. DOT) Federal Highway Administration (FHWA) "Status of the Nation's Highways, Bridges, and Transit: 2006 Conditions and Performance" document which is discussed below). This is the primary reasoning behind the requirement for two monitors in CBSAs with more than 2,500,000 people. EPA also believes that having multiple monitors in the largest CBSAs will allow better understanding of the differences that may exist between roads in the same CBSA due to fleet mix, congestion patterns, terrain, or geographic locations. However, EPA believes that a network with substantially fewer monitors in correspondingly fewer CBSAs, as the commenters suggested, would lead to an insufficient monitoring network lacking a balanced approach needed for a regulatory network intended to support the revised NAAQS on a national basis.

On a related note to those comments that suggested focusing more near-road monitors only in the larger CBSAs, EPA proposed that any CBSAs with one or more road segments with an Annual Average Daily Traffic (AADT) count greater than or equal to 250,000 must have a second monitor if they do not already have two near-road monitors because of the population threshold. Such an AADT-triggered monitor would account for situations where a relatively less populated area has a very highly trafficked road. In this case, EPA notes that because those road segments with 250,000 AADT have been identified by U.S. DOT FHWA (*http://www.fhwa.dot.gov/policyinformation/tables/02.cfm*) as being the top 0.03 percent of the most traveled public road segments, that they are the most heavily trafficked roads in the country. Again noting that NO_2 concentrations are significantly associated with traffic counts (Gilbert *et al.* 2007), these roads segments likely have the greatest potential for high exposures directly connected to motor vehicle emissions in the entire country. Typically, these very highly trafficked roads are in the largest populated CBSAs, such as those with 2,500,000 people or more, and are somewhat atypical for CBSAs with less than 2,500,000 people. As a result, EPA believes it is appropriate to require a second monitor in a CBSA that has one or more road segments with 250,000 AADT counts or more if they do not already have two near-road monitors required due their population.

EPA received comments requesting that EPA explain the rationale for the selection of the population thresholds that trigger minimum monitoring requirements and also to reconsider the size of the network. For example, NYDOT suggested that this final rule explain the basis for the 350,000 and 2,500,000 population thresholds that will establish near-road monitors. In another comment, the Clean Air Council (CAC) questioned the selected population thresholds, noting that they believe that the population thresholds that were proposed were too high. Specifically, CAC stated that "at 350,000 persons, numerous metro areas in the mid-Atlantic and Northeastern States with urban cores and highways running through will likely be exempted from the new monitors." The Spokane Regional Clean Air Agency stated that they "do not believe it is necessary to require air quality monitoring for NO_2 near major roadways in every metropolitan area. It is our [SRCAA's] view that EPA could establish a statistically significant number of air quality monitoring stations near roadways and develop a correlation between traffic density and ambient NO_2 levels." Further, the EPA received many State comments suggesting reductions to the overall size of the near-road network; however the commenters did not provide very specific suggestions on how EPA should accomplish that reduction in size. For example, the Regional Air Pollution Control Agency, which represents a portion of Ohio, stated "given the fairly standard fleet of vehicles on the nation's major highways, we urge EPA to consider the need for 142 near-roadway monitors. Perhaps a limited number of monitors across the country would suffice to sufficiently characterize near-roadway NO_2 levels." These State commenters provided various reasons which are discussed throughout this document suggesting that the network be reduced in size, including funding concerns (section III.B.1.b), the perceived need to implement a smaller near-road research network in lieu of a regulatory network (section III.B.1.b), safety issues (section III.B.7.b), and problems with State implementation plans (section VI. D) and designation issues (section V).

EPA notes that the intent of the first tier of the network design is to support the revised NAAQS in measuring peak NO_2 exposures in an area by including a minimum number of monitors resulting in a sufficiently sized national near-road monitoring network that will provide data from a geographically and spatially diverse array of areas, in terms of population, potential fleet mixes, geographic extent, and geographic setting, from across the country. The U.S. Department of Transportation (U.S. DOT) Federal Highway Administration (FHWA) "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 (U.S.) 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 (U.S.) 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. The basis for the selection of the proposed CBSA population level of 350,000 to trigger the requirement of one near-road monitor was chosen in an attempt to provide near-road monitoring data from a diverse array of areas, as noted above. However, in response to the significant number of comments discussed above, which in various ways encouraged at least a reduction of the size of the required near-road network or the implementation of a relatively smaller research network, EPA reconsidered the population threshold that will require one near-road NO_2 monitor in a CBSA.

EPA reviewed the data, such as population, geographic, and spatial distribution, associated with particular CBSA areas that would and would not be included in particular CBSA population thresholds. According to the 2008 U.S. Census Bureau estimates (*http://www.census.gov*) there are 143 CBSAs with 350,000 or more persons (including territories) which contain approximately 71% of the total population (excluding territories). These

CBSAs collectively represent territory in 44 States, the District of Columbia, and Puerto Rico. For comparison, there are 391 CBSAs with 100,000 or more persons, which contain approximately 86% of the total population (excluding territories). These particular CBSAs collectively represent territory in 49 States, the District of Columbia, and Puerto Rico. Further, there are 102 CBSAs with 500,000 or more persons, which contain approximately 66% of the total population (excluding territories). These 102 CBSAs collectively represent territory in 43 States, the District of Columbia, and Puerto Rico. Finally, there are 22 CBSAs with 2,500,000 or more persons, which contain approximately 39% of the total population, collectively representing territory in 19 States, the District of Columbia, and Puerto Rico. In comparison to the CBSA population threshold of 350,000, the 500,000 population threshold has 41 less CBSAs. However, the percentage of the total U.S. population residing in these two sets of CBSAs differs by only approximately 5 percent of the total population (*e.g.*, 71% in CBSAs of 350,000 or more versus 66% in CBSAs of 500,000 or more persons). Also, when comparing the number of States that have some amount of their territory included in these CBSAs, the difference between the two sets of CBSAs differs by only 1 State (Alaska).

Further, EPA notes that the REA Air Quality Analysis, (REA, section 7.3.2) estimated the exceedences of health benchmark levels across the United States, including explicit consideration of on- or near- roadway exceedances in 17 urban areas associated with CBSA populations ranging from approximately 19,000,000 to 540,000. The analysis indicated that all 17 of the areas under explicit consideration were estimated to experience NO_2 concentrations on or near roads that exceeded health benchmark levels.

c. Conclusions Regarding the First Tier (Near-Road Monitoring Component) of the Network Design

After consideration of public comments, and in light of the information discussed above, the Administrator has chosen to finalize the CBSA population threshold for requiring a minimum of one near-road monitor in CBSAs with a population of 500,000 or more persons. The Administrator is finalizing the other thresholds that will trigger a second near-road monitor as proposed. Accordingly, one near-road NO_2 monitor is required in CBSAs with a population greater than or equal to 500,000 persons and a second near-road monitor is 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 Annual Average Daily Traffic (AADT) count greater than or equal to 250,000.

The Administrator has concluded that using a population threshold of 500,000 to require a minimum of one near-road monitor in a CBSA provides a sufficiently sized, national network of near-road monitors that will provide data from a geographically and spatially diverse set of CBSAs that supports the intent of the revised NAAQS and continues to meet the monitoring objectives of the network. Combined with the forty additional monitors that the Regional Administrators are required to site, discussed below, the monitoring network would cover an additional percentage of the total population.

EPA believes that selecting a lower population threshold, such as 100,000 or, to a lesser degree, 350,000, as discussed in the above examples, would create a much larger network of required near-road monitors but would provide diminished population coverage per monitor, compared to that provided by the 500,000 threshold. EPA notes that if a particular area, such as one with a population less than 500,000 people, might warrant a near-road monitor, the Regional Administrator has the authority to require additional monitors. The Regional Administrators' authority is discussed in section III.B.4. Further, States have the right to conduct additional monitoring above the minimum requirements on their own initiative. In the Administrator's judgment, selecting a higher threshold, such as 2,500,000, as was suggested by some commenters, does not provide a sufficient geographical and spatially diverse near-road network, compared to that provided by the 500,000 threshold. The selection of the 2,500,000 population threshold to trigger a second near-road monitor, as noted earlier in this section, is based on the fact that the larger urban areas in the country are likely to have a greater number of major roads across a potentially larger geographic area, and have a corresponding increase in potential for population exposure to elevated levels in different settings.

Changing the CBSA population threshold 350,000 to 500,000 results in a near-road monitoring network requiring approximately 126 monitors distributed within 102 CBSAs. Compared to the total number of required near-road monitors that would have resulted from the proposed CBSA population threshold of 350,000 (167 monitors), an estimated 41 fewer monitors are required. EPA has also recognized that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups, (as discussed in sections II.B.4 and II.F.4.d) are at particular risk of NO_2-related health effects. The Administrator is therefore requiring the Regional Administrators, working in collaboration with States, to site forty monitors in appropriate locations, focusing primarily on protecting such susceptible and vulnerable communities. This decision is discussed in detail in section III.B.4.

3. Second Tier (Area-Wide Monitoring Component) of the Network Design

The following paragraphs provide background, rationale, and details for the final changes to the second tier of the two-tier NO_2 network design. In particular, this section will focus on the threshold that triggers area-wide monitoring requirements. Area-wide site selection and siting criteria details will be discussed in a subsequent section.

a. Proposed Second Tier (Area-Wide Monitoring Component) of the Network Design

As the second tier of the proposed two-tier network design, EPA proposed to require monitors to characterize the expected maximum NO_2 concentrations at the neighborhood and larger (area-wide) spatial scales in an area. This component of the two-tier network design provides information on area-wide exposures that may occur due to an individual or a group of point, area, on-road, and/or non-road sources. Further, area-wide sites serve multiple monitoring objectives aside from NAAQS comparison to both the 1-hour and the annual NAAQS, including photochemical pollutant assessment, aiding in ozone forecasting, aiding in particulate matter precursor analysis and particulate matter forecasting. We proposed to require one area-wide monitoring site in each CBSA with a population greater than or equal to 1,000,000. We proposed that these area-wide sites were to be sited to represent an area of highest concentration at the neighborhood or larger spatial scales. Based on 2008 Census Bureau statistics, there are 52 CBSAs with 1,000,000 people or more, which would result in an estimated 52 area-wide monitors in as many CBSAs being minimally required. EPA also proposed to allow any current photochemical assessment monitoring station (PAMS) sites that are sited where the highest NO_2 concentrations occur in an urban area and represent a neighborhood or urban scale to satisfy the area-wide monitoring requirement.

b. Comments

Most commenters who commented on area-wide monitoring supported the adoption of the alternative area-wide network design and did not specifically comment on the area-wide monitoring component of the proposed two-tier network design. However, EPA did receive comments from public health organizations on area-wide monitoring in the context of the proposed network design. The public health group commenters, including the ALA, EJ, EDF, and the NRDC, stated they "oppose the proposed requirement to retain only 52 air monitors to measure area-wide concentrations of NO_2."

EPA understands the perceived concern to be that with this provision, EPA is actively reducing the number of required area-wide monitors. Prior to this rulemaking, the Ambient Air Monitoring Regulations, 71 FR 61236 (Oct. 17, 2006) (2006 monitoring rule) removed minimum monitoring requirements for NO_2, and the rationale for that action is explained in that rule; however, the 2006 Monitoring rule has had a limited impact to date, evidenced by the fact that the size of the NO_2 network has remained relatively steady at around 400 monitors, a majority of which are area-wide monitors, that were operating in 2008 (Watkins and Thompson, 2008). The stability of the NO_2 network is due in large part to the fact that area-wide monitors serve multiple monitoring objectives, including photochemical pollutant assessment, pollutant forecasting, and in some cases, support to ongoing health research. However, considering the objective of this two-tier network design, particularly the first tier, of supporting the revised NAAQS to protect against peak NO_2 exposures, some shrinkage in the area-wide network is appropriate and likely. EPA believes that the actual number of area-wide monitors that will operate in the NO_2 network will be greater than the minimally required 52 sites, but likely less than the current number. States and Regional Administrators will work together on which area-wide sites may warrant retention above the minimum required if States request existing area-wide sites to be shut down or relocated.

c. Conclusions on the Second Tier (Area-Wide Monitoring Component) of the Network Design

Area-wide monitoring sites serve multiple monitoring objectives aside from NAAQS comparison to both the 1-hour and the annual NAAQS, including photochemical pollutant assessment, ozone forecasting, particulate matter precursor analysis and particulate matter forecasting. EPA recognizes that a significant portion of the existing NO_2 monitoring network can be characterized as area-wide monitors and that these monitoring sites serve multiple monitoring objectives, as noted above. In order to ensure that a minimum number of area-wide monitors continue operating into the future, we are finalizing the proposed minimum monitoring requirements for area-wide monitors, where one area-wide monitor is required in any CBSA with 1,000,000 people or more. Since there were no adverse comments received with regard to allowing PAMS stations that meet siting criteria to satisfy minimum monitoring requirements for area-wide monitors, we are finalizing that allowance as proposed. EPA encourages States to use the upcoming 2010 network assessment process to review existing area-wide NO_2 sites to help determine what monitors might meet minimum monitoring requirements and whether or not other existing monitors warrant continued operation.

4. Regional Administrator Authority

The following paragraphs provide background, rationale, and details for the final changes to Regional Administrator authority to use discretion in requiring additional NO_2 monitors beyond the minimum network requirements. The proposed rule estimated that approximately 167 near-road monitors would be required within CBSAs having populations of 350,000 or more persons. As discussed above in section III.B.2, in response to public comments, particularly from States, EPA is changing the population threshold for siting a minimum of one near-road NO_2 monitor from CBSAs with 350,000 or more persons to CBSAs with 500,000 or more persons. EPA estimates that this change in the population threshold will result in a reduction in the number of minimally required near-road NO_2 monitors by approximately forty monitors. EPA has also recognized that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups (as discussed in sections II.B.4 and II.F.4.d) are at particular risk of NO_2-related health effects. The Administrator is therefore requiring the Regional Administrators, working in collaboration with States, to site these forty monitors in appropriate locations, focusing primarily on protecting susceptible and vulnerable communities. In addition, the Regional Administrators, working with States, may take into account other considerations described below in using their discretion to require additional monitors.

a. Proposed Regional Administrator Authority

EPA proposed that Regional Administrators have the authority to require monitoring at their discretion in particular instances. First, EPA proposed that the Regional Administrator 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. Second, EPA proposed to allow Regional Administrators the discretion to require additional near-road monitoring sites to address circumstances where minimum monitoring requirements are not sufficient to meet monitoring objectives, such as where exposures to NO_2 concentrations vary across an area because of varied fleet mixes, congestion patterns, terrain, or geographic areas within a CBSA. And third, EPA proposed that Regional Administrators have the discretion to require additional area-wide NO_2 monitoring sites above the minimum requirements for area-wide monitors where the minimum requirements are not sufficient to meet monitoring objectives.

b. Comments

EPA received comments from the Center on Race, Poverty and Environment expressing concern that the proposed monitoring provisions fail to consider "disproportionately impacted communities" which include people of color and of lower socioeconomic status. The commenter argues that this is "a gaping hole" in the proposed monitoring system and disproportionately impacts minority and low income populations in rural communities. In addition, the National Tribal Air Association stated that "Indian Tribes and Alaska Natives are highly susceptible to health impacts as a result of NO_2 exposure" and "the prevalence and severity of asthma is higher among certain ethnic or racial groups such as Indian Tribes and Alaska Natives," which is also discussed in section II.B.4 and the ISA (ISA, section 4.4).

The proposed rule provided the Regional Administrators with the authority to use their discretion and consider certain factors to require monitors above the minimum number in a CBSA. The proposal described one example where a Regional Administrator might require an additional near-road monitor where "a particular community or neighborhood is significantly or uniquely affected by road emissions." EPA recognizes that susceptible and vulnerable populations, which include asthmatics and disproportionately exposed groups, as noted in section II.F.4.d, are at particular risk of NO_2-related health effects, both because of increased exposure and because these groups have a higher prevalence of asthma and higher hospitalization rates for asthma. As noted above, in conjunction with raising the threshold for requiring one near-road NO_2 monitor in CBSAs with 500,000 persons or more, EPA is requiring the Regional Administrators, under their discretionary authority, to work with States to site an additional forty monitors, nationally, focusing primarily on communities where susceptible and vulnerable populations are located. To address the risks of increased exposure to these populations, the Administrator has determined that it is appropriate and necessary, under this provision, to ensure these additional forty monitors are sited primarily in communities where susceptible and vulnerable populations are exposed to NO_2 concentrations that have the potential to exceed the NAAQS (due to emissions from motor vehicles, point sources, or area sources). As a result of this action, the total number of monitors required through this rulemaking is generally equivalent to the proposed number of minimally required monitors.

EPA received comments from public health groups (*e.g.*, ALA, Center on Race, Poverty, and the Environment, EDF, EJ, NRDC) and the Swinomish Tribe, who suggested that EPA expand monitoring coverage to address impacts from stationary sources outside of urban areas. For example, ALA, EDF, EJ, and NRDC, stated that "EPA should require States and local offices to review inventory data to identify any potential NO_2 hotspots outside of those large metropolitan areas. For instance, if a large power plant or any other source is creating elevated NO_2 levels in proximity to homes, schools or other sensitive sites, in an area of less than one million people, EPA should consider requiring a monitor."

EPA recognizes that there are major NO_2 sources outside of CBSAs that have the potential to contribute to NO_2 concentrations approaching or exceeding the NAAQS. The issue is whether such monitoring should be addressed through a more extensive set of minimum requirements that might include monitoring near all large stationary sources such as airports, seaports, and power plants, which could lead to deploying a large number of monitors. EPA believes that a more reasonable approach to address monitoring needs related to the diverse set of point, area, and non-road mobile NO_2 sources, whether inside or outside of CBSAs, is to provide Regional Administrators the authority to require additional monitoring in areas where these impacts could occur. While the proposal did not specifically state that Regional Administrators could require non-area-wide monitors outside of CBSAs, EPA believes that it is important that Regional Administrators have the authority to require NO_2 monitoring in locations where NO_2 concentrations may be approaching or exceeding the NAAQS, whether located inside or outside of CBSAs. Therefore, in the final rule, EPA is not limiting the Regional Administrators' discretionary authority to require NO_2 monitoring only inside CBSAs; instead, the EPA is providing Regional Administrators the authority to site monitors in locations where NO_2 concentrations may be approaching or exceeding the NAAQS, both inside or outside of CBSAs.

The EPA also received comments from some State groups (*e.g.* the New York Department of Environmental Conservation (NYSDEC), New York Department of Transportation (NYSDOT), and the New York City Law Department) and an industry group (the Council of Industrial Boiler Operators) requesting greater clarification on the way in which Regional Administrators may use their authority to require additional monitors above the minimum requirements. For example, the Council of Industrial Boiler Operators stated that "this [Regional Administrator authority] unreasonably vests an unbounded amount of discretion in EPA to determine when "minimum monitoring requirements are not sufficient" and which neighborhoods are "uniquely affected," and impose additional monitoring requirements where all applicable monitoring requirements are already met by the State and local agency."

The authority of Regional Administrators to require additional monitoring above the minimum required is not unique to NO_2. For example, Regional Administrators have or are proposed to have the authority to use their discretion to require additional Pb monitors (40 CFR Part 58 Appendix D section 4.5), and have the discretion to work with States or local agencies in designing and/or maintaining an appropriate ozone network, per 40 CFR Part 58 Appendix D section 4.1. EPA believes that while the NO_2 monitoring network is sufficiently sized and focused, a nationally applicable network design may not account for all locations in which potentially high concentrations approaching or exceeding the NAAQS exist. Therefore, EPA believes it is important for Regional Administrators to have the ability to address possible gaps in the minimally required monitoring network, by granting them authority to require monitoring above the minimum requirements.

One case in which the Regional Administrator may exercise discretion in requiring a monitor might be a location or community affected by a stationary source where the required near-road NO_2 monitor site is not the location of the maximum hourly concentration in a CBSA. For any given CBSA, there is the possibility that the maximum NO_2 concentrations could be attributed to impacts from one, or a combination of, multiple sources that could include point, area, and non-road source emissions in addition to on-road mobile source emissions. As a result, the Regional Administrator may choose to require monitoring in such a location. In addition, there is the possibility that a single source or group of sources exists which may contribute to concentrations approaching or exceeding the NAAQS at locations inside or outside CBSAs, including rural communities. In such cases, Regional Administrators, working with States, may require a monitor in these locations. Further, if there are NO_2 sources responsible for producing more widespread impacts on a community or relatively larger area, Regional Administrators may require an area-wide monitor to assess wider population exposures, or to support other monitor objectives served by area-wide monitors such as photochemical pollutant assessment or pollutant forecasting.

Regional Administrators may also require additional monitoring where a State or local agency is fulfilling its minimum monitoring requirements with an appropriate number of near-road monitors, but an additional location is identified where near-road population exposure exists at concentrations approaching or exceeding the NAAQS. In this case, the exposure may be due to differences in fleet mix, congestion patterns, terrain, or geographic area, relative to any minimally required monitoring site(s) in that area. We note that such areas might exist in CBSAs with populations less than 500,000 persons.

EPA recognizes that high concentrations of NO_2 that approach or exceed the NAAQS could potentially occur in a variety of locations in an area, and we believe that Regional Administrators should have the discretion to require additional monitoring when a location is identified based on the factors discussed in the paragraph above. In such situations, State or EPA Regional staff is likely to have identified these locations through data analysis, such as the evaluation of existing ambient data and/or emissions data, or through air quality modeling. Such information may indicate that an area has NO_2 concentrations that may approach or exceed the NAAQS, and that there is potential for population exposure to those high concentrations.

The Regional Administrator would use this authority in collaboration with State agencies. We expect Regional Administrators to work with State and local agencies to design and/or maintain the most appropriate NO_2 network to meet the needs of a given area. For all the situations where a Regional Administrator may require additional monitoring, including the forty additional monitors the Regional Administrators are required to site, EPA expects Regional Administrators to work on a case-by-case basis with States. Further, for the forty additional monitors that will focus primarily on protecting susceptible and vulnerable communities, EPA intends to work with States to develop criteria to guide site selection for those monitors.

c. Conclusions on Regional Administrator Authority

EPA is requiring Regional Administrators to work with States to site forty NO_2 monitors, above the minimum number required in the two-tier network design, focused primarily in susceptible and vulnerable communities exposed to NO_2 concentrations that have the potential to approach or exceed NAAQS. In addition, recognizing that a nationally applicable monitoring network design will not include all sites with potentially high concentrations due to variations across locations, and in response to public comments, the Administrator is providing Regional Administrators with the discretion to require additional monitors above the minimum requirements.

Regional Administrators may also use their discretionary authority to require monitoring above the minimum requirements as necessary to address situations inside or outside of CBSAs in which (1) The required near-road monitors do not represent all locations of expected maximum hourly NO_2 concentrations in an area and NO_2 concentrations may be approaching or exceeding the NAAQS in that area; (2) areas that are not required to have a monitor in accordance with the monitoring requirements and NO_2 concentrations may be approaching or exceeding the NAAQS; or (3) the minimum monitoring requirements for area-wide monitors are not sufficient to meet monitoring objectives. In all cases in which a Regional Administrator may consider the need for additional monitoring, EPA expects that Regional Administrators will work with the State or local agencies to evaluate evidence that suggests an area may warrant additional monitoring. EPA also notes that if additional monitoring should be required, as negotiated between the Regional Administrator and the State, the State will modify the information in its Annual Monitoring Network Plan to include any potential new sites prior to approval by the EPA Regional Administrator.

5. Monitoring Network Implementation

The following paragraphs provide background, rationale, and details for the final changes to the approach for the monitoring network implementation.

a. Proposed Monitoring Network Implementation Approach

EPA proposed that State and, when appropriate, local air monitoring agencies provide a plan for deploying monitors in accordance with the proposed network design by July 1, 2011. EPA also proposed that the proposed NO_2 network be physically established no later than January 1, 2013.

b. Comments

Most environmental and public health group commenters suggested that EPA change the implementation date from the proposed January 1, 2013 to a date that would require the minimum required NO_2 network to be deployed sooner than proposed. Most States and State group commenters, along with industry group commenters, recommended that EPA keep the network implementation date as January 1, 2013, or move it later than proposed. Those commenters who suggested moving it later noted that issues with monitoring site identification, site development, and overall lack of experience working in the near-road environment would make implementation difficult under the proposed implementation deadline.

EPA recognizes the challenges involved with deploying the two-tier network design by the January 1, 2013 date. We recognize the need for additional information and plan to aid State agencies in the network implementation process, particularly by developing guidance in partnership with affected stakeholders, ideally including at a minimum NACAA and the States. EPA agrees with NACAA's suggestion that the CASAC Ambient Air Monitoring and Methods subcommittee should be consulted as part of developing any guidance developed for near-road monitoring, and has already begun the process by scheduling meetings with them regarding near-road monitoring. Further, EPA believes that collaboration with the States and State groups in developing guidance will be highly beneficial to the implementation process. This would allow for those States that do have increased experience in near-road monitoring to support the guidance development process and provide a conduit for sharing experiences amongst all stakeholders.

In perspective, EPA believes that the approximate 2 years and 11 months between promulgation of this rulemaking and the mandated January 1, 2013 network implementation date includes extra time relative to what is traditionally allowed for network implementation following rulemakings. We are also cognizant of the time needed to collect complete data that would allow data from the two-tier network to be considered for designations and for use in the next NO_2 NAAQS review data from the 2013, 2014, and 2015 years would provide critical information in the next NAAQS review, intended to occur on a 5-year cycle, and for use in subsequent designations. Even with complete data from 2013, 2014, and 2015 years designations would not occur until 2017, at the earliest.

c. Conclusions on Monitoring Network Implementation

EPA is finalizing the date by which State and, when appropriate, local air monitoring agencies shall establish the required NO_2 monitoring network as January 1, 2013, as was proposed. We believe that the allotted time for implementation will allow for the development of guidance documentation, particularly allowing for interactions with CASAC and NACAA/States, and for the processes that will be involved in deploying this network. However, EPA recognizes that the network implementation process, particularly for near-road monitors, will include the assessment of road segments in CBSAs to identify locations of maximum expected hourly NO_2 concentrations, identifying and working with other State and local agencies, such as transportation officials, as needed on issues regarding access and safety, and the exchange of information and feedback on potential sites with EPA, prior to any commitment to selecting and presenting new sites in an annual monitoring plan. As a result, based on feedback received through public comments, and to allow for more time to process guidance information, to carry out the deployment processes, and to allow for information exchanges to occur, we are changing the date by which State and, when appropriate, local air monitoring agencies shall provide a plan for deploying monitors in accordance with required network design, including the monitors required under the Regional Administrators' discretional authority which are to be primarily focused on providing protection to susceptible and vulnerable populations, as discussed in section III.B.4, from July 1, 2011 to July 1, 2012. EPA strongly encourages State and local air agencies to supply as much information as possible on the NO_2 sites they may be considering, including possible site coordinates if available, or have possibly selected, to satisfy the minimum NO_2 network monitoring requirements in their Annual Monitoring Network Plan submitted July 1, 2011.

6. Near-Road Site Selection

The following paragraphs provide background, rationale, and details for the final changes to the approach and criteria by which required near-road sites shall be selected.

a. Proposed Near-Road Site Selection Criterion

EPA proposed that the required 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 that proposed for 40 CFR Part 58 Appendix E (discussed in III.B.7). 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, we proposed that 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. Comments

EPA received many comments from CASAC, public health groups, States and State groups, and industry groups on the proposed process by which States will select near-road sites. CASAC, along with some health group and State commenters questioned how States should select a site near the road with the highest ranked AADT possible, noting that EPA did not appear to require States to account for other factors. For example, one CASAC panel member noted that siting monitors based on traffic counts alone might miss locations where maximum NO_2 concentrations would occur. They proceeded to recommend the use of modeling to assist in the site selection process. In another example, the ALA, EDJ, EJ, and NRDC, stated that "Near-road monitor placement should be determined not only by the highest AADT volumes in a given CBSA, but also by the highest heavy-duty truck volumes." NACAA also expressed concerns on "* * * basing monitor locations on the annual average daily traffic (AADT) without regard to vehicle mix or dispersion characteristics * * *".

EPA does not intend for AADT counts to be the sole basis for choosing a near-road site. As noted earlier in section III.B.2, there is a general relationship between AADT and mobile source pollution, where higher traffic counts correspond to higher mobile source emissions. The use of AADT counts is intended to be a mechanism for focusing on identifying the locations of expected maximum NO_2 concentrations due to mobile sources. There are other factors that can influence which road segment in a CBSA may be the actual location where the maximum NO_2 concentrations could occur. These factors include vehicle fleet mix, roadway design, congestion patterns, terrain, and meteorology. When States identify their top-ranked road segments by AADT, EPA intends for States to evaluate all of the factors listed above in their site selection process, due to their influence on where the location of expected maximum NO_2 concentration may occur. As a result of the comments indicating a need for clarification, EPA will specifically list the factors that must be considered by States in their site selection process once a State has identified the most heavily trafficked roads in a CBSA based on AADT counts. In addition, EPA proposed that States consider these factors when they are required to place two near-road monitors in a CBSA, *i.e.*, CBSAs with a population of 2,500,000 persons or more. EPA notes that these factors will be used in differentiating the two monitoring sites from each other, providing further characterization of near-road environments in 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 in different settings. Finally, EPA notes that air quality models, which were noted by the CASAC panel member to be considered for use in near-road site selection, are tools that EPA believes will be useful, and likely used by some States to inform where near-road sites need to be placed.

EPA received comments from some State and industry commenters (*e.g.* Iowa, NY DEC, Edison Electric Institute, and Savannah River Nuclear Solutions) who suggested that potential population exposure should be a first-level metric in the near-road monitoring site selection process, instead of a second-level metric as EPA had proposed.

EPA notes that the intent of the revised primary NO_2 NAAQS is to protect against the maximum allowable NO_2 concentration anywhere in an area, which includes ambient air on and around roads. This would limit exposures to peak NO_2 concentrations, including those due to mobile source emissions, across locations (including those locations where population exposure near roads is greatest) in a given CBSA or area, with a relatively high degree of confidence. We also note the agency's historical practice has been to site ambient air monitors in locations of maximum concentration, at the appropriate spatial scale. If EPA were to allow population, population density, or another population weighted metric to be a primary factor in the decision on where required near-road NO_2 monitors are to be located, it is possible that the required near-road monitors in a CBSA would not be located at a site of expected maximum hourly near-road NO_2 concentration. By monitoring in the location of expected maximum 1-hour concentrations, near-road monitoring sites will likely represent the highest NO_2 concentrations in an area directly attributable to mobile sources or a group of sources that includes mobile sources. The proposed rule did permit, and the final rule states, that States are to consider population in the site selection process in situations when a State identifies multiple candidate sites where maximum hourly NO_2 concentrations are expected to occur.

EPA received a comment from HCPHES suggesting that required monitoring should take into consideration the location of other major mobile sources for NO_2 emissions such as airports and seaports. EPA also received a comment from the South Carolina Department of Health and Environmental Control stating that a near-road network does not address "widespread pollutants from numerous and diverse sources."

EPA recognizes that there are major NO_2 sources outside of CBSAs that have the potential to contribute to NO_2 concentrations approaching or exceeding the NAAQS. The issue is whether such monitoring should be addressed through a more extensive set of minimum requirements that might include monitoring near all large stationary sources such as airports, seaports, and power plants, which could lead to deploying a large number of monitors. EPA believes that a more reasonable approach to address monitoring needs related to the diverse set of point, area, and non-road mobile NO_2 sources, whether inside or outside of CBSAs, is to provide Regional Administrators the authority to require additional monitoring in areas where these impacts could occur. Providing the Regional Administrators with the discretion to require additional monitors allows them to effectively address such situations, even if that area is satisfying minimum monitoring requirements. This Regional Administrator authority is discussed above in section III.B.4. EPA also notes that State and local agencies may also monitor such locations on their own initiative.

One State commenter, the Wisconsin Department of Natural Resources, requested that the term "major road" be defined and also requested clarification on what "top-ranked" means with regard to AADT counts on road segments. While the term "major road" is widely used in literature and can be found to be defined differently from one scientific study to another, here, EPA is using it in its commonly understood meaning as a road that is relatively heavily trafficked. EPA also does not believe it is appropriate to provide a bright-line definition for "top-ranked". Each CBSA will have a different distribution of total road segments and corresponding AADT counts on those segments. Further, since required near-road monitors are to be sited in locations of expected maximum concentrations, a percentile restriction on "top ranked" roads is unnecessary. The intent of the requirement to rank all road segments by AADT counts and select a site, considering the other local factors noted above, near a "top-ranked" road segment is to focus attention on the most heavily trafficked roads, around which there is higher potential for maximum NO_2 concentrations to occur.

c. Conclusions on Near-Road Site Selection

We are finalizing the near-road site selection criteria as proposed, and are clarifying that the proposal intended the selection criteria to include consideration of localized factors when identifying locations of expected maximum concentrations. As a result, required 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, considering fleet mix, roadway design, congestion patterns, terrain, and meteorology, where maximum hourly NO_2 concentrations are expected to occur and siting criteria can be met in accordance with 40 CFR Part 58 Appendix E. As was noted in section III.B.5 above, EPA will work with States to assist with the near-road site selection process through the development of guidance material and through information exchanges amongst the air monitoring community.

We are also finalizing the requirement, as proposed, that when 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, as was proposed.

7. Near-Road Siting Criteria

The following paragraphs provide background, rationale, and details for the final changes to the siting criteria for required near-road monitoring sites.

a. Proposed Near-Road Siting Criteria

EPA proposed 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. We solicited comment on, but did not propose, having near-road sites located on the predominantly downwind side of the target roadways. EPA proposed that the monitor probe shall be located within 2 to 7 meters above the ground, as is required for microscale $PM_{2.5}$ and PM_{10} sites. We also proposed 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.

b. Comments

EPA received comments from a number of States (*e.g.* Michigan, Mississippi, and Tennessee) indicating that the near-road network poses significant safety issues and a related need for increased logistical flexibility for installing a monitoring site. For example, the Mississippi Department of Environmental Quality states that "Given the fact that these NO_2 sites will be required to be housed in shelters that are within 50 meters of the road, we believe that these buildings could be large and pose a serious risk to drivers on the road."

EPA notes that in all instances of field work, safety is a top priority. In this instance of near-road monitoring, we are dealing with the safety of the public driving on roads and the monitoring staff who may operate the near-road monitoring station as well. There are various ways to install near-road sites while ensuring worker and traffic safety, and safety is an important part of the logistical considerations that States should consider when selecting and installing near-road sites. In many cases, State and local monitoring agencies may be able to work with their State or local transportation officials during the site selection process to deal with access and safety issues. In public comments, AASHTO recommended that "* * * State and local air monitoring agencies be required to coordinate with State and local DOTs for near-road monitoring during the establishment of the monitoring plan." Although EPA cannot require States to coordinate with other State or local entities, EPA believes that transportation officials would likely be able to assist in finding solutions to ensure safety while working with monitoring agencies in accommodating a new near-road monitoring station. An example of a step that could be taken to alleviate safety concerns might be purposefully placing a monitoring site behind existing barriers like guardrails and fencing, or possibly by installing a short distance of such barriers to protect the site workers, site infrastructure, and nearby traffic. In addition, EPA notes that the 50m distance proposed is wide enough to accommodate a site that would satisfy many setback provisions that exist for private or commercial building permits near roads, and may be viewed as a confirmation that our proposed siting criteria are safely attainable.

Some State commenters (*e.g.* AASHTO, NYSDOT, and Wisconsin) suggested that the allowable maximum distance a near-road monitoring probe can be from the target road be increased from 50 meters to something wider, such as 200 meters. Conversely, there were some State, environmental, and industry commenters (*e.g.* NESCAUM,[24] Group Against Smog and Pollution, and Air Quality Research and Logistics) who suggested that the proposed range was appropriate, or, as suggested by both NESCAUM and the Group Against Smog and Pollution, the allowable distance should be reduced to as close as 30 or 20 meters to the nearest edge of the traffic lanes of the target road segment, respectively.

EPA believes that increasing the allowable distance above 50 meters would compromise the intent of near-road monitoring. As was noted in the proposal and this document, the ISA (2.5.4 and 4.3.6) and REA (7.3.2) indicate that on-road, mobile source derived NO_2 exhibits a peak concentration on or very near the source road, and those concentrations decay over a variable but relatively short distance back to near area-wide or background (upwind of the target road) concentrations. 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, but the peak concentrations are occurring on or very near the source roadway. The behavior of NO_2 concentrations and the actual distance over which concentrations return to near area-wide or background levels 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). Therefore, monitor probe placement at increasing distances from a road, such as 200 meters, will correspondingly decrease the potential for sampling maximum concentrations of NO_2 due to the traffic on the target road. Baldauf *et al.* (2009) indicate that monitoring probes would ideally be situated between 10 and 20 meters from the nearest traffic lane for near-road pollutant monitoring.

Regarding the comments suggesting required monitor probes be closer than 50 meters, EPA believes the allowable distance of 50 meters that a near-road NO_2 probe can be from the target road provides enough flexibility for the logistical issues that can occur on a case-by-case basis, which is inherent in monitoring site placement, while not sacrificing the potential to monitor the peak NO_2 concentrations. However, in light of the information provided here on how NO_2 peak concentrations can decay over relatively short distances away from roads, EPA strongly encourages States to place near-road sites, or at least monitor probes, as close as safely possible to target roads to increase the probability of measuring the peak NO_2 concentrations that occur in the near-road environment, again noting that Baldauf *et al.* (2009) indicate that monitor probes would ideally be situated between 10 and 20 meters from the nearest traffic lane for near-road pollutant monitoring.

EPA also proposed that required near-road NO_2 monitor probes 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. EPA expects that when a State makes a measurement in determining whether an NO_2 inlet probe is no greater than 50 meters away, horizontally, from the outside nearest edge of the traffic lanes of the target road segment, that the measurement would likely represent a path to the monitor probe that is normal to the target road. However, EPA notes that the monitor probe will likely be influenced by various parts of the target road segment that are at a relative angle compared to the normal transect between the road and the monitor probe. EPA is not adjusting the wording of this requirement, but does intend for States to consider more than one linear pathway between the target road and the monitor probe being clear of obstructions when considering candidate site locations.

EPA received comments on the solicitation for comment on requiring near-road monitoring sites to be placed on the downwind side of the target road where the commenters (*e.g.* NACAA,[25] NESCAUM, and the Clean Air Council) encouraged such a requirement. Conversely, other commenters (*e.g.*, Air Quality and Logistics and NYSDEC suggested that such a requirement may be overly restrictive and not necessary. For example, NYSDEC stated that "It is important to avoid making the monitor siting criteria too restrictive. It is very likely that in some CBSAs, finding suitable locations near the busiest road segments will not be possible. It is also important to remember that the NO_2 monitoring instrumentation provides data continuously. Sites located downwind of sources will likely be impacted more frequently than the sites located upwind particularly when the sites are more than 50 meters from the source, and are preferred, but either side of the road will be downwind some of the time. Many of the highest NO_2 concentrations are also likely to occur during inversion periods and during calm meteorological conditions when the upwind-downwind designations have little meaning."

EPA noted in its proposal that 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. Further, 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, at least in part, to 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, but also reduces the absolute need to be downwind of the road. EPA believes that very few, if any, near-road sites would be able to be situated in a location that was always downwind. For example, a hypothetical

[24] NESCAUM officially supported the alternative network design; however, they made suggestions regarding the near-road network in the event EPA finalized the proposed two-tier network design.

[25] NACAA made a statement containing many concerns about the near-road monitoring component proposal which included a passage regarding the lack of requiring sites to be downwind. They expressed concern in "* * * allowing upwind siting of monitors over a wide range of horizontal and vertical distances from the road * * *".

site may have winds routinely out of several different cardinal directions throughout the year, without one being a dominant direction. As a result, given variable meteorology, for some period of a year, a given near-road site may not be downwind of the target road, no matter which side of the road it is on. Therefore, EPA is not finalizing a requirement that near-road sites must be climatologically downwind of the target road segment because of the additional limitations this introduces to finding potential site candidates in exchange for what may be a small increase in the opportunity to monitor peak NO_2 concentrations. However, EPA encourages States to place monitors in the climatologically downwind direction whenever possible, in an attempt to measure the peak NO_2 concentrations more often than not. One way States may identify where the predominantly downwind location might be for candidate sites could be to use portable meteorological devices to characterize meteorological tendencies, in addition to evaluating other available meteorological data sources.

EPA proposed that required near-road NO_2 monitor probes be located within 2 to 7 meters above the ground, as is required for microscale $PM_{2.5}$ and PM_{10} sites. EPA also proposed 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. NESCAUM commented that "EPA needs to reconcile near-roadway NO_2 probe height requirements with the existing *micro-scale near-roadway* CO probe height requirement of 2.5 to 3.5 meters above prevailing terrain. NESCAUM supports using this existing height for all near-roadway pollution monitors, as it minimizes probe height effects on measurements, and allows for proper measurement of collocated particle number concentration (which requires a very short inlet, *i.e.*, on the order of inches) and CO." NYSDEC commented that "The height requirement may not be practical for road segments in dense urban areas where existing buildings heights may exceed 7 meters. The requirement to maintain a 1 meter clearance from a supporting wall or structure may not be adequate for taller walls often found in urban areas. These walls can create down washing and street canyon effects which will make the resulting data less representative of nearby areas and will make interpretation of the resulting data difficult. However, there will need to be consistency between similar site settings." Finally, EPA received comments from some health groups (*e.g.*, ALA, EJ, EDF, and NRDC) who commented that "the lower end of the proposed height of 2 to 7 meters appears to capture the highest NO_2 concentrations, and more accurately represents human exposure at the breathing zone."

In the proposal, EPA noted that 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). EPA recognizes that consistency across sites with regard to probe height is desirable, and consistency with microscale, urban canyon CO sites might also be desirable. However, as was noted in the earlier discussion on "downwind" site placements, it is important to avoid making the monitor siting criteria too restrictive. An allowable range between 2 and 7 meters provides more flexibility in site installation, which EPA considers important because of the variety of siting situations each State may have to deal with for each individual site. While EPA agrees that a tighter allowable range such as 2.5 to 3.5 meters would reduce site to site variability and keep probes nearer the microscale siting requirements of CO, the wider range of 2 to 7 meters still provides an adequate amount of site to site consistency. EPA may also address this issue through forthcoming guidance, where an increased consistency for probe heights in similar situations such as urban canyons may be a site implementation goal, within the required 2 to 7 meter probe height range. Further, EPA believes that although certain situations, as noted by NYSDEC, may exist where the 1 meter clearance from walls or structures may be problematic near taller buildings or walls, this requirement is consistent with similar such clearance requirements for microscale CO sites in similar such situations that exist in urban canyons.

In the proposed rule, EPA proposed in the siting criteria language that the subsequent residence time of the pollutant in the sample line between the inlet probe and the analyzer cannot exceed 20 seconds. EPA received comments from Air Quality Research and Logistics regarding guidelines for maximum allowable inlet length and sample residence time, where they stated that "* * * the fast photodynamic O_3-NO_X equilibrium may occur in darkened sample lines at residence times of 10–20 seconds (Butcher *et al.* 1971; Ridley *et al.* 1988; Parrish *et al.* 1990). EPA should correct this apparent error by specifying much lower maximum residence times (*e.g.*, 1–2 seconds) or accounting for this effect by reporting 'corrected' values in error by no more than the allowed rounding convention (*e.g.*, ±1 ppb)."

EPA notes that in 40 CFR Part 58 Appendix E, paragraph (9)(c), states that sample probes for reactive gas analyzers, particularly NO_Y monitors, at NCore monitoring sites must have a sample residence time less than 20 seconds. EPA believes this rule is also appropriate for NO_2 monitors, particularly if a monitor inlet manifold is extended away from the main monitoring shelter. EPA does agree that shorter sample residence time in the inlet manifold is desirable. Although we do not believe it appropriate to require residence times on the order of 1 to 2 seconds, and do not believe correcting values is appropriate (which was not a concept which was proposed), we do encourage States to use best practices in selecting non-reactive manifold materials, and to install sampling manifolds in an efficient manner that minimizes sample residence time. While EPA proposed this concept in the preamble to the proposed rule, we did not include it in the proposed regulatory text. The final rule includes regulatory text on this subject at 40 CFR Part 58 Appendix E, paragraph (9)(c).

c. Conclusions on Near-Road Siting Criteria

We are finalizing the near-road NO_2 monitor siting criteria, as proposed, where (1) required near-road NO_2 monitor probes 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, (2) required near-road NO_2 monitor probes 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, (3) required near-road NO_2 monitors are required to have sampler inlets between 2 and 7 meters above ground level, and (4) residence time of NO_2 in the sample line between the inlet probe and the analyzer does not exceed 20 seconds.

8. Area-Wide Monitor Site Selection and Siting Criteria

The following paragraphs provide background, rationale, and details for the final changes to the site selection and monitor siting criteria for required area-wide monitoring sites.

a. Proposed Area-Wide Monitor Site Selection and Siting Criteria

EPA proposed that sites required as part of the second tier of the NO_2 monitoring network design, known as the area-wide monitoring component, be sited to characterize the highest expected NO_2 concentrations at the neighborhood and larger (area-wide) spatial scales in a CBSA.

b. Comments

While most commenters who supported area-wide monitoring did so with regard to the adoption of the alternative area-wide network design rather than as part of the proposed approach, only a few commented on the actual sites and siting criteria. The Dow Chemical Company suggested that area-wide sites should be located at least 1,000 meters away from any major roads or intersections to ensure that the concentration of NO_2 measured is representative of an area-wide concentration instead of peak near-road concentrations.

EPA notes that in order for an NO_2 monitoring site to be classified as a neighborhood (or larger) spatial scale site, it must meet the roadway set-back requirements in Table E–1 of 40 CFR Part 58 Appendix E. EPA believes that this existing set-back table is appropriate to use to ensure that any NO_2 site that may be intended as an area-wide site will be sufficiently distanced from any major road. For example, an NO_2 monitoring site may be considered neighborhood scale if it is 10 or more meters from the edge of the nearest traffic lane of a road with 10,000 or less AADT counts.

c. Conclusions on Area-Wide Monitor Site Selection and Siting Criteria

We are finalizing the requirement that any sites required as part of the second tier of the NO_2 monitoring network design, known as the area-wide monitoring component, be sited to characterize the highest expected NO_2 concentrations at the neighborhood and larger (area-wide) spatial scales in a CBSA.

9. Meteorological Measurements

The following paragraphs provide background, rationale, and details for the final changes to the requirement of meteorological monitoring at near-road monitoring sites.

a. Proposed Meteorological Measurements

In further support of characterizing the peak NO_2 concentrations occurring in the near-road environment, EPA proposed 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.

b. Comments

EPA received comments from the South Carolina Department of Health and Environmental Control commented that the recording of air turbulence data at near-road monitoring stations should be encouraged but not required. Other States (*e.g.*, Alaska, North Carolina, and Wisconsin) provided comments that did not support the proposed meteorological measurement requirements, noting issues with costs, problems siting the probe nearer to structures and to the ground than is typically done, and that the averaging period required to better understand turbulence (through anemometry data) in the near-road environment requires a much higher frequency than what is typically reported.

EPA is removing the proposed requirements that would have required meteorological monitoring at near-road NO_2 monitoring stations. However, EPA strongly encourages States to do some meteorological monitoring to better characterize the conditions under which they are acquiring NO_2 data. The near-road microscale environment is complex, and understanding the turbulent dispersion that may be affecting NO_2 measurements, along with having a basic understanding of from which direction the measured NO_2 concentrations are coming from, which are very informative in the effort to fully understand the data being collected. At a minimum, basic anemometry data would be useful in identifying whether the site is upwind, downwind, or otherwise oriented, relative to the target road.

c. Conclusions on Meteorological Measurements

We are not finalizing the proposal 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.

C. Data Reporting

The following paragraphs provide background, rationale, and details for the final changes to the data reporting requirements, data quality objectives, and measurement uncertainty.

1. Proposed Data Quality Objectives and Measurement Uncertainty

In the proposal, EPA noted that 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. We also noted that many 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. We believe these data reporting procedures are appropriate to support the revised primary NO_2 NAAQS.

EPA proposed to develop data quality objectives (DQOs) for the proposed NO_2 network. We proposed 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.

2. Comments

EPA received comments from the State of Missouri, supporting the proposed DQOs and goals for measurement uncertainty, and from North Carolina, suggesting that measurement uncertainty goals match those of the NCore multi-pollutant network.

EPA agrees that it is desirable to have measurement uncertainty goals that match that of other pollutants. EPA originally proposed the goals for precision and bias under consideration that there may be a need to account for potential increased uncertainty in 1-hour near-road NO_2 data. However, we agree with the suggestion from the State of North Carolina, and are changing the goals 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 10 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent. These goals match the existing goals for NO_2 and are consistent with historical measurement uncertainty goals.

3. Conclusions on Data Quality Objectives and Measurement Uncertainty

We are finalizing the approach to develop data quality objectives, and are changing the proposed goal for measurement uncertainty, where the goals 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 10 percent and for bias as an upper 95 percent confidence limit for the absolute bias of 15 percent.

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

The EPA proposed 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 detailed the computations necessary for determining when the proposed 1-hour and existing annual primary NO_2 NAAQS are met. The proposed Appendix S also addressed data reporting, data completeness considerations, and rounding conventions.

Two versions of Appendix S were proposed. The first applied to a 1-hour primary standard based on the annual 4th high value form, while the second applied to a 1-hour primary standard based on the 99th percentile daily value form.

The final version of Appendix S is printed at the end of this notice and applies to an annual primary standard and a 1-hour primary standard based on the 98th percentile daily value form. Appendix S is based on the 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 1-hour standard when making nonattainment determinations and other findings related to attainment or violation of the standard.

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

The EPA is also making 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 final NO_2 NAAQS.

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 pre-existing annual NO_2 NAAQS, originally adopted in 1977, contained 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.

A. Interpretation of the Primary NAAQS for Oxides of Nitrogen for the Annual Primary Standard

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 regulatory text at 40 CFR 50.11, anticipating and resolving in advance various future situations that could occur. 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 addressed several issues in ways which are specific to the individual primary NO_2 standards, as described below.

1. Proposed Interpretation of the Annual Standard

The proposed data interpretation provisions for the annual standard are consistent with the pre-existing instructions included along with the statement of the level and form of the standard in 40 CFR 50.11. 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).

In the proposal, EPA noted that 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 also incorporated some such features.

2. Comments on Interpretation of the Annual Standard

We received four comments, all from State agencies, on data interpretation for the annual NO_2 standard. Of the four commenters, two recommended the use of a weighted annual mean to appropriately implement the annual primary standard. Two other commenters asserted that there is no strong seasonality in NO_2 concentrations, and that therefore there is no need to use a weighted annual mean or to require data completeness quarter-by-quarter.

3. Conclusions on Interpretation of the Annual Standard

Upon investigating the issue of NO_2 seasonality using data from AQS as part of considering the comments, we have found that there are notable variations in quarterly mean NO_2 concentrations. It is therefore quite possible that an unweighted annual mean calculated without a quarter-by-quarter data completeness requirement might not represent the true annual mean as well as a weighted annual mean calculated with a quarter-by-quarter completeness requirement. However, the current practice of requiring 75% completeness of all of the hours in the year and calculating the annual mean without weighting has been retained in the final rule, because of its simplicity and because we believe it will not interfere with effective implementation of the annual NAAQS. No area presently is nonattainment for or comes close to violating the annual standard. Therefore, the choice between the two approaches can only have a practical effect, if any, on whether at some time in the future an area is determined to be newly violating the annual standard. If a monitor has a complete and valid design value below the standard using the unweighted mean approach (with only an annual data completeness requirement) but the design value would be considered incomplete and invalid under a hypothetical weighted mean approach (with a quarterly completeness requirement), the monitor would in either case be considered not to be violating and its data would not be the basis for a nonattainment designation. If a monitor has a design value above the standard using the unweighted annual mean approach but is incomplete with respect to a hypothetical quarterly completeness requirement, then the two approaches would have different implications for the determination of a violation. A quarterly completeness requirement would make a finding of violation impossible, unless the Administrator chose to treat the data as if complete under another provision of the final rule. The unweighted annual mean approach would allow but not force a finding of violation, because the Administrator will have discretion to make any such findings because there will be no mandatory round of designations for the annual standard given that the annual standard has not been revised in this review. The Administrator will be able to consider the representativeness of the unweighted annual mean when deciding whether to make a discretionary nonattainment redesignation. Given that the annual standard requires only one year of monitoring data for the calculation of a design value, little time will be lost if the Administrator chooses to work with a State to obtain a new design value based on more complete and/or seasonally balanced monitoring data.

B. Interpretation of the Primary NAAQS for Oxides of Nitrogen 1-Hour Primary Standard

1. Proposed Interpretation of the 1-Hour Standard

With regard to data completeness for the 1-hour primary standard with a 4th highest daily value form, the proposed Appendix followed 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 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 was proposed to be applied at the daily and quarterly levels.

Recognizing that there may be years with incomplete data, the proposed text provided that a design value derived from incomplete data would 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 high values to exceed the standard. In this situation, more complete monitoring could not possibly have indicated that the standard was actually met.

Second, we proposed a diagnostic data substitution test which was 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.

It should be noted that one possible 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.

Also, we proposed 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.

The second version of the proposed Appendix S contained 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 had somewhat different provisions for dealing with data incompleteness. One difference was 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 provided 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 $PM_{2.5}$ 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 provided instructions for rounding (not truncating) the average of three annual 99th percentile hourly concentrations before comparison to the level of the primary NAAQS.

2. Comments on Interpretation of the 1-Hour Standard

Three commenters expressed the view that the 75% completion per quarter requirement should apply with respect to the 1-hour standard. A fourth commenter recommended that the requirement be increased to 82%. Another person commented that the requirement of 75% of the hours in a day is too stringent. The commenter noted that it would be inappropriate not to count the day if the maximum concentration observed in the hours measured is sufficiently high to make a difference with regard to compliance with the NAAQS. A comment was received that the substitution test should not be included, on the grounds that nonattainment should not be declared without irrefutable proof. This commenter also said that the same completeness requirement as used for nonattainment should be used for attainment. We received one comment that the computation of design values where multiple monitors are present at a site should be averaged and not taken from a designated primary monitor.

3. Conclusions on Interpretation of the 1-Hour Standard

Consistent with the Administrator's decision to adopt a 98th percentile form for the 1-hour NAAQS, the final version of Appendix S is based on that form. Table 1 has been revised from the version that was proposed, so that it results in the selection of the 98th percentile value rather than the 99th percentile value.

We agree with the three comments expressing the view that the requirement for 75% data completeness per quarter should apply with respect to the 1-hour standard. A fourth comment recommended that the requirement be increased to 82%. We believe 82% is too stringent because of the number of monitors that would not achieve such a requirement and we believe that 75% captures the season. We agree that an incomplete day should be counted if the maximum concentration observed in the hours measured is sufficiently high to make a difference with regard to compliance with the NAAQS, and we have accounted for that in section 3.2.c.i by validating the design value if it is above the level of the primary 1-hour standard when at least 75 percent of the days in each quarter have at least one reported hourly value. We agree that substitution should not be used for the establishment of attainment/nonattainment. The commenter who remarked on this issue appears not to have understood that the specific proposed substitution tests have essentially zero probability of making a clean area fail the NAAQS, or vice versa, because the substituted values are chosen to be conservative against such an outcome. As noted in section 3.2(c)(i), when substitution is used, the 3-year design value based on the data actually reported, not the "test design value", shall be used as the valid design value.

In the course of considering the above comment regarding data substitution tests to be used in cases of data incompleteness, EPA has realized that there could be some cases of data incompleteness in which the proposed procedure for calculating the 1-hour design value might result in an in appropriately low design value. As proposed, only days with measurements for at least 75% of the hours in the day would be considered in any way when identifying the 99th percentile value (99th for purposes of the adopted NAAQS). However, there could be individual hours in other, incompletely monitored days that had measured concentrations higher than the identified 98th percentile value from the complete days. It would be inappropriate not to consider those hours and days in some way. However, if all days with at least one hourly concentration were used to identify the 99th percentile value without any regard to their incompleteness, this could also result in a design value that is biased low because the extra days could increase the number of "annual number of days with valid data" enough to affect which row of Table 1 of Appendix S is used. It could, for example, result in the 8th highest ranked daily maximum concentration being identified as the 98th percentile value (based on Table 1 of Appendix S) rather than a higher ranked concentration; this would also be inappropriate because days which were not monitored intensively enough to give a reasonable likelihood of catching the maximum hourly concentration would in effect be treated as if they had such a likelihood. For example, 50 days with only one hourly measurement during a time of day with lower concentrations would "earn" the State the right to drop one notch lower in the ranking of days when identifying the 98th percentile day, inappropriately. The final version of Appendix S solves this problem by providing that two procedures be used to identifying the 98th percentile value, the first based only on days with 75% data completeness and the second based on all days with at least one hourly measurement. The final design value is the higher of the two values that result from these two procedures.

With regard to situations with multiple monitors operating at one site, we think as discussed in the proposal, that designation of a primary monitor is preferable to averaging the data from multiple monitors based on administrative simplicity and transparency for the public, and is unbiased with respect to compliance outcome provided the State is able to make the designation only before any data has been collected.

Finally, as proposed, the final version of Appendix S has a cross reference to the Exceptional Events Rule (40 CFR 50.14) with regard to the exclusion of data affected by exceptional events. In addition, the specific steps for including such data in completeness calculations while excluding such data from actual design value calculations is clarified in Appendix S.

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."

EPA proposed revised exceptional event data flagging and documentation deadlines in FR 34404 [**Federal Register**/Vol. 74, No. 134/Wednesday, July 15, 2009/Proposed Rules] and invited comments from the public. The Agency received no comments related to the revised proposed schedule for NO_2 exceptional event data flagging and documentation deadlines.

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.

The final rule text at the end of this notice shows the changes that will 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.

Table 1 below summarizes the data flagging and documentation deadlines corresponding to the two year designation schedule discussed in this section. If the promulgation date for a revised NO_2 NAAQS occurs on a different date than January 22, 2010, EPA will revise the final NO_2 exceptional event flagging and documentation submission deadlines accordingly to provide States with reasonably adequate opportunity to review, identify, and document exceptional events that may affect an area designation under a revised NAAQS.

TABLE 1—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
NO_2/1-Hour Standard (100 PPB)	2008	July 1, 2010 [a]	January 22, 2011.
	2009	July 1, 2010	January 22, 2011.
	2010	April 1, 2011 [a]	July 1, 2011.[a]

[a] 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. Designation of Areas

A. Proposed Process

The CAA requires EPA and the States to take steps to ensure that the new or revised NAAQS are met following promulgation. The first step is to identify areas of the country that do not meet the 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 should be designated as nonattainment, attainment, or unclassifiable for the new NAAQS. 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."

No later than 120 days prior to promulgating designations, EPA is required to notify States of any intended modifications to their designations 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, the EPA must promulgate the designation that it deems appropriate.

Accordingly, Governors must submit their initial NO_2 designation recommendations to EPA no later than January 2011. If the Administrator intends to modify any State's recommendation, the EPA will notify the Governor no later than 120 days prior to 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 finalized.

B. Public Comments

Several industry commenters requested that EPA slow the timeline for implementing a near-roadway monitoring network and designating roadway areas because they believe EPA lacks significant information about the implementation and performance of a national, near-roadway monitoring network. Two commenters also requested that if a near-roadway monitoring network is deployed, that 1-hour NO_2 standards be made more lenient until the next review period so that more information will be available about near-roadway NO_2 concentrations before a stringent standard is selected.

A response to commenters' requests that EPA slow the monitoring implementation schedule and the request that EPA make the 1-hour NO_2 standard more lenient until the next review period are addressed in sections III.B.5 and II.F.4.D, respectively.

Section 110(d)(1)(B) requires the EPA to designate areas no later than 2 years following promulgation of a new or revised NAAQS (*i.e.*, by January 2012). 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 an additional year would not result in significant new data to inform the initial designations. A near-roadway monitoring network is not expected to be fully deployed until January 2013 therefore, EPA must proceed with initial designations using air quality data from the existing NO_2 monitoring network. Because none of the current NO_2 monitors are sited to measure near-roadway ambient air, we expect that most areas in the country with current NO_2 monitors will not violate the new NO_2 NAAQS. In the event that a current NO_2 monitor indicates a violation of the revised standards, EPA intends to designate such areas "nonattainment" no later than 2 years following promulgation of the revised standards. We intend to designate the rest of the country as "unclassifiable" for the revised NO_2 NAAQS until sufficient air quality data is collected from a near-roadway monitoring network. Once the near-roadway network is fully deployed and 3 years of air quality data are available, the EPA has authority under the CAA to redesignate areas as appropriate from "unclassifiable" to "attainment" or "nonattainment." We anticipate that sufficient data to conduct designations would be available after 2015.

A number of commenters, largely from industry groups, focused on the concern that a near-roadway monitoring network would lead to regional nonattainment on the basis of high NO_2 concentrations found near roadways. These commenters requested that any future nonattainment areas be limited to the area directly surrounding roadways found to have above-standard NO_2 concentrations.

The CAA requires that any area that does not meet a NAAQS or that contributes to a violation in a nearby area that does not meet the NAAQS be designated "nonattainment." States and EPA will need to determine which sources and activities contribute to a NAAQS violation in each area. Depending on the circumstances in each area this may include sources and activities in areas beyond the area directly surrounding a major roadway. EPA intends to issue nonattainment area boundary guidance after additional information is gathered on the probable contributors to violating near-roadway NO_2 monitors.

C. Final Designations Process

The EPA intends to promulgate initial NO_2 designations by January 2012 (2 years after promulgation of the revised NAAQS). Along with today's action EPA is also promulgating new monitoring rules that focus on roadways. As noted in section III, States must site required NO_2 near-roadway monitors and have them operational by January 1, 2013. States will need an additional 3 years thereafter to collect air quality data in order to determine compliance with the revised NAAQS. This means that a full set of air quality data from the new network will not be available until after 2015. Since we anticipate that data from the new network will not be available prior to the CAA designation deadlines discussed above, the EPA intends to complete initial NO_2 designations by January 2012 using the 3 most recent years of quality-assured air quality data from the current monitoring network, which would be for the years 2008–2010. The EPA will designate as "nonattainment" any areas with NO_2 monitors recording violations of the revised NO_2 NAAQS. We intend to designate all other areas of the country as "unclassifiable" to indicate that there is insufficient data to determine whether or not they are attaining the revised NO_2 NAAQS.

Once the NO_2 monitors are positioned in locations meeting the near-roadway siting requirements and monitoring data become available, the Agency has authority under section 107(d)(3) of the CAA to redesignate areas as appropriate from "unclassifiable" to "attainment" or "nonattainment." The EPA intends to issue guidance on the factors that States should consider when determining nonattainment boundaries after additional information is gathered on the probable contributors to violating near-roadway NO_2 monitors.

VI. 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.[26] 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 help areas meet 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 and nonattainment new source review (NSR). *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 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.

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

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

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. Classifications

1. Proposal

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 for certain pollutants including NO_2 in sections 191 and 192: 18 months from nonattainment designation for the submittal of an attainment plan, and as expeditiously as possible, but no later than 5 years from nonattainment designation for areas to attain the standard. In the proposal, EPA stated its belief that classifications are unnecessary in light of these relatively short deadlines.

2. Public Comments

One commenter stated that they disagree with EPA's decision not to impose non-attainment classifications on areas with measured near-road NO_2 concentrations in excess of the new NO_2 standard, and urged EPA to provide a graduated non-attainment classification system for the new standard. According to the commenter, "a classification system defining higher levels of non-attainment with increasingly stringent requirements at those levels is one that allows for finer calibration of air quality regulatory response defined at the Federal level."

As stated in the proposed rule, Section 192(a), of part D, of the CAA specifically provides an attainment date for areas designated as nonattainment for the NO_2 NAAQS. Therefore, EPA has legal authority to classify NO_2 nonattainment areas, but the 5-year attainment date addressed under section 192(a) cannot be extended pursuant to section 172(a)(2)(D). Based on this limitation, EPA proposed not to establish classifications within the 5-year interval for attaining any new or revised NO_2 NAAQS. It is also EPA's belief that given the short deadlines that States have to develop and submit SIP's and for areas to achieve emissions reductions in order to attain the standard within the 5 year attainment period, a graduated classifications system would not be appropriate. Therefore, EPA is using it's discretion under the CAA not to establish classifications.

3. Final

EPA is not making any changes to the discussion on classifications in the proposed rule. Therefore, there will be no classifications for the revised NO_2 NAAQS.

B. Attainment Dates

The maximum deadline 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 NAAQS for NO_2 if revised, which will be codified at 40 CFR part 50, Appendix F.

1. Attaining the NAAQS

a. Proposal

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.

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion on attaining the NAAQS in the proposed rule.

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

a. Proposal

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."

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion on consequences of failing to attain by the statutory attainment date in the proposed rule.

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

1. Proposal

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.[27] 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 and 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.

2. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion on section 110(a)(2) NAAQS infrastructure requirements in the proposed rule.

D. Attainment Planning Requirements

1. Nonattainment Area SIPs

a. Proposal

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)

[27] 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.

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 contains an attainment demonstration that 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 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.

b. Public Comments

Several commenters indicated that EPA should take steps to ensure that States actually require mobile source emissions reductions in order to attain the NO_2 NAAQS as opposed to controlling point sources. Another commenter went further and stated that States be required to control on-road emissions as opposed to emissions from stationary sources and in particular EGUs. This commenter also indicated that EPA should delay nonattainment designations until States had a cost effective means of reducing on-road emissions of NO_2.

EPA cannot require States to develop a SIP that only addresses one type of source, in this case on-road mobile sources. States may select appropriate control measures to attain the NAAQS and EPA must approve them if they otherwise meet all applicable requirements of the Act. *See* CAA 116. EPA expects that States will evaluate a range of control measures that will reduce NO_2 emissions within the time allowed to attain the standard. This would include the emissions reductions attributable to Federal controls on on-road and non-road mobile sources, and controls that they have put in place to reduce NO_X emissions in order to attain the 8-hour ozone NAAQS and/or the $PM_{2.5}$ NAAQS. If these existing controls are not sufficient for an area to reach attainment with the NO_2 NAAQS, EPA would expect the State to implement additional control measures that would bring the area into attainment by the deadline. For a designation based on data from a near roadway monitor EPA would expect the States to give primary consideration to controlling emissions from on-road sources; however, it is likely that other types of sources contribute to the concentrations that are measured at a near roadway monitor and a State may decide to implement controls on these other contributing sources.

The Clean Air Act requires that EPA finalize designations within two years after a NAAQS is revised unless the available air quality data is insufficient to make designations by that time. In that case, EPA must finalize designations within three years after the NAAQS is revised. As discussed elsewhere in today's final rule, EPA believes that it has sufficient data to make designations within two years and that most areas will be designated as unclassifiable at that time. Taking the additional year provided by the CAA would not allow additional data from the new near roadway monitors to be factored into the designations process in any event. Therefore, it is EPA's intention to designate areas within two years as required by the Act. EPA intends to redesignate areas once it has sufficient data from the new monitoring network to designate areas as clearly attaining or not attaining the standard.

c. Final

The EPA is not making any changes to the discussion on nonattainment area SIPs in the proposed rule.

2. New Source Review and Prevention of Significant Deterioration Requirements

a. Proposal

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.[28] 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

[28] 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.

unclassifiable for any criteria pollutant, is constructed, or undergoes a major modification.[29] 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 source NSR program addresses both major and minor sources which undergo construction or modification activities that do not qualify as major, and it applies, as necessary to assure 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 assure 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 may apply.

b. Public Comments

One commenter claimed that EPA's setting of a more stringent standard, *i.e.,* short-term NO_2 NAAQS, could have important implications for NSR and PSD and title V permits. Another commenter indicated that the promulgation of a new 1-hr NO_2 short-term standard could create the need for a short-term PSD increment. Another commenter stated that a 1-hr NO_2 Significant Impact Level (SIL) should be developed.

The EPA acknowledges that a decision to promulgate a new short-term NO_2 NAAQS will clearly have implications for the air permitting process. The full extent of how a new short-term NO_2 NAAAQS will affect the NSR process will need to be carefully evaluated. First, major new and modified sources applying for NSR/PSD permits will initially be required to demonstrate that their proposed emissions increases of NO_X will not cause or contribute to a violation of either the annual or 1-hour NO_2 NAAQS and the annual PSD increment. In addition, we believe that section 166 of the CAA authorizes us to consider the need to promulgate a new 1-hour increment. Historically, EPA has developed increments for each applicable averaging period for which a NAAQS has been promulgated. However, increments for a particular pollutant do not necessarily need to match the averaging periods that have been established for NAAQS for the same pollutant. *Environmental Defense Fund, Inc.* v. *EPA,* 898 F.2d 183, 189–190 (DC Cir. 1990) ("* * * the 'goals and purposes' of the PSD program, set forth in 160, are not identical to the criteria on which the ambient standards are based.") Thus, we would need to evaluate the need for a new 1-hour NO_2 increment in association with the goals and purposes of the statutory PSD program requirements.

We also believe that there may be a need to revise the screening tools currently used under the NSR/PSD program for completing NO_2 analyses. These screening tools include the significant impact levels (SILs), as mentioned by one commenter, but also include the significant emissions rate for emissions of NO_X and the significant monitoring concentration (SMC) for NO_2. EPA intends to evaluate the need for possible changes or additions to each of these important screening tools for NO_X/NO_2 due to the addition of a 1-hour NO_2 NAAQS. If changes or additions are deemed necessary, EPA will propose any such changes for public notice and comment in a separate action.

c. Final

The EPA is not making any changes to the discussion concerning the requirements for NSR and PSD as stated in the proposed rule.

3. General Conformity

a. Proposal

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:[30] carbon monoxide (CO), lead (Pb), nitrogen dioxide (NO_2), ozone (O_3), particulate matter ($PM_{2.5}$ and PM_{10}), and sulfur dioxide (SO_2). 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.

b. Final

EPA did not receive any comments on this aspect of the proposed rule and is not making any changes to the discussion concerning general conformity stated in the proposed rule.

[29] 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).

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

4. Transportation Conformity

a. Proposal

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 (O_3), 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 51.390, and Part 93, Subpart A establishes the criteria and procedures for determining whether transportation activities conform to the SIP. The EPA is not making changes to the Transportation Conformity rule in this rulemaking. However, in the future, EPA will review the need to conduct a 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.

b. Public Comments

Several commenters stated that transportation conformity could stop the funding of highway and transit projects in NO_2 nonattainment areas. These commenters stated that if an area fails to demonstrate conformity, it enters a conformity lapse and only certain types of projects can be funded during a lapse. The commenters further stated that the NO_2 NAAQS will require more areas to determine conformity for the first time. The commenters also expressed concern that the NO_2 NAAQS proposal did not contain sufficient information to understand to what extent revisions to the NAAQS, and the NO_2 monitoring requirements, will result in transportation conformity requirements for individual transportation projects such as the need for a hot-spot analysis. The commenters further stated that hot-spot analyses could result in needless delays for transportation improvement projects.

With regard to the comment that more areas will have to demonstrate conformity for the first time due to the revisions to the NO_2 NAAQS, given that today's final rule is requiring that near roadway monitoring be carried out in urban areas with populations greater than 350K, EPA believes that most areas with such populations that would be designated nonattainment for NO_2 are already designated nonattainment or maintenance for one or more of the other transportation-related criteria pollutants (ozone, $PM_{2.5}$, PM_{10} and carbon monoxide). As such, these areas would have experience in making transportation conformity determinations. If areas with no conformity experience are designated nonattainment for the NO_2 NAAQS, EPA and U.S. DOT would be available to assist areas in implementing the transportation conformity requirements.

The commenter expressed concern that transportation conformity could stop highway and transit funding because areas could experience a conformity lapse and in such cases only certain types of projects could be funded. A conformity lapse occurs when an area misses a deadline for a required conformity determination. A new nonattainment area must demonstrate conformity within one year after the effective date of its designation. For any areas designated nonattainment for the revised NO_2 NAAQS in early-2012, they would have to determine conformity within one year of the effective date of that designation which would be in early-2013. If that date was missed, a lapse would occur and only projects exempt from conformity such as safety projects, transportation control measures in an approved SIP for the area and projects or project phases that were approved by U.S. DOT before the lapse began can proceed during the lapse. EPA's experience in implementing the 1997 ozone and $PM_{2.5}$ NAAQS shows that nearly all areas make their initial conformity determinations within the one-year grace period. Areas can also lapse if they fail to determine conformity by an applicable deadline such as determining conformity within two years after motor vehicle emissions budgets are found adequate. However, areas that miss one of these conformity deadlines have a one-year grace period before the lapse goes into effect. During the grace period, the area can continue to advance projects from the transportation plan and transportation improvement program. EPA's experience is that areas generally are able to make a conformity determination before the end of the grace period.

The commenter expressed concern that the NO_2 NAAQS proposal did not contain sufficient detail concerning possible project-level requirements for transportation projects and that any requirements for hot-spot analyses could needlessly delay transportation projects. As EPA indicated in the NPRM, EPA is considering whether to revise the transportation conformity rule to establish requirements that would apply to transportation plans, transportation improvement programs and/or transportation projects in NO_2 nonattainment and maintenance areas. If EPA concludes that the conformity rule must be revised in light of the final NO_2 NAAQS, we will conduct notice and comment rulemaking to accomplish the revisions. At that time interested parties will have the opportunity to comment on any transportation conformity NPRM. This is the same course of action that EPA has taken with respect to revising the transportation conformity rule for the ozone and $PM_{2.5}$ NAAQS.

With regard to the commenter's assertion that a requirement for hot-spot analyses for individual projects would needlessly delay transportation projects, EPA disagrees. First, CAA section 176(c)(1)(B) requires that transportation projects not cause new violations or make existing violations worse, or delay timely attainment or cause an interim milestone to be missed. EPA would only impose a hot-spot requirement for projects in NO_2 nonattainment and maintenance areas if they are necessary to comply with CAA conformity requirements and therefore are needed to protect public health by reducing exposures to unhealthy levels of NO_2 that could be created by the implementation of a proposed highway or transit project. The public would be exposed to unhealthy levels of NO_2 if a highway or transit project caused a new violation of the NO_2 NAAQS, made an existing violation worse, or delayed timely attainment or delayed achieving an interim emissions milestone. If any delay in the project did occur, it would not be viewed as needless as it occurred for the important purpose of protecting the exposed public's health. Second, EPA does not agree that requiring a hot-spot analysis would needlessly delay projects in NO_2 nonattainment areas. Such hot-spot analyses, if they are eventually required, generally would be done as part of the NEPA process, which these projects are already subject to; therefore, conducting an NO_2 hot-spot analysis would not be introducing a new step to a project's approval process, but rather would add one additional analysis which must be completed as part of an existing project approval process.

c. Final

EPA is not making any changes to the discussion concerning transportation conformity as stated in the proposed rule.

VII. 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. This section describes the conforming changes that were proposed, major comments received on these changes, EPA's responses to these comments and final decisions on the AQI breakpoints. Recognizing the importance of revising the AQI in a timely manner to be consistent with any revisions to the NAAQS, EPA proposed conforming changes to the AQI in connection with the final decision on the NO_2 NAAQS if revisions to the primary standard were 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 did 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, EPA proposed to set this value to be between 0.040 and 0.053 ppm NO_2, 1-hour average. EPA proposed that the figure 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 noted that 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, and solicited comments on this range for an AQI of 50 and the appropriate basis for selecting an AQI of 50 within this range.

With regard to an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, 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 proposed to set the AQI value of 150 to be between 0.360 and 0.370 ppm NO_2, 1-hour average.

EPA received comments from several State environmental agencies and organizations of State and local agencies that generally expressed the view that the AQI was designed to provide the public with information about regional air quality and therefore it should be based on community-wide monitors. These commenters went on to state that using near-road NO_2 monitors for the AQI would present problems because they would not represent regional NO_2 concentrations and it would be difficult to communicate this type of information to the public using the AQI. Some expressed concern that NO_2 measured at near-roadway monitors could be the critical pollutant and could drive the AQI even though it may not represent air quality across the area. Other agencies expressed concern that there is currently no way to forecast ambient NO_2 levels near roadways. One State agency commented that the AQI is intended to represent air quality where people live, work and play.

EPA agrees with commenters that the AQI should represent regional air quality, and that measurements that apply to a limited area should not be used to characterize air quality across the region. Community-wide NO_2 monitors should be used to characterize air quality across the region. However, the AQI reporting requirements encourage, but do not require, the reporting of index values of sub-areas of an MSA. We agree with the commenter that stated the view that the AQI is intended to represent air quality where people live, work and play. To the extent that near-roadway monitoring occurs in areas where people live, work or play, EPA encourages reporting of the AQI for that specific sub-area of the MSA (64 FR 42548, August 4, 1999). We also agree that it may be difficult to communicate this type of information and we plan to work with State and local air agencies to figure out the best way to present this information to the public using the AQI. Air quality forecasting is recommended but not required (64 FR 42548, August 4, 1999). EPA will work with State agencies that want to develop a forecasting program.

With regard to the proposed breakpoints, EPA received few comments. The National Association of Clean Air Agencies commented that it would be confusing to the public to have an AQI value of 50 set below the level of the annual NO_2 standard. We agree with this comment, and therefore have decided that it is appropriate to set the AQI value of 50, the breakpoint between the good and moderate ranges, set at the numerical level of the annual standard, 53 ppb NO_2, 1-hour average. The AQI value of 100, the breakpoint between the moderate and unhealthy for sensitive groups category, is set at 100 ppb, 1-hour average, the level of the primary NO_2 NAAQS. EPA is setting an AQI value of 150, the breakpoint between the unhealthy for sensitive groups and unhealthy categories, at 0.360 ppm NO_2, 1-hour average.

VIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action" because it was deemed to "raise novel legal or policy issues." Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 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 final rule.

B. Paperwork Reduction Act

The information collection requirements in this final 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 requirements are not enforceable until OMB approves them.

The Information Collection Request (ICR) document prepared by EPA for these revisions to part 58 has been assigned EPA ICR number 2358.02.

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 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 $3,261,007. 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.

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 final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final 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 Ass'ns* v. *EPA*, 175 F.3d 1027, 1044–45 (DC cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the 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.

D. Unfunded Mandates Reform Act

This 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. Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

With regard to implementation guidance, the CAA imposes the obligation for States to submit SIPs to implement the NO_2 NAAQS. In this final 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.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments.

E. Executive Order 13132: Federalism

This action 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.

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

This action does not have Tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). 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 action.

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

This action is subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by Executive Order 12866, and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. The final 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 Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action 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. 27_2 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 final rulemaking involves technical standards. Therefore the Agency conducted a search to identify potential applicable voluntary consensus standards. However, we identified no such standards, and none were brought to our attention in comments. Therefore, EPA has decided to use the technical standard described in Section III.A of the preamble.

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 final 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 final rule will establish uniform national standards for NO_2 in ambient air.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on April 12, 2010.

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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: January 22, 2010.

Lisa P. Jackson,

Administrator.

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

PART 50—NATIONAL PRIMARY AND SECONDARY AMBIENT AIR QUALITY STANDARDS

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

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

■ 2. Section 50.11 is revised to read as follows:

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

(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 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 98th percentile of the daily maximum 1-hour average concentration is less than or equal to 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 adding an entry to the end of table in paragraph (c)(2)(vi) to read as follows:

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

* * * * *

(c) * * *

(2) * * *

(vi) * * *

TABLE 1—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
* * *	*	* *	*
NO_2/1-Hour Standard (100 PPB)	2008	July 1, 2010 [a]	January 22, 2011.
	2009	July 1, 2010	January 22, 2011.
	2010	April 1, 2011 [a]	July 1, 2011 [a].

[a] 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 to Part 50 is added to read as follows:

Appendix S to Part 50—Interpretation of the Primary National Ambient Air Quality Standards for Oxides of Nitrogen (Nitrogen Dioxide)

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 98th percentile daily maximum 1-hour values for a monitoring site (referred to as the "1-hour primary standard design value").

98th percentile daily maximum 1-hour value is the value below which nominally 98 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 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, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, 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, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, 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, including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator; 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, excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator, 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 non-excluded 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 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 98th 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 98th percentile value is accomplished as follows.

(i) The annual 98th percentile value for a year is the higher of the two values resulting from the following two procedures.

(1) Procedure 1.

(A) For the year, determine the number of days with at least 75 percent of the hourly values reported including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(B) For the year, from only the days with at least 75 percent of the hourly values reported, select from each day the maximum hourly value excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(C) Sort all these daily maximum hourly 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 98th 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) as determined from step (A). The corresponding "n" value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of daily site values for year y. Thus, $P_{0.98,\ y}$ = the nth largest value.

(2) Procedure 2.

(A) For the year, determine the number of days with at least one hourly value reported including State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(B) For the year, from all the days with at least one hourly value reported, select from each day the maximum hourly value excluding State-flagged data affected by exceptional events which have been approved for exclusion by the Administrator.

(C) Sort all these daily maximum 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 98th 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) as determined from step (A). The corresponding "n" value in the right column identifies the rank of the annual 98th percentile value in the descending sorted list of daily site values for year y. Thus, $P_{0.98,\ y}$ = the nth largest value.

(b) The 1-hour primary standard design value for a site is mean of the three annual 98th percentile values, rounded according to the conventions in section 4.

TABLE 1

Annual number of days with valid data for year "y" (cn_y)	$P_{0.98,\,y}$ is the nth maximum value of the year, where n is the listed number
1–50	1
51–100	2
101–150	3
151–200	4
201–250.	5
251–300	6
301–350	7
351–366	8

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 the definitions for "AADT" 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(d), 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, 2012. The plan shall provide for all required monitoring 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, and E 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 and PAMS 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 by adding paragraph 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 by adding paragraph 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 paragraph 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 500,000 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 500,000 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, considering fleet mix, roadway design, congestion patterns, terrain, and meteorology, where maximum hourly NO_2 concentrations are expected to occur 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 shall consider 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 utilizing chemiluminescence FRMs must include at a minimum: NO, NO_2, and NO_X.

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 Administrators, in collaboration with States, must require a minimum of forty additional NO_2 monitoring stations nationwide in any area, inside or outside of CBSAs, above the minimum monitoring requirements, with a primary focus on siting these monitors in locations to protect susceptible and vulnerable populations. The Regional Administrators, working with States, may also consider additional factors described in paragraph (b) below to require monitors beyond the minimum network requirement.

(b) The Regional Administrators may require monitors to be sited inside or outside of CBSAs in which:

(i) The required near-road monitors do not represent all locations of expected maximum hourly NO_2 concentrations in an area and NO_2 concentrations may be approaching or exceeding the NAAQS in that area;

(ii) Areas that are not required to have a monitor in accordance with the monitoring requirements and NO_2 concentrations may be approaching or exceeding the NAAQS; or

(iii) The minimum monitoring requirements for area-wide monitors are not sufficient to meet monitoring objectives.

(c) 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 address the data needs for an area, and include all monitors under this provision in the annual monitoring network plan.

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 represents 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 represents 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 multi-pollutant 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. Appendix E to Part 58 is amended as follows:

■ a. By revising paragraphs 2, and 6.1.

■ b. By adding paragraphs 4(d) and 6.4.

■ c. By revising paragraphs 9(c), 11 and 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 $3\pm\frac{1}{2}$ 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. * * *

(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 the 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 form the Table E–1 of this appendix. The sum of these distances must not be greater than 10 percent of the total monitoring path length.

* * * * *

9. * * *

(c) No matter how nonreactive the sampling probe material is initially, after a period of use reactive particulate matter is deposited on the probe walls. Therefore, the time it takes the gas to transfer from the probe inlet to the sampling device is also critical. Ozone in the presence of nitrogen oxide (NO) will show significant losses even in the most inert probe material when the residence time exceeds 20 seconds.[26] Other studies [27] [28] indicate that a 10 second or less residence time is easily achievable. Therefore, sampling probes for reactive gas monitors at NCore and at NO_2 sites must have a sample residence time less than 20 seconds.

* * * * *

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 as by revising paragraph 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 AQIs	
O_3 (ppm) 8-hour	O_3 (ppm) 1-hour[1]	$PM_{2.5}$ ($\mu g/m^3$)	PM_{10} ($\mu g/m^3$)	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	0–0.053	0–50	Good.
0.060–0.075	....	15.5–40.4	55–154	4.5–9.4	0.035–0.144	0.054–0.100	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	0.101–0.360	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	0.361–0.64	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-hours 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. 2010–1990 Filed 2–8–10; 8:45 am]

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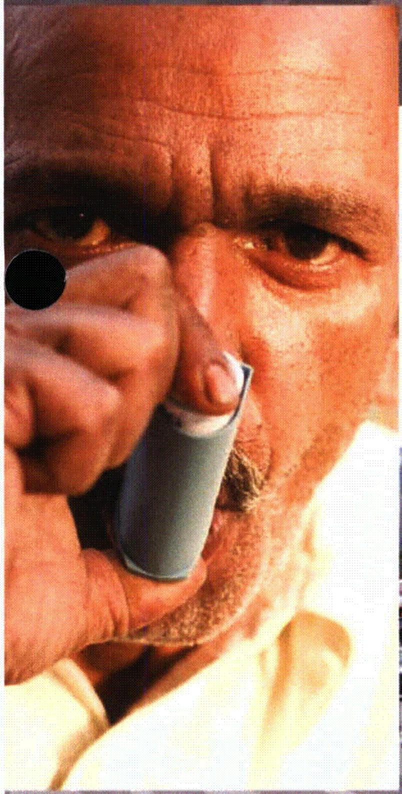
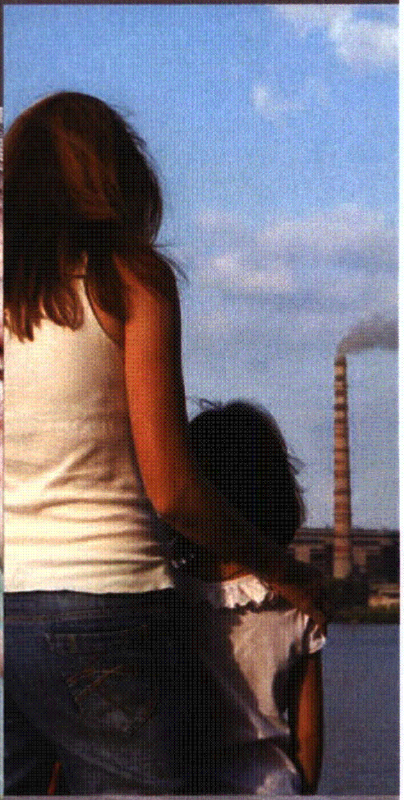
Air Pollution and the Health of New Yorkers:

The Impact of Fine Particles and Ozone



NYC Health

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Executive Summary

Air pollution is a leading environmental threat to the health of urban populations overall and specifically to New York City residents. Clean air laws and regulations have improved the air quality in New York and most other large cities, but several pollutants in the city's air are at levels that are harmful.

This report provides estimates of the toll of air pollution on the health of New Yorkers. It focuses on 2 common air pollutants—fine particulate matter ($PM_{2.5}$) and ozone (O_3). Emissions from fuel combustion directly and indirectly cause many cities to have high concentrations of these pollutants. Both have been extensively researched and are known to contribute to serious illnesses and death, especially from lung and heart diseases, at concentrations prevailing in New York City today.

Air pollution, like other significant risk factors for poor health such as smoking and obesity, is rarely indicated as the cause of an individual hospital admission or death in official records. Statistical methods, therefore, must be used to apply research findings about the relationship between exposures and the risk of illnesses and death to actual population rates of morbidity and mortality to calculate estimates of the public health burden caused by air pollution. In this report, the New York City Department of Health and Mental Hygiene used methods developed by the U.S. Environmental Protection Agency to estimate the impact of air pollution on the numbers of deaths, hospital admissions and emergency department visits caused by exposure to $PM_{2.5}$ and ozone at current concentrations in New York City.

Health Department estimates show that each year, $PM_{2.5}$ pollution in New York City causes more than 3,000 deaths, 2,000 hospital admissions for lung and heart conditions, and approximately 6,000 emergency department visits for asthma in children and adults. A modest reduction of 10% in current $PM_{2.5}$ levels could prevent more than 300 premature deaths, 200 hospital admissions and 600 emergency department visits annually, while attaining the goal of "cleanest air of any big city" would result in even greater public health benefits (**Table 1**).

Table 1. Health impacts from current $PM_{2.5}$ exposure and benefits of reducing exposure in New York City.*

Health Effect	Age Groups Affected (in years)	Annual Health Events Attributable to Current $PM_{2.5}$ Levels	Annual Health Events Avoided If $PM_{2.5}$ Levels Were Reduced by 10%	Annual Health Events Avoided If $PM_{2.5}$ Levels Were Reduced to Cleanest Air of Any Large City
Premature mortality	30 and above	3,200	350	760
Hospital admissions for respiratory conditions	20 and above	1,200	130	280
Hospital admissions for cardiovascular conditions	40 and above	920	100	220
Emergency department visits for asthma	Under 18	2,400	270	580
Emergency department visits for asthma	18 and above	3,600	390	850

$PM_{2.5}$=particulate matter

* Based on 2005-2007 data on air pollution, mortality and illnesses

Ozone causes an estimated 400 deaths from all causes, more than 800 hospital admissions and more than 4,000 emergency department visits among children and adults. Reducing ozone levels by 10% could prevent more than 80 premature deaths, 180 hospital admissions and 950 emergency department visits annually (**Table 2**).

Other Health Department estimates show that the public health impacts of air pollution in New York City fall especially heavily on seniors, children with asthma and people living in low-income neighborhoods. Even modest reductions in the levels of these pollutants could prevent hundreds of deaths, hospital admissions and emergency department visits (**Tables 1 and 2**).

This study shows that despite improvements in air quality, air pollution is one of the most significant environmental threats to New Yorkers, contributing to approximately 6% of deaths annually. To reduce this toll, action is needed to address important local pollution sources; PlaNYC, the city's sustainability plan, has already launched, completed and planned several emission-reducing initiatives that will result in cleaner air and fewer serious illnesses and premature deaths in all parts of the city.

Table 2. Health impacts from current O_{3i} exposure and benefits of reducing exposure in New York City.*

Health Effect	Age Groups Affected (in years)	Annual Health Events Attributable to Current O_3 Levels	Annual Health Events Avoided If O_3 Levels Were Reduced by 10%
Premature mortality	All ages	400	80
Hospital admissions for asthma	Under18	420	90
Hospital admissions for asthma	18 and above	450	90
Emergency department visits for asthma	Under18	1,800	370
Emergency department visits for asthma	18 and older	2,900	600

O_3=ozone

* Based on 2005-2007 data on air pollution, mortality and illnesses

Introduction and Background

Air pollution is one of the most serious environmental threats to urban populations (Cohen 2005). Exposures vary among and within urban areas, but all people living in cities are exposed, and many are harmed, by current levels of pollutants in many large cities. Infants, young children, seniors and people who have lung and heart conditions are especially affected, but even young, healthy adults are not immune to harm from poor air quality. Exposures to common urban air pollutants have been linked to a wide range of adverse health outcomes, including respiratory and cardiovascular diseases, asthma exacerbation, reduced lung function and premature death (U.S. Environmental Protection Agency 2006, 2009).

Prior to the advent of clean air laws in developed countries, the lethal effects of air contaminants from fuel combustion were dramatically evident during several severe air pollution episodes. In 1952, shortly after the 5-day London "Great Smog" episode, for example, it became clear to officials and the public that thousands had died and many tens of thousands were sickened by soot and sulfur dioxide (Davis 2002, Bell 2001). The episode was caused by burning coal, petroleum-based fuels and gas with no control on emissions, in combination with stagnant weather conditions. The extremely high levels of pollution caused large and marked increases in the number of daily deaths and illnesses from lung and heart disease, evident despite the lack of sophisticated statistical analyses.

Other severe air pollution episodes, such as in 1948 in Donora, Pennsylvania, (Helfand, 2001) in the 1950s and in the 1960s in New York City (McCarroll, 1966) and elsewhere, raised awareness that unregulated burning of fossil fuels in and near cities was harmful to public health. Eventually, state, local and, finally, federal laws and regulations such as The Clean Air Act began to turn the tide in controlling emissions.

Because of improvements in air quality, such deadly air pollution episodes are rare in U.S. cities. Modern research methods have shown, however, that deaths and serious illnesses from common air pollutants still occur at levels well below regulatory standards, and at current levels in New York and most large cities. Local actions to further reduce air pollution will mean changes in policies and behaviors, and will require significant investments in new vehicles and other equipment. Local officials and the public, therefore, must understand the magnitude and distribution of mortality and disease caused by air pollution in order to weigh the benefits against the cost of improving air quality.

This report provides estimates of the toll that air pollution takes on the health of New Yorkers, focusing on 2 common air pollutants—fine particulate matter ($PM_{2.5}$) and ozone (O_3). Both pollutants are among the most studied of environmental hazards, are found in New York City's air at concentrations above clean air standards, and are known to adversely affect health at levels in our air today (Silverman 2010, Ito 2010). The report contains estimates of the number of emergency department visits, hospitalizations and deaths attributable to these pollutants overall and for various population groups, and the number of adverse health events that could be prevented by improvements in air quality.

The estimates in this report are based on methods used by the U.S. Environmental Protection Agency to quantify the harm from air pollution and the benefits of clean air regulations. Similar methods are used to estimate the health impacts of smoking, obesity, heat waves and other important public health risks (U.S. Environmental Protection Agency, 2010, Centers for Disease Control and Prevention, Danaei 2009).

Sources and Health Effects of Fine Particulates and Ozone

Fine Particles ($PM_{2.5}$) are small, airborne particles with a diameter of 2.5 micrometers or less. Major sources of $PM_{2.5}$ include on-road vehicles (trucks, buses and cars); fossil fuel combustion for generating electric power and heating residential and commercial buildings; off-road vehicles (such as construction equipment); and commercial cooking (U.S. Environmental Protection Agency, National Emissions Inventory). Fine particles can also become airborne from mechanical processes such as construction or demolition, industrial metal fabrication, or when traffic or wind stirs up road dust.

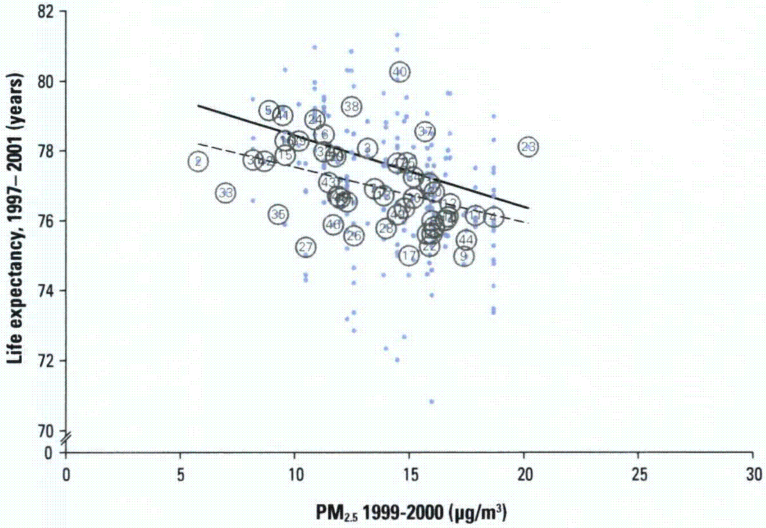
Fine particles in New York City's air come from sources both within and outside of the city; the outside sources account for more of the city's air pollution, but local sources account for differences in $PM_{2.5}$ concentration between locations within the city. The Health Department, in the ongoing New York City Community Air Survey (NYCCAS), is studying the impact of local sources (such as traffic and burning residual oil) on neighborhood air quality.

$PM_{2.5}$ is small enough to be inhaled deep into the lungs and affects both respiratory and cardiovascular system functions. Changes observed in people exposed to $PM_{2.5}$ include increased airway inflammation and sensitivity, decreased lung function, changes in heart rhythm and blood flow, increased blood pressure, increases in the tendency to form blood clots, and biological markers of inflammation (U.S. Environmental Protection Agency 2009). These health effects cause increases in symptoms, emergency department visits, hospital admissions and deaths from heart and lung diseases (Bell 2009, Krewski 2009, Silverman 2010).

Studies show that, even at current levels, short-term exposures to combustion-related pollutants exacerbate respiratory and cardiovascular conditions, and increase mortality risk. Higher, long-term average concentrations increase the cumulative risk of chronic diseases and death. One recent study (Pope 2009) showed that in cities with higher average $PM_{2.5}$, the population's life expectancy was reduced by an average of more than half of a year for every 10 μg/m³ increase in concentration (**Figure 1**). Data from the study also showead that reductions in $PM_{2.5}$ concentrations during the 1980s and 1990s accounted for approximately 15% of the overall increase in life expectancy during that period.

O_3 is not emitted directly from fuel combustion; it is produced by chemical reactions involving nitrogen oxides (NO_x)—a mixture including nitric oxide (NO) and nitrogen dioxide (NO_2)—volatile organic compounds and sunlight. O_3 concentrations typically peak in the afternoon and are highest in the summer, when daylight hours are long and temperatures are high. Although NO_x

Figure 1. Lower life expectancy is associated with living in cities with higher $PM_{2.5}$ levels.* §



$PM_{2.5}$=particulate matter

* Dots represent population-weighted mean life expectancies at the county level and circles labeled with numbers represent population-weighted mean life expectancies at the metropolitan-area level. Solid lines represent regression lines with the use of county-level observations, and broken lines represent regression lines with the use of county-level and metropolitan area-level observations.

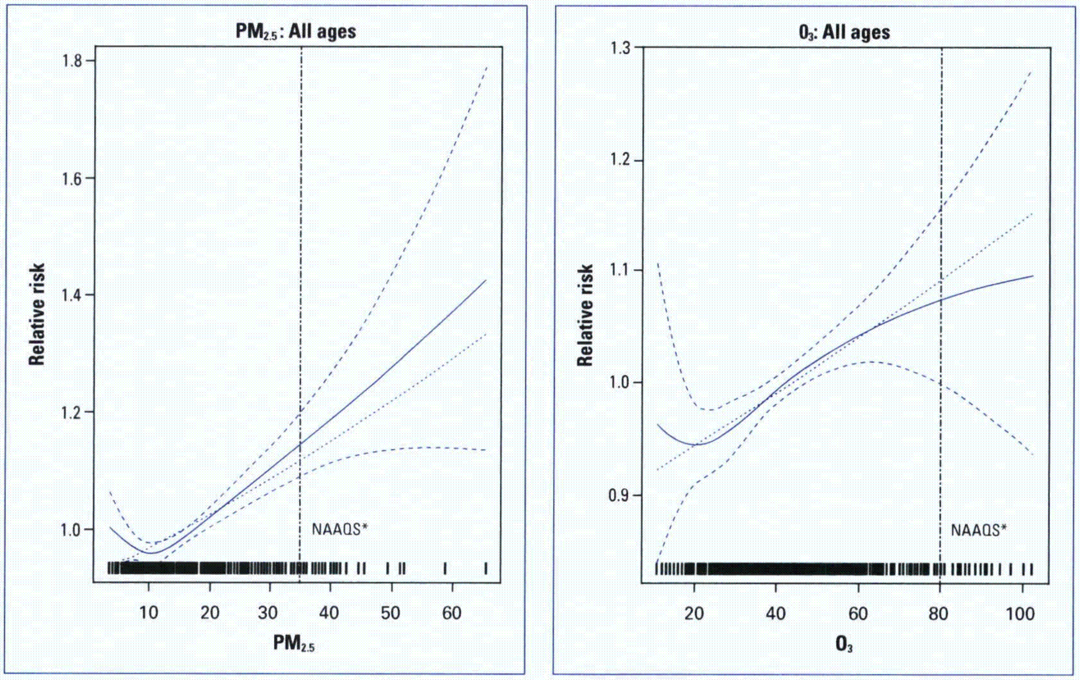
§ Reprinted from Fine-Particulate Air Pollution and Life Expectancy in the United States, *N Engl J Med.* 2009;360:376-386. C. Arden Pope II, Majid Ezzati and Douglas W. Dockery with Permission from the New England Journal of Medicine.

emissions from vehicles contribute to higher ozone in urban areas, in city locations where fresh NO_x emissions are concentrated, NO reacts with, and removes, ozone from the atmosphere in a reaction known as ozone "scavenging." As a result, concentrations in urban areas with an abundance of NO_x from traffic sources tend to have somewhat lower concentrations of ozone than more suburban locations downwind from the city center.

O_3 reacts with and damages organic matter such as plant foliage, the human airway and other lung tissues. Exposure to O_3 causes irritation and inflammation of the lungs, and leads to coughing, wheezing, worsening of asthma and lowered resistance to lung infections. Physical activity during peak ozone periods increases exposure and the likelihood of symptoms. Long-term exposure to higher O_3 levels can permanently reduce lung function. (Calderón-Garcidueñas 2003, Rojas-Martinez 2007) These health effects of O_3 contribute to increased emergency department visits, hospital admissions and deaths on days with higher ozone concentrations (Silverman 2010, Ito 2007, Huang 2005), and to increased mortality associated with chronic ozone exposure (Jerrett 2009).

Studies have shown that for both $PM_{2.5}$ and O_3 exposure, health effects occur at concentrations well below the current National Ambient Air Quality Standards; this effect was clear in a study of asthma hospitalizations in New York City

Figure 2. The risk of hospitalization for asthma increases with increases in daily levels of $PM_{2.5}$ and O_3 in New York City.



$PM_{2.5}$=particulate matter

O_3=ozone

* NAAQS- National Ambient Air Quality Standard

The figure shows at levels below and above the National Ambient Air Quality Standard (NAAQS) an increasing risk of hospitalization for asthma with increasing $PM_{2.5}$ and O_3 levels. The solid lines are smoothed fit data, with long broken lines indicating 95% confidence bands. The short broken lines are linear fitted lines. The vertical dotted lines are the current NAAQS for $PM_{2.5}$ and the 1997 NAAQS for O_3 (current 2007 O_3 NAAQS is 75ppb). The density of lines at the bottom of the figure indicates the number of days measured at a given concentration sample size.

Reprinted from Permission from Elsivier: Silverman RA, Ito K. Age-Related Associations of Fine Particles and Ozone with Sever Acute Asthma in New York City. *J Allergy Clin Immunol.* 2010; 125(2):367-373

(**Figure 2**) (Silverman 2010). Elderly people, children and infants, and people with lung or heart disease are most affected by exposure to both pollutants. There is evidence that medications used to manage lung or heart disease may reduce the severity of health effects caused by air pollution (Liu 2009, Qian 2009). As a result, populations and neighborhoods with higher rates of chronic disease and less access to quality health care may be more affected by air pollution-related health problems.

Studies of Air Pollution and Population Health

Illnesses caused by air pollution, such as asthma attacks, heart attacks and stroke, have multiple causes; as a result, most health events triggered by air pollution cannot be identified directly. Research, however, has shown that there is an increase in these events on days with higher air pollution concentrations and in cities where pollution concentrations are higher on average. There are 2 types of studies (see below) that researchers use to quantify the relationship between the concentrations of pollutants measured in the air and the risk of adverse health effects in the population. The report uses the results from both types of studies to estimate air pollution health impacts in New York City.

One type of study assesses the acute effects of short-term exposures to a specific air pollutant. These studies use statistical methods for analyzing time-series data to assess whether the health events under study, such as daily emergency department visits for asthma, are more frequent on or shortly after days when air pollution concentrations are higher. These models also control for other factors that vary with time and can influence health events, such as the season, weather and day of the week. The daily risk of a particular health event is related to the daily concentration of a pollutant as a so-called concentration-response function. In **Figure 2**, for example, researchers analyzed daily hospitalizations for asthma using time series models. The estimates showed that, for a daily (8-hour maximum) ozone concentration increase of 22 parts per billion during the warm season (April through August), asthma hospital admissions among children 6 to 18 years of age increased an average of 20% (Silverman 2010). Due to random variation in daily counts of any health event, estimating an acute effect concentration-response function reliably requires analyzing a large amount of data (usually over several years).

Another type of study assesses the health effects of chronic (long-term) exposure to air pollution. This type of study may involve following a study population over time and comparing the risk of health events among individuals living in multiple cities with different average levels of air pollution. In chronic effect studies, the statistical analyses may be used to also adjust for individual factors such as smoking and weight. The amount of increase in risk is related to a given change in average air pollution concentration to estimate a chronic exposure concentration-response function.

Methods

Overall Approach

In this report, methods were adapted from those utilized by the U.S. Environmental Protection Agency and state air quality regulatory agencies to estimate changes in the number of illnesses and deaths that could occur in a population if air pollution concentrations were reduced by a specified amount (U.S. Environmental Protection Agency 2010, 2008) (**Figure 3**). This method:

- Uses air quality monitoring data to characterize current, or baseline, air pollution levels
- Specifies comparison air quality conditions, such as possible reductions in air pollution concentrations or levels that meet other air quality goals
- Computes the hypothetical change in air pollution concentrations as the difference between the current and the comparison levels within each neighborhood
- Uses the change in air pollution concentrations, concentration-response functions from the epidemiological literature, and local population and baseline health event rates to calculate the health impact associated with the change in ambient air quality, by neighborhood.
- Combines these neighborhood health impacts to estimate citywide impacts

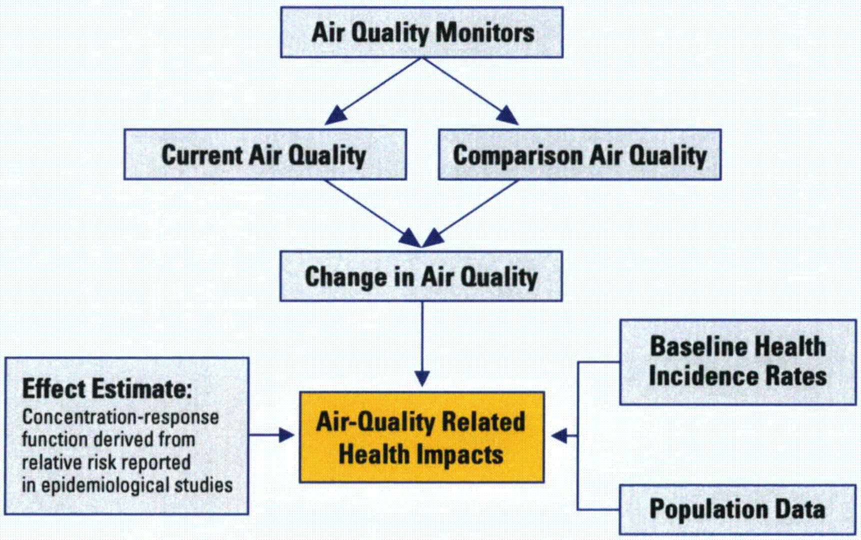
This health impact analysis was conducted using U.S. Environmental Protection Agency's Benefits Mapping and Analysis Program (BenMAP), a Geographic Information System-based program that allows analysts to systematically calculate health impacts across regions of interests.

Data Sources

Concentration-Response Functions

Recent epidemiological studies of the relationship of $PM_{2.5}$ and O_3 to mortality, hospital admissions and emergency department visits were reviewed. Although hundreds of studies have been published on the health effects of $PM_{2.5}$ and O_3, studies used for the main analyses were those most relevant to the current New York City population.

Figure 3. Flow chart illustrating the Air Pollution Health Impact Analysis Approach.



The studies used in this report were taken from peer-reviewed scientific journals in the past decade and, to account for local study area demographics and pollutants, effect estimates from studies of New York City were used when possible. If local studies were not available, those used contained effect estimates from recent large, multi-city studies or those included in recent U.S. Environmental Protection Agency regulatory impact analyses (EPA 2008, EPA 2010). The studies chosen, and the corresponding concentration-response functions used for this report, are summarized below and in **Tables 3 and 4**. The abstracts are available in an online appendix, which also provides health impact estimates from other studies not included in this report. The Discussion section in this report details variables and limitations in selecting suitable concentration-response functions.

Particulate Matter Studies

One study (Krewski, 2009) followed 500,000 members of the American Cancer Society in 116 cities who participated in a cohort study from 1982 through 2000. The risk of death among the cohort was estimated in relation to the city's annual average $PM_{2.5}$ concentrations; all-cause mortality rates in adults increased by 6% for every 10 µg/m^3 increase in annual $PM_{2.5}$.

Another study (Ito, 2007) studied daily hospital emergency department visits for asthma in people of all ages treated at public hospitals in New York City from 1999 through 2002. To allow for different effects of $PM_{2.5}$ related to physical activity and particle composition in different seasons, separate analyses were completed for the warm and cold seasons. In the warm season, emergency department visits increased by 23%,

Table 3. $PM_{2.5}$ effect estimates used in this report.

	Health Effect	Age Group (in years)	Acute or Chronic Exposure/Metric Average	Effect Estimate	Study Location	Source of Effect Estimate
$PM_{2.5}$	Premature mortality	30 and older	Chronic/Annual	6% increase in all-cause mortality associated with 10 µg/m^3 increase in $PM_{2.5}$	United States (116 cities)	Krewski, 2009
	Emergency department visits for asthma	All ages	Acute/Daily 24-hour	Relative risk of 1.23 (summer) and 1.04 (winter) per 25.4 µg/m^3 and 21.7 µg/m^3 respective increase in $PM_{2.5}$	New York City	Ito, 2007
	Hospital admissions for all cardiovascular causes	40 and older	Acute/Daily 24-hour	0.8% (warm season) and 1.1% (cold season) increase in daily cardiovascular disease hospitalizations per 10 µg/m^3 increase in $PM_{2.5}$	New York City	Ito, 2010
	Hospital admissions for all respiratory causes	20-64	Acute/Daily 24-hour	2.2% increase in daily chronic respiratory disease hospitalizations per 10 µg/m^3 increase in $PM_{2.5}$	Los Angeles	Moolgavkar, 2000
		65 and older	Acute/Daily 24-hour	1.3%-4.3% increase in daily chronic respiratory disease admissions with 10 µg/m^3 increase per $PM_{2.5}$ (depending on season)	26 U.S. communities	Zanobetti, 2009

$PM_{2.5}$=particulate matter

on average, for each 25.4 µg/m³ increase in daily $PM_{2.5}$; in the cold season, the increase was 4% per 21.7 µg/m³. Similar methods were applied to emergency hospitalizations for cardiovascular health events (Ito, 2010) in New York City among adults aged 40 years of age and older, using hospital discharge data from the New York Statewide Planning and Research Cooperative System, which includes all New York City hospitals. The results showed, per 10 µg/m³ increase in average daily $PM_{2.5}$ concentrations, a 0.8% increase in cardiovascular hospitalizations in the warm season and a 1% increase in the cold season.

A study from Los Angeles County of adults 20 to 65 years of age (Moolgavkar, 2000) was used to analyze respiratory hospital admissions associated with $PM_{2.5}$ concentrations. This study estimated the association between $PM_{2.5}$ and daily hospital admissions for chronic obstructive pulmonary disease; there was a 2.2% increase in these admissions for every 10 µg/m³ increase in average daily $PM_{2.5}$.

A larger, national study (Zanobetti, 2009) analyzed hospital admissions for all respiratory causes among adults more than 65 years of age living in 26 U.S. communities. The authors found increases in daily respiratory admissions ranging from 1.3% in the summer to 4.3% in the spring for every 10 µg/m³ increase in average daily $PM_{2.5}$.

Ozone Studies

Three studies were selected to provide concentration-response functions for ozone and mortality, emergency department visits for asthma and hospital admissions for asthma (**Table 4**). All studies provided estimates across all age groups for populations in New York City.

One study (Huang 2005) showed a 2.3% increase in daily cardiovascular and respiratory deaths for every 10 parts per billion increase in average ozone concentrations over the week before death. Another study (Ito, 2007) observed an increase in relative risk of 1.32 per 53.5 parts per billion increase in maximum ozone concentrations for emergency department visits for asthma. Another study (Silverman 2010) documented that the relative risk for hospitalization increased by 1.06 to 1.20 (depending on age) per 22 parts per billion increase in maximum ozone.

Table 4. O_3 effect estimates used in this report.

	Health Effect	Age Group	Acute or Chronic Exposure Metric	Effect Estimate	Study Location	Source of Effect Estimate
O_3	Premature mortality	All ages	Acute, daily 24-hour average	2.33% increase in cardiovascular and respiratory mortality per 10ppb increase in ozone levels over the previous week	New York City	Huang, 2005
	Emergency department visits for asthma	All ages	Acute, daily 8-hour maximum	Relative risk of 1.32 per 53.5 ppb increase in ozone	New York City	Ito, 2007
	Hospital admissions for asthma	All ages	Acute, daily 8-hour maximum	Relative risk of 1.06-1.20 (varies by age group) per 22 ppb increase in ozone	New York City	Silverman, 2010

O_3=ozone
ppb=parts per billion

Air Quality Data

Particulate Matter

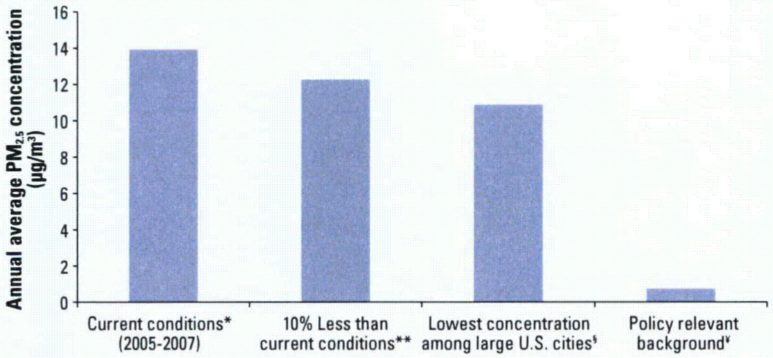
Current air quality conditions were based on measured daily $PM_{2.5}$ from all regulatory monitors within New York City and adjacent counties over 3 years (2005-2007) (U.S. Environmental Protection Agency Air Quality System). The regulatory monitors do not capture the full range of neighborhood variations documented by the Health Department's NYCCAS; these year-round estimates were not available for this report, but will be used in future health impact studies. Preliminary analyses by the Health Department indicate that using NYCCAS data will produce similar results for citywide health impact estimates, but somewhat different results by neighborhood.

The influence of year-to-year changes in meteorology and unique emissions patterns was minimized by calculating baseline $PM_{2.5}$ concentrations as a 3-year average. Since air pollution levels and health events vary by season, current conditions were defined as quarterly averages of daily $PM_{2.5}$ concentrations. First, at each monitor, quarterly averages were calculated for each year and then averaged across the 3 years. Daily average concentrations for each quarter were then assigned to each of 42 New York City United Hospital Fund neighborhoods, using a method that assigns greater weight to monitors in or near to a neighborhood (U.S. Environmental Protection Agency, 2010).

Baseline $PM_{2.5}$ concentrations were compared to 3 comparison scenarios (**Figure 4**):

1. **Policy-relevant background.** This is an estimate, based on air pollution models, of the level of natural background $PM_{2.5}$ concentrations that would exist without sources of air pollution from human activity in the United States, and which therefore cannot be affected by emissions control efforts (Environmental Protection Agency, 2009). Policy-relevant background is approximately 5% of current average $PM_{2.5}$ concentrations in New York City. Although achieving policy-relevant background is not possible, it provides a comparison for calculating the overall health burden from exposure to fine particles from man-made sources. Since background pollution levels vary by season, the quarterly average policy-relevant backgrounds modeled for the Northeast in were applied (U.S. Environmental Protection Agency, 2009).
2. **10% improvement.** This is a analysis of the health benefits that would result if $PM_{2.5}$ concentration were 10% less, a modest improvement, than current concentrations New York City.
3. **Lowest concentration among large U.S. cities.** In 2007, New York City's first comprehensive sustainability plan, PlaNYC set the goal of achieving "the cleanest air quality of any big U.S. city" by 2030. The benefits of achieving this goal was modeled by comparing levels in the city from 2005 through 2007 to the lowest levels measured in U.S. cities with populations larger than one million people. Achieving this goal would require a 22% reduction in average $PM_{2.5}$ concentrations.

Figure 4. Baseline annual average $PM_{2.5}$ levels in New York City (2005-2007) and levels in comparison scenarios.



$PM_{2.5}$=particulate matter

* Current conditions=annual average PM2.5 concentrations, 2005-2007 Source: United States Environmental Protection Agency Air Quality System (AQS)

** 10% Less than Current Conditions=2005-2007 Annual average concentrations reduced by 10%, calculated from USEPA AQS

§ Lowest concentration among large US Cites: Lowest 2005-2007 annual average concentrations among the 9 US cities with greter than 1.000.000 residents.

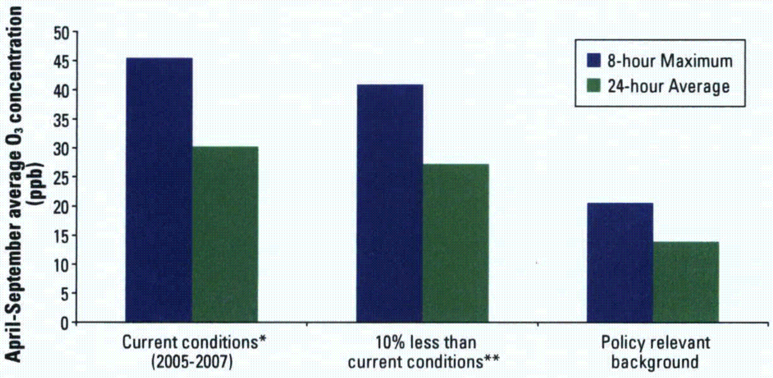
¥ Policy relevant background – Annual average $PM_{2.5}$ concentrations in U.S. Northeast assuming no anthropogenic emissions from sources within the U.S., as predicted by the Community Multiscale Air Quality Modeling System (CMAQ) and the Goddard Earth Observing System (GEOS)-Chem model Source: EPA 2009

Ozone

Although ozone is always present in New York City's air, concentrations are much higher in the summer. Since many studies of ozone health effects focus on the warm season, this study included only New York City's ozone season (April 1st - September 30th).

Current air quality conditions were based on ozone data from all regulatory monitors within the city and adjacent counties over 3 years (2005-2007) (EPA Air Quality System). Using 3 years of data reduces the influence of year-to-year weather and emission changes on the estimates. Since epidemiological studies model the risk estimates using a variety of averaging times, several exposure metrics were computed for consistency with the effect estimates (24-hour average, daily 8-hour maximum). First, at each monitor, quarterly averages (April-June and July-September) were calculated for each year and then averaged across the 3 years. Average concentrations for each quarter were assigned to each of 42 New York City United Hospital Fund neighborhoods, using a method that gives monitors in or near to a neighborhood a greater weight (EPA 2010).

Figure 5. Baseline warm season average O_3 levels in New York City (2005-2007) and levels in comparison scenarios.



O_3=ozone

ppb=parts per billion

* Current Conditions=average ozone concentrations, April-September 2005-2007, measured at monitors within New York City and adjacent counties. (Source: Environmental Protection Agency Air Quality System (AQS)).

** 10% Less than current conditions=April-September 2005-2007 average concentrations reduced by 10%, calculated from USEPA AQS§

§ Policy-relavent background=April-September 2005-2007 Northeast U.S. average ozone concentration assuming no anthropogenic emissions from U.S., as predicted by the GEOS-Chem Model. Source: Fiore 2004

Figure 5 shows current baseline ozone concentrations and 2 comparison scenarios:

1. **Policy-relevant background** – This is an estimate based on air pollution models of the natural background ozone concentrations that would exist without sources of air pollution from human activity, and therefore cannot be affected by emissions control efforts (Fiore 2004). We converted the 4-hour, afternoon average policy-relevant background estimate in the Northeast to the policy-relevant background estimate for different metrics used in the ozone studies considered in the health impact assessment by computing the ratio of the 4-hour average to the 8-hour maximum or the 24-hour average, calculated from the hourly monitoring data from sites used in the analysis. Policy-relevant background is approximately 45% of current average ozone concentrations in New York City and a smaller proportion of the concentration on days with poor air quality. Although achieving this level is not possible, it provides a means for measuring the overall health burden from exposure to ozone.
2. **10% improvement** – A comparison ozone concentration 10% less than current concentrations was used to estimate the health benefits associated with a modest improvement in New York City air quality.

Baseline Population and Health Data

Mortality data for New York City residents were provided by the Health Department's Bureau of Vital Statistics for 2005 through 2007. Based on the underlying cause of death, daily counts were summarized and rates of all-cause mortality were calculated across 22 age groups for the $PM_{2.5}$ impact estimates, and for the subset of mortality due to cardiovascular and respiratory causes matching a specific case definition (Huang, 2005) for ozone impact estimates.

Hospital admissions and emergency room visits for New York City residents (from the New York Statewide Planning and Research Cooperative System) for the same 3 years (2005-2007) was used to summarize daily counts and rates across 22 age groups. Using diagnostic codes in the hospital discharge data, case definitions were matched to each of the studies with concentration response functions.

All 3 datasets contain ZIP code of residence from which data were aggregated to the United Hospital Fund neighborhood definition, consisting of 42 adjoining ZIP code areas. The 22 age-specific population denominators for 2005 through 2007 were produced by the Health Department using data from the U.S. Census Bureau Population Estimate Program and housing unit data obtained from the New York City Department of City Planning.

Results

The main analyses used for each pollutant to estimate health impacts of $PM_{2.5}$ and ozone in New York City included:

1. The total citywide health impact for each health endpoint studied, using the policy-relevant background comparison to estimate the overall burden (preventable events if all human sources of the pollutant were eliminated) and other comparisons to estimate the health events that could be prevented with air pollution improvements
2. For each health endpoint, maps showing the rate of air pollution-attributable health events for current conditions compared to the policy-relevant background by United Hospital Fund neighborhood
3. For each health endpoint, the estimated proportion and rate of air pollution-attributable health events for current conditions compared to the policy relevant background in different age groups and comparisons of United Hospital Fund neighborhoods grouped by the proportion of people living in poverty

An online appendix contains results from additional analyses using other studies to obtain concentration response functions and other data.

Particulate Matter Health Impacts

Current exposures to the annual average concentrations of $PM_{2.5}$ above background concentrations cause more than 3,000 premature deaths, more than 2,000 hospitalizations due to respiratory and cardiovascular causes, and approximately 6,000 emergency department visits for asthma (**Table 5**) in New York City annually. Even a feasible, modest reduction (10%) in $PM_{2.5}$ concentrations could prevent more than 300 premature deaths, 200 hospital admissions and 600 emergency department visits. Achieving the PlaNYC goal of "cleanest air of any big city" would result in even more substantial public health benefits.

Table 5. Annual health events attributable to citywide $PM_{2.5}$ levels and the health benefits of reduced $PM_{2.5}$ levels.

			Annual Health Events Attributable to Current $PM_{2.5}$ Compared to Background Levels			Annual Health Events Prevented: $PM_{2.5}$ Levels Reduced 10%			Annual Health Events Prevented: $PM_{2.5}$ Levels Reduced to Cleanest Air of Any Large City		
	Health Effect	Age Group	Number of Events (95% CI)*	Rate per 100,000 people	Percent (%) of Events**	Number of Events (95% CI)	Annual Rate per 100,000 people	Percent (%) of Events**	Number of Events (95% CI)*	Annual Rate per 100,000 people	Percent (%) of Events**
$PM_{2.5}$	Premature mortality	30 and older	3,200 (2200,4100)	65	6.4	380 (240,460)	7.1	0.7	760 (520,1000)	16	1.5
$PM_{2.5}$	Hospital admissions for respiratory conditions	20 and older	1,200 (460,1900)	20	2.6	130 (50,210)	2.1	0.3	280 (109,460)	4.7	0.6
$PM_{2.5}$	Hospital admissions for cardiovascular conditions	40 and older	920 (210,1630)	26	1.1	100 (20,170)	2.8	0.1	220 (50,380)	6.0	0.3
$PM_{2.5}$	Emergency department visits for asthma	Under 18	2,400 (1400,3400)	130	5.6	270 (160,370)	14	0.6	580 (340,810)	30	1.3
$PM_{2.5}$	Emergency department visits for asthma	18 and older	3,600 (2200,4900)	57	6.1	390 (240,550)	6.3	0.7	850 (520,1200)	14	1.5

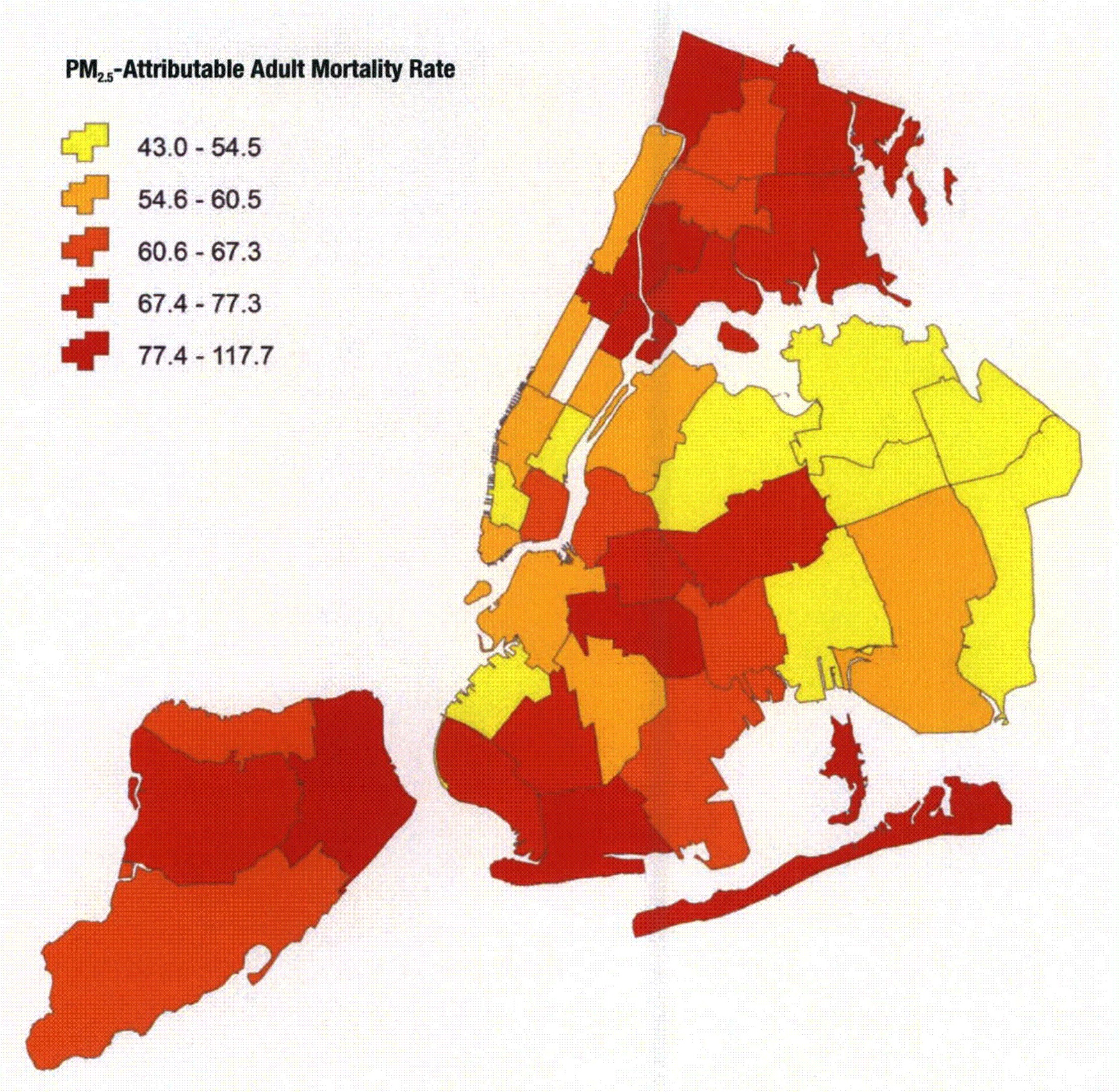
$PM_{2.5}$=particulate matter
* CI=Confidence Interval
** Percent of certain citywide health events attributable to $PM_{2.5}$ in the specified age range.

Mortality

An estimated 3,200 deaths annually among adults 30 years of age and older are attributed to $PM_{2.5}$ at current levels in New York City (**Table 5**). Chronic $PM_{2.5}$-attributable premature mortality varies considerably across demographic groups and neighborhoods. The $PM_{2.5}$-attributable mortality rates per 100,000 population varied by more than 2-fold, with the highest burdens in sections of the Bronx, Northern Manhattan, parts of Southern Brooklyn and the Rockaways (**Figure 6**).

Nearly 3 in 4 deaths (73%) attributable to $PM_{2.5}$ occur in adults age 65 years and older (**Figure 7**), reflecting the higher overall mortality rates this age group.

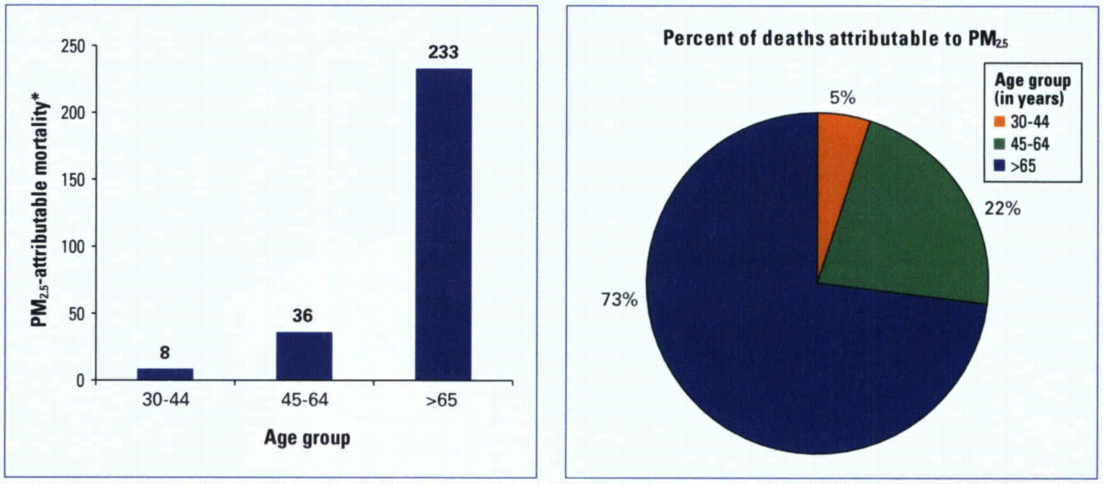
Figure 6. Rates of $PM_{2.5}$-attributable mortality vary by 2.7-fold across New York City neighborhoods.



$PM_{2.5}$=particulate matter

The rate of $PM_{2.5}$-attributable deaths is highest in the poorest neighborhoods, but more than 1 in 4 (27%) attributable deaths occurs in more affluent neighborhoods (**Figure 8**).

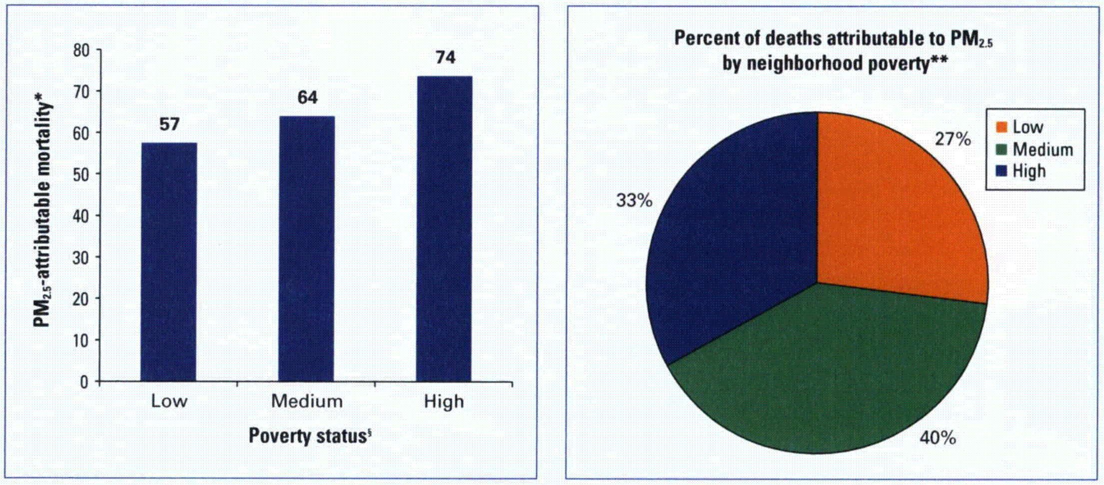
Figure 7. Nearly 3 in 4 deaths attributable to $PM_{2.5}$ occur in adults 65 years of age and older.*



$PM_{2.5}$=particulate matter

*Attributable mortality rate per 100,000 persons, annually

Figure 8. The $PM_{2.5}$-attributable mortality rate is 28% higher in neighborhoods with high, as compared to low, poverty rates.



$PM_{2.5}$=particulate matter

* Attributable mortality rate per 100,000 persons above 30 years of age, annually

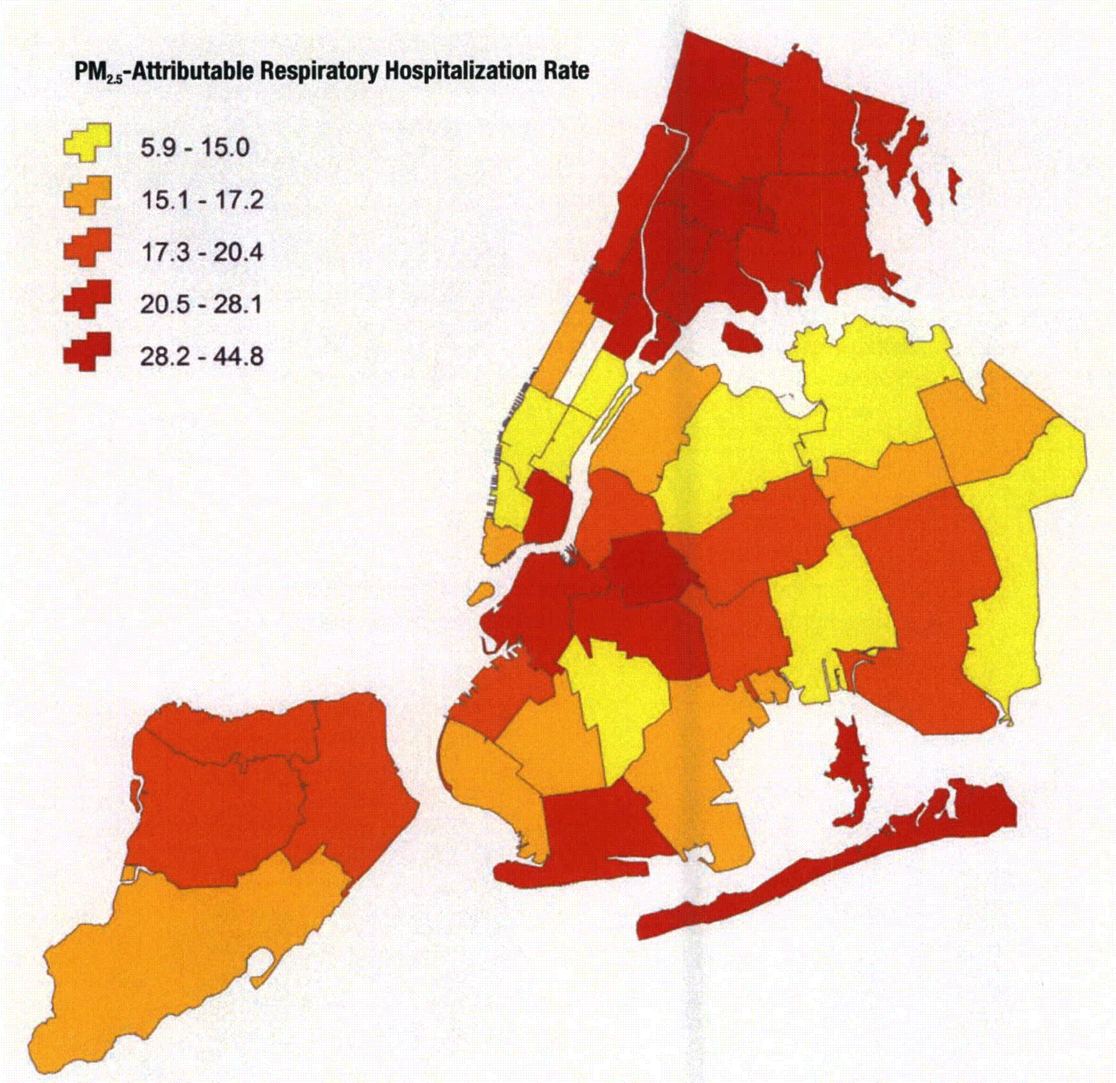
** Among adults 30 years of age and older

§ Poverty Status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Hospital Admissions for Respiratory Disease

Approximately 1,200 annual hospital admissions for respiratory disease among New York City adults age 20 years and older are attributable to current levels of $PM_{2.5}$ (**Table 5**). Across city neighborhoods, the rate of respiratory hospitalization among adults attributable to $PM_{2.5}$ per 100,000 persons varies more than 7-fold, with the highest burdens found in sections of the South Bronx, Northern Manhattan and Northern Brooklyn (**Figure 9**). This pattern reflects the variation, by neighborhood, in overall respiratory hospitalization rates in adults.

Figure 9. $PM_{2.5}$-attributable respiratory hospitalization rates vary 7.6-fold across New York City neighborhoods.

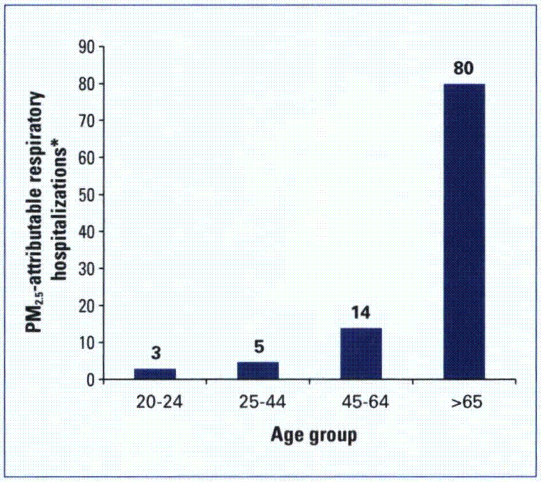


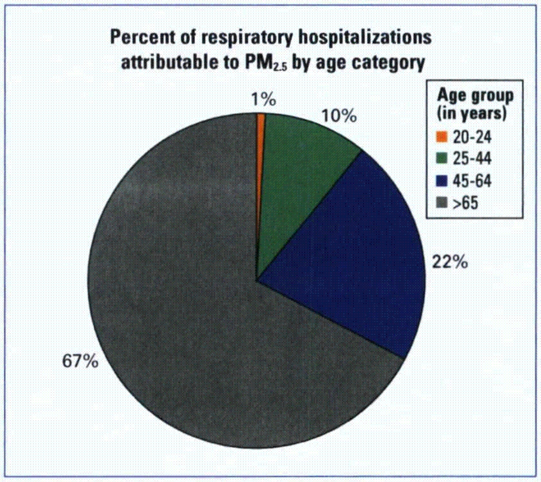
$PM_{2.5}$=particulate matter

Overall, older adults (65 years of age and older) have much higher rates of respiratory hospitalizations and account for 67% of estimated $PM_{2.5}$-attributed respiratory hospitalizations (**Figure 10**).

The estimated rate of $PM_{2.5}$-attributable respiratory hospitalization is nearly twice as high in high poverty, compared to low poverty, neighborhoods (**Figure 11**).

Figure 10. Two-thirds of respiratory hospitalizations attributable to $PM_{2.5}$ occur in adults 65 years of age and older.

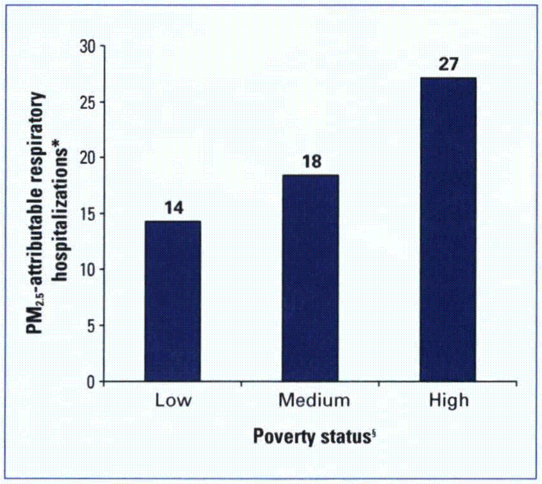


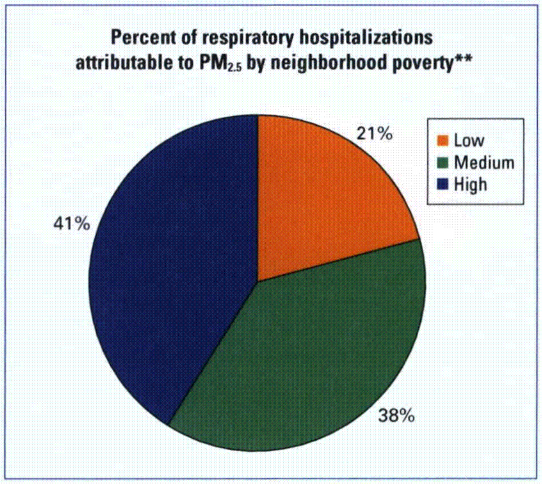


$PM_{2.5}$=particulate matter

*Attributable mortality rate per 100,000 persons, annually

Figure 11. The $PM_{2.5}$-attributable respiratory hospitalization rate is 90% higher in neighborhoods with high, as compared to low, poverty rates.





$PM_{2.5}$=particulate matter

* Attributable respiratory hospitalization rate per 100,000 persons >20 years of age

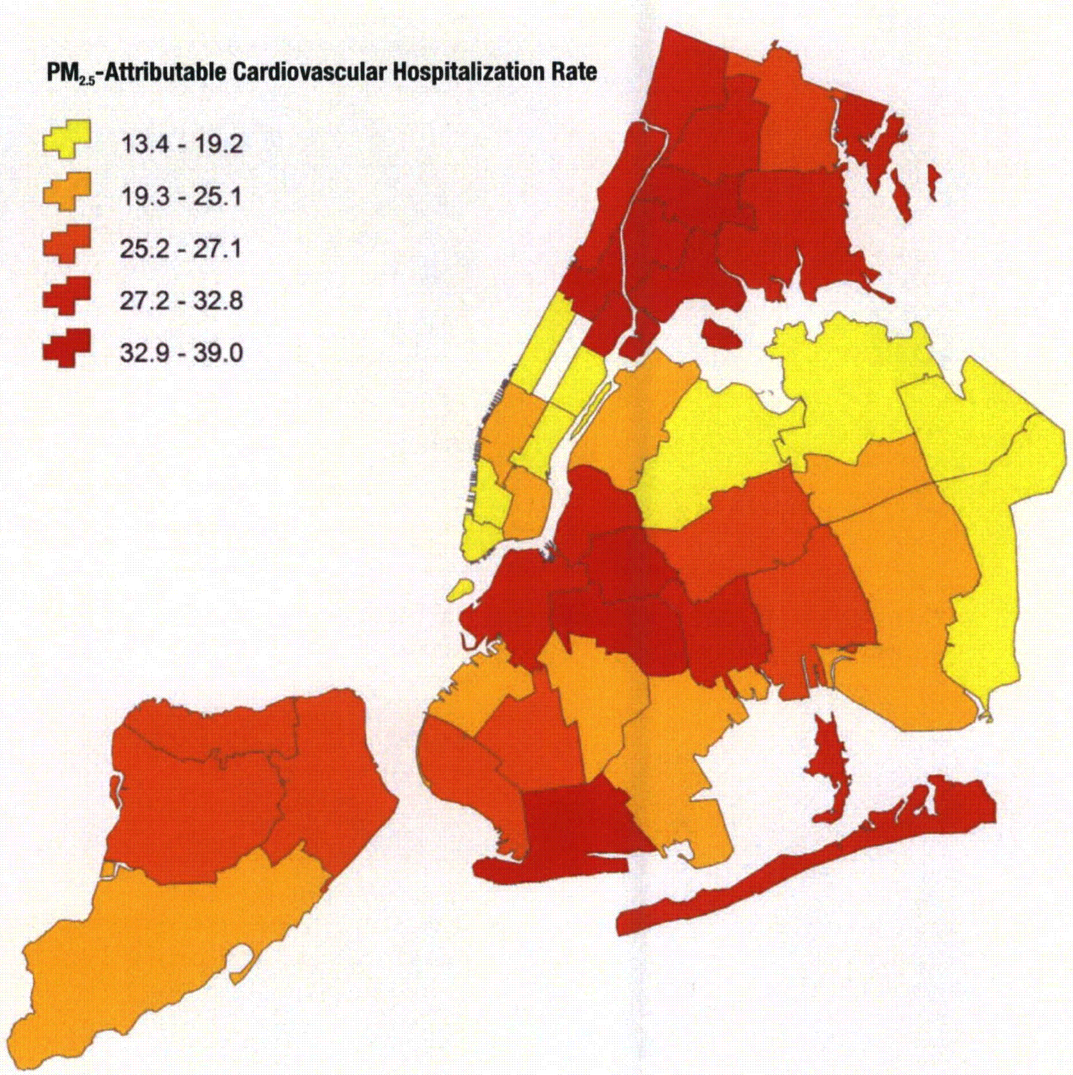
** Among adults above 20 years of age

§ Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Hospital Admissions for Cardiovascular Disease

Among residents age 40 years and older, an estimated 920 annual hospitalizations for cardiovascular events are attributable to current $PM_{2.5}$ levels in New York City (**Table 5**). These rates vary much less (3-fold) across the city than rates of respiratory hospital admissions (7.5-fold); the highest rates occur in the Bronx, Northern Manhattan, North-Central Brooklyn and parts of Southern Brooklyn (**Figure 12**).

Figure 12. $PM_{2.5}$-attributable cardiovascular hospitalization rates vary 2.9-fold across New York City neighborhoods.

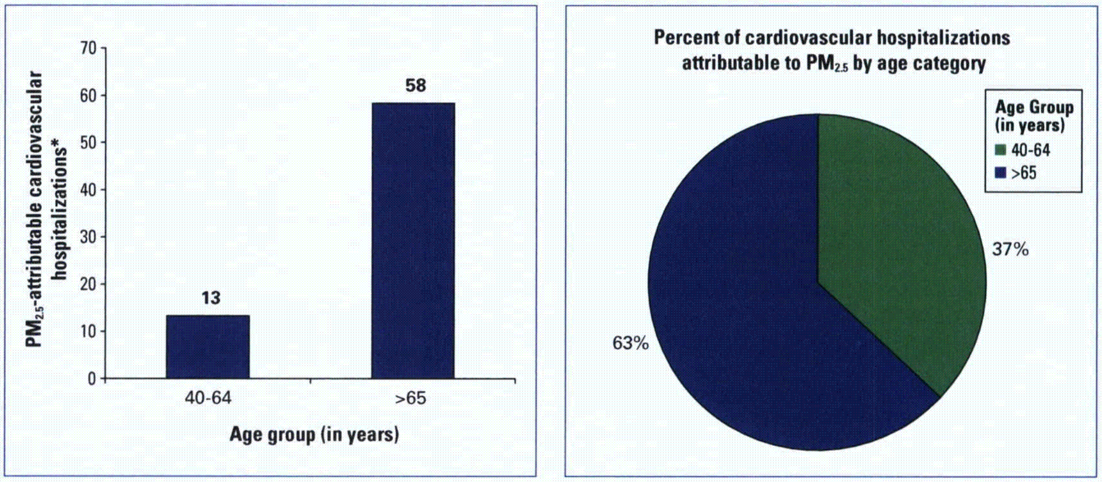


$PM_{2.5}$=particulate matter

Adults older than 65 years of age have rates 4.5 times higher than younger adults of $PM_{2.5}$-attributable hospitalization for cardiovascular events; overall, an estimated 63% of $PM_{2.5}$-attributed cases occur in older adults (**Figure 13**).

Neighborhoods with a high rate of poverty have a 1.6-fold higher rate of $PM_{2.5}$-attributable cardiovascular hospital admissions than do low poverty neighborhoods (**Figure 14**).

Figure 13. More than three-fifths of hospital admissions for cardiovascular disease attributable to $PM_{2.5}$ occur in adults older than 65 years of age.

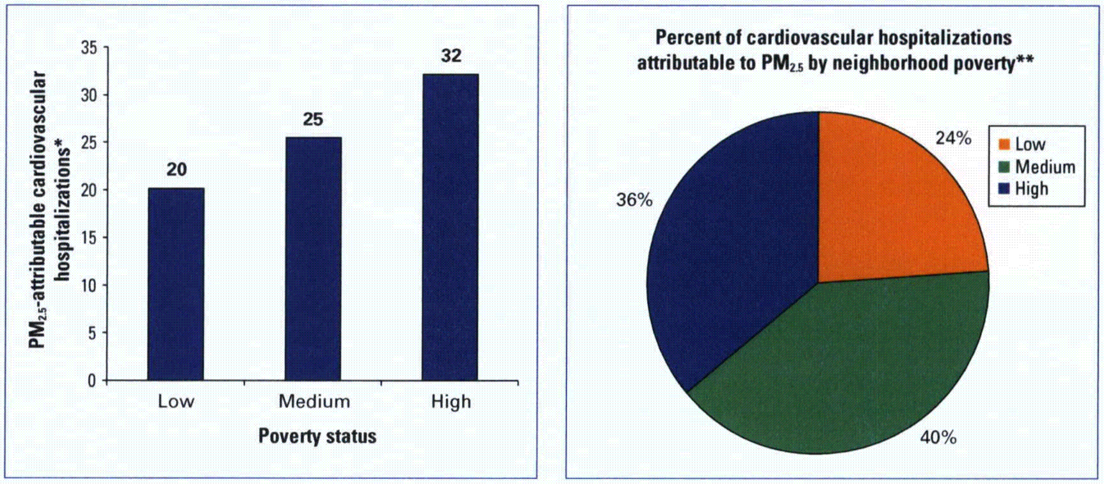


$PM_{2.5}$=particulate matter

* Attributable cardiovascular hospitalization rate per 100,000 persons, annually

§ Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000.

Figure 14. The $PM_{2.5}$-attributable cardiovascular hospitalization rate is 60% higher in neighborhoods with high, as compared to low, poverty rates.



$PM_{2.5}$=particulate matter

* Attributable cardiovascular hospitalization rate per 100,000 persons above 40 years of age

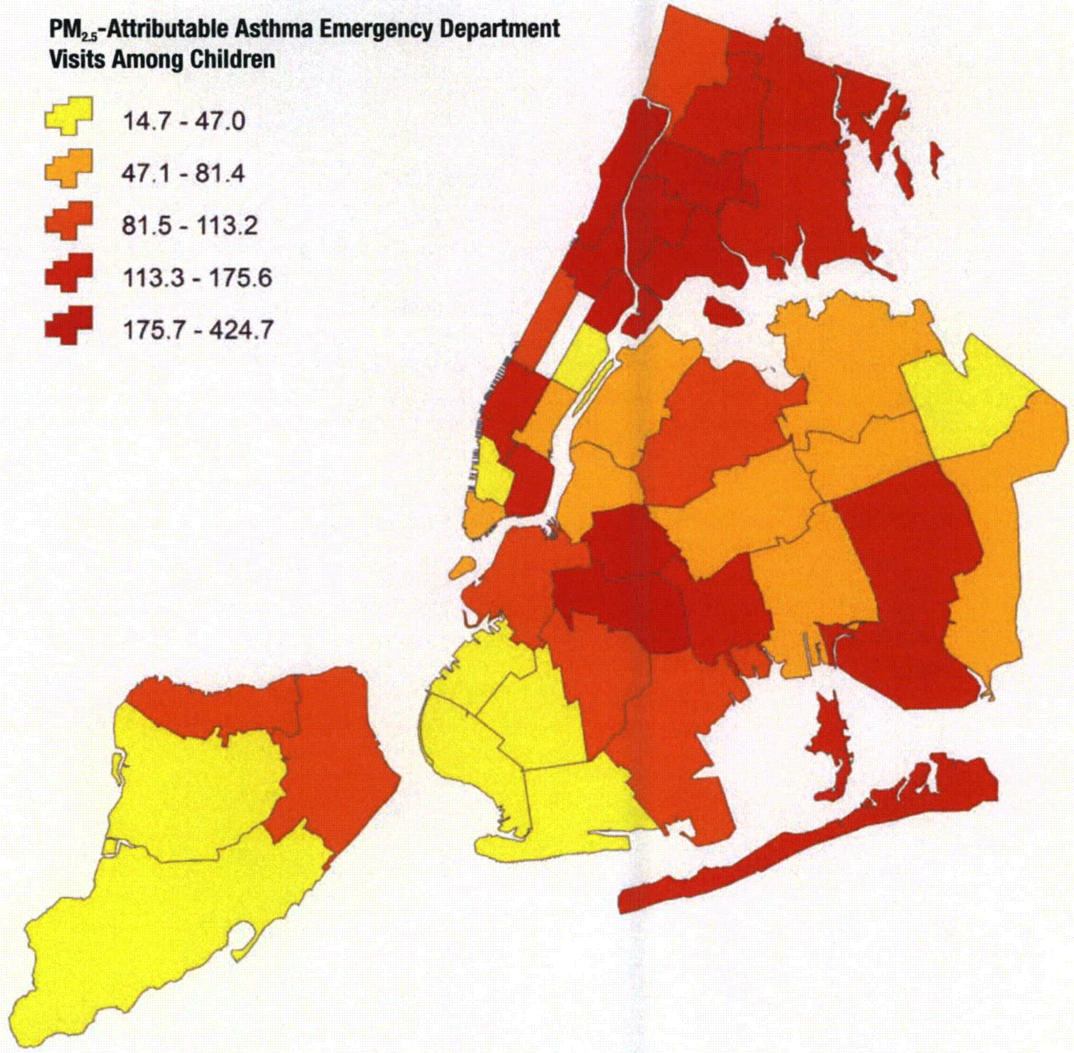
** Among adults above 40 years of age

Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Emergency Department Visits for Asthma in Children

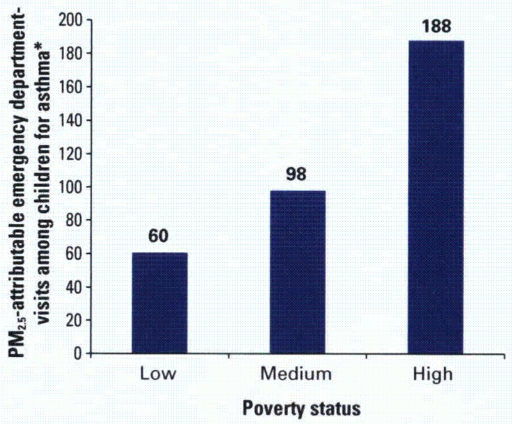
More than 2,400 emergency department visits annually for asthma among New York City children are attributable to current $PM_{2.5}$ levels (**Table 5**). These rates vary greatly, from approximately 15 per 100,000 people younger than 18 years of age, to more than 175 visits per 100,000 in areas with the higher poverty rates (Northern Manhattan, large areas of the Bronx, Central Brooklyn, parts of Eastern Queens and the Rockaways), reflecting the variation in overall asthma emergency department visit rates in children (**Figure 15**).

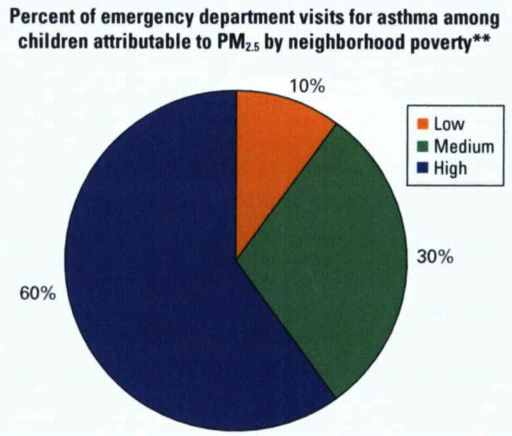
Figure 15. $PM_{2.5}$-attributable asthma emergency department visit rates among children younger than 18 years of age vary nearly 30-fold across New York City neighborhoods.



$PM_{2.5}$=particulate matter

Figure 16. $PM_{2.5}$-attributable asthma emergency department rates among children are more than 3 times higher in high poverty, compared to low poverty, neighborhoods.





$PM_{2.5}$=particulate matter

* Attributable rate of emergency department visits for asthma per 100,000 persons under 18 years of age

** Among children <18 years of age

Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

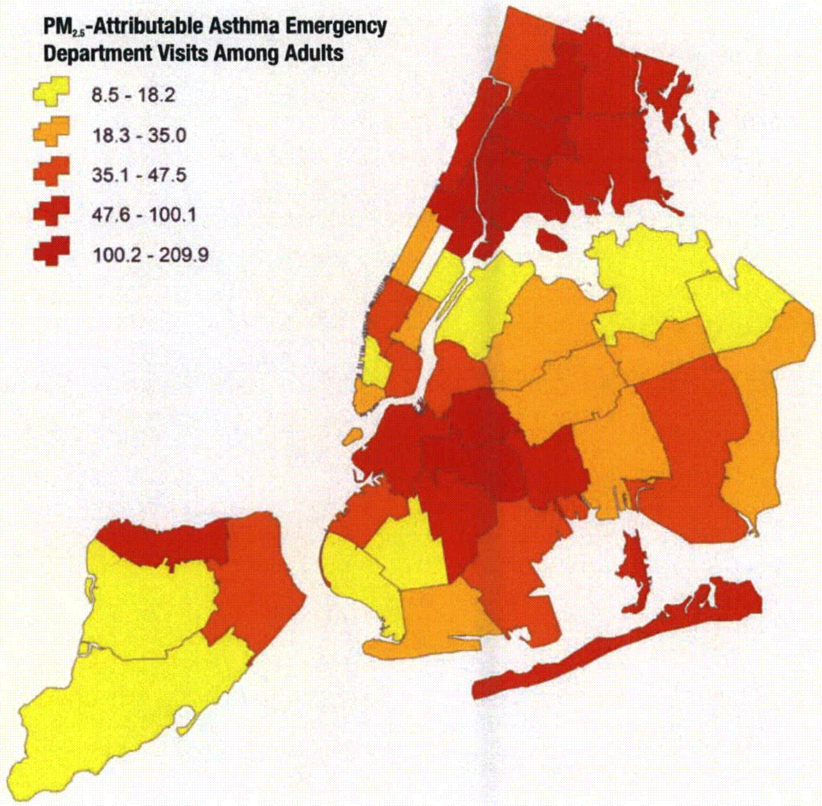
The rates are 3 times higher in the most impoverished neighborhoods (**Figure 16**), which are responsible for more than 60% of $PM_{2.5}$-attributable emergency department visits for pediatric asthma.

Emergency Department Visits for Asthma in Adults

An estimated annual 3,600 emergency department visits for asthma among New York City adults every year in New York City are attributable to $PM_{2.5}$ (**Table 5**). These rates vary considerably, from as low as 9 per 100,000 population in Southern Staten Island and Southwest Brooklyn, to as high as 100 to 200 visits per 100,000 in Northern Manhattan, large areas of the Bronx, Central Brooklyn, parts of Eastern Queens, the Rockaways and parts of Northern Staten Island (**Figure 17**).

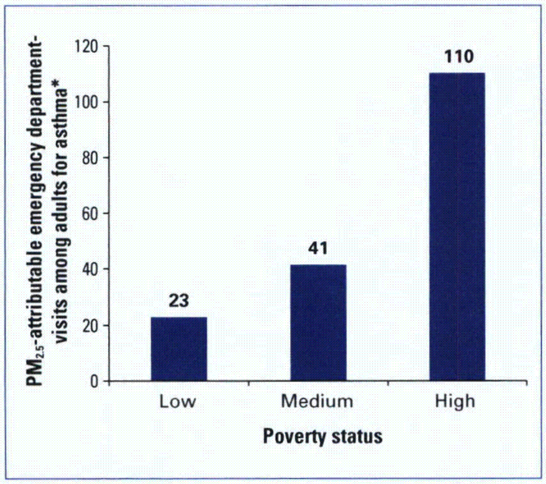
Disparities by neighborhood poverty are large; there is a 5-fold increase in high poverty, compared to low poverty, neighborhoods (**Figure 18**).

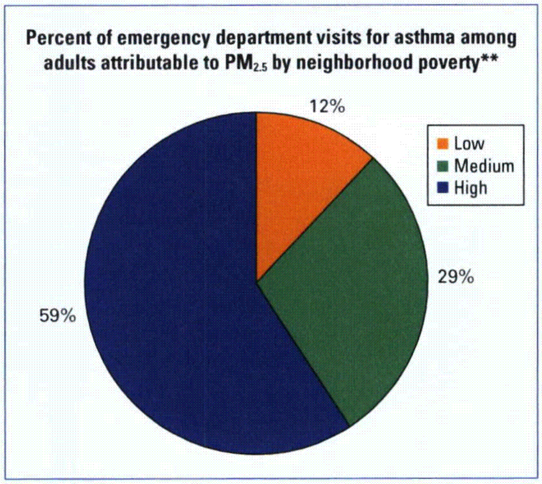
Figure 17. $PM_{2.5}$-attributable asthma emergency department visit rates among adults 18 years and older vary 25-fold across New York City neighborhoods.



$PM_{2.5}$=particulate matter

Figure 18. $PM_{2.5}$-attributable asthma emergency department visit rates in adults is nearly 5 times higher in neighborhoods with high, as compared to low, poverty.





$PM_{2.5}$=particulate matter

* Attributable rate of emergency department visits for asthma per 100,000 persons above 18 years of age

** Among adult >18 years of age

Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Ozone Health Impacts

In New York City, based on the concentration-response functions used in the main analysis of this report, current exposures to average concentrations of ozone from April through September above background concentrations cause more than 400 premature deaths, 850 hospitalizations for asthma and 4,500 emergency department visits for asthma annually (**Table 6**). Even a feasible, modest reduction of 10% in ozone concentrations could prevent more than 80 premature deaths, 180 hospital admissions and 950 emergency department visits.

Table 6. Annual health events attributable to citywide O_3 levels and the health benefits of reduced O_3 levels.

			Annual Health Events Attributable to Current Ozone Compared to Background Levels			Annual Health Events Prevented If Ozone Levels Reduced by 10%		
	Health Effect	Age Group	Number of Events (95% CI)**	Annual Rate per 100,000 people	Percent (%) of Events*	Number of Events (95% CI)**	Annual Rate per 100,000 people	Percent (%) of Events
O_3-Related Health Effects	Premature mortality	All Ages	400 (200,600)	4.9	3.1	80 (40,120)	1.0	0.6
	Hospital admissions-asthma	Less than 18 years	420 (260,580)	21	11	90 (50,130)	4.4	2.4
	Hospital admissions-asthma	18 and older	450 (240,650)	7.2	6.1	90 (50,130)	1.5	1.2
	Emergency department visits for asthma	Less than 18 years	1,800 (1300,2200)	91	10	370 (260,470)	19	2.0
	Emergency department visits for asthma	18 and older	2,900 (2100,3600)	45	11	600 (430,770)	9.5	2.2

O_3=ozone

* Annual Percent of April through September health events of a given type and in the specific age group that is attributable to O_3

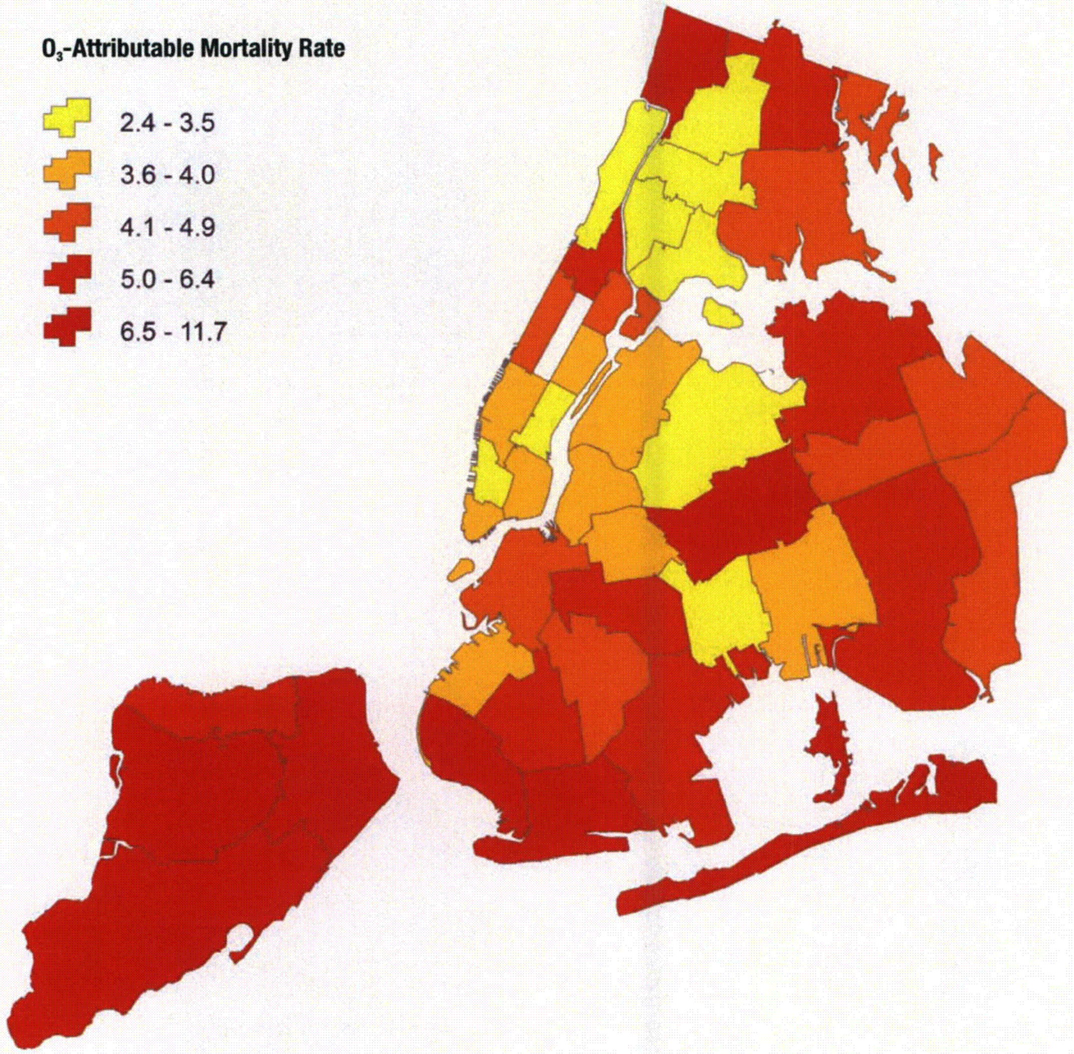
** CI=Confidence interval

Mortality

An estimated 400 ozone-attributable deaths occur in New York City annually. By neighborhood, rates of ozone-attributed mortality vary from 2.4 to 11.7 per 100,000 persons. Areas with the highest burden are located outside the city center, in Southern Brooklyn and Staten Island, Central Queens and Northwestern Bronx (**Figure 19**).

Nearly 85% of ozone-attributed mortality is among adults older than age 65 years of age (**Figure 20**).

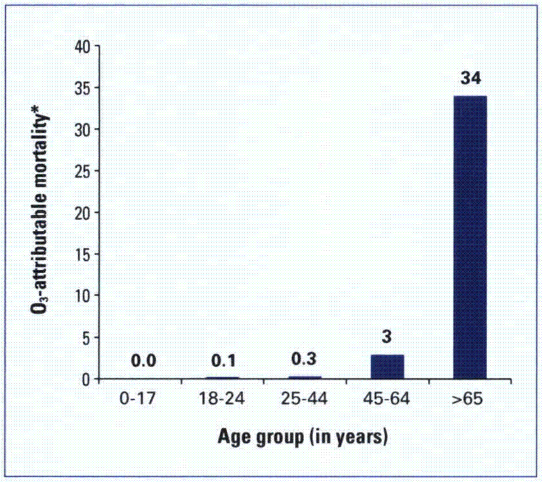
Figure 19. O_3-attributable mortality rates vary 5-fold across New York City neighborhoods.

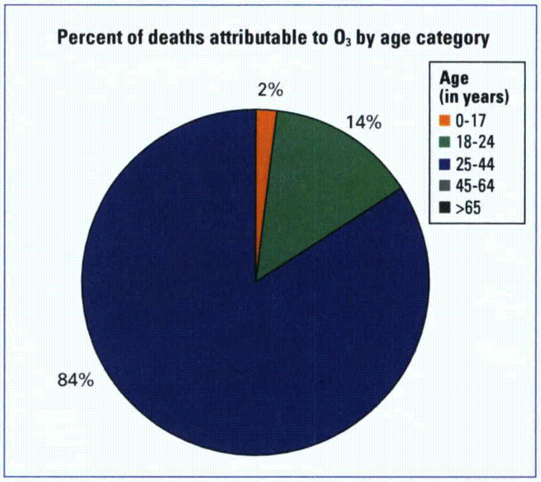


O_3=ozone

Contrary to the trends evident in $PM_{2.5}$ morbidity and mortality rates, ozone-attributable mortality is relatively evenly distributed according to neighborhood income (**Figure 21**).

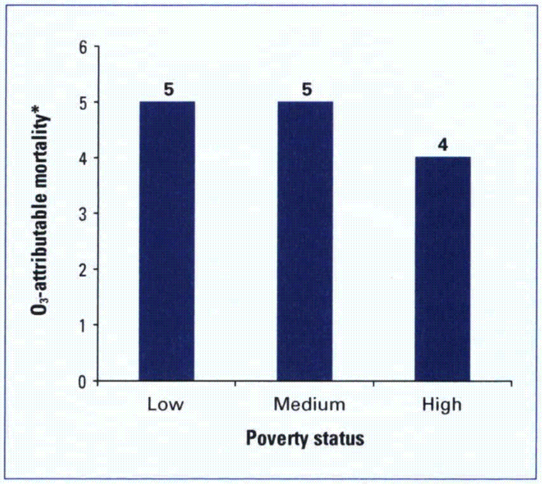
Figure 20. More than four-fifths of deaths attributable to O_3 occur in adults 65 years of age and older.

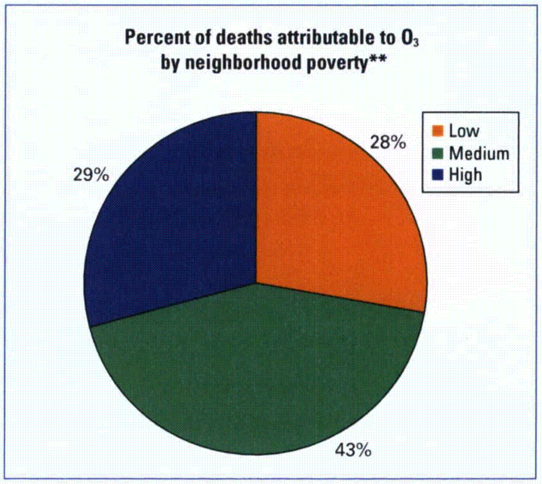




O_3=ozone
* Attributable mortality rate per 100,000 persons, annually

Figure 21. Ozone-attributable mortality rates are similar in neighborhoods with high, as compared to low, poverty rates.



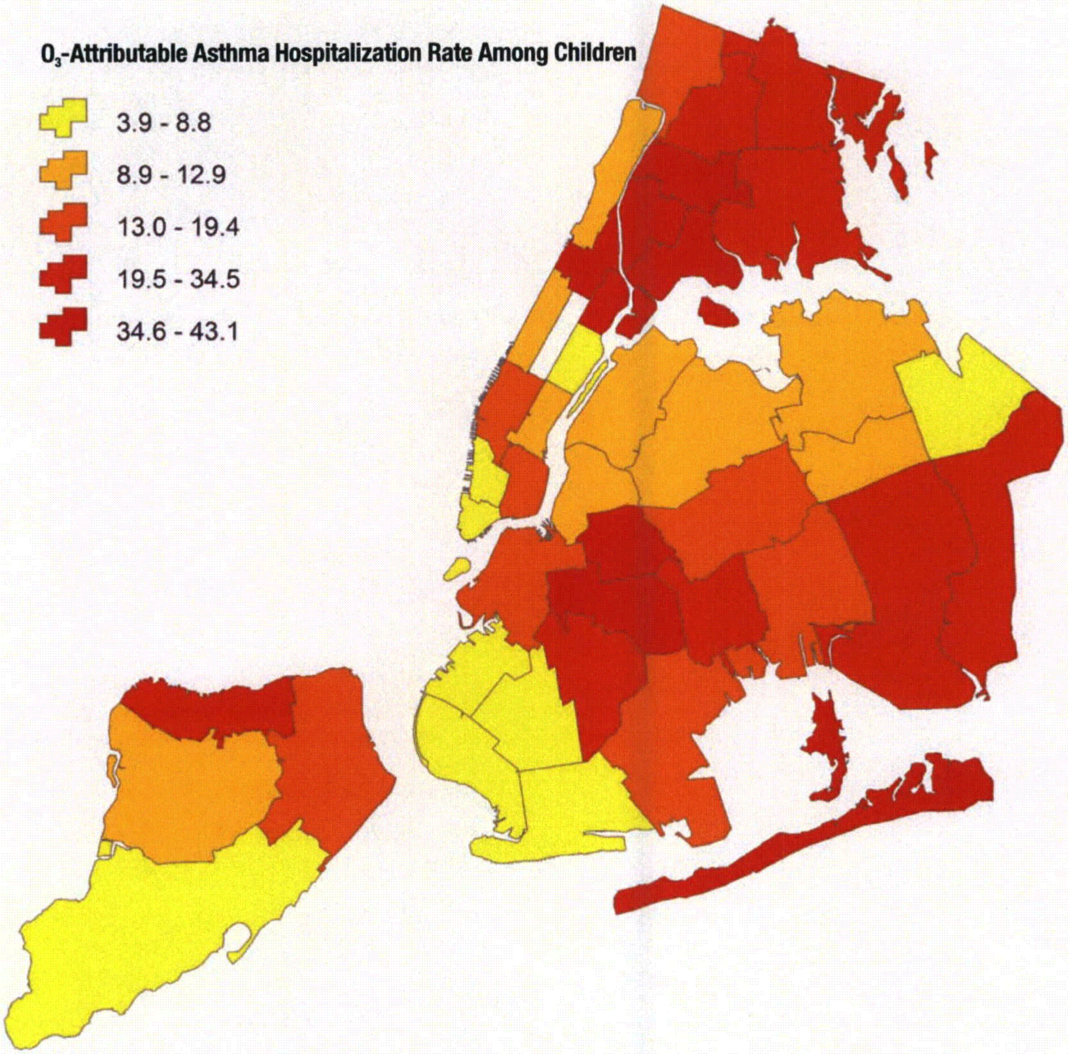


O_3=ozone
* Attributable mortality rate per 100,000 persons, annually
Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Hospital Admissions and Emergency Department Visits for Asthma in Children

More than 400 hospital admissions and 1,700 emergency department visits annually for asthma among children are likely attributable to ozone exposure in New York City (**Table 6**). As is the case for underlying rates of urgent care for asthma, rates vary by neighborhood, from approximately 4 to 43 ozone-attributable hospital admissions per 100,000 children. Ozone-attributable asthma admissions are most

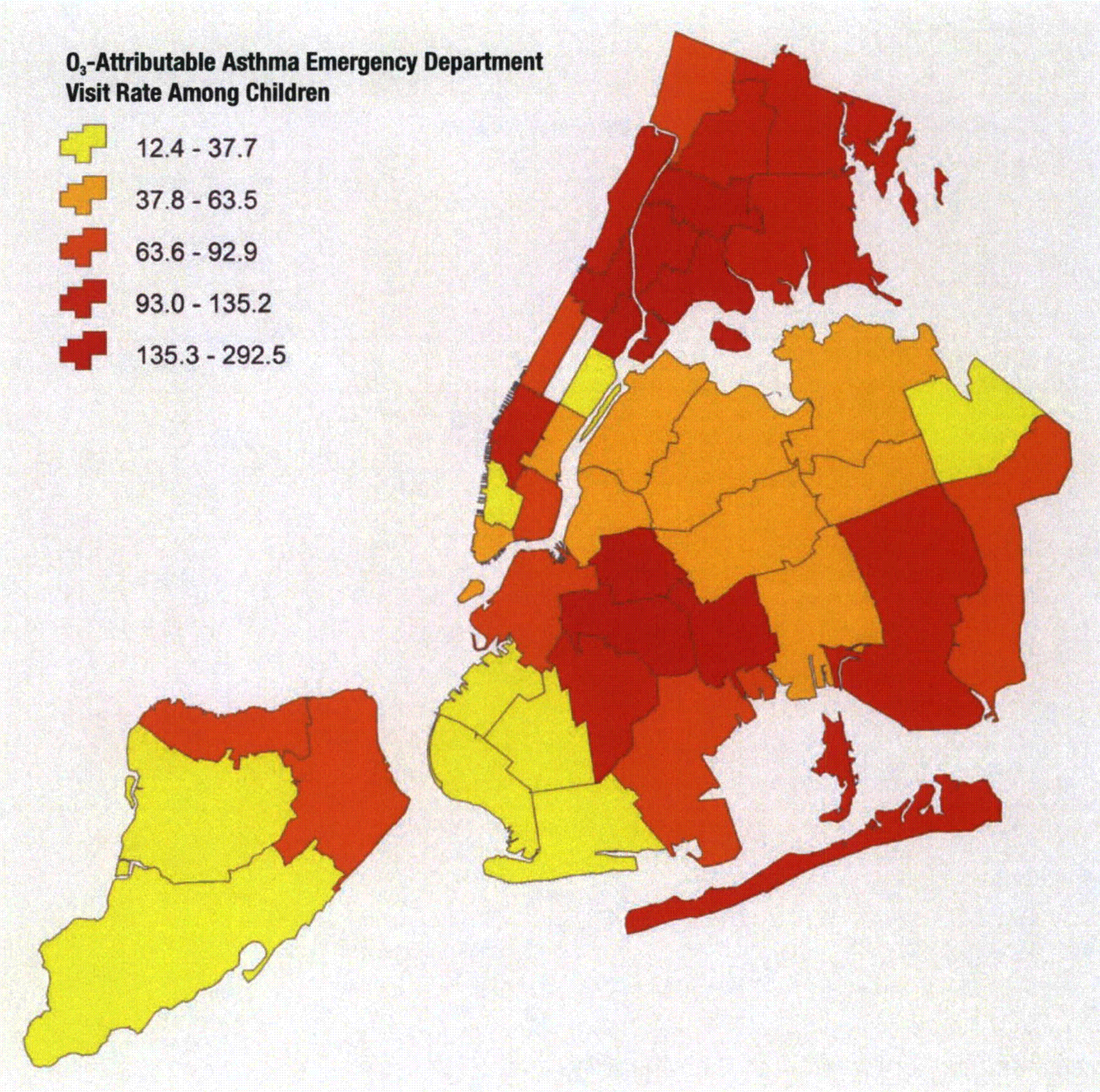
Figure 22. O_3-attributable asthma hospitalization rates among children younger than 18 years of age vary 11-fold across New York City neighborhoods.



O_3=ozone

concentrated in Northern Manhattan, the Bronx, Central Brooklyn, and parts Eastern-Central Queens and the Rockaways (**Figure 22**). Asthma emergency department visits attributable to ozone follow a similar geographic pattern, ranging from 12 to nearly 300 emergency department visits per 100,000 children (**Figure 23**).

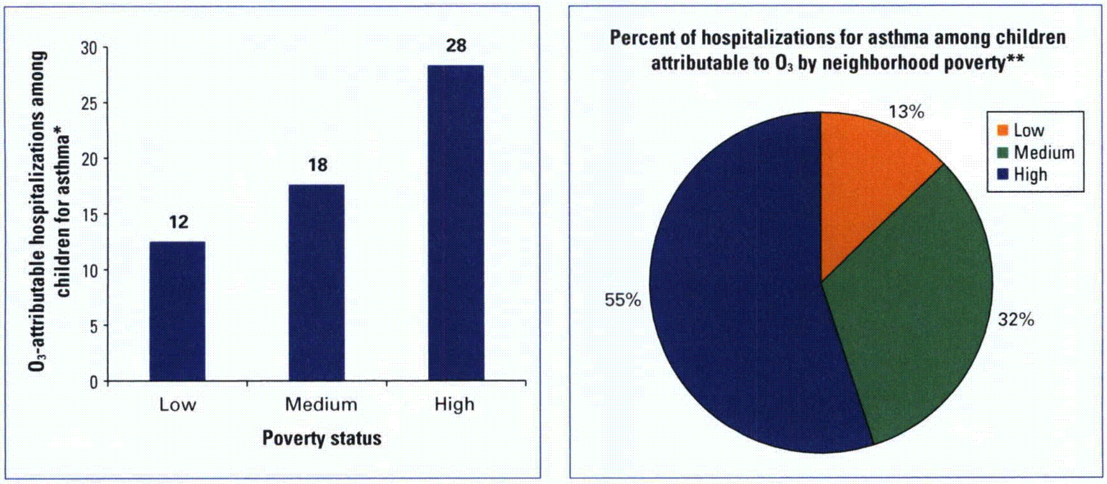
Figure 23. O_3-attributable rates of emergency department visits for asthma among children younger than 18 years vary 24-fold across New York City neighborhoods.



O_3=ozone

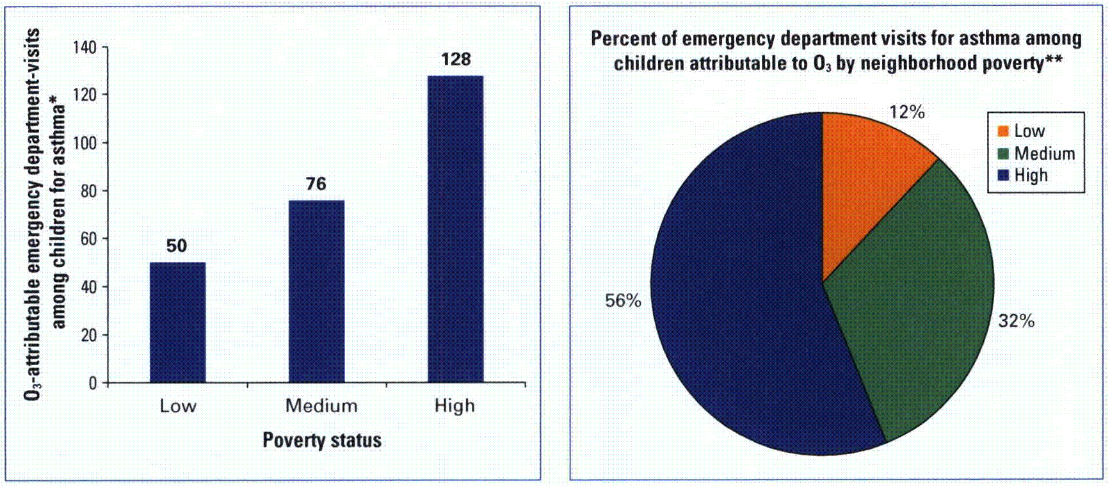
High poverty neighborhoods bear 55% of the burden of ozone-attributable asthma hospital admissions (**Figure 24**) and account for 56% of emergency department visits (**Figure 25**) among children.

Figure 24. O_3-attributable asthma hospitalization rates among children younger than 18 years of age is more than two times higher in neighborhoods with high, as compared to low, poverty rates.



O_3=ozone
* Attributable asthma hospitalization rate per 100,000 persons under 18 years of age
** Among children younger than18 years of age
Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Figure 25. O_3-attributable rates of emergency department visits for asthma among children younger than 18 years are more than twice as high in neighborhoods with high, as compared to low, poverty rates.

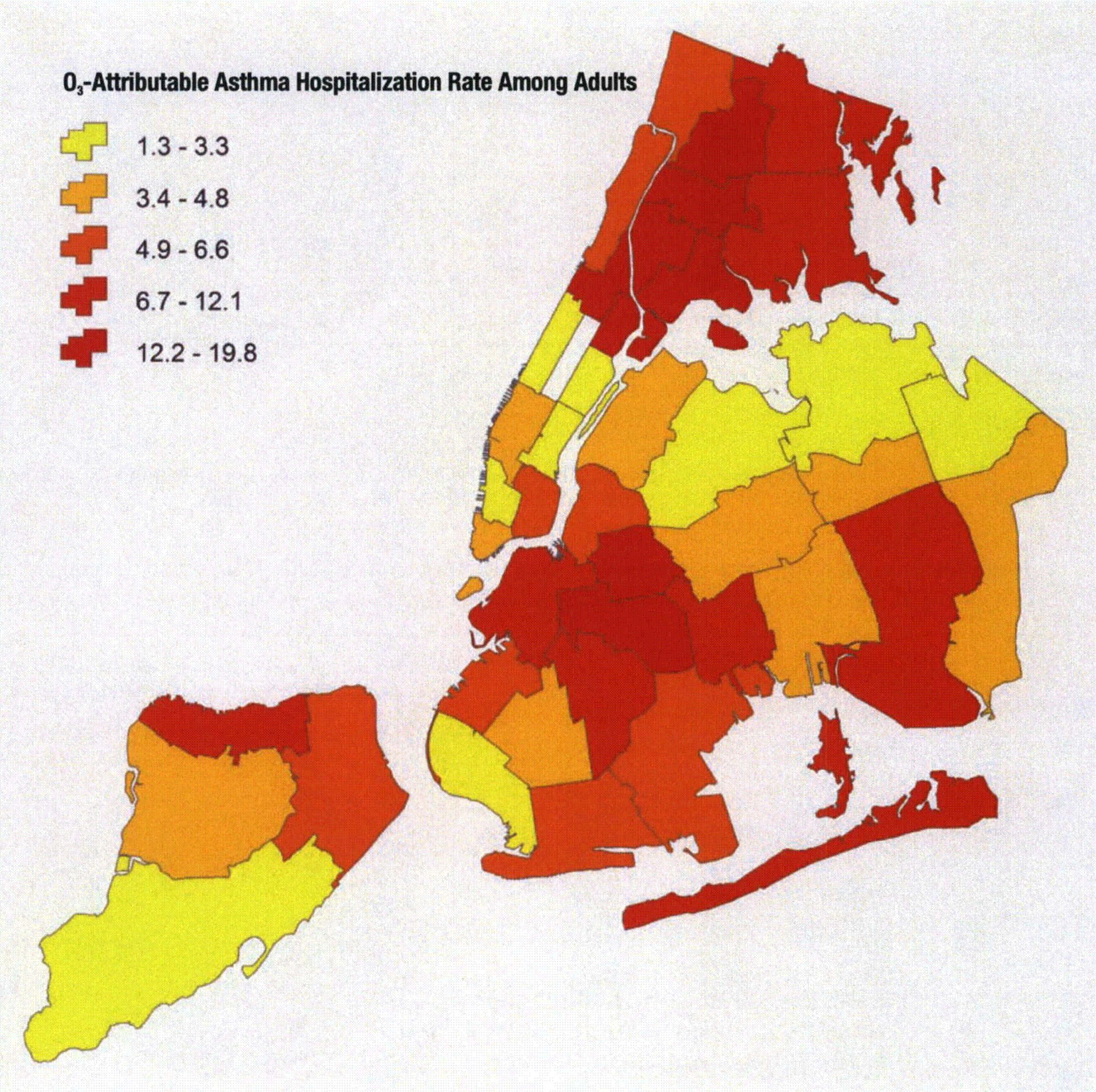


O_3=ozone
* Attributable rate of emergency department visits for asthma per 100,000 persons under 18
** Among children younger than 18 years of age
Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Hospital Admission and Emergency Department Visits for Asthma in Adults

Nearly 450 annual hospital admissions and nearly 3,000 emergency department visits for asthma among New York City adults are likely attributed to ozone (**Table 6**). Rates of ozone-attributable asthma hospitalization range from approximately 1 to 20 people per 100,000 adults older than 18 years of age (**Figure 26**, and ozone-attributable emergency visits range from 7 to 156 people per 100,000 (**Figure 27**).

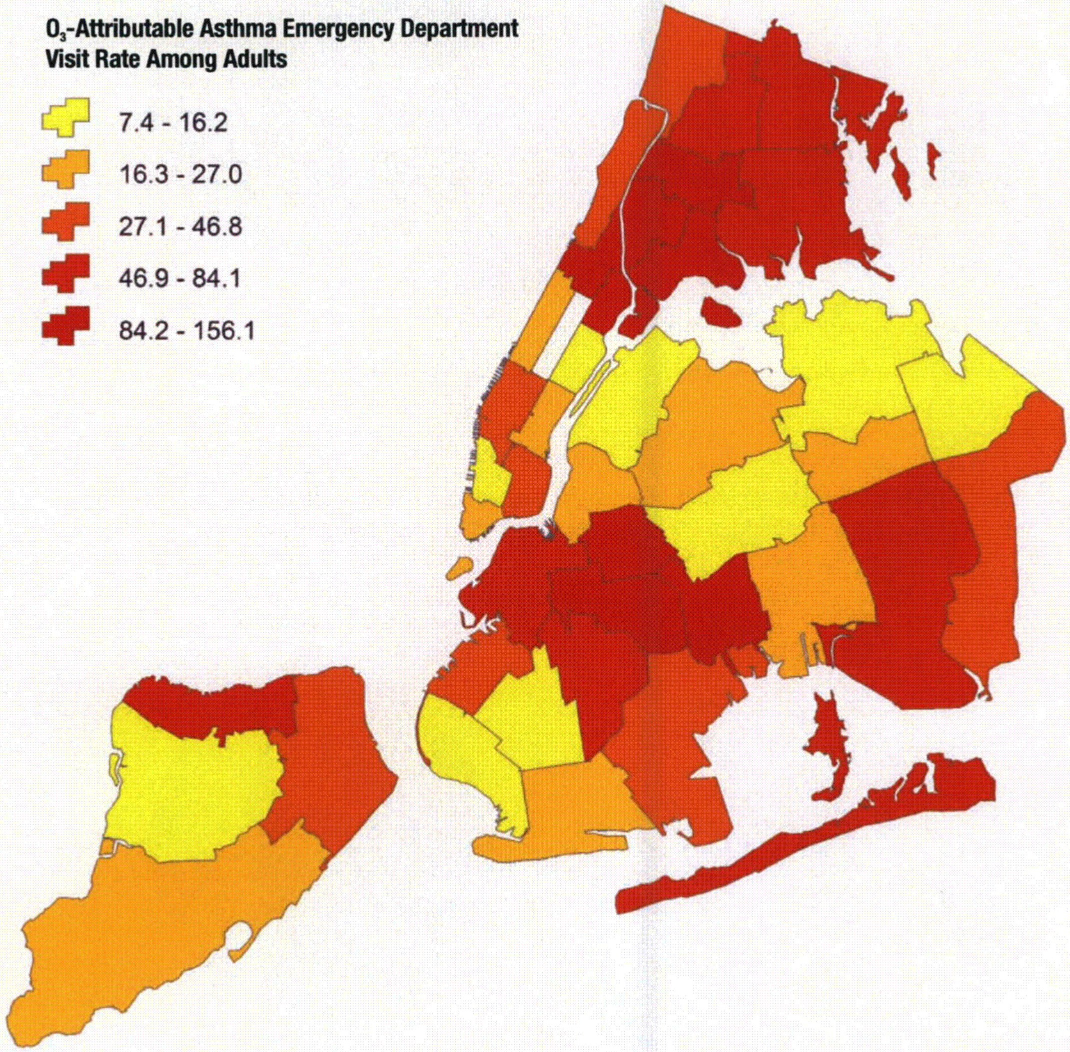
Figure 26. O_3-attributable asthma hospitalization rates vary 15-fold among adults 18 years and older across New York City neighborhoods.



O_3=ozone

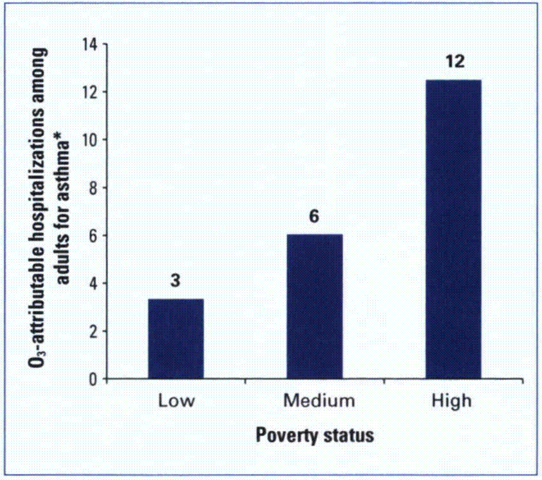
Neighborhood patterns of ozone-attrbutable hospitalizations and emergency department visits for asthma are similar in adults and children. In high poverty neighborhoods, rates are 4-fold higher for ozone-attributable asthma hospital admissions (**Figure 28**) and 4.5-fold higher for ozone-attributable emergency department visits (**Figure 29**).

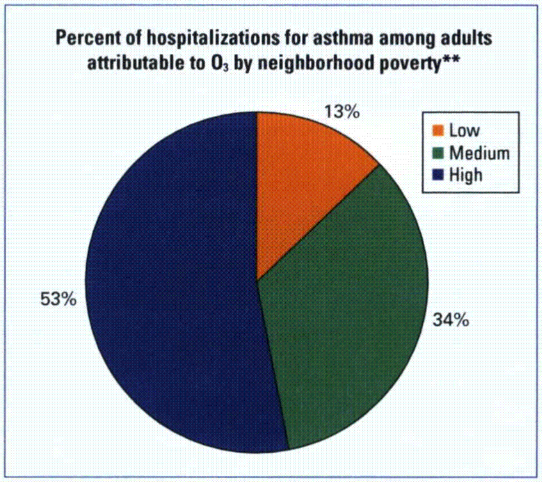
Figure 27. O_3-attributable rates of emergency department visits for asthma among adults 18 years and older vary 21-fold across New York City neighborhoods



O_3=ozone

Figure 28. O_3-attributable asthma hospitalization rates among adults 18 years and older are 4 times higher in neighborhoods with high, as compared to low, poverty rates.





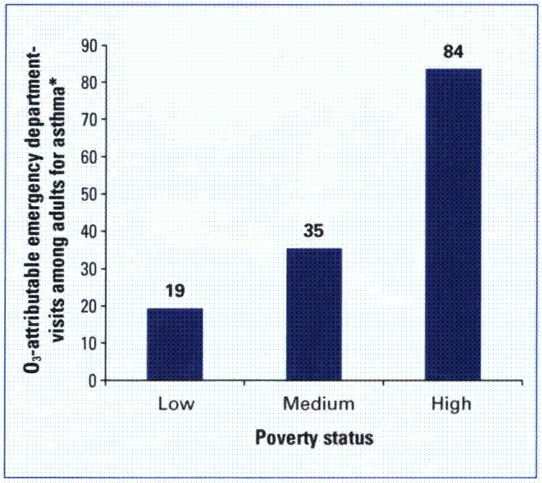
O_3=ozone

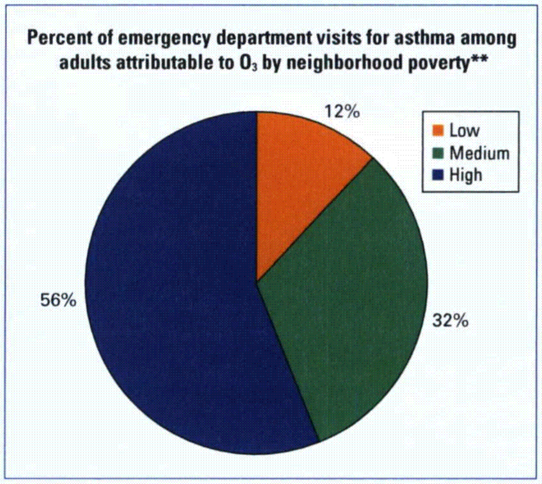
* Attributable rate of emergency department visits for asthma per 100,000 person 18 years of age and older

** Among adults 18 years of age and older

Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Figure 29. O_3-attributable rates of emergency department visits for asthma among adults 18 years and older is over 4 times higher in neighborhoods with high, as compared to low, poverty rates.





O_3=ozone

* Attributable rate of emergency department visits for asthma per 100,000 person 18 years of age and older

** Among adults 18 years of age and older

Poverty status: Low, medium and high poverty tertiles are calculated using percent of residents within a neighborhood who are at <200% federal poverty level, based on data from U.S. Census 2000

Limitations

While health impact assessment is a useful tool to translate complex technical studies into their implications for the health of a populations, the estimates produced have limitations to consider in their interpretation.

Health endpoints. This report is limited to health outcomes for which reliable neighborhood level data for New York City are available—deaths, hospital admissions and emergency department visits. For each serious health event caused by air pollution, there are many more individuals who have symptoms related to air pollution that limit their activities, cause school and work absences and reduce their quality of life.

Concentration-response functions. Estimated concentration response functions vary among scientific studies because:

- Concentration-response functions are based on an estimate that has some sampling (random) errors that are reflected in the confidence intervals (**see Tables 5 and 6**).
- Different populations may respond differently to air pollution; for example, some studies show that people with asthma that take inhaled corticosteroids may respond less to air pollution exposure (Hernandez-Cadena 2009, Koening 2003).
- Stress associated with poverty may increase the effects of air pollution.
- The mixtures of air pollutants in different cities might interact to enhance the toxicity of individual pollutants.
- Fine particles vary in their composition and likely vary in their effects, depending on their source (for example, $PM_{2.5}$ emitted by residual oil-burning contains higher concentrations of nickel and other metals, which may make them more harmful).

An example of the uncertainty related to choice of concentration-response functions, the main analysis of $PM_{2.5}$-attributable mortality in this report used a concentration-response functions estimate based on the Krewski (2009) analysis of the American Cancer Society (ACS) Cohort. Although this is the largest and most recent study on the effects of $PM_{2.5}$ on mortality, the ACS population includes a smaller proportion of low-income and minority people than as is the case in New York City. A sensitivity analysis (see online appendix) shows the estimated mortality burden using a concentration-response function based on the Laden (2006) analysis of the Harvard Six Cities cohort. Although smaller than the American Cancer Society cohort, the Harvard Six Cities cohort includes a more diverse population similar to New York City's, and the Harvard Six Cities concentration-response function estimates a much stronger effect of $PM_{2.5}$ on mortality. Although a larger estimate of $PM_{2.5}$-attributable deaths (approximate 8,000 per year) calculated based on the Harvard Six Cities study may be more realistic, this report relied on the American Cancer Society study to produce a more conservative estimate.

Single vs. multi-pollutant models. Studies have already shown that $PM_{2.5}$ and O_3 are harmful. In addition, their presence indicates the presence of other harmful pollutants that are influenced by the same sources and weather patterns. Motor vehicles that emit $PM_{2.5}$, for example, also emit harmful oxides of nitrogen, toxic volatile organic compounds and ultrafine particles. Weather conditions that trap $PM_{2.5}$ emissions near ground level also trap other pollutants. As a result, the times of year and locations of high $PM_{2.5}$ concentrations tend to have higher concentrations of multiple pollutants. Multi-pollutant models are used by researchers to distinguish the health effects of one pollutant while controlling for co-pollutants that tend to vary with the pollutant under study. These studies are less useful, however, in estimating the impacts and benefits of reducing pollution because measures to reduce $PM_{2.5}$ emissions will often reduce emissions of other harmful pollutants. Studies on concentrations of individual air pollutants and the risk of health effects that don't control for other pollutants (single pollutant models) are more appropriate for estimating the impact of increasing or decreasing $PM_{2.5}$ concentrations and other pollutants that tend to vary with $PM_{2.5}$. This report mainly relies on similar single pollutant models.

Air pollution can cause and exacerbate chronic diseases. It has been known for many years that $PM_{2.5}$ and ozone can exacerbate acute health problems; for example, both can trigger an asthma attack in someone with asthma. In this report, the estimates of the acute effects of air pollution on hospital care for respiratory and cardiovascular disease are for exacerbation only. Recent evidence has shown, however, that exposure to air pollutants near busy roads can also cause new cases of chronic lung and heart diseases. In a recent health impact assessment for European cities, the authors applied this new evidence and estimated that air pollution may cause as much as 25% to 30% of strokes and heart attacks in adults age 65 years and older, and 15% to 25% of hospitalizations and other respiratory illnesses among asthmatic children. These amounts are much higher than those estimated for New York City; the numbers in this report are very conservative.

Other limitations. Regulatory monitors do not capture the full range of neighborhood variation in air quality throughout the city. Future reports will apply measurements from the New York City Community Air Survey (NYCCAS) to estimate health impacts. In this report, the burden of air pollution is defined as the difference between current levels and a theoretical policy relevant background that has never been measured by researchers. This model assumes that the same relationship between pollutant levels and health effects is found below the lowest measured level, an assumption supported by the lack of evidence of a health effect threshold.

Discussion

The scientific evidence for the harmful effects of $PM_{2.5}$ and ozone is extensive, but studies do not easily convey the public health dimensions of the air pollution problem or how it compares to other challenges facing the city. In this report, methods used by regulators to evaluate the risks of air pollution and benefits of control measures are combined with New York City neighborhood health data that reflect the wide disparities in health and susceptibility to air pollution effects. The resulting estimates better reflect the large overall burden of air pollution and its distribution across the across the city, which falls especially hard on high poverty communities, seniors and children and adults with asthma. While these estimates are useful, they cannot capture the human toll behind the statistics—frightening trips to the emergency room for children with asthma and their families, heart attacks and disabling strokes, and the untimely deaths of loved ones.

How do the estimates in this report compare to other estimates for New York City alone, the nation and the world? The U.S. Environmental Protection Agency has estimated that in New York City, 1,500 to 2,000 deaths, 800 to 950 hospital admissions for cardiovascular disease, and 4,500 to 5,200 asthma related emergency department visits annually are attributed to exposures to $PM_{2.5}$ (Environmental Protection Agency). Anenberg (2010) estimated that current levels of fine particles and ozone are responsible for 35,000 respiratory deaths, 124,000 cardiopulmonary deaths and 17,000 lung cancer deaths in North America. Studies by the World Health Organization have estimated that outdoor particulate matter air pollution is responsible for 800,000 premature deaths globally each year (Cohen 2005). Worldwide, outdoor air pollution ranks third only behind indoor air pollution from fuel combustion, and unsafe water, sanitation and hygiene in terms of attributable deaths due to environmental risk factors (Ezatti 2006). Much of the global burden of air pollution falls in developing countries where rapid urbanization is combined with a lack of pollution controls.

Why are these results important for New Yorkers? While the city's air quality has improved in recent decades, air pollution causes (conservatively) 6% of annual deaths in the city each year, making it one of the most significant environmental health problems. Furthermore, air quality improvements will have significant and immediate health benefits at a scale second only to reductions in smoking rates, among recent city initiatives. To reduce the toll from air pollution, actions are needed to address important local sources, such as motor vehicle exhaust, building heating oil and aging power plants with outmoded technology. As part of the city's sustainability plan, PlaNYC, many emission reduction initiatives have been completed or launched; others are planned. The steps needed will produce many benefits beyond health, such as reducing greenhouse gas emissions. But investments and behavior changes are also needed, making it important for New Yorkers to understand the burden of air pollution on New Yorkers' health, the health benefits of addressing it and the costs of inaction.

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NEW YORK STATE
DEPARTMENT OF
ENVIRONMENTAL CONSERVATION

About Ozone

Ozone is a pollutant found during the unpleasant and unhealthy air condition called *smog*. Unlike other air pollutants, ozone is not emitted by pollution sources. Instead, it is formed in the air itself -- high temperatures (over 80°F) and sunlight set off chemical reactions involving so-called ozone *precursors*, which are hydrocarbons such as gasoline vapors, and nitrogen dioxide from vehicles and smokestacks. The end result is ozone (O_3), a highly reactive chemical "cousin" of the oxygen (O_2) that we all need to survive.

Ozone Harms Environment and Health

Ozone damages crops and forests, structures, and human health. In the environment, this reactive gas can attack surfaces, fabrics and rubber materials, and is toxic to some crops, vegetation and trees.

When the air is highly polluted with ozone, some people experience smarting eyes and irritated air passages. As ozone levels increase, the severity of the effects increases, and more people become affected. Ozone can cause a variety of respiratory problems, including coughing, shortness of breath, decreased lung function, increased susceptibility to respiratory infection. Asthma and other respiratory ailments may worsen and victims can develop severe respiratory problems.

New York State Warns of High Ozone Levels

Public health officials caution against strenuous outdoor activity when ozone levels are high. To help people decide when to curtail activity, DEC forecasts ozone pollution and, in cooperation with the NYS Department of Health, posts warnings on this website if dangerous conditions are expected to occur. These warnings are also aired through the media, and are available on the toll-free Ozone Hotline at 800-535-1345.

Overall levels of ozone have been systematically declining in New York State and other northeastern states during the past two decades. This decline is the result of motor vehicle exhaust emission controls, lower volatility fuels, stringent control of industrial pollution sources, and other measures that have reduced ozone precursors.

DEC Monitors Ozone Pollution

Unhealthful ozone levels do still occur, however, particularly in New York City and the lower Hudson Valley. DEC's ozone monitoring network provides real-time information on ozone concentrations to the general public, and meets state and federal requirements.

The ozone advisories are developed based on DEC's constant monitoring of ozone levels at 30 sites across the state. Recent results of ozone monitoring can be found in the New York State Ambient Air Quality Report.

Protecting Your Health During a Health Advisory

All people, especially children, those who exercise or work outdoors, and those with respiratory diseases, should limit strenuous outdoor activity during the afternoon and early evening hours, when ozone levels are highest. If you have asthma or other respiratory problems, stay in a cool area and, if possible, where the air is filtered or air-conditioned. Schedule outdoor exercise and children's outdoor activities for the morning hours. Individuals who experience respiratory symptoms may wish to consult their doctors.

Reducing Ozone Pollution

Reducing ozone in the air requires action on multiple fronts.

- DEC controls pollution from smokestacks through a statewide permitting program.
- State and federal controls on vehicle exhausts, along with programs requiring inspection and maintenance of vehicle emission control devices, reduce emission of nitrogen oxides.
- Use of low volatility fuels during the warm months reduces hydrocarbon vapors in the air.
- Drivers can prefer low-emission vehicles, limit their driving, and refuel with care to avoid spillage.
- Homeowners can use water-based paints, store and handle gasoline and other solvents carefully.

More about About Ozone:

Ozone - the Pollution Paradox - Ozone, too much is harmful. But so is too little. The paradox is not contradictory. When it comes to ozone the where makes the difference.

Ground Level Ozone Monitoring Sites - The primary purpose for maintaining ground level ozone sites is to measure, on a continuous basis, the concentration of various pollutants, including ozone, in the ambient (outdoor) air.

Ozone Questions and Answers - Questions and answers about ozone.

Reducing Air Pollution from Lawn and Garden Equipment - Facts and Tips on Reducing Summertime Air Pollution from Powered Lawn and Garden Equipment

U.S. Energy Information Administration

NATURAL GAS

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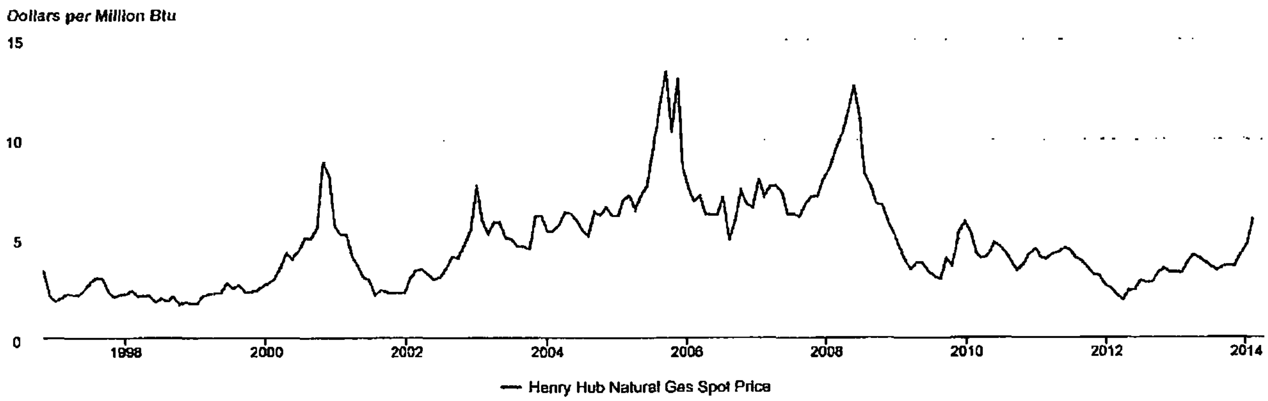
Henry Hub Natural Gas Spot Price



Source: U.S. Energy Information Administration

Chart Tools

no analysis applied

Henry Hub Natural Gas Spot Price (Dollars per Million Btu)

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1997	3.45	2.15	1.89	2.03	2.25	2.20	2.19	2.49	2.88	3.07	3.01	2.35
1998	2.09	2.23	2.24	2.43	2.14	2.17	2.17	1.85	2.02	1.91	2.12	1.72
1999	1.85	1.77	1.79	2.15	2.26	2.30	2.31	2.80	2.55	2.73	2.37	2.36
2000	2.42	2.66	2.79	3.04	3.59	4.29	3.99	4.43	5.06	5.02	5.52	8.90
2001	8.17	5.61	5.23	5.19	4.19	3.72	3.11	2.97	2.19	2.46	2.34	2.30
2002	2.32	2.32	3.03	3.43	3.50	3.26	2.99	3.09	3.55	4.13	4.04	4.74
2003	5.43	7.71	5.93	5.26	5.81	5.82	5.03	4.99	4.62	4.63	4.47	6.13
2004	6.14	5.37	5.39	5.71	6.33	6.27	5.93	5.41	5.15	6.35	6.17	6.58
2005	6.15	6.14	6.96	7.16	6.47	7.18	7.63	9.53	11.75	13.42	10.30	13.05
2006	8.69	7.54	6.89	7.16	6.25	6.21	6.17	7.14	4.90	5.85	7.41	6.73
2007	6.55	8.00	7.11	7.60	7.64	7.35	6.22	6.22	6.08	6.74	7.10	7.11
2008	7.99	8.54	9.41	10.18	11.27	12.69	11.09	8.26	7.67	6.74	6.68	5.82
2009	5.24	4.52	3.96	3.50	3.83	3.80	3.38	3.14	2.99	4.01	3.66	5.35
2010	5.83	5.32	4.29	4.03	4.14	4.80	4.63	4.32	3.89	3.43	3.71	4.25
2011	4.49	4.09	3.97	4.24	4.31	4.54	4.42	4.06	3.90	3.57	3.24	3.17
2012	2.67	2.51	2.17	1.95	2.43	2.46	2.95	2.84	2.85	3.32	3.54	3.34
2013	3.33	3.33	3.81	4.17	4.04	3.83	3.62	3.43	3.62	3.68	3.64	4.24
2014	4.71	6.00										

- = No Data Reported; -- = Not Applicable; NA = Not Available; W = Withheld to avoid disclosure of individual company data.

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Referring Pages:

- Natural Gas Futures Prices (NYMEX)