Responses to Significant Comments on the 2009 Proposed Rule on the Primary National Ambient Air Quality Standards for Nitrogen Dioxide (July 15, 2009; 74 FR 34404)

Docket Number OAR-2006-0922

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Frequently Cited Documents

The following documents are frequently cited throughout EPA's response to comments, often by means of the short names listed below:

Integrated Science Assessment (ISA):

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

Preamble to the final rule (final notice):

> Preamble to the Final Rule on the Review of the Primary National Ambient Air Quality Standards for Nitrogen Dioxide; to be published in the *Federal Register* in January or February of 2010.

Proposal notice:

> Primary National Ambient Air Quality Standard for Nitrogen Dioxide: Proposed Rule. 74 FR 34404, July 15, 2009.

Risk and Exposure Assessment (REA):

> EPA. (2008b). Risk and Exposure Assessment to Support the Review of the NO_2 Primary National Ambient Air Quality Standard. Office of Air Quality Planning and Standards, Research Triangle Park, NC. Available at: http://www.epa.gov/fedrgstr/EPA-AIR/2009/July/Day-15/a15944.pdf

Acronyms and Abbreviations

AADT	Annual average daily traffic
AAM	Alliance of Auto Manufacturers
AAQM	Ambient Air Quality Monitoring
AASHTO	American Association of State Highway and Transportation Officials
ACC	American Chemistry Council
ACSBPP	Annapolis Center for Science-Based Public Policy
AGCA	Association General Contractors of America
AHR	Airways hyperresponsiveness
AQRL	AirQuality Research and Logistics
ALA	American Lung Association
ANPR	Advance Notice Of Proposed Rulemaking
API	American Petroleum Institute
AQI	Air quality index
ATS	American Thoracic Society
CAA	Clean Air Act
CAAPCOA	California Air Pollution Control Officer's Association
CAC	Clean Air Council
CASAC	Clean Air Scientific Advisory Committee
CBSA	Core-based statistical area
CE	Consumers Energy
CO	Carbon monoxide
COPA	Colorado Petroleum Association
CSE	Coalition for a Safe Environment
Dow	Dow Chemical Company
EDF	Environmental Defense Fund
EEI	Edison Electric Institute
EJ	EarthJustice
EMA	Engine Manufacturers Association
EPA	U.S. Environmental Protection Agency
Exxon	ExxonMobil Refining and Supply Company
FEM	Federal Equivalent Method
FEV	Forced Expiratory Volume
FRM	Federal Reference Method
GASP	Group Against Smog and Pollution
HCPHES	Harris County Public Health and Environmental Services

HEI	Health Effects Institute
HLI	Healthy Lungs Initiative
IADNR	Iowa Department of Natural Resources
INDEM	Indiana Department of Environmental Management
INGAA	Interstate Natural Gas Association of America
IPAMS	Independent Petroleum Association of Mountain States
ISA	Integrated Science Assessment
MET	Meteorological
MODNR	Missouri Department of Natural Resources Air Pollution Control Program
NAAQS	National Ambient Air Quality Standards
NACAA	National Association of Clean Air Agencies
NAM	National Association of Manufacturers
NCDENR	North Carolina Department of Environment and Natural Resources
NESCAUM	Northeast States for Coordinated Air Use Management
NIOSH	National Institute of Occupational Safety and Health
NMA	National Mining Association
NMED	New Mexico Environment Department Air Quality Bureau
NO_2	Nitrogen Dioxide
NO_X	Nitrogen Oxides
NPRA	National Petrochemical and Refiners Association
NRDC	National Resource Defense Council
NSR	New Source Review
NTAA	National Tribal Air Association
NYDOH	New York Department of Health
NYSDEC	New York State Department of Environmental Conservation
OIPA	Oklahoma Independent Petroleum Association
OLM	Ozone Limiting Method
OSHA	Occupational Safety and Health Association
PAW	Petroleum Association of Wyoming
PEL	Permissible Exposure Level
PM	Particulate Matter
ppb	Parts Per Billion
ppbv	Parts Per Billion by Volume
ppmv	Parts Per Million by Volume
PSD	Prevention of Significant Deterioration
PVMRM	Plume Volume Molar Ratio Method
QC	Quality control

REA	Risk and Exposure Assessment
RHAMC	Respiratory Health Association of Metropolitan Chicago
RIA	Regulatory Impact Analysis
SCAQMD	South Coast Air Quality Management District
SDDENR	South Dakota Department of Environment and Natural Resources
SIL	Significant Impact Level
SIP	State Implementation Plan
STEL	Short-Term Exposure Level
TFI	The Fertilizer Institute
TXCEQ	Texas Commission on Environmental Quality
UPA	Utah Petroleum Association
UARG	Utility Air Regulatory Group
VADOT	Virginia Department of Transportation

I. Introduction

This document, together with the preamble to the final rule on the review of the primary national ambient air quality standards (NAAQS) for nitrogen dioxide (NO_2), presents the responses of the Environmental Protection Agency (EPA) to the public comments received on the 2009 NO_2 NAAQS proposal notice (74 FR 34404). All significant issues raised in timely public comments have been addressed. Where comments were submitted after the close of the public comment period, EPA has responded to the extent feasible.

Due to the number of comments that addressed similar issues, this response-to-comments document does not generally cross-reference each response to the commenter(s) who raised the particular issue involved, although commenters are identified in some cases where they provided particularly detailed comments that were used to frame the overall response on an issue.

The responses presented in this document are intended to augment the responses to comments that appear in the preamble to the final rule or to address comments not discussed in the preamble to the final rule. Although portions of the preamble to the final rule are paraphrased in this document where useful to add clarity to responses, to the extent any ambiguity is introduced by this paraphrasing, the preamble itself remains the definitive statement of the rationale for the revisions to the standards adopted in the final rule.

In many instances, particular responses presented in this document include cross references to responses on related issues that are located either in the preamble to the NO_2 primary NAAQS final rule, or in this Response to Comments document. In other instances the comment is appropriately addressed by the Agency's discussion in other parts of the record. All issues on which the Administrator is taking final action in the NO_2 primary NAAQS final rule are addressed in the NO_2 NAAQS rulemaking record.

Accordingly, this Response to Comments document, together with the preamble to the NO_2 primary NAAQS final rule and the information contained in the Integrated Science Assessment (ISA) (EPA, 2008a), the Risk and Exposure Assessment (REA) (EPA, 2008b), and the Notice of Proposed Rulemaking should be considered collectively as EPA's response to all of the significant comments submitted on EPA's 2009 NO_2 primary NAAQS proposed rule. This document incorporates directly or by reference the significant public comments addressed in the preamble to the NO_2 NAAQS final rule as well as other significant public comments that were submitted on the proposed rule.

Consistent with the final decisions presented in the notice of final rulemaking, comments on the following topics are addressed in this document: the scientific evidence and exposure/risk information (section II); the adequacy of the current NO_2 standard to protect public health (section III); revisions to the current standard in terms of indicator (section IV.A), averaging time (section IV.B), form (section IV.C), and level (section IV.D); revisions to the NO_2 monitoring network (section V); the air quality index (VI); the process for reviewing the standard (section VII); interpretation of the Clean Air Act (section VIII); and implementation of the standard (section IX);.

II. Responses to Significant Comments on the Scientific Evidence and Exposure/Risk Information

A. General comments on the scientific evidence

(1) *Comment:* Some commenters (e.g., AAM, ACC) stated that it is not clear what was meant in the ISA by a "likely causal" relationship, stating that this classification is "somewhat ambiguous" and "at odds with" frameworks developed by IARC and NAS/IOM (ACC, p. 2) These groups concluded that it would have been preferable not to include this characterization of the evidence in the ISA.

Response: EPA's causality framework is not at odds with other frameworks. EPA's use of a five-level hierarchy in the ISA is consistent with EPA's Guidelines for Carcinogen Risk Assessment (EPA, 2005). Excerpts from those guidelines are included in Annex A (AX1 pp. 1-6 to 1-9); the second of five descriptors is "Likely to be Carcinogenic to Humans." IARC's classification of carcinogens is also excerpted in Annex A (AX1 pp. 1-14 to 1-20), and it includes Group 1 (carcinogenic), Group 2A (probably carcinogenic), Group 2B (possibly carcinogenic), Group 3 (not classifiable) and Group 4 (probably not carcinogenic). In contrast with commenters' assertion that IARC's system differs from EPA's, these five groups and subgroups are clearly analogous to the five tiers in EPA's framework. Commenters also refer to the NAS/IOM framework (IOM, 2007) that was used as a resource for EPA's causal framework and excerpted in Annex A (AX1 pp. 1-9 to 1-12). The four categories used in that system – "sufficient", "equipoise and above", "below equipoise" and "against" – are different from those used in most other classifications. However, the IOM report included detailed discussion of the approach to evaluating evidence from across scientific disciplines that served as an important resource for EPA's weight of evidence determination. In developing its framework drawing causal inferences, EPA carefully considered and drew upon the work of previous assessments to build a framework for determination of causality that is consistent with EPA's cancer risk assessment guidelines as well as those of other expert organizations. The development and implementation of this framework has been lauded by the CASAC in recent ISA reviews such as that in the PM NAAQS review (Samet, 2009a).

B. Comments on the epidemiologic evidence

(1) *Comment:* Several industry groups (e.g., API, AAM, ACC) commented that the epidemiologic studies did not support a causal relationship between NO_2 and health effects due to uncertainties and issues related to model specification. These commenters state that EPA has ignored or understated issues such as selection of degrees of smoothing appropriate to adjust for weather and time trends and selection of lag period.

Response: EPA has not ignored issues related to model specification for epidemiologic studies, such as selection of models and approaches to adjust for meteorological and temporal variables. EPA agrees with commenters that these are important issues. In this and previous NAAQS reviews, EPA has carefully evaluated such issues, including

sponsorship of workshops and special analyses of epidemiologic data, such as the Health Effects Institute (HEI) report (2003) cited by several commenters (e.g., ACC, AAM). As observed in the NOx ISA (p. 3-1), extensive discussions of the issues surrounding model selection and model specification have been presented in the PM AQCD (EPA, 2004) and the Ozone AQCD (EPA, 2006) and are thus not reiterated at length in this ISA. The NOx ISA makes clear, however, that these issues were were carefully considered in selecting studies for inclusion in the ISA and interpreting the results of the body of epidemiologic evidence.

Commenters specifically refer to the Health Effects Institute report on the reanalysis of a series of time-series epidemiologic studies to evaluate alternative modeling strategies, and include a brief quote from the Health Review Committee Panel (HEI, 2003): "Neither the appropriate degree of control for time, nor the appropriate specification of the effects of weather, has been determined for time-series analysis." (ACC, p. 7, quoting HEI, 2003, p. 269). Taken in full context, it can be seen not as condemnation of all epidemiologic time-series studies but rather as a call for further investigation. The primary conclusion drawn by the HEI panel was, rather: "The overall impact of revising these studies include: While the number of studies showing an association of PM with mortality was slightly smaller, the PM association persisted in the majority of studies. In some of the large number of studies in which the PM association persisted, the estimates of PM effect were substantially smaller. In the few studies in which investigators performed further sensitivity analyses, some showed marked sensitivity of the PM effect estimate to the degree of smoothing and/or the specification of weather" (HEI, 2003, p. 269). The results of this extensive set of reanalyses was thoroughly discussed in the PM AQCD (EPA, 2004, Section 8.4.2). EPA has not ignored or downplayed these issues, in fact, EPA has scrutinized epidemiologic studies and has funded independent reanalyses of epidemiologic studies.

EPA observes that the reanalyses discussed above and cited by commenters are primarily on PM health effects studies. Few reanalyses have specifically focused on NOx; however EPA has recognized that model specification issues are generally similar for both PM and the gaseous criteria air pollutants. EPA agrees that model specification and control of time-varying factors such as weather, remains important and has considered the available evidence in its evaluation of epidemiologic studies. The EPA also agrees with commenters that season-specific analyses have not been widely used in epidemiologic studies for NOx,[1] however, EPA observes that a number of studies included in the ISA did report results from seasonal models. The EPA disagrees that the available studies can support a conclusion that air pollution effects are consistently and strongly modified by season. In summary, EPA has not ignored the potential influence of model selection and specification in reviewing epidemiologic studies; rather, EPA has scrutinized such issues in previous assessments as well as the NOx ISA. These issues were fully considered in

[1] It should be noted that use of smaller data subsets will markedly reduce statistical power to detect associations and also reduce the precision on any findings when the data are stratified by season.

drawing the conclusion that there was a likely causal relationship between short-term exposure to NOx and respiratory morbidity.

(2) *Comment:* AAM challenges ISA conclusions on several health outcome categories on pp. 31-44. The commenter contends that "EPA overstates the strength and consistency of epidemiological evidence regarding various potential health effects".

Response: The EPA disagrees with these commenters approach to assessing health effects evidence as well as their conclusion regarding the lack of a scientific basis to support the continuation of NAAQS to protect against the health effects of NO_2. The EPA contrasts these commenters' narrow focus on counting the numbers of epidemiologic studies that report results with statistical significance, without regard to other considerations that are important to consider in a comprehensive appraisal of the evidence, with the approach taken by EPA in the ISA. Specifically, EPA recognizes the distinction between evaluation of the relative scientific quality of individual study results, and evaluation of the pattern of results in a body of evidence. The EPA has done both. The more detailed characterizations of individual studies include assessment of the quality of the study, based on criteria for assessment of the epidemiologic studies that are described in Section AX 1.1.2 (pg. 1-3) and Figure AX1.1-1 (pg. 1-2) of the Annexes to the ISA for Oxides of Nitrogen. Statistical significance is an indicator of the precision of a study's results, which is influenced by the size of the study, as well as exposure and measurement error, model specifications, and other such factors.

In developing an integrated assessment of the health effects evidence for NO_2, EPA has emphasized the importance of examining the pattern of results across various studies, and not focusing solely on statistical significance as a criterion. It is important not to focus on results of statistical tests to the exclusion of other information. As observed by Rothman (1998):

> Many data analysts appear to remain oblivious to the qualitative nature of significance testing. Although calculations based on mountains of valuable quantitative information may go in to it, statistical significance is itself only a dichotomous indicator. As it has only two values, significant or not significant, it cannot convey much useful information….Nevertheless, P-values still confound effect size with study size, the two components of estimation that we believe need to be reported separately. Therefore, we prefer that P-values be omitted altogether, provided that point and interval estimates, or some equivalent, are available. (Rothman, 1998, p. 334)

The concepts underlying EPA's approach to integrated assessment of statistical associations reported for the health effects on NO_2 have been discussed in numerous publications, including a recent report by the U.S. Surgeon General on the health consequences of smoking (Centers for Disease Control and Prevention, 2004). This

report also cautions against over-reliance on statistical significance in evaluating the overall evidence for an exposure-response relationship.

Hill made a point of commenting on the value, or lack thereof, of statistical testing in the determination of cause: "No formal tests of significance can answer those [causal] questions. Such tests can, and should, remind us of the effects the play of chance can create, and they will instruct us in the likely magnitude of those effects. Beyond that, they contribute nothing to the 'proof' of our hypothesis" (Hill 1965, p. 299).

Hill's warning was in some ways prescient, as the reliance on statistically significant testing as a substitute for judgment in a causal inference remains today (Savitz et al., 1994; Holman et al., 2001; Poole 2001). To understand the basis for this warning, it is critical to recognize the difference between inductive inferences about the truth of underlying hypotheses, and deductive statistical calculations that are relevant to those inferences, but that are not inductive statements themselves. The latter include p values, confidence intervals, and hypothesis tests (Greenland 1998; Goodman 1999). The dominant approach to statistical inference today, which employs those statistical measures, obscures this important distinction between deductive and inductive inferences (Royall 1997), and has produced the mistaken view that inferences flow directly and inevitably from data. There is no mathematic formula that can transform data into a probabilistic statement about the truth of an association without introducing some formal quantification of external knowledge, such as in Bayesian approaches to inference (Goodman 1993; Howson and Urbach 1993). Significance testing and the complementary estimation of confidence intervals remain useful for characterizing the role of chance in producing the association in hand (CDC, 2003, pp. 23-24).

Accordingly, the statistical significance of individual study findings has played an important role in EPA's evaluation of the study's results and EPA has placed greater emphasis on studies reporting statistically significant results. However, in the broader evaluation of the evidence from many epidemiologic studies, EPA has also emphasized the pattern of results for drawing conclusions on the relationship between NO_2 and health outcomes, as well as consideration of the integration of epidemiologic evidence with findings from laboratory studies.

The EPA considered the results of studies conducted in many different countries to draw conclusions about the likelihood of a causal relationship between NO_2 and health outcomes. Because EPA places greater weight on US and Canadian studies in determining standard levels, the ISA, REA and proposal notice present graphical results from epidemiologic studies in these two countries, standardized to a common increment of NO_2, and based on similar analytic strategies (i.e. single-pollutant results). EPA believes that the examination of multipollutant model results and the inherent instability that often occurs in effect estimates for correlated pollutants in such studies justifies the use of single pollutant model results, in addition to multi-pollutant model results, for comparing effect estimates for NO_2 and health outcomes.

The comparisons across studies in the ISA begins with an evaluation of the overall pattern of excess risk results – whether generally positive or centered around zero - the consistency in size of effect estimates, the precision of the studies evidenced in the width of the confidence intervals, with special attention to comparisons of similar effect categories.

Finally, it is important to reiterate that the EPA's evaluation of the scientific evidence used in the current NO_X NAAQS review was the subject of exhaustive and detailed review by the CASAC and the public. Two drafts of the ISA were released for CASAC and public review at public meetings. Evidence related to the substantive issues raised by submitted comments were evaluated in the ISA drafts and discussed at length in public CASAC meetings. This process ensured that overemphasis on any study or group of studies was addressed. Following the final meeting with CASAC on the ISA, the CASAC panel found the coverage of the literature in the ISA to be appropriate.

(3) *Comment:* Several industry groups (e.g., API, AAM, ACC, ACSBPP, CE, COPA, Dow, EEI, EMA, Exxon, NMA, TFI, UARG) and an individual (Roger McClellan) commented that, given the presence of numerous copollutants in the air, epidemiologic studies do not support the contention that NO_2 itself is causing health effects. These groups concluded that EPA has overstated the strength and consistency of the epidemiologic evidence. For example, API commented that "These [epidemiologic] studies do not provide support for a causal association between short-term NO_2 exposure and respiratory effects and, thus, do not provide appropriate support for a 1-hour daily maximum NO_2 standard." API also stated that "Most [epidemiologic studies] only report statistically significant findings in single-pollutant, but not multi-pollutant, models, and no statistically significant finding is large, robust, or consistent." Several industry commenters (e.g., API, ACC, ACSBPP) further noted that the ISA relies primarily on single-pollutant models when interpreting epidemiologic studies, rather than evaluating the results within the context of the full suite of air pollutants. These commenters noted that this can lead to overestimating NO_2 effects and to double or triple counting by attributing effects to NO_2 in the current review that are attributed to different pollutants in other NAAQS reviews. Similar conclusions were also expressed by other commenters.

Response: These comments and EPA's responses are discussed in section II.E.2.a of the final rule. The Administrator's consideration of the epidemiologic evidence specifically as it relates to decisions on the adequacy of the current standard, the averaging time of a new short-term standard, and the level of the short-term standard are discussed in sections II.E and II.F of the final rule.

EPA has not focused solely on the results of single pollutant models, but has also carefully examined the implications on multiple pollutant results. The greatest weight of evidence for multi-pollutant results has been placed on two-pollutant models (NO_2 plus one additional pollutant), as the inclusion of each additional pollutant in the model can decrease model stability. This decrease in model stability is often reflected in wider confidence intervals, making it less likely for a statistically significant result to be

observed. Thus, when a statistically significant effect estimate observed in a single pollutant model is no longer statistically significant in a copollutant model (even though the magnitude and direction of the effect estimate has not changed substantially), this may be an artifact of model instability. Results in Figures 3.1-5, 3.1-7, 3.1-10 and 3.1-11, indicate that the association of NO_2 with respiratory morbidity is robust to the addition of copollutants. While some individual studies may report specific findings that are more influenced by copollutants, Figures 3.1-5, 3.1-7, 3.1-10 and 3.1-11 clearly demonstrate EPA's conclusion of robustness.

The EPA strongly disagrees that the agency is "double or triple counting by attributing effects to NO_2 in the current review that are attributed to different pollutants in other NAAQS reviews". The EPA consistently recognizes that other pollutants are also associated with health outcomes, as is reflected in the fact that EPA has established regulations to limit emissions of the particulate criteria pollutants as well as other gaseous criteria pollutants. In its assessment of the health evidence regarding NO_2, EPA has carefully evaluated the potential for confounding, effect measure modification or other interactions between NO_2 and other criteria pollutants, and concluded that the results attributable to NO_2 are robust.

(4) *Comment:* Some industry groups (e.g., API, Exxon Mobil (Exxon)) commented that reliance on central monitors in epidemiologic studies leads to a high degree of exposure misclassification. Specifically, Exxon commented that "there is a lack of correlation between measurements from ambient monitors for NO_2 and those from personal monitors for NO_2. This makes the observational epidemiology data invalid for assessing the connection between exposure and health effects for NO_2." API commented that "All [epidemiologic] studies used measurements from central monitors, which likely led to a high degree of exposure misclassification."

Response: As discussed in the ISA (section 5.2.2), EPA agrees that there is variability in the extent to which NO_2 concentrations measured by ambient monitors correlate with personal exposures. However, EPA disagrees with the conclusion of the commenter that "This makes the observational epidemiology data invalid for assessing the connection between exposure and health effects for NO_2." Rather, as noted in the conclusions of the ISA (section 5.2.2, p. 5-3), "The errors and uncertainties associated with the use of ambient NO_2 concentrations as a surrogate for personal exposure to ambient NO_2 generally tend to reduce rather than increase effect estimates, and therefore are not expected to change the principal conclusions from NO_2 epidemiologic studies." Therefore, EPA continues to judge that it is appropriate to consider the NO_2 epidemiologic evidence in reviewing the NAAQS.

(5) *Comment:* UARG also stated the following with regard to the epidemiologic evidence:

> Another compelling source of uncertainty regarding the epidemiologic studies on which EPA relies is the discrepancy

between the levels at which health effects were observed in these studies versus human clinical studies. The epidemiologic studies on which EPA relies in the Proposed Rule report effects at NO_2 concentrations much lower than the doses used in human clinical studies.

Response: As discussed in detail in the final notice (sections II.A and II.F.4), controlled human exposure studies reported effects down to the lowest concentration evaluated; no studies have been conducted at lower concentrations. While these concentrations are higher than the mean concentrations reported in epidemiologic studies, it is important to note that epidemiologic studies 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 highest 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 that are higher than the area-wide concentrations measured in study locations.

As noted in the ISA (section 5.3.2.1 and Figure 2.4-13), 1-hour NO_2 concentrations measured at area-wide monitors in the United States have been observed in the range of 100 to 200 ppb. In addition, even higher 1-hour NO_2 concentrations could occur on and/or around major roads, where NO_2 concentrations could be 30-100% higher than measured by existing area-wide monitors (section II.A.2 of the final notice). Therefore, EPA does not agree that the NO_2 concentrations that occurred in the locations of epidemiologic studies did not include concentrations that overlapped with those reported to cause respiratory effects in controlled human exposure studies.

(6) *Comment*: AAM contends that "the ISA uses the results of respiratory symptom studies to claim coherence with the hospital and ED admission results. However the authors of the Mortimer et al. and Schildcrout et al. multi-city studies that the Agency relies on do not implicate NO_2, per se, but summer time air pollution and fine PM, respectively", and claims that the characterization of the results in studies by Mortimer et al. (2002), and Schildcrout et al. (2006) is not consistent with the authors' conclusions.

Response: The commenter is wrong in the characterization of these studies. They have inaccurately characterized the authors' conclusions from these studies. In fact, Mortimer et al. (2002) concluded that "Nitrogen dioxide, sulphur dioxide, and particles with a 50% cut-off aerodynamic diameter of 10 μm were associated with increases in symptoms, with nitrogen dioxide exhibiting the strongest influence". Similarly in the Schildcrout et al. (2006) study, the authors conclude that "Among the pollutants studies, carbon monoxide and nitrogen dioxide appeared to capture the most relevant health information. Sulfur dioxide showed less evidence for a relation with asthma exacerbations unless it was

considered in combination with carbon monoxide or nitrogen dioxide. There was no evidence of a warm-season effect of ozone or of a year-round effect of PM_{10}." In fact, fine PM ($PM_{2.5}$) was not even included in the study by Schildcrout et al. (2006), though the commenter contends that the authors implicate "fine PM" as the agent causing the respiratory morbidity.

(7) *Comment:* Several industry groups (e.g., ACC, API, NAM) commented on the reliance on the epidemiologic study by Delfino et al. (2002). Specifically, as part of a Request for Correction (RFC) submitted under EPA's Information Quality Guidelines[2], NAM stated the following:

> In the Final REA, EPA relied on a purported association between short-term NO_2 exposure and asthma from a study that was not properly reviewed in the Final ISA to support selection of a lower bound for potential short-term NO_2 standards. This use of a study that has not been fully reviewed by EPA scientists violates EPA Guidelines requiring use of the "best available science." The study in question did not find any association between asthma symptoms and NO_2 exposure after controlling for the effect of particulates. EPA must include a proper review of this study in the Final ISA, and must explain why it believes the study would provide any support for selection of a standard for NO_2.

Response: These comments and EPA's responses are discussed in detail in section II.E.2.a of the final rule.

(8) *Comment:* As part of that RFC, NAM also stated the following:

> EPA assessments of several studies in the Final ISA differ materially from analyses of these same studies in EPA documents for prior NAAQS. Differing scientific evaluations by EPA which appear to depend on the regulatory purpose for which data are being evaluated violate EPA Guidelines requiring "objectivity."

[2] NAM submitted a Request for Correction under the Information Quality Act in regards to the ISA for NOx (and seeking conforming changes to the final REA for the primary NO_2 NAAQS). http://www.epa.gov/QUALITY/informationguidelines/documents/09002.pdf. Consistent with EPA's Information Quality Guidelines, EPA responded to this request by deferring to the notice and comment process, despite NAM's failure to submit a comment during the initial comment period relating to these documents. http://www.epa.gov/QUALITY/informationguidelines/documents/09002-response.pdf. EPA has addressed NAM's concerns in the final notice and this RTC. EPA has fully satisfied the requirements of the Information Quality Act, and has acted consistently with EPA's Information Quality Guidelines.

> EPA must either correct its current analyses to be consistent with its prior conclusions or explain why it believes those prior conclusions were incorrect.

Response: These comments and EPA's responses are discussed in detail in section II.E.2.a of the final rule.

C. Comments on the controlled human exposure evidence

(1) *Comment:* A number of industry commenters disagreed with EPA's reliance on a meta-analysis of controlled human exposure studies, which was included in the final ISA. API stated that "Evidence from controlled human exposure studies of airway hyperresponsiveness in sensitive individuals does not support the need for a short term standard at the levels on which US EPA is taking comment." ACC described a number of shortcomings of the ISA meta-analysis. These commenters generally referenced a recently published meta-analysis (Goodman et al., 2009) and recommended that EPA rely on that meta-analysis rather than the analysis included in the final ISA. Roger McClellan made similar comments and also referenced a recently published article in support of his views (Hesterberg et al., 2009).

Response: EPA generally disagrees with the commenters' characterization of the "meta-analysis" of NO_2-induced airway responsiveness. Furthermore, EPA has considered the Goodman et al. (2009) study and has provided a detailed response to these comments in section II.E.2.b of the final rule.

(2) *Comment:* NAM provided the following comment as part of their RFC.

> If EPA elects to retain the meta-analysis in the Final ISA, EPA must correct the Final ISA to resolve inconsistencies between the conclusions in the section on Airway Hyperresponsiveness and in the summary chapter.

Response: EPA disagrees with this comment and finds there is no inconsistency to be resolved between the discourse presented in the Final ISA Section 3.1.3 (Airway Hyperresponsiveness) and associated text presented in the Final ISA Section 5.3.2.1. (Respiratory Effects Related to Short-Term Exposure). The section in Chapter 3 of the Final ISA to which the commenter refers was clearly labeled as a summary of the previous section. Specifically, section 3.1.3.3. was entitled "Summary of Short-Term Exposure on Airway Responsiveness." Summaries are intended to provide brief statement of main points or substance of a matter. However, just as an abstract of a paper, summaries do not present all substantive or pertinent matter contained in the larger body of a paper or, in this case, the previous section on airways responsiveness. Furthermore, in Section 3.1.7 (Summary and Integration–Respiratory Health Effects with Short-term Exposure) it is specifically stated on pg 3-42 that, "Nonspecific responsiveness was also increased following 30-min exposures of resting asthmatic subjects to 0.2- to 0.3-ppm NO_2 and following 1-h exposures to 0.1-ppm NO_2." In Section 5.3.2.1 it is stated on pg

5-10 and 5-11 that, "…increases in nonspecific hyperresponsiveness were observed … between 0.2 and 0.3 ppm NO_2 for 30-min exposures and at 0.1 ppm NO_2 for 60-min exposures in asthmatics." Thus, there is clearly no merit to the commenters' assertion of inconsistency in presentation of levels to which asthmatics experience NO_2-induced airway hyperresponsiveness between Chapters 3 and 5.

(3) *Comment:* Some commenters (e.g., API, COPA) concluded that AHR is not an appropriate endpoint to inform decisions on standard level. Because exposure to other agents in combination with exposure to NO_2 is required to trigger AHR, the commenters said EPA would need to demonstrate the frequency and extent of exposure to these other agents and whether these exposures would occur at sufficient concentrations to actually trigger AHR. And if AHR is occurring subsequent to ambient NO_2 exposure, the commenters argued that the frequency of NO_2-induced AHR versus background rates of AHR has not been documented; therefore, the significance to public health of a NAAQS based on this endpoint cannot be determined (COPA, API). Specifically, API stated the following:

> EPA has not documented the frequency of NO_2-induced AHR, if in fact it is occurring, subsequent to exposure to NO_2 in ambient air. Nor has the Agency compared the estimated frequency of AHR induced through combined exposure to ambient NO_2 and provocative agents in the environment to background rates of AHR produced by other causes. Thus, it is not possible to judge the signficance to public health of a NAAQS based on reducing the estimated reduction in the incidence or magnitude of AHR, or whether reducing ambient NO_2 will have any measurable impact on the overall incidence of AHR.

Response: EPA disagrees with these commenters' views on NO_2-induced airway responsiveness. EPA believes that its interpretation of airway hyperresponsiveness following short-term exposure to NO_2 is appropriate and supported by the available scientific information. Human clinical studies provided evidence for airway hyperresponsiveness, i.e., a heightened bronchoconstrictive response to a challenge agent, following short-term exposure to NO_2 (see sections 3.1.3 and 3.1.7 of Final ISA). Since these experimental human studies evaluated the airway responsiveness to challenge agents following exposure to both NO_2 and clean air as a control, they allowed determination of the independent contribution of NO_2 on airway responsiveness. An evaluation of all other agents or factors that might affect airway responsiveness, as suggested by the commenters, would not better define the independent effect of NO_2 on airway responsiveness. Table 3.1-3 in the Final ISA specifically provided the fraction (or frequency) of NO_2-exposed asthmatics experiencing non-specific airway hyperresponsiveness. 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). Given this, combined with the large size of the asthmatic population in the U.S., 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). CASAC endorsed this conclusion in their letters to the Administrator on the final REA and on the proposal (Samet, 2008b; Samet, 2009b).

(4) *Comment:* Comment: API expressed the concern that EPA is not using a standard approach to establishing NAAQS. As an example they note that, while EPA has characterized Forced Expiratory Volume (FEV) decrements in the past as adverse health effects, the NO_2 Gradient meta-analysis (Goodman et al, (2009) showed decrements in FEV of only 1.6 percent. In revising the ozone NAAQS, a decrement of 3 percent was characterized by EPA as "relatively small" and seemingly not adverse.

Response: EPA disagrees with the commenters' interpretation of NO_2-induced changes in airway responsiveness and their approach taken to discern the magnitude of this response. Due to differences in study protocols in the NO_2-airway response literature (ISA, section 3.1.3), EPA judged it appropriate in the ISA meta-analysis to assess only the fraction of asthmatics experiencing increased or decreased airway responsiveness following NO_2 exposure. Examples of differences in the study protocols include the NO_2 exposure method (i.e., mouthpiece versus chamber), subject activity level (viz., rest versus exercise) during NO_2 exposure, choice of airway challenge agent, and physiological endpoint used to quantify airway responses. Therefore, EPA judged it inappropriate in the ISA meta-analysis to try to assess the magnitude of the NO_2-induced change in airway responsiveness. EPA further notes that Goodman et al. (2009) also recognized heterogeneity among studies as a limitation in their analyses.

EPA further disagrees with the commenter's comparison and interpretation of the effect of ozone on FEV_1 versus the effect of NO_2 on airway responsiveness to challenge which was subsequently assessed by FEV_1 in some studies and by other physiological endpoints such as specific airway resistance in other studies. Ozone itself causes transient decrements in FEV_1, whereas, NO_2 does not. Rather, in individuals with asthma, NO_2-induces an increase in the responsiveness of the airways to subsequent challenge. FEV_1 is only one of several physiological endpoints used to discern that a change in airway responsiveness has occurred. Based on studies that evaluated these different endpoints, 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). Given this, combined with the large size of the asthmatic population in the U.S., 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). CASAC endorsed this conclusion in their letters to the Administrator on the final REA and on the proposal (Samet, 2008b; Samet, 2009b). In summary, ozone causes transient changes in FEV_1, whereas, NO_2 causes transient changes in airway responsiveness. These are different health endpoints and EPA disagrees with the commenter's comparison and interpretation.

(5) *Comment:* AAM concludes that "[r]eliance on the Orehek et al. 1976 study in an unpublished meta-analysis to claim an effect at 0.10 ppm is scientifically unsound."

Response: Orehek et al. (1976) was peer-reviewed and published in a scientific journal. EPA specifically recognized criticism of the statistical approach used by Orehek in section 15.3.1 of the 1993 NOx CD. However, the statistical significance of findings presented by Orehek et al. (1976) were not material to inclusion of data into the meta-analysis provided in the 1993 NOx CD or the Final ISA. EPA rejects the assertion that inclusion of the Orehek et al. (1976) study in its meta-analysis was scientifically unsound. EPA further notes that the Orehek et al. (1976) study data were also included in the analysis by Goodman et al. (2009).

(6) *Comment:* AAM also concludes that "[t]he effects of NO_2 from controlled studies have not changed materially since the last review." Given this, they question EPA's conclusion that exposure to NO_2 concentrations at or above 100 ppb could increase airway responsiveness in asthmatics.

Response: As shown in Table 15-10 of the 1993 NOx CD, data from four studies at 100 ppb and a study at 140 ppb were analyzed as a group and showed increased airway responsiveness in 65% of resting asthmatics ($p < 0.01$). As shown in Table 3.1-3 of the Final ISA, even when this analysis is limited to three studies of changes in nonspecific airway responsiveness following exposure to 0.1 ppm NO_2, 66% of resting asthmatics ($p \leq 0.05$) experienced an increase in airway responsiveness. Therefore, as discussed in section II.E.2.b of the final rule, EPA concludes that scientific evidence reviewed in both the 1993 NOx CD and Final ISA support that exposure of asthmatic individuals to levels of 0.1 ppm NO_2 and greater results in an increase in their airway responsiveness. In addition, since the 1993 NOx CD, there is a substantial new body of epidemiological evidence showing that short-term NO_2 exposure is associated with a broad range of respiratory morbidity effects (Final ISA, Section 3.1). This new epidemiological evidence is consistent with and supported by controlled human exposure studies showing effects of NO_2 on airway responsiveness.

(7) *Comment:* AAM concluded that, because clinical studies of NO_2-induced airway hyperresponsiveness have not reported increased respiratory symptoms or medicine use in exposed subjects, the NO_2 effect on airway responsiveness is not adverse.

Response: The intent of the clinical studies to which the commenter refers was to evaluate the effect of NO_2 exposure on airway responsiveness, not to evaluate the effect of airway hyperresponsiveness on respiratory symptoms or medicine use. EPA disagrees with the commenters' characterization of these studies.

D. Comments on air quality, exposure, and risk analyses

(1) *Comment:* Several commenters discussed the analyses of NO_2-associated exposures and health risks presented in the REA. As in past reviews (EPA 2005a, 2007a, 2007b), 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. A few industry commenters (e.g., API, NMA, UARG) 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 noted 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.

Response: These comments and EPA responses are discussed in detail in section II.E.2.c of the final rule.

(2) *Comment:* API/AECOM (December 1, 2008 memo) specifically commented on the EPA approach used to assess air quality that would just meet the current and alternative standards. The three major comments were focused results in the EPA memo by Rizzo (2008) that investigated trends in NO_2 air quality concentrations over time. The commenters charged that (1) the high concentration to low concentration air quality comparisons are not linear and not proportional, (2) even with "a good fit to the data, the peak-to-mean ratio depends on the extremes of the distribution", and added that the good statistical fits Rizzo (2008) provided are the result of the "middle percentile values, e.g., from 10% to 90%", and (3) the ambient concentration adjustment "does not consider the atmospheric chemistry that is involved in the formation of NO_2 from NO_X emissions".

Response: The current and alternative standard air quality scenarios are hypothetical scenarios, with the adjustments to the ambient concentrations determined by an analysis of the historical trends in air quality data at each monitor. EPA noted in the REA (section 7.4.5) that "there is uncertainty in adjusting concentrations" considering uncertainty in "future source emission scenarios and how these would relate to observed trends in current and historical air quality." However, given the demonstrated strong relationship of these concentrations over time by Rizzo (2008), EPA believed a proportional approach would best represent the modeled air quality scenarios. EPA agrees that demonstration of a linear relationship between the high and low concentration years is not the same as a proportional relationship. EPA acknowledged the presence of features that deviate from proportionality in the air quality comparisons (i.e., presence of positive and negative regression intercepts, curvilinear relationships) as potentially contributing to uncertainty in the estimated concentrations used in the alternative air quality standard scenarios (REA page 131).

The Rizzo (2008) analysis of air quality concentration trends not only provided graphical comparisons and general goodness of fit statistics but also provided statistics on the individual points that deviated significantly from linearity for up to three high-year to low-year comparisons per monitor. "Studentized residuals were computed and compared to a students t distribution at a significance level of 10%" (Rizzo (2008) page 5). The identified points are provided in a series of tables for each ambient monitor in the six cities analyzed (Tables 1 to 6). On average, 71 percent of the points that significantly deviated from linearity occurred at the absolute extreme ends of the air quality distribution (i.e. the minimum (0) and maximum (100^{th}) percentile values). When

considering deviations that occurred at the upper percentiles (i.e.,≥95th percentile),[3] an even greater percentage (74%) occurred at the absolute maximum value. This indicates that the linear relationship extends well beyond the 90th percentile value for the majority of the comparisons; that is on average, the upper bound of the linear range extends through the 99th percentile of the distribution.

EPA acknowledged that, given the scenario modeled and the deviations from proportionality, the selected approach may contribute to both over and under-prediction in ambient concentrations (Table 7-31, REA). As far as the impact of deviations from proportionality, Rizzo (2008) added that "[i]n the majority of the monitor cases, the y-intercept of the best fit line is positive" and that this "indicates a larger decline between high and low year concentrations in the upper end of the distribution than in the lower percentiles". Further Rizzo (2008) stated "[m]ost although not all of the 98th and higher percentile points that deviate from their best fit lines do fall below the line", meaning "that percentile point has declined even more strongly than the middle of the distribution". For these cases (where a positive intercept exists and upper percentile points are below the linear regression line), when adjusting concentrations *upwards* based on the annual average concentration, the adjusted upper percentile concentrations would be *lower* than that observed during a comparable high concentration year. Most of the alternative standard scenarios required an upward adjustment (see comment below). Therefore, it is possible that most of the extreme upper percentile concentrations used in the alternative standard scenarios were *under-estimated* using the proportional adjustment approach rather than over-estimated. At the limited number of monitor-years noted by Rizzo (2008) where a negative regression intercept was present and upper percentile points are above the linear regression line, it is possible that the extreme upper percentile concentrations used in the alternative standard scenarios were over-estimated.

EPA agrees with the commenter that the primary transformation reaction for NO_2 is through reaction with atmospheric oxidants, primarily ozone. However, this transformation reaction and the potential amount of ozone needed for the reaction to occur is not needed to address the hypothetical alternative air quality scenarios . One focus of the NAAQS review is to determine the level of the pollutant that is protective of public health. In this instance, the integrated review plan poses a series of questions relevant to the NO_X review including "Do exposure estimates suggest that exposures of concern for NO_X-induced health effects will occur with current ambient levels of NO_2 or with levels that just meet current, or potential alternative, standards?" (US EPA, 2007a). As stated, the objective is to determine what level of NO_2 is considered protective against health effects associated with NO_2 exposures, not what level of NO_2 is plausible under certain atmospheric conditions. It can also be stated that future strategies that control ambient ozone concentrations such that the ozone NAAQS would be met are to protect against the health effects associated with ambient ozone (and other atmospheric oxidants ozone is serving as a surrogate for), not ambient NO_2.

[3] There were no upper percentile values less than the 95th percentile determined as statistically significant.

(3) *Comment*: Comments from the American Chemistry Council (ACC; May 30, 2008 memo) were also directed towards analyses of the current and alternative air quality scenarios, however these commenters primarily questioned the relationship between analyses conducted by McCurdy (1994) used in the prior 1995 NAAQS review and the current analyses. These commenters suggest that conclusions drawn during this current NAAQS review regarding the relationship between concentrations and benchmark exceedances differ from conclusions drawn in the previous NAAQS review. The commenters also charge that "for each monitor in the city, EPA determined the annual average concentration and scaled all hourly concentrations by the ratio of the current standard (53 ppb) and the annual average concentration." A series of comments were received in three technical memos dated by the ACC on May 30, 2008 (regarding the 1st draft REA), September 26, 2008 (regarding the 2nd draft REA without chapter 8), October 22, 2008 (regarding the 2nd draft REA chapter 8), and summarized in their September 14, 2009 memo.

Response: The conclusions drawn in the current NAAQS review regarding the relationship between annual average NO_2 concentrations and frequency of 1-hour benchmark exceedances are not necessarily contrary to conclusions made in the prior NO_2 primary NAAQS review, as the ACC suggests. In fact, section A-6 of Appendix A (US EPA, 2008c) documents the investigation of both linear and non-linear relationships between number of benchmark level exceedances and the annual average NO_2 concentrations using recent ambient monitoring data (i.e., years 1995-2006). As described in the Scope and Methods Plan (US EPA, 2007), EPA planned to perform a similar non-linear regression modeling approach first described by McCurdy (1994). The non-linear regression approach used by McCurdy (1994) to support the previous 1995 NAAQS review was developed to estimate the number of exceedances associated with varying annual average concentrations, including the current standard of 0.053 ppm.

As part of the current review, EPA expanded the regression approach used by McCurdy (1994) and evaluated four different regression models (either using normal or Poisson distributions by linear and exponential links) and using either all data combined or data stratified by location (see Appendix A-6, US EPA, 2008c). The current regression analysis included construction of a model similar to that used by McCurdy (1994) (i.e., a normal distribution, an exponential link, and stratified by location). The performance of all regression models constructed was evaluated using R-square and log-likelihood statistics. While a model employing a Poisson distribution and using an exponential link function demonstrated the best performance of the models currently investigated (i.e., it was still a non-linear relationship though different from that derived by McCurdy (1994)), the overall predictive capabilities of such a regression approach was generally poor, particularly for evaluating annual average NO_2 concentrations just meeting the current standard. For many locations, there were extremely wide 95% prediction intervals estimated using the regression models, a direct result of data limitations (i.e., there were very few exceedances of benchmark concentrations > 150 ppb using recent ambient concentrations and most locations had annual average NO_2 concentrations well below the current standard). These results presented in the REA are entirely consistent

with the statement made in the 1995 staff paper that was cited by the ACC as a different conclusion:

> However, because all areas of the country reporting NO_2 air quality data are attaining the existing standard and because of the nonlinear relationship of 1-hour peaks and annual averages, it is not possible to estimate with any degree of confidence what the frequency and magnitude of 1-hour peaks would be if the standard was selected from the upper end of the suggested range.

Based on the performance results of the regression analyses (and documented in Appendix A-6), an alternative approach was selected to evaluate the number of benchmark exceedances associated with annual average and other time-averaged NO_2 concentrations. Rather than using a regression model constructed from the *as is* air quality to extrapolate to ambient levels approaching the current or alternative standards, EPA adjusted the ambient NO_2 concentrations such that they simulate levels of NO_2 that just meet a standard. These adjusted ambient data "allow comparisons of the level of public health protection that could be associated with just meeting the current and potential alternative standards" (REA, page 59).

A proportional approach was used to adjust the *as is* air quality to simulate air quality just meeting the current and alternative standards (see REA section 6.3.1 and Appendix A-7). Because all locations currently have ambient NO_2 concentrations below the current standard, an approach was needed to, at a minimum, adjust concentrations upwards to reflect concentrations that just meet the current annual average standard in the location. The approach also needed to be appropriate for adjusting air quality that just meets several potential alternative standards, standards of varying form (98^{th} and 99^{th} percentile), concentration level (50, 100, 150, 200 ppb), and averaging time (1-hour). A proportional adjustment approach was selected by EPA and justified by the results of two analyses: the evaluation of the stability in hourly and annual average concentration variability over the span of the data used in the analysis (Appendix A-7) and the comparisons of concentration distributions of historical and recent air quality (Rizzo, 2008). While annual and hourly NO_2 concentrations have steadily declined over time, the concentration variability in each of these measures has generally remained constant over the same time period (Figure A-100). Concentration trends within monitoring sites in six cities were evaluated to determine how the distribution of air quality changed with time at each monitor. In comparing high concentration (historical air quality) to low concentration years (recent air quality) at the same ambient monitor, the majority of monitors demonstrated features of proportionality, that is the proportional change in concentration at each percentile of the air quality distribution was similar. The results of both of these analyses indicated that a proportional approach can be used to adjust ambient concentrations (upwards or downwards) in representing alternative air quality conditions.

Ambient measurements at a *single monitor* were used within each of the 17 named locations and with the two aggregate locations to estimate the specific adjustment factors

needed to simulate air quality just meeting the current and alternative standards. This single design monitor in each location was selected by having the highest annual average NO_2 concentration or the highest 98th or 99th 1-hour daily maximum NO_2 concentration to estimate the respective adjustment factors. Because the concentration adjustment was considered proportional, all 1-hour concentrations were multiplied by the same specific factor developed for each air quality scenario and in each location. The adjustment factors developed from the *single monitor* in each location was applied to concentrations at all monitors within each location, such that *only one monitor* had concentrations that just met the current or alternative standard (i.e., the design monitor), while all other monitors in that location had ambient concentrations below that of the current or alternative standards (page 61, REA). Following the proportional adjustment of ambient NO_2 concentrations (as well as when using the *as is* air quality), the number of exceedances of each benchmark were counted. This approach does not assume there is a linear relationship between the annual average NO_2 concentration and the number of benchmark exceedances. The commenter is confusing the proportional approach used to adjust the ambient concentrations (where comparisons of high concentration with low concentrations demonstrate features of proportionality – see Rizzo, 2008) with the regression models that related the number of exceedances with the annual average concentrations (which is not linear, as demonstrated by the conclusions in the prior 1995 review, is discussed above, and is documented in REA Appendix A-6). The two approaches are not comparable in this regard, though the objective of each analysis is the same; to estimate of the number of 1-hour benchmark exceedances when considering alternative air quality scenarios.

There is uncertainty associated with such a concentration adjustment and has been qualitatively described in REA section 7.4.5. However, EPA notes that there is likely less uncertainty in the approach and results generated when using adjusted concentrations that are closest to existing *as is* air quality. For most locations, this was the either a 98th or 99th percentile alternative standard at a 1-hour daily maximum concentration of 50 ppb (see Table A-107).[4] On average, to have air quality just meet the alternative 1-hour daily maximum standard level of 50 ppb, the minimum concentration adjustment was less than 10% and ranged from a low of zero percent (i.e., the *as is* air quality for a given location had either the 98th or 99th 1-daily maximum equal to 50 ppb) to only as high as 28 percent. To simulate just meeting the 50 ppb level of either the 98th or 99th percentile 1-hour daily maximum standard, a downward adjustment of air quality was applied in most locations and year-group of data considered.[5] To just meet the 100 ppb level (either form of the 1-hour daily maximum standard), all locations required an upward adjustment. At this 100 ppb level, the 99th percentile daily maximum standard required the lowest concentration adjustment at all locations; on average, the upward concentration adjustment was 70% (min 1%, max 131%). Taken together, this means that most

[4] Only Los Angeles (2001-2003), Other CMSA/MSA (2001-2003), and Provo (2004-2006) had *as is* air quality more similar with a 1-hour 99th percentile 100 ppb standard level out of a total of 38 location/year-group combinations.

[5] When considering the two forms (98th and 99th), the 19 locations, and two year-groups (2001-2003 and 2004-2006), 61/76=80% needed a downward adjustment to meet the 50 ppb level.

locations have *as is* concentrations within the range of the two alternative standard levels of 50 to 100 ppb and within the range of the newly proposed standard. As the data for simulating just meeting these standard levels required the least concentration adjustment, there is less of an impact of the uncertainty associated with the air quality adjustment procedure on the estimated number of daily benchmark exceedances associated with these air quality scenarios.

(4) *Comment:* AAM (September 14, 2009 memo) claimed that the approaches used in the REA to characterize health risks from ambient NO_2 lead to significant overestimation of actual risk. Specifically, they argued that the first approach (comparing monitoring data with potential health benchmarks) is known to overestimate the distribution of actual human exposures because monitored concentrations do not necessarily equal human exposures.

Response: EPA believes that the ambient air quality has been appropriately characterized in chapter 7 of the REA. The REA also provides ample context for how the ambient air quality data can serve as a useful indicator of human exposure (sections 2.3.2, 6.1, 9.6, and 10.3.2). EPA recognizes that population personal exposure is not directly equivalent to ambient air quality measurements however there is no justification for discounting the ambient monitoring data simply because they are perceived by AAM to "overestimate personal exposures." The data represent actual measurements of NO_2 levels that a population may be exposed to, provided the population encounters the given concentration in both space and time.

EPA notes that the available evidence indicates that at-risk populations can be exposed to ambient NO_2 concentrations greater than that represented by an ambient monitor. EPA has clearly stated in the REA and NPRM that the current ambient monitoring network does not have a sufficient number or appropriate siting of monitors to reflect NO_2 concentrations occurring on or near major roads in most, if not all, urban areas of the U.S. The existing monitoring network is not designed to capture the spatial gradient in NO_2 concentrations surrounding roadways in any location, which is why modeling approaches were selected by EPA staff to estimate on- and near-road NO_2 concentrations.

(5) *Comment:* AAM (September 14, 2009 memo) commented that "there are no reliable data indicating either on-road or near-road exposure in recent years that exceed the 0.20 or 0.30 benchmarks" and referenced several studies to support their claim.

Response: EPA notes first that the benchmark values have an averaging time of 1-hour. None of the studies cited by the AAM reported 1-hour NO_2 concentrations. For example, AAM cites Beckerman et al. (2008) and Singer et al. (2004), which were both studies where *weekly* average concentrations were measured. A paper by Roorda-Knape et al. (1998) is also mentioned, where *two-week* average concentrations were measured. Given the expected diurnal and day-of-week variation of NO_2 concentrations (see ISA, section

2.4.4) it is not a surprise that the average concentrations reported in these studies do not approach a peak 1-hour NO_2 concentration at or above 200 ppb.

There were only two studies cited by AAM that measured NO_2 concentrations inside vehicles: a study by Westerdahl et al. (2005) conducted in Los Angeles, CA and one by Riediker et al. (2003) conducted in Raleigh, NC. EPA notes that the researchers in the Los Angeles study did measure NO_2 concentrations across a two-hour averaging period, which is the closest any measurement study came to a 1-hour averaging period. However, based on the study design, the primary purpose of the study is to collect data more relevant for PM exposure than for NO_2 exposure. The time-of-year the data were collected may not correspond to when NO_2 concentrations are highest. The NO_x ISA reported that "in Los Angeles and Riverside, CA, monthly maxima tend to occur from autumn through early winter, with minima occurring from spring through early summer". EPA notes that the Westerdahl et al. (2005) measured NO_2 on February 14th and 20th and April 7th and 16th (see Table 2 of Westerdahl et al., 2005). In addition, the study drive times when measurements were collected did not necessarily correspond to when NO_2 peak concentrations are expected to occur. According to the NO_x ISA, "NO_2 typically exhibits daily maxima during the morning rush hours". Drive times selected for evaluation in the Westerdahl et al. (2005) study were as follows: 2-6PM, 11AM-1PM, 9AM-12PM, and 11AM-2PM, times-of-day that do not correspond to the morning rush hours.

In the second study cited by AAM that reported NO_2 concentrations on-roads and inside vehicles, Riediker et al (2003) reported that sample averaging times were about 9-hours in duration and all occurred "during late-shift patrols (3 p.m. to midnight)". As discussed above by EPA, these collection times are not consistent with the averaging time of interest (i.e., 1-hour) or the time-of-day when maximum concentrations are expected to occur (i.e., morning rush hours). Second, the monitoring events in the Riediker et al. (2003) study did not always occur on- or near major roadways. Often times the automobile was parked in a lot, potentially further limiting the measurement of any maximum NO_2 concentrations. Riediker et al. (2003) states "[o]n average, troopers spent 35% of their shift away from the car, either in the office, in jail, in hospitals, for dinner", etc. The authors of the study also note that "pollutant concentrations in the occupied cars were significantly higher compared to the parked cars (Mann-Whitney U-test)" (Riediker et al., 2003). In their comments, AAM stated that the maximum concentration of 0.548 ppm reported by Riedeker et al. (2003) was "flawed" and "invalid". Nowhere in the Riediker et al. (2003) paper was it stated that the 9-hour average NO_2 measurement was flawed or invalid, only mentioned as an "outlier". Thus, this maximum reported NO_2 concentration remains a valid measurement. In further review of this paper, EPA notes also that the reported maximum 8-hour average roadside NO_2 concentration did in fact exceed 200 ppb (212.1 ppb; see Table 1 of Riedeker et al. (2003)), contradicting the above AAM comment. Given the diurnal profile of NO_2, this suggests that on this day there was likely more than one hour where roadside concentrations exceeded 200 ppb.

(6) *Comment:* AAM (September 14, 2009 memo) commented that the distribution of ratios used to represent the relationship between on-road and ambient concentrations in the air

quality characterization (chapter 7 of the REA) resulted in overestimates of on-road NO_2 concentrations. AAM refer to a statement made by Westerdahl et al. (2005) regarding the relationship between on-road and ambient concentrations that "roadway concentrations of [CO and] NO_2 were usually no more than about twice the ambient concentrations". They further comment that higher ratios developed using lower background concentrations will not be appropriate in urban situations having a high background and will "substantially over-estimate the on-road increment".

Response: EPA notes that this statement made by Westerdahl et al. (2005) supports an upper bound for the ratio between on-road and away from road concentrations of at least two. In other words, on-road NO_2 concentrations may be at least 100% higher than away from road concentrations. This percent difference is consistent with statements made in the REA about the on-road concentrations that "simulated on-road annual average NO_2 concentrations are, on average, 80% higher than the respective ambient levels at distances ≥100 m from a road" (section 7.3.2, page 97) and statements made in the ISA regarding the relationship between the two concentrations (section 2.5.4, page 2-36). In addition, the use of "usually" by Westerdahl et al. (2005) in their description indicates that most of the time the ratio was a factor of two or less, but also suggests that there were some instances that the factor difference was greater than two. This statement also supports the ratios EPA used to adjust ambient NO_2 concentrations in estimating on-road concentrations. Table 7-10 (REA) indicates that most of the ratios (64% and 79%, for the summer and not summer ratios, respectively) used by EPA in estimating on-road NO_2 concentrations were less than a factor of two.[6] EPA also note that in addition to the several papers EPA used to develop the on-road ratios used in Chapter 7 of the REA, an average factor of two enhancement on- or near roads concentrations is also reported by Beckerman et al. (2008) using the normalized NO_2 concentrations provided in that study (see Figure 4 of Beckerman et al., 2008).

EPA believes that the ratio approach developed from measurement data available in near-road studies and used to simulate the on-road NO_2 concentrations in the REA chapter 7 was reasonable. EPA acknowledged in the REA that there is uncertainty in the estimated on-road NO_2 concentrations, particularly when using ambient monitoring concentrations that may have been influenced by non-road sources (e.g., section 7.4.6 REA, page 135). We agree with AAM that this particular uncertainty in the approach used to simulate on-road concentrations would tend to lead to overestimation of on-road NO_2 concentrations. However, EPA notes that there are other sources of uncertainty indentified in the approach used that could also contribute to underestimation of on-road concentrations. Localized areas such as those within urban street canyons, tunnels, and major intersections may have instances where on-road NO_2 concentrations are greater than a factor of two times the ambient monitor concentration. For example, Vardoulakis et al. (2004) reported mean NO_2 concentrations at a major intersection were about 2.1 times greater than on-road NO_2 concentrations measured a few hundred meters distance away.

[6] Note that to generate the ratio, the *m* factor has a value of 1 added to it. See REA equation (7-2).

The ISA (section 2.5.4) reported that NO_X concentrations can be 7 times greater at a tunnel exit when compared with NO_X concentrations measured at the tunnel entrance. Note that the maximum ratio used to simulate on-road concentrations in the air quality characterization was 3.7 (REA, Table 7-10).

In addition, EPA also acknowledged that there could be uncertainty in the application of ratios developed from rural locations to urban locations (see REA page 137). However, given the limited information on the characterization of the study areas used to develop the data, the limited number of studies containing relevant data, and that there was no apparent difference observed in the distribution of developed ratios when considering the study locations as having a rural or urban designation, EPA elected to stratify and apply the ratios based on observed seasonal differences in the distributions.

(7) *Comment:* AAM commented (September 14, 2009 memo) that AERMOD was developed and tested primarily for stationary source applications. AAM referenced a recent EPA review of 21 air-quality modeling tools that simulate line-type sources to use in near roadways applications (EPA/600/R-09/001) including an evaluation of AERMOD and several other roadway dispersion models. AAM states that this "EPA review indicates that AERMOD has not been compared rigorously for line source applications and that it contains a very simplistic algorithm for line sources."

Response: First, the highways in Atlanta were simulated not as line sources, but as a set of area sources, a common use of this regulatory model.

Second, the referenced EPA review (US EPA, 2008) explicitly cites numerous comparisons of AERMOD in various configurations to the performance of some of the other available models, with AERMOD consistently providing reasonable concentration predictions. For example, "AERMOD was evaluated with respect to other models such as ADMS-Roads, ISCST3, and CTDMPLUS. When considering only the highest predicted and observed concentrations, it was found that ISCST3 overpredicts by a factor of seven, on average, whereas ADMS-Roads and AERMOD underpredicted, on average, by about 20%. It also was determined that ADMS-Roads performance is slightly better than AERMOD (Hanna et al., 1999). In complex terrain, AERMOD consistently produced lower regulatory design concentrations than ISCST3, not an unexpected result because ISCST3 uses algorithms from a screening model (COMPLEX1) in its calculations. In comparisons with CTDMPLUS and observed data, AERMOD consistently performed better than CTDMPLUS, a model approved by EPA for regulatory applications in complex terrain. The model has not been compared rigorously for line-source applications. Because AERMOD is used most commonly for dispersion analyses of stationary point sources, area sources, and volume sources, there is no accommodation for different roadway geometries (e.g., bridges and deep roadway cuts)." Although AERMOD does not currently accommodate complex roadway geometries, enhanced turbulence, plume rise, and other characteristics of near road dispersion can be accounted for by selection of appropriate input parameters, such as initial sigma-y, initial sigma-z, and emission release heights (each of which are documented in the REA).

Furthermore, according to Appendix W (70 FR 68218), "AERMOD is a best state-of-the-practice Gaussian plume dispersion model whose formulation is based on planetary boundary layer principles" and is the current preferred model for near-field and urban-scale air dispersion modeling applications. While Appendix W lists CALINE-3 as the preferred model for roadways, this model is not generally applicable for modeling long periods in very large, complex modeling domains such as that considered here. In fact, CALINE- 3 and CAL3QHCR rely on older dispersion algorithms from ISCST2 (Bailey, 2009), further justifying the use of AERMOD rather than CALINE-3 or CAL3QHCR.

We note also that currently available versions of the MOVES emissions model will predict NO_X emissions 30-50 percent higher than the MOBILE model used in the present analysis (Beardsley, 2009), suggesting that the newer emissions model would have predicted even higher NO_X concentrations and therefore higher NO_2 concentrations.

Moreover, following analysis of this dispersion model review report (US EPA, 2008) by Isakov (2009), AERMOD was chosen as the best platform for further model development to address roadway scenarios. Given the diversity of source emissions, complexity of the scenario to be modeled in an urban environment, and requisite spatial and temporal resolution for detailed analyses used in estimating exposures, AERMOD was also judged here to be the most appropriate model for this application.

(8) *Comment:* AAM (September 14, 2009 memo) believes that the second approach used to characterize health risk (estimating risk based on detailed exposure modeling), for a variety of reasons, overestimates the risk from NO_2. One reason identified by AAM was that since AERMOD is not a photochemical model, it does not include the key reactions converting NO to NO_2 in urban areas. In particular, concern was expressed by the commenter regarding EPA assumptions made for the photochemical conversion rate as an air pacel moves downwind, and questioning whether peak NO_2 concentrations are likely to occur on or next to the roadway.

API/AECOM (September 14, 2009 memo) had similar comments regarding the OLM and PVMRM methods used by AERMOD, that is "[b]oth methods are simple and conservative because they assume that only nitric oxide titration by ozone (Equation 2) governs NO_2 formation and that all of the ambient ozone can be consumed". Later they commented "consideration should be given to using a model platform that includes plume transport time so that if time dependant chemical reactions are needed, they can be included as a function of transport time".

Response: As discussed in the REA, the AERMOD model was selected to provide the high spatial resolution required for this exposure assessment. Although the chemical parameterizations of the AERMOD model are far less detailed than the chemistry algorithms in photochemical models, in the near field, no photochemical model would have provided the necessary spatial resolution for this study. Furthermore, most photochemical models are optimized for predictions of O_3, and may not provide adequate performance in predicting NO_2, even at the coarser spatial scales at which they are

applied. Given these considerations, AERMOD was judged to be the most appropriate model for this application.

EPA recognizes that numerous photochemical reactions take place in the troposphere that influence the relative concentrations of NO and NO_2 from NO_X emissions. The complex reactions can be commonly summarized as:

$$VOC + NO_X + h\nu \Rightarrow O_3 + PAN + HNO_3 \ldots + Particles, etc. \quad (1)$$

(Finlayson-Pitts and Pitts, 1999). However, to a first order, the characterization of the ratio of concentration of NO to NO_2 can be represented by the photostationary state equation:

$$[O_3] = \frac{j_3[NO_2]}{k_4[NO]} \quad (2)$$

where j_3 results from the following

$$NO_2 + h\nu \Rightarrow NO + O \quad (3)$$

and k_4 from the following

$$O_3 + NO \Rightarrow NO_2 + O_2. \quad (4)$$

(e.g., Atkinson et al., 1988).

This describes a photostationary state where NO and O_3 cannot coexist in significant concentrations and the concentration of NO_2 is proportional to the concentration of O_3. The commenter(s) stated that the mechanisms in AERMOD do not appropriately parameterize the role of organics in the processing of NO to NO_2 via equation (2). However, although NO is converted to NO_2 in a reaction sequence initiated by the hydroxyl radical in an attack on organic compounds and involving numerous free radicals, much of the OH and HO_2 radicals involved are themselves created by photo-reactions involving O_3. Thus, to the first approximation, equation (2) is a reasonable approximation of the balance of NO_2 and NO_X, particularly during the daytime when NO_2 concentrations are highest.

While the OLM/ARM workgroup (1998) noted that "oxidation by ozone is typically the main reaction for NO_2 formation", and that "the reaction rate is essentially instantaneous", they also noted that "the total amount of NO_2 conversion is limited by how quickly the plume entrains surrounding air". Therefore, the OLM algorithms may somewhat overstate the on-road and near-road NO_2 concentrations (all other factors being equal) by not accounting for the possibility of limited entrainment of O_3-laden air in locations with limited mixing, such as street canyons. However, given the rapid formation of NO_2 in the presence of ozone, we feel that incorporating transport time into

a model formulation would be unlikely to substantially affect model predictions in this application.

The location of the peak NO_2 concentration in this study were derived from objective modeling predictions, not *a priori* assumptions. OLM's characterization of NO_2/NO_X ratios as a function of downwind distance is documented in a series of sensitivity tests by MACTEC (2004). The concentration of NO_2 is a function of both the photostationary balance of equation (2) within the plume and the decreasing concentrations of the dispersing plume.

Despite certain limitations in the OLM approach identified above, the model predictions show good agreement with measured values off the roadway. And as discussed below, the onroad model predictions compare favorably with reported measurement values at other locations.

(9) Comment: API/AECOM commented that "there are many other sources of NO that are already competing for ambient ozone"… "unless the ambient monitor is located in an area similar to the source, it is unrealistic to assume that all of the monitored ozone is available to convert NO to NO_2" at the source location.

Response: We agree that the modeling methodologies could be strengthened by enhanced resolution of O_3 concentrations. However, the scale over which the reactions occur is critical. Monitors should represent the average concentrations to which the plumes are exposed in traveling from a source to the receptor, not the O_3 concentrations immediately adjacent to source, where the noted titration will reduce the O_3 concentrations below that available elsewhere in the domain.

The exception would be where the receptor <u>is</u> immediately adjacent to the source, e.g., the on-road and near-road microenvironments. In these cases, the OLM algorithms may somewhat overstate the on-road and near-road NO_2 concentrations (all other factors being equal) by not accounting for the possibility of limited entrainment of O_3-laden air in locations with limited mixing, such as street canyons. However, for this study the overall model performance appears to be reasonable, both when compared to literature values and when compared to regional observations (see comments responses 8 through 10 below).

(10) *Comment:* AAM (September 14, 2009 memo) commented that, "In addition to mis-characterizing the spatial distribution of NO_2, AERMOD mis-characterizes the temporal distribution, as shown in Figure 8-7 of the REA where the modeled peak NO_2 from the morning rush hour occurs about three hours earlier than the peak in the monitored concentrations in Atlanta." They further comment "maximum concentrations occur under conditions of minimum dispersion where the impact of turbulence and heat generated by traffic will be greatest. Since the EPA review acknowledges that AERMOD has not been rigorously evaluated for line source applications and the algorithm is

simplistic compared to other line source models that account for turbulence and other traffic effects in greater detail, its predictions of maximum roadway impacts are suspect."

API/AECOM had similar comments on the diurnal concentration profile stating "AERMOD is somewhat successful in simulating the afternoon dip in NO_2 concentrations associated with increased atmospheric ventilation, but the model substantially overestimates (with about 50% to 70% over prediction) and prematurely times the early morning and evening peaks. The overestimates are probably associated with an overestimation of ambient ozone and the overly conservative treatment of atmospheric reactions that limit peak NO_2 concentrations."

Response: The discrepancy between modeled and observed peak concentration when considering the diurnal profile is less likely due to the model parameterizations employed than to limitations in the underlying hourly vehicle activity data from TDM modeling outputs. The activity data were based on TDM modeling outputs from the regional planning organization and considered the best available information, although somewhat limited in specification of the temporal profile. Furthermore, the OLM mechanism should not be related to any morning overpredictions since the ambient ozone concentrations are generally low at that time. The uncertainty regarding this input variable and magnitude of impact on estimated concentrations was acknowledged by EPA in section 8.12.1.4 of the REA.

We agree that with equivalent emissions, maximum concentrations will occur under conditions of minimal dispersion, such as low wind speeds and mixing heights. During these times, typically early morning, effects of vehicle induced turbulence could be significant. However, in the present study, over-predictions occur primarily during the afternoon traffic peak, when ambient turbulence should dominate any traffic induced values and ambient temperatures are high, minimizing buoyancy effects. Thus any model over-predictions at these times are less likely to be due to the parameterized traffic impacts on dispersion.

As discussed above, the cited EPA review notes that AERMOD is commonly used for area source applications, which was the way roadway links were characterized for this study; and input parameters were selected to account for roadway effects.

(11) *Comment:* AAM (September 14, 2009 memo) commented that the data in the "REA shows in Figures 8-6 and 8-7 that the AERMOD-estimated concentrations substantially overestimate measured NO_2 concentrations in Atlanta particularly at the upper percentiles of the distribution. Figure 8-8 also indicates that AERMOD overestimates the maximum on-road concentrations compared to the ratio method used in Chapter 7, which as shown above, itself overestimates maximum on-road exposures."

A few other commenters made similar comments. For example, ACSBPP and API concluded that AERMOD may overestimate NO_2 concentrations, particularly in the upper percentiles of the distribution. These commenters generally concluded that, by

relying on the AERMOD dispersion model, EPA may be overestimating the risks from current ambient concentrations and the contributions to risk from on-roadway and near-roadway exposures.

Response: Figure 8-8 compares on-road to non-road receptor concentration ratios generated by using the concentrations estimated by AERMOD with concentration ratios generated using the measurement data extracted from the extant literature (i.e., the *empirical method*). This figure does not compare on-road concentration predictions. Figure 8-8 shows that AERMOD generally predicts both higher and lower (i.e., more variable) concentration ratios than the empirical method. The accuracy of neither method could be demonstrated with direct observations, due to the lack of available on-road, or even near-road, measurement data in the modeling domain. But as noted in the REA, given the greater number of receptors modeled by AERMOD, the AERMOD approach may better represent the variability in NO_2 concentration ratios than the empirical method.

Table 8-7 presents a comparison of on-road NO_2 concentration predictions between the two methods. The comparison suggests that the AERMOD on-road concentration predictions are higher than those of the empirical method by about 10 to 15 ppb at each percentile level. EPA notes however that the accuracy of neither method could be demonstrated with direct observations, due to the lack of available on-road measurement data in the modeling domain.

Figures 8-6 and 8-7 show that in the off-road environment, the high end of the concentration distribution is overestimated at the exact location of one monitor (ID 130890002), but shows very good agreement at the exact locations of the other two (IDs 130893001 and 131210048). For example, Table B-37, which presents the data used to construct Figure 8-6, shows that for the latter two monitors, the discrepancies between the AERMOD predictions and the measured values for percentiles 90 through 99 is less than 10 ppb. In addition, discrepancies between observed and predicted concentrations are even less when the envelope of all receptors within 4 km of the monitoring location is considered.

(12) *Comment:* AAM (September 14, 2009 memo) comment that "measured concentrations in on-road and near-road studies documented in the ISA and summarized in the previous section demonstrate that there are no valid measurements of NO_2 exposures as high as the upper percentiles of exposure predicted by AERMOD. The REA refers to the 0.548 ppm maximum NO_2 concentration in Riedecker et al. (2003) to support the upper end of the AERMOD predictions, but, as Riedecker et al. admits, it is not a valid measurement. There is additional evidence in the literature that microscale monitoring will not identify unmonitored "hot spots" of exposure to motor vehicle pollutants. The South Coast Air Quality Management District has carried out two studies that compared motor vehicle air toxic exposures at microscale sites in Los Angeles suspected of being unmonitored "hot spots" with exposures at current monitoring sites. In both cases, the exposures at the anticipated hot spots were similar to the exposures at the fixed neighborhood-scale monitoring sites."

Response: As noted above, when comparing predicted concentrations, either from AERMOD or the empirical method, to any measurement data, it is important to consider differences in averaging times. For example, Riediker et al. (2003) measured NO_2 inside North Carolina Highway Patrol cars on duty in Raleigh and determined mean concentrations of about 42 ppb with a range of 2 – 548 ppb for measurements of varying durations, with an average sampling duration of about 9 hours. As described above, the authors did not state the maximum concentration of 548 ppb was "invalid" but as an outlier. According to Riediker et. al. (2003), invalid measurements resulting from "laboratory or handling problems were excluded from the analysis." Note that the roadside measurements from the same study have a mean concentration of about 50 ppb with a range of 13 – 212 ppb (about an 8 hour averaging time). The present study in Atlanta estimated hourly average on-road concentrations of 43 ± 25 ppb (mean and standard deviation) and a maximum value of 556 ppb (REA Table 8-7). Even without considering study differences (e.g., averaging times, times-of-year, times-of-day included), the mean and maximum AERMOD on-road concentration predictions are comparable with the mean and maximum measured roadside concentrations reported by Riediker et al (2003).

In another study CARB (2003) measured NO_2 concentrations inside school buses on urban and suburban/rural routes in Los Angeles with average commute time of approximately 85 minutes and found commute average concentrations of about 70 ppb (urban; range 34 – 120 ppb) and 45 ppb (Rural/suburban; range 23 – 68 ppb). The mean and standard deviation of the on-road concentrations from the Atlanta exposure assessment are also consistent with this measurement study.

EPA disagrees with the commenters about the relevance of the MATES studies (II and III) referred to by the commenter to the exposure assessment presented in the REA. First, the MATES studies were designed estimate risk associated with longer-term exposures to air toxics, not short-term 1-hour exposures to nitrogen dioxide. In fact, NO_2 was not measured in either of these studies. The ambient monitoring was conducted in neighborhoods potentially downwind of important emissions sources; no measurements were made on-roadways. Comparisons were made between concentrations measured at neighborhood microscale monitors to fixed site monitors located several miles away. The studies do not compare on-road, near-road, and away from road concentrations along a specific transect line. The study monitoring objectives were to not only assess potential mobile source influence to neighborhood air quality, but also considered influence from other localized sources. For example, in the MATESII study (SCAQMD, 2000) only 3 of 14 microscale monitoring sites used for their "hot-spot" analysis were selected "because of influence and proximity to major mobile sources.

Conclusions reported by SCAQMD (2000) are consistent with the AAM comments in that "the monitoring at each of the 14 microscale sites did not register significantly higher levels of any toxic air contaminants." SCAQMD also added that "it cannot be concluded that 'hot spots' do not exist at other locations." The latter statement is made because of extreme limitations noted in the microscale monitoring program and to caution readers

against drawing particular conclusions based on the data. SCAQMD notes that "the intent to investigate a number of different sites, with available resources, limited the power of the microscale study to detect localized disparities in air toxic levels. The microscale study should therefore be regarded as more of a "pilot study" than as a study to definitively address possible differences in community air pollutant exposures within the South Coast Air Basin. These factors should be taken into consideration to avoid possible over-interpretation of the results." EPA notes that in the summary statements made for one of the microscale monitors placed to capture potential mobile source influences, "measured concentrations indicate more on-road activity at Montclair than at Fontana" (SCAQMD, 2000).

The MATESIII study does not refer to the monitoring of "hot spots" at all. The selection of monitoring sites "was done to ensure sufficient resolution to monitor representative concentrations of varying land use types and characterize spatial gradients in the Basin" (SCAQMD, 2008). The authors also note "[a]s in MATES II, due to the limited number of mobile monitoring platforms, each microscale site study lasted for a shorter duration than the overall study for approximately two to several months." This suggests the same caution should be applied regarding the over-interpretation of the results as recommended for the MATESII study. It was not apparent to EPA how many of the five microscale sites used in this study were placed in areas expected to receive significant mobile source influence, however SCAQMD found statistically significantly higher concentrations of mobile-source related pollutants at two of their microscale monitors compared with corresponding measurements at paired fixed site monitors. For example, 24-hour average concentrations of benzene, ethylbenzene, toluene, and xylene were 5 to 6 times as higher at the Santa Ana site than at the Anaheim site (SCAQMD 2008, page 5-8). The other three microscale monitors may have been sited to capture localized emissions other than mobile sources, given high concentrations noted for hexavalent chromium, 1,3-butadiene, and manganese composition in PM_{10}. While limited in direct relevance to the REA, in general, the overall trend in both MATES studies support the importance of mobile source influence to ambient concentrations.

(13) *Comment:* AAM (September 14, 2009 memo) commented on the approach used to estimate in-vehicle and near-road concentrations used to estimate exposures. Specifically they state that based on the AERMOD on-road to non-road receptor concentrations, "multiplicative factors from 1 to as high as 10 to 30 inappropriately were being used to estimate near-road exposures from the estimates of ambient concentrations." The commenter argued that "multiplicative factors as high as 30 are clearly suspect compared to the data in the literature on in-vehicle NO_2 exposures" They also question the use of the same APEX proximity factor for both in-vehicle and near-road microenvironments given the sharp reduction in NO_2 concentrations with distance from a roadway.

Response: EPA compared the on-road/non-road ratio distributions derived from the AERMOD hourly receptor concentrations with those of the ratios derived from on-road/near-road measurement study data (REA Figure 8-8, Appendix B Table B-39). For this comparison, the AERMOD concentrations were first time-averaged across seven days to approximate the time-averaging of the literature-derived measurement data (i.e.,

most of these observations were time-averaged over 7 to 14 days). The seasonal patterns of the ratios was consistent (summer ratios > not summer ratios), though the AERMOD generated ratios exhibited greater variability and had consistently higher values at the upper percentiles of the distribution. The maximum ratio for the not-summer season based on the empirical data was equal to the value of the 76th percentile AERMOD derived ratio. The maximum ratio for the summer season based on the empirical data was equal to the value of the 85th percentile AERMOD derived ratio. Note that the AERMOD ratios were generated using concentrations from 5,570 on-road receptors simulated in the modeling domain and the corresponding nearest non-road receptor at a distance ≥ 100 meters from the road. Given the greater diversity of the AERMOD modeled receptor locations compared with the literature derived data (a total of 11 studies using 36 roadway sites), we expected there would be greater variability and hence a greater range of ratios in the AERMOD derived ratios.

The ratios used for the APEX modeling were calculated using the AERMOD predicted hourly concentrations. Ratios having a 1-hour averaging time are most appropriate for this APEX application since the PROX factor is applied to a 1-hour ambient concentration. EPA expected that there would be greater variability in the 1-hour ratios, likely generating a distribution of PROX factors having a greater range of values than observed with the longer averaging time. EPA notes that there are no data reported in the extant literature that have on-road/non-road concentrations or ratios of 1-hour averaging time. In addition to the seasonal influences observed (summer/not-summer), EPA also stratified the ratios by the time-of-day based on analysis of this as a potential influential factor. Three time ranges were selected to further stratify the ratios. Lognormal distributions were then fit to each of the six stratifications, with lower and upper bounds of the distributions approximated by using the 5th and 95th percentiles (Appendix B Table B-42). In probabilistic exposure analyses, setting bounds on a fitted distribution is a commonly used method to control against exceptional or potentially unrealistic values. Note in REA Table 7-34, the minimum and maximum observed on-road ratios were at the 2.3-7.8th and 94.4-97.8th percentiles, respectively of a lognormal fitted distribution, supporting the selection of the 5th and 95th percentiles as reasonable lower and upper bounds.

In evaluating the ratio distributions, clearly the daytime (6AM-7PM) ratio distributions are distinct and higher than the nightime ratio distributions (7PM-6AM), confirming that stratification by at least two time-of-day ranges was appropriate. Again, seasonal differences were consistent with that of the ratios derived from the empirical data, confirming that seasonal stratification was appropriate. EPA acknowledges that it is possible that there are other potential influential factors that could be considered in further stratifying and applying the PROX factors, but given the limited time and resources allocated to perform the assessment, additional analyses were not performed.

When considering (1) the absence of observed on-road concentrations of 1-hour averaging times, (2) having no on-road concentration measurements within the modeling domain, (3) the reasonable agreement in the AERMOD concentration predictions with available measurement data, and (4) the reasonable agreement in the AERMOD on-road

concentration predictions with simulated on-road concentrations using the empirical ratios, EPA believes that the PROX factor distributions generated are an adequate representation of the relationship between on-road and non-road concentrations, even with upper bounds of the distributions that extend to values of 9 to 30. Again, EPA is not aware of any 1-hour measurement data derived from a study conducted in a similar urban environment across an entire year that could confirm or refute the level of the upper bound used for each of the ratio distributions.

EPA used the same on-road PROX factor distributions to calculate the near-road microenvironmental concentrations. The near-road microenvironment generally refers to locations in close proximity to vehicle emissions such as sidewalks, bus stops, and parking garages, where concentrations would likely be similar to those on roadways. Not accounting for decay/dispersion of the on-road concentration with such short distances from a roadway was considered by EPA as an appropriate assumption. EPA notes that the maximum concentration does not always occur on the roadway, it can occur at a distance from the road (e.g., Beckerman et al., 2008). Therefore, there may be instances where the near-road concentrations are either greater than or less than that observed on the road. In the absence of robust measurement data to inform the development of a potential adjustment factor to approximate on-road exposure concentrations that deviate above or below nearby on-road concentrations, EPA assumed a relationship of unity.

EPA recognizes that when using these ratio distributions to estimate in-vehicle or near-road exposures, there may be instances where these ratios are unsuitably applied to an exposure event, given other potential influential factors mentioned above that are not considered in the exposure calculation. This is an important uncertainty that could contribute to both over- and under-estimates in exposure concentrations. We acknowledged that accurately modeling the upper percentiles of the distribution is of concern given that the exposure metric of interest is exposures above selected benchmark levels. EPA qualitatively summarized the overall impact of these and other input data uncertainties in the REA (section 10.3.2.1) indicating that there is the "possibility that we are over-predicting upper percentile NO_2 exposures" and therefore over-predicting the number of days with exceedances, particularly the highest benchmark levels. Given the duration of the exposure assessment (i.e., an entire year), this uncertainty is likely to have a greater impact on the number of days per year an individual was estimated to experience an exposure above a benchmark rather than the estimated number/percent of persons exposed above a particular benchmark level, though the magnitude of which remains uncertain for either exposure metric.

(14) *Comment:* AAM (September 14, 2009 memo) commented that a study by Chock (1977) "demonstrated that the turbulence and heat generated by the traffic had a significant effect on the on-road and near-road wind and concentration fields". They further add "[t]hese effects limit concentrations that can build up on and near roadways under adverse ambient meteorology and are not included in AERMOD."

Response: We agree that road-induced turbulence and buoyancy effects will dominate in the early morning hours where stability is likely high and mixing heights and

temperatures are low. In these cases, the local mechanical turbulence will overwhelm the ambient turbulence and lead to the effects explicitly designed to be sampled by Chock.

As noted above, on-road vehicle induced turbulence and plume rise were addressed in the selection of input parameters for initial horizontal and vertical dispersion and emission release heights for on-road, as documented in the REA (section 8.4.3.3). Additionally, to mitigate morning over-predictions, the mechanical mixing height was raised in cases where AERMOD-defined mixing heights were judged to be unreasonably low, as discussed in the REA.

(15) *Comment*: API/AECOM (September 14, 2009 memo) commented on the importance of developing a database that "provides information on NO_2 to NOx emission ratios" suggesting that "the estimation of the NO_2 to NO_X ratio is critical in modeling peak hourly NO_2 concentrations.

Response: We agree that knowledge of the initial NO_2/NO_X ratio is limited and that the ratio can be variable. Although we note that EPA's new mobile source emissions model, MOVES, can provide separate estimates of NO, NO_2, and NO_X emissions.

We also note that the importance of the accuracy of the initial ratio depends on the degree of conversion of NO to NO_2 predicted by the model. That is, in cases where more complete conversion is predicted, the sensitivity of the final NO_2/NO_X ratio to its initial value is minimized. In the present exposure assessment where the dispersion model predicts a high rate of conversion, this effect of this on the output concentration will be small.

Furthermore, Carslaw (2005) attributes much of the observed increase in NO_2/ NO_X emissions ratios to the increased use of diesel particulate filters (DPF) in London, UK. Even if this supposition is correct, it is unlikely to be relevant to the present modeling results. For comparison, diesel vehicles make up over fifty percent of new light duty vehicles in the EU (Dieselnet, 2008) whereas the North American diesel passenger vehicle market share is less than 1 percent (Haight, 2003). Regardless, we agree that, generally, improved characterization of this ratio would be advantageous in future modeling efforts.

(16) *Comment:* One commenter drew attention to a potential error that causes underestimation of NO_2 impacts using the modeling software AERMOD (CAAPCOA). They provided the following description this error and other modeling shortcomings that will affect the models used to inform the selection of a short-term NO_2 standard:

"The use of AERMOD with a more refined Conversion Tier (e.g., OLM [Ozone Limiting Method] or PVMRM [Plume Volume Molar Ratio Method]) produces lower 1-hour NO_2 impacts than less refined methods do. However, California air district modelers have discovered that an error exists in the multi-source, combined-plume application of AERMOD (the OLMGROUP keyword) that

biases the results low. This means that 1-hour NO_2 levels calculated using the more refined methods may be underestimating the impact. Furthermore, the AERMOD model requires newer MET [meteorological] data sets that are more complicated and require data inputs that may not be readily available for all areas in California. Consequently, not all air districts have converted to the AERMOD model."

The commenter urges EPA to address this potential model error prior to establishing a 1-hr NO_2 standard.

Response: EPA was aware of this error while conducting the NO_2 exposure assessment. The version of AERMOD that was used in our analysis had been corrected for this error.

(17) *Comment*: In their October 22, 2008 memo, the ACC commented that the exposure assessment results for Philadelphia (1st draft REA) were very different from results presented for Atlanta (Final REA). They specifically noted "there are substantially higher numbers of exceedances and numbers of individuals exposed to repeated exceedances for Atlanta compared to Philadelphia". The commenter requested discussion or comparisons of the differences between the two locations.

Response: EPA considered performing the exposure modeling in five locations described in the Scope and Methods Plan (i.e., Atlanta, Detroit, Philadelphia, Phoenix, and Los Angeles) however there were limited data, time, and resources available to perform exposure modeling in all five locations. Following the CASAC review of the 1st draft REA and considering comments made on that document, EPA judged the model evaluations to be an important factor in selecting a location for an improved exposure assessment. Given the availability of personal exposure measurements within a similar time frame as the exposure modeling and a complementary quantitative risk assessment to be performed in the same location, EPA elected to focus the exposure modeling effort on Atlanta, GA rather than continue with the modeling that was initiated for the 1st draft REA (i.e., Philadelphia County).

The exposure modeling approach used for Philadelphia in the 1st draft REA (and documented in Appendix B-3 of the final REA) is not directly comparable to the exposure modeling performed for Atlanta (REA, Chapter 8). Therefore, a direct comparison of the exposure results obtained for each location would be unreasonable. As stated in REA Appendix B, section B-1, "due to differences in the approach used in the Philadelphia analysis, the results are not directly comparable to the Atlanta case-study." For example, one of the most significant differences between the two assessments was how the emissions from minor roadways were addressed. In Atlanta minor roadways were modeled as area sources using AERMOD, considered by EPA an important improvement to the modeling approach used for this assessment. In Philadelphia minor roads were not modeled as emission sources, but considered as part of the unaccounted concentration when comparing the modeled concentrations considering all other emission sources at the ambient monitor locations. It is possible that these differing model approaches used were related to another important difference: the derived distributions of

in-vehicle and near-road proximity factors. In Atlanta, the proximity distributions were stratified by season and hour-of-day, having a time-weighted geometric mean of about 2.7 (REA Appendix B, Table B-42). In Philadelphia, the proximity distributions were stratified only by hour-of-day, having a time-weighted geometric mean of about 1.4 (REA Appendix B, Figure B-11). These examples were just two of several important differences designed to improve the Atlanta assessment for the 2nd draft and final REA, building upon what was learned from the 1st draft approach used for Philadelphia. No improvements or adjustments were made to the exposure modeling approach used for Philadelphia, thus results for that assessment should only be considered as preliminary.

(18) *Comment:* Some commenters (e.g., API) noted that indoor NO_2 concentrations can be higher than the levels that EPA is considering for an hourly NO_2 NAAQS due to indoor emission sources. These commenters conclude that, given that people spend the majority of their time indoors, the Agency should consider NO_2 exposures indoors when evaluating whether the proposed NAAQS would have a meaningful effect on risk from NO_2.

Response: We agree that indoor concentrations of NO_2 can be elevated relative to ambient concentrations, particularly in indoor environments containing sources of NO_2 such as gas stoves (ISA, section 2.5.5). Indoor sources were considered as part of the exposure assessment presented in the REA. Even when indoor sources were included in modeling, the majority of exposures to peak NO_2 concentrations (i.e., 1-hour concentrations at or above 100 ppb) were attributable to roadway-associated sources (REA, Figures 8-17 and 8-18).

(15)

III. Responses to Significant Comments on the Adequacy of the Current Standard

(1) *Comment:* CASAC agreed 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. Their letter to the Administrator on the final REA (Samet, 2008) 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." In supporting adoption of a more stringent NAAQS for NO_2, CASAC generally relied on 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.

A number of public commenters also called for revising the current standard. This included environmental groups (e.g., CAC, EJ, EDF, NRDC, GASP); medical/public health organizations (e.g., AACPR, ALA, AMA, ATS, NAMDRC, NACPR, ACCP); State, local, and tribal agencies and organizations (e.g, NACAA, NESCAUM, agencies in CA, IA, IL, MI, MO, NC, NM, NY, TX, VA, WI, and tribes including NTAA, Fon du Lac); and a number of individual commenters. These commenters generally 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 this conclusion, these commenters typically relied upon the evidence and information presented in the proposal and on CASAC's recommendation.

Response: We generally agree with these commenters' conclusions regarding the adequacy of the current standard. The Administrator's conclusions regarding adequacy are discussed in more detail in section II.E.3 of the final rule.

(2) *Comment:* Some industry commenters (e.g., AAM, API, Dow, INGAA, UARG), one State commenter (INDEM), and Roger McClellan expressed support for retaining the current annual standard alone. In supporting this view, these commenters generally concluded that available evidence supports a judgment that the current standard provides adequate protection of public health. They also typically concluded that the available evidence and information is not sufficient to support revision of the standard. These commenters generally relied upon their judgments regarding the scientific evidence and exposure/risk information and on the uncertainties associated with that evidence and information, as discussed above (section II) in more detail. For example, the 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." The 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." Roger McClellan commented that "there is a substantial body of scientific information to under-gird a policy judgment to re-affirm the present annual standard set at 0.053 ppm NO_2 measured at area-wide monitoring sites."

Response: These comments and EPA's responses are discussed in detail in section II.E.2 of the final rule. The Administrator's conclusions on the adequacy of the current standard are described in section II.E.3 of the final rule.

(3) *Comment:* The Oklahoma Independent Petroleum Association (OIPA) pointed out that "since 1990, NO_2 emissions have decreased 35% despite the 63% increase in the gross domestic product, a 45% increase in the vehicle miles traveled, a 21% increase in population, and a 20% increase in energy consumption. Between 2001 and 2007, NO_2 emissions decreased by 20%. In addition, EPA anticipates that nitrogen oxide (NO_x) emissions will decrease substantially over the next 20 years as a result of the ongoing implementation of mobile source emissions standards." As a result of these and similar statements by commenters, several groups concluded that a more stringent NO_2 standard is unnecessary because the current standard is sufficient to protect against both long- and short-term exposures (e.g., API, Dow, INGAA, VADOT, MODNR, INDEM).

Response: As noted by the commenters, NO_X emissions have decreased and are expected to continue to decrease as a result of ongoing implementation of mobile source emissions standards. However, the Clean Air Act (section 109) requires that primary NAAQS "shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." Given this requirement, the primary NAAQS are set such that, in the Administrator's judgment, public health is protected with an adequate margin of safety in locations that meet the standards. As discussed more fully in the final rule (section II.E.3), the scientific evidence and the exposure/risk information support the Administrator's conclusion that important NO_2-related public health risks are present in some locations with ambient NO_2 concentrations below those allowed by the current annual standard and that a new standard is needed to provide the requisite degree of protection for public health.

IV. Comments on A New Short-Term NO_2 Primary Standard

This section discusses comments received on EPA's proposed 1-hour standard. Some commenters provided comments on the cost or economic impact of monitoring, implementation, or compliance associated with the proposed NO_2 NAAQS. As noted in section I.B of the preamble, the Clean Air Act bars consideration of costs in setting the NAAQS, and accordingly EPA has not considered costs, including the costs or economic impact of monitoring, implementation or compliance, in revising the NO_2 NAAQS.

A. Indicator

CASAC and some public commenters addressed the issue of the indicator for the standard (AAM, API, Dow, and MODNR). All of these commenters endorsed the proposal to continue to use NO_2 as the indicator for ambient NO_x, though some commenters expressed the need for special considerations when using NO_2 as a surrogate for NO_x.

(1) *Comment:* API concluded that the proposed regulatory language would change the denomination of the standard from one regulating NO_2 to one regulating oxides of nitrogen, with compliance to be determined by measurement of NO_2 in the ambient air. API recommends that EPA clearly state that this language is not a substantive change and merely reflects the continuation of the Agency's regulation of NO_2 (and only NO_2) as an indicator for all oxides of nitrogen.

Response: We agree that no substantive change is being made with regard to the indicator and that NO_2 is the indicator for the oxides of nitrogen. This is indicated in the regulatory text for 50.11 in the final rule.

(2) *Comment:* Some commenters (e.g., AAM) asserted that the tendency to overestimate NO_2 concentrations with the Federal Reference Method (FRM) should be considered with regard to margin of safety, and that EPA should develop an FRM not prone to positive interference.

Response: EPA is required to set the NAAQS at a level requisite to protect public health "allowing a margin of safety". Thus, EPA takes "margin of safety" into consideration in setting the NAAQS. EPA separately considers the accuracy and precision of measurement methods in determining FRM and FEM requirements. The Administrator believes that the continued use of the chemiluminescence FRM is appropriate for comparison to the NAAQS. The issue of interference in FRM measurements and the discussion of the development of alternative methods that could be used in determining NO_2 concentrations are discussed in section III.A.1 of the preamble to the final rule. Although the FRM can be subject to positive artifacts resulting in varying degrees of overestimation of NO_2 concentrations, this overestimation should be minimized for monitors sited in urban locations, particularly near NO_X sources such as roads. Additionally, the ISA concluded that for monitors sited in urban locations near roadways or other sources of NO_X emissions, the overestimation of NO_2 concentrations is typically less than 10% (ISA, section 2.3).

B. Averaging time

(1) *Comment:* 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, 2009b):

> 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 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 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 (ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC); and a number of individual commenters. The supporting rationale offered by these commenters often acknowledged the recommendations of CASAC and the Administrator's rationale as discussed in the proposal.

Response: We agree with these comments on the need for a new 1-hour standard. Comments on averaging time are discussed in section II.F.2.b of the final rule. The Administrator's final decision on averaging time is discussed in section II.F.2.c of the final rule.

(2) *Comment:* Though many industry commenters recommended not revising the current annual standard (see above), 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., CPA, Dow, NAM, PAW, UPA).

Response: 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 are discussed in detail in section II.E.2 of the final notice. The Administrator's conclusions regarding averaging time are discussed in section II.F.2.c of the final notice.

(3) *Comment:* Two state commenters recommended that further studies be conducted to determine whether the 24-hr standard is as protective of human health as the 1-hr standard (e.g., NYDOH, SDDENR). One of these commenters specifically noted that epidemiological studies do not provide sufficient evidence that distinguishes effects between 1-hour and 24-hour exposure periods (SDDENR).

Response: The Administrator's conclusion that available scientific evidence supports setting an NO2 standard with a 1-hour averaging time is described in detail in section II.F.2.c of the final notice. In addition, EPA notes that the court-ordered schedule for this review requires a notice of final rulemaking to be signed by January 22, 2010.

C. Form

(1) *Comment:* Many commenters emphasized that, for a standard reflecting the maximum allowable NO_2 concentration anywhere in an area (i.e., the approach adopted in the final rule, section II.F.4.d), a form should be chosen that provides regulatory stability. To this end, CASAC favors a 3-year average of the 98th percentile (or 7th or 8th highest) of the distribution of annual 1-hour daily maximum concentrations. Specifically, CASAC commented that "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."

A number of other commenters also recommended a form based on the 3-year average of the 98th percentile (or 7th or 8th highest) of the distribution of annual 1-hour daily maximum concentrations (e.g., Dow, SDDENR, NCDENR, API, PAW, VADOT, ACC, ExxonMobil, INDEM, NESCAUM, AQRL, and IPAMS). These commenters typically argue that the 98th percentile form will provide a more stable statistic and, therefore, will better protect against unusual events and the possibility that concentrations measured by near-road monitors will be highly variable and responsive to small changes in monitor placement.

Response: EPA agrees with the comments that a 98th percentile form is appropriate. Her consideration of comments on form and her rationale for her final decision are discussed in detail in sections II.F.3.b and II.F.3.c, respectively.

(2) *Comment:* Several commenters recommended either a 99th percentile form or a more stringent form. For example, some commenters recommended a "no exceedance" form, claiming that such a form would provide "more coherence in the protection for a standard that targets peak exposures than a form based in the 98th or 99th percentile" (ALA, EJ, EDF, NRDC). These same commenters noted that if EPA is unwilling to accept a "no-exceedence" form, they strongly favor a 99th percentile standard over a 98th percentile standard. They pointed out that a 98th percentile form would allow for as many as 21 exceedances in a three-year period, and concluded that this would be unacceptable.

Alternatively, GASP recommends using a form allowing one exceedence per year over a three-year period, arguing that this will prevent several of the top measurements that contribute to adverse health effects from being dismissed. Several commenters prefer the 3-year average of the 99th percentile (or 4th highest) of the distribution of 1-hour daily maximum concentrations (e.g., TXCEQ, HLI, RHAMC, MODNR, NMED, NESCAUM).

Response: The Administrator recognizes that the public health protection provided by the 1-hour NO_2 standard is based on the entire standard including the level of the standard (see below), in conjunction with the averaging time and form of the standard. In light of her decision to set a new 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area (see section II.F.4.d of the final rule), she concludes (consistent with the advice of CASAC) that an appropriate consideration with regard to form is the extent to which specific statistics could be unstable in 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. This decision is discussed in section II.F.3.c of the final rule.

(3) *Comment:* Some commenters stated a preference for expressing the form in terms of the nth highest concentration rather than in terms of a percentile. These commenters believe that using the nth highest form would increase transparency (e.g., Dow, AQRL). AQRL noted that "it can provide an unambiguous determination of a 'design value' in the face of missing data if concentrations are high. The percentile form does not provide that certainty if data are missing."

Response: We disagree that a percentile form does not provide certainty regarding the determination of the design value. As discussed above, and in the final rule (section II.F.3), the Administrator has determined it appropriate to set a form based on the 3-year average of the 98th percentile of the annual distribution of 1-hour daily maximum NO_2 concentrations. The interpretation of this standard, including requirements for when data are missing, is described in Appendix S to 40 CFR part 50 and in section IV of the preamble to the final rule.

D. Approach and level

1. Comments on the approach to setting the standard

(1) *Comment:* We received a number of comments on the most appropriate approach to setting the 1-hour NO_2 standard. In their comments on the proposal, CASAC was split

regarding the most appropriate approach to setting the 1-hour standard. In their letter to the Administrator on the proposal (Samet, 2009b), 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.

As indicated in their letter, the majority of CASAC Panel members favored the proposed approach of setting a 1-hour standard that reflects the maximum allowable 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. The recommendation of these 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 contrast, the 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 and that this introduces uncertainty into the use of these studies to inform a standard that reflects the maximum allowable NO_2 concentration anywhere in an area. 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 now relies" (Samet, 2009b). These CASAC Panel members also noted uncertainties associated with identifying appropriate monitoring sites near roads (see below and section III.B.2 of the final notice for more discussion of monitoring comments).

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 the majority of environmental organizations (e.g., CAC, EDF, EJ, GASP, NRDC), by the ALA, and by a number of 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 were typically consistent with the rationale discussed by the Administrator in the proposal in support of setting a 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area.

Consistent with the view of the minority of CASAC Panel members, several industry groups and an individual commenter (Roger McClellan) noted uncertainties associated with using epidemiologic studies to inform decisions on a standard reflecting the maximum allowable NO_2 concentration anywhere in an area. Specifically, Roger McClellan stated the following:

> In considering the results of the six epidemiological studies that are at the core of the EPA assessment, it is important to recognize all of them used NO_2 concentration data from central area monitors as a surrogate for personal exposure. These data are not applicable to establishing standards for near roadway monitors.

Similar concerns with the proposed approach were expressed by several industry groups.

Response: As described in detail in section II.F.4.c of the final notice, the Administrator agrees with the majority of CASAC Panel members and other commenters who concluded that the most appropriate approach to setting the 1-hour NO_2 standard is to set a standard reflecting the maximum allowable NO_2 concentration anywhere in an area. Her consideration of the uncertainties associated with this approach, as stated by the minority of CASAC Panel members and industry commenters, is also discussed in the final notice (sections II.F.4.b and II.F.4.c).

(2) *Comment:* Some industry groups concluded that EPA is inappropriately combining decisions on the standard with decisions on the monitoring network. Specifically, AAM states the following with regard to the proposed approach

> [T]he effective stringency of a NAAQS depends on more than simply the numerical level selected. It also depends on the sensitivity of the monitoring system, and the ability of that system to determine accurately the ambient levels of the pollutant in a consistent manner at monitoring stations across the country. By affixing the stringency of a primary NAAQS to a monitoring system that does not now exist and will be subject to varying interpretation by regional, state and local officials, EPA is in effect delegating the final decision on the NAAQS standard to those

officials, contrary to statutory requirements that judgments concerning such standards reside with the Administrator.

Response: We disagree with this characterization of the standard. As discussed in detail in the final notice (section II.F.4.c), the Administrator is setting a 1-hour standard reflecting the maximum allowable NO_2 concentration anywhere in an area. It follows from this standard that monitors should be placed in locations where maximum NO_2 concentrations are expected to occur. As discussed in the final notice (section II.A.2 and II.F.4.c), available information supports the conclusion that these maximum concentrations will occur around major roads in many areas. Therefore, the Administrator is requiring monitors within 50 m of major roads (see section III of the final notice). In situations where maximum NO_2 concentrations are expected to occur in locations other than near major roads (e.g., near multiple smaller roads and/or stationary sources), the Regional Administrator can also require monitors in these locations. EPA establishes criteria for the method of monitoring and for quality assurance/quality control (QA/QC). Any hourly data from monitors meeting FRM/FEM and QA/QC requirements will be considered in making designations.

(3) *Comment:* Several industry and state commenters recommended that EPA select its alternate monitoring proposal of using area-wide monitors to be used in conjunction with a new short-term NO_2 standard (e.g., EMA, SCCC, NMED). In their recommendation of the alternate monitoring network, NMED noted that the use of area-wide monitors is more applicable for measuring ambient air concentrations than near-road monitors since few people live or work as close to major roadways as near-road monitoring stations would be required to be located. Other commenters (e.g., Exxon) also concluded that monitor siting requirements should allow for consideration of population.

Response: As noted in the proposal and the final notice (section II.F.4.c), millions of people in the United States live, work and/or attend school near important sources of NO_2, including major roads. In addition, people commuting on major roads can be exposed to elevated NO_2 concentrations. As described in the preamble, the Administrator concludes that short-term elevated NO_2 concentrations, including those occurring on or near roads, pose public health risks. The Administrator further concludes it is appropriate to locate monitors where maximum concentrations are expected to occur, and that generally it is appropriate to locate monitors near major roads. States are to consider population in the site selection process if a state identifies multiple acceptable candidate sites where maximum hourly NO_2 concentrations are expected to occur.

(4) *Comment:* AQRL commented that EPA's alternative monitoring approach should not be chosen and implemented if one of the principal reasons for the proposed 1-hr NO_2 standard is to develop the near-road monitoring network.

Response: The rationale supporting a 1-hour standard reflecting the maximum allowable NO_2 concentration anywhere in an area is discussed in detail in section II.F.4.d. This rationale does not include the development of a near-road monitoring network.

(5) *Comment:* Several commenters (e.g., AAM, API) concluded that it is not appropriate to use the information discussed in the proposal on the NO_2 concentration gradient around roads to inform decisions on the 1-hour standard. AAM concluded that the focus of the proposed approach on NO_2 concentrations around major roadways is not justified (and would result in a standard that is more stringent than necessary) 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. AAM used data from the existing NO_2 monitoring network as the basis for their conclusion that "roadside monitors are not measuring high NO_2 concentrations." Specifically, they claim that their analyses suggest the following:

- Many of the presently located urban monitoring sites are already located within 50 meters of a major roadway.
- These monitors are not measuring the high concentrations that are of concern to EPA.
- Consequently, there does not appear to be a need to initiate a massive deployment of new NO_2 monitors within 50 m of major roadways.

Other commenters also noted that the highest concentrations of NO_2 may be in urban canyons, near stationary sources, or near airports (e.g., NESCAUM).

Response: With regard to the general point made by several commenters that maximum NO_2 concentrations may not always occur near major roads, 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 allowed for situations where this is not the case. Specifically, 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.[7] 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.

With regard to the analyses submitted by AAM, 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:

[7]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).

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

In contrast, to support their conclusions about the NO_2 concentration gradient, AAM relies largely on an analysis of existing NO_2 monitors that focused on 6 locations with a total of 42 monitors. While this analysis does provide information on NO_2 concentrations at different distances from roads, the existing NO_2 monitoring network was not designed to characterize the spatial gradients in NO_2 concentrations surrounding roadways. Rather, concentrations of NO_2 measured by existing monitors may likely reflect contributions from a combination of mobile and stationary sources, with one or the other dominating depending on the proximity of the monitors to these sources.

Specifically, one example used by the commenters to support their conclusion that NO_2 concentrations near roads are not elevated is that of St. Louis, where the monitors closer to a road measured lower NO_2 concentrations than a monitor farther away from the road. However, a closer look at the monitor classified as being away from the road provides a potential explanation for these observations and illustrates the limitations of relying exclusively on the existing monitoring network to characterize the NO_2 concentration gradient around roads. The monitor used (ID 295100086) is characterized by EPA's Air Quality System (AQS) as having a "high concentration" monitoring objective, is 133 m from a major road, and is surrounded by 35 NO_X emission sources within 10 km having median emissions of about 17 tons per year (see REA, Appendix A, Tables A-7 and A-8). Thus, the single site used in St. Louis for the $\geq$ 100 m bin may not necessarily reflect concentrations at a site distant from a roadway, is likely not exclusively impacted by roadway emissions, and would likely not be useful in determining the relationship between near-road NO_2 concentrations and those away from the road. The REA identified and discussed situations such as this as an important uncertainty when estimating on-road concentrations (REA, section 7.4.6, page 135).

Given the considerations above, we conclude that the analysis submitted by AAM, which does not consider relevant lines of evidence and information other than their analysis of existing monitors, does not appropriately characterize the relationship between NO_2 concentrations near roads and those away from roads.

2. Comments on standard level

(1) *Comment:* 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). Though, as discussed above, they were split on which approach should be adopted for setting the 1-hour standard, 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 and a monitoring network is established that includes monitors near major roads), 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, 2009b) 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 80ppb 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.

A number of State and local agencies and organizations also expressed support for setting the level of the 1-hour NO_2 standard within the proposed range of 80 to 100 ppb, though only a few of these 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.

Response: As is discussed in section II.F.4.d of the final rule, the Administrator has judged it appropriate to set a standard level of 100 ppb. Her rationale, which incorporates her consideration of the above comments, is discussed in detail in this section.

(2) *Comment:* A number of environmental organizations (e.g., CAC, CSE, 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 well as the NO_2 exposure and risk information.

Some of these commenters noted that the 98^{th} 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, EF, 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 U.S. 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.

Some of these commenters also concluded that the proposed range of standard levels fails to provide a margin of safety for effects reported in controlled human exposure studies.

Response: The Administrator's decision to set a standard level of 100 ppb is discussed in detail in section II.F.4.d of the final rule. The rationale for this decision includes consideration of the above comments. Specific comments on standard level are discussed in section II.F.4.c of the final rule.

(3) *Comment:* Several environmental and public health groups (e.g., ALA, EDF, EJ, NRDC) concluded that the REA analyses of NO_2 exposures and risks suggest that "only an hourly standard of no more than 50 ppb would protect against harm from peak exposures."

Response: We disagree with this characterization. As discussed in sections II.C and II.F.4.d of the final rule, the analyses of different potential alternative standards in the REA are based on the current monitoring network, which contains primarily area-wide monitors. The Administrator concludes that the results of exposure and risk analyses provide support for limiting area-wide NO_2 concentrations to no higher than 100 ppb. The Administrator is setting a new 1-hour standard that reflects the maximum allowable NO_2 concentration anywhere in an area. Therefore, when considering the REA analyses in the context of such a standard, the Administrator considered available information on the relationship between the higher NO_2 concentrations around roads and area-wide NO_2 concentrations. Specifically, as described in detail in section II.F.4.d, she noted that a

standard level of 100 ppb reflecting the maximum allowable NO_2 concentration anywhere in an area would be expected to limit area-wide NO_2 concentrations to approximately 50 to 75 ppb. Therefore, she concluded that a standard level of 100 ppb, for a standard that reflects the maximum allowable NO_2 concentration anywhere in an area, is consistent with conclusions based on the NO_2 exposure and risk information.

(3) *Comment:* Several industry groups (e.g., AAM, Dow, NAM, NPRA) and Roger McClellan 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 typically emphasized uncertainties in the scientific evidence. Specifically, 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. Some industry groups also concluded that epidemiologic studies should not be used to inform decisions on the standard level because these studies were based on area-wide, rather than near-road, NO_2 concentrations. 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. 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.

Response: 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 in section II.E.2 of the final rule and above (section II) in this Response to Comments Document. The Administrator's conclusions on standard level are described in section II.F.4.d of the final rule.

(4) *Comment:* Some commenters argued that EPA should not adjust the standard level to account for postulated near-road concentrations because, due to differences in concentration gradient, it would establish a level that is arbitrary and variable across locations (e.g., NPRA, NYSDEC, AAM). AAM further argued that EPA's information about the concentration gradient was not sufficiently precise or "factual" to inform EPA's decision making.

Response: As described in section II.F.4.d of the final rule, EPA has not adjusted the standard level to account for near-road concentrations. Rather, the Administrator has considered the extent to which specific standard levels would be expected to protect against exposure to the distribution of NO_2 concentrations across an area and, therefore, against the array of respiratory effects that have been linked to short-term NO_2 exposures. These considerations are described in detail in section II.F.4.d of the final rule. EPA

disagrees with AAM's suggestion that information about the concentration gradient should be disregarded in reviewing the standard.

(5) *Comment:* One commenter (NYDOH) concluded that too much weight has been placed on clinical studies and that more emphasis should be placed on epidemiologic studies in setting the standard level.

Response: As discussed in detail in section II.F.4.d of the final rule, the Administrator has considered both the controlled human exposure and epidemiologic evidence in setting the standard level. Both lines of evidence provide information on the extent to which specific NO_2 standards would be expected to protect against the range of respiratory effects that have been linked to short-term exposures to NO_2.

(6) *Comment:* INGAA pointed out that the related health-based standards (e.g., Short-term Exposure Level (STEL) or ceiling Permissible Exposure Level (PEL) from Occupational Safety and Health Association (OSHA) or the National Institute of Occupational Safety and Health (NIOSH)) are higher than the proposed NO_2 NAAQS. They claimed that personnel have not been negatively affected by NO_2 exposures at their facility. The commenter also observed that "when comparing the relative margin of OSHA or NIOSH standards to the NAAQS for other gases, the proposed NO_2 NAAQS is more stringent. For example, the OSHA NO_2 PEL (ceiling) is 5 ppmv [parts per million by volume] (i.e., 5000 ppbv [parts per billion by volume]) and the NIOSH STEL is 1 ppmv (1000 ppbv). These levels are one to two orders of magnitude higher than ranges being considered by EPA for the 1-hour NO_2 NAAQS. By comparison, the CO [carbon monoxide] NAAQS 1-hour average standard is 35 ppmv, compared to a NIOSH STEL of 200 ppmv, a factor of 5.7. This appears to indicate a more conservative approach for the proposed NO_2 NAAQS."

Response: The CAA requires that air quality criteria and NAAQS be reviewed periodically. After consideration of the latest scientific knowledge, the NAAQS must be set at levels that are, in the Administrator's judgment, requisite to protect public health, including the health of sensitive subpopulations, with an adequate margin of safety. The Administrator has considered this requirement in setting a new 1-hour NO_2 standard as described in section II.F.4. In contrast, occupational standards, such as those mentioned by the commenter, are established based on different legal requirements and may not be updated in the same manner as the NAAQS. Therefore, there is no expectation that the ratio of the NAAQS to an occupational standard would be a basis for selecting a NAAQS.

(7) *Comment:* NESCAUM argues that "while ozone rapidly oxidizes NO to NO_2, there is usually insufficient ozone to produce substantially elevated levels of NO_2 from this reaction in near-roadway exposure scenarios during morning rush hours, nighttime, and at least half of the year (during the non-ozone season)."

Response: While EPA acknowledges that the extent to which NO_2 concentrations near roads are elevated will vary with ozone concentrations, we disagree with the conclusion

that NO_2 concentrations near roads are not usually elevated substantially. As discussed in the final rule (sections II.A.2 and II.F.4), elevated NO_2 concentrations do occur on and around roads and people who live, work, and/or attend school near major roads, or commute in vehicles on major roads, can be exposed to these elevated concentrations. For example, based on NO_2 monitoring studies 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). In addition, a considerable fraction of the population resides, works, or attends school near major roadways and 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).[8] Furthermore, in California, 2.3% of schools with a total enrollment of more than 150,000 students were located within approximately 500 feet of high-traffic roads (ISA, section 4.4).

(8) *Comment:* Harris County Public Health and Environmental Services (HCPHES) noted that EPA's REA "concludes that it is appropriate to focus on studies that evaluated NO_2 health effect associations using both single- and multi-pollutant models. However, HCPHES believes that insufficient study and attention has been given to such synergistic effects. Because of this insufficiency, HCPHES believes that EPA should include an adequate margin of safety and set the one-hour standard sufficiently below the upper limit of 100 ppb leaning more towards the bottom end of the proposed range."

Response: The Administrator's decision on standard level, including her consideration of the requirement to provide an adequate margin of safety, is discussed in detail in section II.F.4.d of the final rule.

(9) *Comment:* AASHTO recommended that EPA should not set its NO_2 standard below background concentrations of NO_2 in order to avoid making the standard unattainable.

Response: As described in detail in section II.F.4.d of the final rule, the Administrator has set an NO_2 NAAQS that, in her judgment, is requisite to protect public health, including the health of sensitive subpopulations, with an adequate margin of safety. In setting such a standard, the Administrator is prohibited from considering such factors as

[8] The most current American Housing Survey (http://www.census.gov/hhes/www/housing/ahs/ahs.html) is from 2007 and lists a higher fraction of housing units within the 300 foot boundary. 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.

projections of areas that will or will not attain the standard. However, EPA notes that we are unaware of any locations with nonanthropogenic background concentrations that would exceed the standard.

3. Comments on the annual standard

(1) *Comment:* With regard to an annual standard, CASAC and a 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 NTAO; environmental/medical/public health groups including ACCP, ALA, AMA, ATS, CAC, EDF, EJ, GASP, NACPR, NAMDRC, NRDC; and industry groups including AAM, API, Dow, INGAA, UARG) 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).

In their comments on the final REA, 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, 2008). A number of State agencies and organizations and industry groups 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 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.[9]

Response: EPA's response to these comments, and the Administrator's conclusions on the annual standard, are discussed in section II.G of the final rule.

(2) *Comment:* Several petroleum industry commenters (API, UPA, IPAMS, PAW, UARG) claimed that EPA did not provide a rationale for changing the units of the annual standard. These commenters assert that the proposal to express the level as 53 ppb is different from the current standard which also expresses the level in terms of

[9] These groups also cited a recent study by Karr et al. (Influence of Ambient Air Pollutant Sources on Clinical Encounters for Infant Bronchiolitis. *Am. J. Respir. Crit. Care. Med.* (2009), Aug. 27, epub ahead of print).

micrograms/m^3 (100 micrograms/m^3). These commenters claim that by shifting to ppb, the stringency of the standard is increased for higher elevations (i.e., at sea level 53 ppb = 100 microgram/m^3, but at 5,000 ft, 53 ppb = 84 micrograms/m^3). PAW specifically stated that "the change in the annual standard from the current mass and volume concentration to a strictly volume concentration represents a significant and unjustified tightening of the standard for high altitude areas, which includes many of the areas in which the oil & gas industry operates in the western states."

Response: The issue raised in the comments is attributed to the mathematical conversion between ppb (a mixing ratio, by volume) and micrograms per cubic meter ($\mu g/m^3$), which is a mass-based metric. According to the ideal gas law (PV=nRT) the number of molecules (n) are proportional to their volumes (V) which in turn is proportional to their pressures (P). Since the total air pressure, and hence the concentration of air, decreases with altitude, a constant mixing ratio will not translate into a constant concentration. Typically, when converting from ppb to $\mu g/m^3$, scientists standardize the process by using a standard pressure and temperature, e.g., 1 atm and 25 C, respectively, in the conversion calculations. This standardization results in the apparent difference in mass concentration provided as an example by the commenter.

EPA notes that "parts per" concentration, such as parts per billion (ppb) or parts per million (ppm), etc., are mixing ratios, and are very common units for measuring gas phase species. Further, the use of mixing ratios is widespread for expressing the relative amounts of species at various altitudes. The chemiluminescence FRM for the NO_2 NAAQS provides in-situ concentration information, in a mixing ratio by volume (e.g., ppb), that is compensated for both temperature and pressure. As a result, chemiluminescence FRM-produced data, which measures concentrations from a known volume of air, is not subject to variation due to ambient temperature or pressure (e.g., altitude).

The parenthetical in the existing standard was intended to be informative, indicating the mass-based measurement corresponding to the level of the standard at standard temperature and pressure. The parenthetical did not create a second standard, allowing compliance with either measurement depending on ambient temperature or pressure, and therefore deletion of the parenthetical is not a change to the standard. Since the FRM is not subject to variation due to ambient temperature or pressure, the ppb level is the only measurement relevant to attainment. However, EPA recognized that the presence of the parenthetical in the standard could be confusing, and determined it was appropriate to delete it to clarify the standard.

V. Technical Issues with Monitoring Requirements

A. Comments on near-road monitor siting requirements

(1) *Comment*: Some state agencies (e.g., AASHTO, NYSDOT, and WIDNR) recommended that the maximum horizontal distance be increased from the proposed 50 meters to as much as 200 meters, noting that a 50 meter limit would be infeasible for many locations and could create a serious safety hazard for monitoring staff and the general public. In contrast, several environmental, and industry groups (e.g., GASP and AQRL) supported the proposed range, and in GASP's case, supported reducing the maximum distance to 30 meters or less in order to reduce the potential variation in roadway distance between monitoring sites and subsequent measurements of near-road NO_2 concentrations.

Response: EPA's decision on the siting criteria for NO_2 monitors requires, among others, that the near-road NO_2 monitors be sited within 50 meters from the roadway. EPA discusses the basis for this decision in detail in section III.B.7 of the preamble to the final rule.

(2) *Comment*: A limited number of comments were received recommending changes to the requirements for the vertical height of the NO_2 monitor inlet manifold. Two state organizations (NESCAUM and NYSDEC) noted that the proposed 2-7 meter vertical range could generate significant variation in the concentrations reported from monitors located at different heights. NESCAUM recommended that the height range be reduced to 2.5-3.5 meters. NYSDEC commented that the proposed vertical height range may not be practical for many sites, especially those located in urban areas. In addition, the ALA, EJ, EDF, and NRDC noted that:

> [T]he 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. Additional monitors at other relationships to these sources may be needed for research purposes, but they should be in addition to those designed to establish the peak exposures for NAAQS compliance purposes.

Response: EPA's decision on the siting criteria for NO_2 monitors requires, among others, that the near-road NO_2 monitors inlet manifolds be placed between 2 to 7 meters above the ground. EPA discusses the basis for this decision in detail in section III.B.7 of the preamble to the final rule. With regard to the ALA, EJ, EDF, and NRDC comment on needing additional monitors for research, EPA does not believe that this particular research issue is appropriate to address through this rulemaking, but rather through ongoing and future research that further characterizes the near-road environment. For the purposes of supporting the revised 1-hour NAAQS, EPA believes that the siting criteria are sufficient and appropriate.

(3) *Comment*: Several groups that support the proposed two-tiered monitoring network requested modifications to the proposed criteria for determining where a near-road monitor should be located. Some environmental/public health organizations (ALA, EJ, NRDC, EDF) commented that "Near-road monitor placement should be determined not only by the highest AADT [annual average daily traffic] volumes in a given [core-based statistical area] CBSA, but also by the highest heavy-duty truck volumes." The NYDOH, IADNR, and some industry groups (e.g., EEI and SRNS) recommend making population a prominent consideration when deciding where to locate monitors. HCPHES recommended that near-road monitoring stations should take into consideration the location of other major mobile and point sources for NO_2 emissions, such as airports, seaports, and power plants, or vulnerable population groups like children, when determining the appropriate locations for near-road monitors.

Response: EPA has clarified that the selection criteria should include the consideration of localized factors when identifying locations of expected maximum concentrations. Near-road sites 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 be highest and the siting criteria can be met in accordance with 40 CFR Part 58 Appendix E. EPA discusses the basis for this decision in detail in section III.B.6 of the preamble to the final rule.

(4) *Comment*: Many state agencies commented that EPA needed to provide greater guidance to state and municipal agencies about where to site near-road monitors. The CAC recommended that state discretion over the location of near-road monitors be limited "such that gaming is not tolerated."

Response: EPA agrees that guidance will be useful in aiding the implementation of a near-road network. As noted in the section III.B.5 of the preamble to the final rule, EPA plans to assist state agencies in the network implementation process, particularly through guidance documentation that the Agency intends to prepare and share with state and local agencies early enough in the overall implementation process to be useful to states in developing their NO_2 monitoring network. Further, EPA encourages state and local monitoring agencies to include or cooperate with transportation officials in the development of the near-road network. EPA believes that state and local monitoring agencies may benefit greatly from working with federal, state, and/or local transportation officials during the development of and long-term maintenance of a near-road network.

EPA believes that the commenter's concern that the state discretion allowed in the placement of near-road monitors may lead to installations in locations unlikely to violate the NAAQS, will be avoided due to the process outlined in 40 CFR §58.10 under which a state's annual monitoring network plan must be made available for public inspection or comment and approved by the EPA Regional Administrator. This process will permit scrutiny of the monitor siting locations and assist in identifying and siting monitors in appropriate locations within CBSAs.

(5) *Comment*: CASAC advised that siting monitors based on traffic counts alone might miss locations where maximum NO_2 concentrations would occur. CASAC recommends that EPA should use model results from Congestion Mitigation and Air Quality Land Use Regression modeling as well as Gaussian plume models and emissions inventories to determine where roadside monitors should be located.

Response: EPA does not intend for AADT counts to be the sole basis for choosing a near-road site. EPA has clarified rule language to reflect that 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 the siting criteria can be met in accordance with 40 CFR Part 58 Appendix E. This issue is discussed in section III.B.6 of the preamble to the final rule. EPA also 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

(6) *Comment*: EPA received a number of comments recommending using different population thresholds, or a different approach in requiring near-road monitors. Several commenters (e.g., NESCAUM, NYSDOT, NYSDEC) recommended using a higher population threshold than that proposed, for example, NYSDEC suggested the population threshold be increased to as much as 2.5 million. Conversely, CAC suggested that the proposed threshold may not be low enough. Other commenters (e.g., AASHTO and HCPHES) recommended that EPA use an AADT threshold (ranging from 100,000 to 250,000 AADT), in lieu of a population threshold, to require near-road monitoring. Another commenter, San Joaquin Air Pollution Control District suggested the using a combination of population and AADT thresholds to require near-road monitors.

Response: EPA's decision is to require one near-road NO_2 monitor 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. EPA discusses the basis for this decision in detail in section III.B.2 of the preamble to the final rule.

(7) *Comment:* EPA received comments suggesting that EPA require monitoring at sites non-near-road locations. One commenter (Center on Race, Poverty, and the Environment) recommended that EPA account for populations in rural areas, such as those impacted by agricultural emissions. The Fond du Lac Band of Lake Superior Chippewa and the NTAA suggested that EPA expand monitoring coverage into rural areas and tribal lands. Other commenters (ATS, AMA, NAMDRC, NACPR, ACCP, and the Swinomish Tribe) also recommended that EPA consider sources other than mobile sources, such as large stationary sources.

Response: As discussed in section II.F.4.d of the final rule, the Administrator has set a new 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area. In her judgment, this new standard will protect public health, including the health of sensitive populations such as asthmatics, with an adequate margin of safety. It follows from this standard that monitors should be placed in locations where maximum NO_2 concentrations are expected. The Administrator has judged that, in many areas, these maximum concentrations are likely to occur around major roads (final rule, sections II.A.2 and II.F.4.d). Therefore, she is requiring NO_2 monitors within 50 meters of major roads. In situations where maximum NO_2 concentrations are likely to occur in locations other than near a major road (e.g., near stationary point or area sources, whether agricultural or industrial (such as those noted by the commenters), the Regional Administrator has the authority to require additional monitors in these locations. Further, the Administrator 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 of the preamble to the final rule) 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.

(8) *Comment:* Two tribal commenters (Fond Du Lac Band of Lake Superior Chippewa and the National Tribal Association) recommended that more monitoring stations be required for rural or tribal roadways since EPA recognized Native Americans as an at-risk population group.

Response: As discussed in section II.F.4.d of the final rule, the Administrator has set a new 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area. In her judgment, this new standard will protect public health, including the health of sensitive populations such as asthmatics, with an adequate margin of safety. It follows from this standard that monitors should be placed in locations where maximum NO_2 concentrations are expected. The Administrator has judged that, in many areas, these maximum concentrations are likely to occur around major roads (final rule, sections II.A.2 and II.F.4.d). Therefore, she is requiring NO_2 monitors within 50 meters of major roads. In situations where maximum NO_2 concentrations are likely to occur in locations other than near a major road (e.g., near multiple smaller roads and/or stationary sources), the Regional Administrator will have the authority to require additional monitors in these locations. EPA notes that it is not in a position to require monitoring by tribes or on tribal land. However, EPA has and will continue to work with tribes in conducting ambient monitoring on tribal lands.

(9) *Comment*: One state agency, NYSDEC requested that CBSAs with populations larger than 2.5 million be allowed to have more than two near-road monitors.

Response: EPA's decision is to require, at a minimum, one near-road NO_2 monitor in CBSAs with a population greater than or equal to 500,000 persons and a second near-

road monitor 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. EPA discusses the basis for this decision in detail in section III.B.2 of the preamble to the final rule. EPA also notes that states always have the ability to conduct additional monitoring above the minimum monitoring requirements at their discretion.

(10) *Comment*: Some public health and environmental groups (e.g., ALA, CAC, and NRDC) suggested that near-road monitors should be required to be located on the downwind side of the target road. Conversely, several commenters (AQRL and NYSDEC) suggested that such a requirement may be over restrictive and not necessary. AQRL commented that siting monitors in downwind locations would not be feasible for all locations and EPA should allow upwind monitoring locations so long as upwind monitors are used in conjunction with air dispersion modeling.

Response: EPA is not going to finalize 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. EPA discusses the basis for this decision in detail in section III.B.7 of the preamble to the final rule.

(11) *Comment*: Several commenters (e.g., CASAC, ACCP, ALA, AMS ATS, EDF, NACPR, NAMDRC, NRDC) made comments that the proposed network should form the basis for a broader near-road monitoring network that would encompass other pollutants as well, i.e., be a multi-pollutant near-road monitoring network. These organizations' recommendations were based on the argument that it makes little sense to only monitor NO_2 concentrations near roads when it is well-understood that many other pollutants, hazardous to the public's health, are emitted by on-road vehicles along with NO_2.

Response: The scope of this rulemaking pertains to the NO_2 NAAQS and the monitoring associated with it. However, EPA agrees that multi-pollutant monitoring is desirable, and believes that the sites required in the near-road component of the NO_2 network design could also be suitable for monitoring other pollutants including carbon monoxide, particulate matter (especially ultra-fine particulate matter), air toxics, and black carbon.

(12) *Comment*: Comments were submitted, particularly from state agencies (e.g., Michigan, Mississippi, and Tennessee), noting that one of the challenges to developing a near-road monitoring network was the potential safety hazard of having a monitoring station located within 50 meters of busy roadways.

Response: EPA notes that in all instances of field work, safety is a top priority. EPA believes that the safety issue raised in public comments is something that is an important component of near-road siting logistics, and that the near-road network can be safely implemented while still serving its intended purpose of providing data on the expected maximum NO2 concentrations that occur within 50 meters of heavily trafficked roads.

EPA discusses this issue in further detail in section III.B.7 of the preamble to the final rule.

(13) *Comment:* The Clean Air Council (CAC) recommended the "EPA not permit alternative monitoring systems on a state-by-state basis if they would hinder uniformity to the extent that public understanding and accountability of government would be degraded." In contrast, the Southeast Michigan Council of Governments (SEMCOG) suggested that, rather than requiring a near-road monitoring network, EPA should enable states to select monitoring locations based on each state's specific needs and issues as part of the state implementation plan (SIP) process.

Response: EPA believes that it must use, and has chosen, a balanced approach in setting monitoring requirements that recognizes the need to have as nationally consistent monitoring network as possible, while allowing an appropriate amount of flexibility so that states are able to comply with monitoring requirements. EPA believes that the near-road site selection process must include certain considerations such as AADT, fleet mix, roadway design, congestion patterns, terrain, and meteorology to identify where maximum hourly NO_2 concentrations are expected occur. While states have flexibility in evaluating what specific thresholds or criteria are appropriate for their particular situations with respect to the metrics listed above, they are to make all effort to meet the primary objective of locating the site in a location of expected concentration. This flexibility is necessary when considering the reality of, for example, safety or site access, and other logistical issues that are inherent to installing a monitoring network that can differ on a case-by-case basis. EPA discusses issues of site selection and siting criteria in further detail in sections III.B.6 and III.B.7 of the preamble to the final rule.

(14) *Comment:* The Spokane Regional Clean Air Authority (SRCAA) noted that it might not be necessary for EPA to require an extensive near-road monitoring network if a smaller network can develop a strong statistical correlation between particular variables (i.e. traffic density, vehicle mix) and above-standard NO_2 concentrations.

Response: EPA believes that the currently available data, and the number of variables that influence the concentration and behavior of NO_2 in the near-road environment, including fleet mix, roadway design, congestion patterns, terrain, and meteorology, do not allow the development of a "strong," and nationally applicable, statistical correlation that would allow the avoidance of what the commenter states is an "extensive" near-road network. (EPA estimates that approximately 126 near road monitors will be needed.) The reasoning behind the size and extent of the near-road monitors required in the two-tier network design, with respect to SRCAA's comments, are discussed in detail in sections III.B.1 and III.B.2 of the preamble to the final rule..

(15) *Comment:* Several environmental and public health groups (e.g., ALA, EDF, EJ, NRDC) pointed out that "only 58 of 489 total NO_2 monitors are sited in areas of expected peak concentrations."

Response: The relative current state of the NO_2 network is detailed in the NOx Network Review and Background document (Watkins and Thompson, 2009), which is posted in the docket. This document provides information and summaries on what EPA believes the current monitoring network, according to state provided meta-data, is addressing.

B. Comments on area-wide monitor requirements

A number of comments were received, particularly from state agencies, in support of maintaining the existing area-wide monitoring network. Comments specific to the siting or area-wide monitors tended to focus on either (1) the need for more area-wide monitors than the proposed 52 or (2) the need to make sure that all area-wide monitors were measuring ambient NO_2 concentrations rather than NO_2 concentrations near major NO_2 emissions sources.

(1) *Comment*: Several industry groups and state agencies (e.g., AAM, EMA, INDEM, and NYSDOT) provided specific comments that they preferred the alternative monitoring approach of using area-wide monitors to measure 1-hour NO_2 concentrations due to the high cost of implementing, operating, and maintaining a near-road monitoring network and the uncertain benefits such a network would provide. In addition, one commenter recommended the area-wide approach because it provided greater flexibility for monitors to be located in places where more people are likely to be exposed to high concentrations of NO_2.

Response: The Administrator has set a new 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area. In her judgment, this new standard will protect public health, including the health of sensitive populations such as asthmatics, with an adequate margin of safety. It follows from this standard that monitors should be placed in locations where maximum NO_2 concentrations are expected. The Administrator has judged that, in many areas, these maximum concentrations are likely to occur around major roads (final rule, sections II.A.2 and II.F.4.d). Therefore, the Administrator has concluded 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 highest 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. The rationale for this decision is discussed in section III.B.1 of the preamble to the final rule.

(2) *Comment*: Several environmental, public health, and tribal organizations (ALA, EDF, EJ, NRDC, NTAA) commented that EPA should require more monitors than currently proposed. Specifically, the ALA, EJ, NRDC, and EDF stated that they "oppose the proposed requirement to retain only 52 air monitors to measure area wide concentrations NO_2" In addition, they commented:

"[The] 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. In particular, certain large agricultural facilities may emanate high concentrations of NO_2 under certain conditions, such as wet weather. Many of these facilities are directly upwind of rural communities, meriting an NO_2 monitor."

Response: EPA recognizes a variety of exposure scenarios can occur in an area such as the ones described by the commenters above. Therefore, the final rule authorizes Regional Administrators to require additional monitors above the minimum required number of monitors in circumstances such as those described by the commenter above where there is a likelihood of high concentrations of NO_2 that approach or exceed the NAAQS. The size and extent of the required area-wide monitors in the network design are discussed in section III.B.3 of the preamble to the final rule. A more detailed discussion of the Regional Administrator authority and some examples where such authority may be exercised is in section III.B.4 in the preamble to the final rule.

(3) *Comment*: One state agency provided comments opposing using only an area-wide network for monitoring NO_2 on the grounds that the network represents an inadequate alternative to the creation of a near-road monitoring network. The commenter was critical of how useful dispersion modeling would be at identifying NO_2 concentrations beyond a monitor's immediate area. The commenter claimed there were too many confounding factors to accurately estimate the NO_2 concentrations near roadways and other NO_2 emissions sources from an area-wide monitor.

Response: The Administrator has set a new 1-hour NO_2 standard that reflects the maximum allowable NO_2 concentration anywhere in an area. In her judgment, using only an area-wide network of NO_2 monitors would not adequately support this new standard because maximum concentrations of NO_2 are likely to occur around major roads (final rule, sections II.A.2 and II.F.4.d)]. The Administrator has concluded 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 highest 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. The rationale for this decision is discussed in section III.B.1 of the preamble to the final rule.

(4) *Comment*: One commenter, Dow, recommended that area-wide monitors should be located at least 1,000 meters 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.

Response: EPA believes that Table E-1 of 40 CFR Part 58 Appendix E, which provides roadway set-back distances for neighborhood and larger scale sites is appropriate to use to ensure that any NO_2 site that is intended as an area-wide site will be located at a sufficient distance from any major road. This issue is discussed section III.B.8.of the preamble to the final rule.

(5) *Comment:* NYSDEC encourages EPA to develop a table for defining the minimum distance to the nearest major roadway that can be used to calculate the area-wide NO_2 concentrations, since specific distances are unlikely to be appropriate for all core based statistical areas (CBSAs).

Response: EPA believes that existing data in 40 CFR Part 58 Appendix E, Table E-1, are appropriate for use in determining the minimum distance a monitoring site must be from a road with a given annual average daily traffic count to be considered a neighborhood or larger spatially representative site. If a state feels that an increased minimum distance compared to Table E-1 is appropriate for an area-wide site in one or more of their particular CBSAs, or on a case-by-case basis, the state can elect to site their area-wide monitors accordingly, so long as they continue to meet siting and network design requirements specified in 40 CFR Part 58.

(6) *Comment:* Several environmental and public health groups (e.g., ALA, EDF, EJ, NRDC) opposed the proposed requirement to retain only 52 air monitors to measure area wide concentrations NO_2.

Response: EPA is not requiring that the current NO_2 network be reduced; rather, EPA has introduced minimum monitoring requirements where there was previously no minimum NO_2 monitoring requirement. This issue is discussed in section III.B.8 of the preamble to the final rule. Further, the relative current state of the NO2 network is detailed in the NOx Network Review and Background document (Watkins and Thompson, 2009), which is posted in the docket. This document provides information and summaries on what EPA believes the current monitoring network, according to state provided meta-data, is addressing.

C. Comments on the need for a research monitoring network

A number of commenters, primarily from industry groups and state agencies recommended that some form of near-road research monitoring network be utilized before a full-scale near-road monitoring network is implemented.

(1) *Comment*: A subset of CASAC panel members recommended establishing a limited roadside monitoring network (20 to 50 monitors in different cities) for the purpose of informing the development of a national network. Specifically, these CASAC member recommended the following:

- A small roadside network could provide more information than a national network of NO_x monitors if the smaller network also monitored other roadway-associated pollutants, including CO and continuous particulate matter (PM) with speciation, and if the network also included detailed meteorological measurements and automatic traffic counters. They note that measuring only NO_2 could lead to the mistaken impression that air quality is deteriorating as diesel particulate filters, which can increase the fraction of NO_x that is emitted as NO2, become more common.

- If EPA undertakes near-road monitoring, the Agency should seek the advice of technical experts, such as those in the CASAC Ambient Air Monitoring and Methods (AAMM) subcommittee.
- Siting criteria should include consideration of such factors as vehicle mix, location of susceptible or vulnerable populations (e.g., schools, hospitals), local physical features such as urban street canyons.
- Such a network should be established quickly to capture ongoing changes in mobile source emissions and should be funded primarily by EPA.

Response: The Administrator has judged that a regulatory, two-tier network design, which includes near-road monitors in urban areas (not a research network), is necessary to support the intent of the revised NAAQS to protect against risks associated with exposures to peak concentrations of NO_2 anywhere in an area. This rationale is discussed in section III.B.1 of the preamble to the final rule. EPA believes that it will be useful to provide guidance to ensure consistent implementation of the monitoring network and has committed to engage the CASAC AAMM subcommittee on this effort, and discusses this issue in section III.B.5 of the preamble to the final rule. In regard to measuring other roadway-associated pollutants, the scope of this rulemaking pertains to the NO_2 NAAQS and the monitoring associated with it. However, EPA agrees that multi-pollutant monitoring is desirable, and believes that the sites required in the near-road network design could be suitable for other pollutants including carbon monoxide, particulate matter (especially ultra-fine particulate matter), air toxics, and black carbon.

(2) *Comment*: Some industry commenters (e.g., CE, EEI, NAM, NPRA, NMC, OIPA, POH, SRNS, SCCC, and SCMA) provided support for a research monitoring network due to perceived weaknesses in the scientific basis for implementing an extensive near-road monitoring network. Generally indicating that a research network would allow EPA to gain a better understanding of near-road peak NO_2 concentrations and their impact on public health before requiring the development of a large and expensive monitoring network. For example, NAM commented:

> If EPA concludes that NO_2 near roadway monitoring is required, the NAM recommends at a minimum, EPA should consider conducting a near roadway "special purpose" monitoring network program. Conducting such a near road 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.

Response: The administrator has judged that a regulatory, two-tier network design, which includes near-road monitors in urban areas (not a research network), is necessary to support the intent of the revised NAAQS to protect against risks associated with exposures to peak concentrations of NO_2 anywhere in an area. EPA believes that the existing near-road research provides a sufficient base of information to implement an appropriately designed near-road monitoring network, and the collective experience that

exists in the ambient monitoring community will allow for successful implementation of that network. EPA discusses the basis and rationale for the two-tier network design, which include near-road monitors for regulatory purposes in section III.B.2 of the preamble to the final rule.

(3) *Comment*: Some state groups (e.g., AASHTO, ILEPA, MIDEQ, MSDEQ, NACAA, NCDENR, NESCAUM, NMED, SCDHEC, SJAQMD, and VDOT) focused their support for a research monitoring program by identifying a need to develop more experience siting near-road monitors. Creating greater certainty about where and how near-road monitors ought to be used could reduce variations in measurement results driven solely by differences in monitor siting. These comments are exemplified by NACAA's comment:

> …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.

Response: The Administrator has judged that a regulatory, two-tier network design, which includes near-road monitors in urban areas (not a research network), is necessary to support the intent of the revised NAAQS to protect against risks associated with exposures to peak concentrations of NO_2 anywhere in an area. EPA believes that the existing near-road research provides a sufficient base of information to implement a appropriately designed near-road monitoring network, and the collective experience that exists in the ambient monitoring community will allow for successful implementation of that network. EPA discusses the basis and rationale for the two-tier network design, which include near-road monitors for regulatory purposes in section III.B.2 of the preamble to the final rule.

(4) *Comment:* The CASAC panel members who support the alternative approach, which is coupled to a monitoring network that includes only area-wide monitors, stated that roadside monitors will likely detect extreme concentrations of NO_2 at certain times (e.g., heavy traffic, idling truck near monitor) and more effort is needed to characterize these measurements and their relationship to traditional area-wide measurements.

Response: EPA believes that some urban areas that will have both area-wide monitors (whether required or not) and near-road monitors may be able to provide data to increase the understanding or possibly quantify the relationship (at least for that particular area) between near-road and area-wide concentrations. Intense investigation of the roadway gradient has been, and will continue to be best served by research studies that utilize transect monitoring and/or saturation monitoring around target road segments.

(5) *Comment:* The CASAC panel members who support the alternative approach, which is coupled to a monitoring network that includes only area-wide monitors, stated that the

siting of the near-road monitors will require consideration of many factors as the monitors will be sensitive to the microscale environment of the location. Because the monitors will capture concentrations at the extreme end of the range, the data from any two given monitors may not be directly comparable if the characteristics of their sites vary greatly.

Response: EPA understands that near-road sites will be microscale in nature, and concentrations at the site will be subject to factors including AADT, fleet mix, roadway design, congestion patterns, terrain, and meteorology. As a result, EPA would expect site to site differences corresponding to variability in the above factors. However, 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. The required near-road monitoring sites are intended to measure the maximum expected concentrations, considering the above factors.

(6) *Comment:* The CASAC panel members who support the alternative approach, which is coupled to a monitoring network that includes only area-wide monitors, stated that siting monitors based on traffic count alone may miss locations where maximum concentrations of NO_2 occur. EPA should investigate model results from Congestion Mitigation and Air Quality (CMAQ) Land Use Regression modeling as well as Gaussian plume models and emissions inventories to determine where roadside monitors should be located.

Response: As noted in section III.B.6 of the preamble to the final rule, EPA does not intend for AADT counts to be the sole basis for choosing a near-road site. EPA understands that 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, which influence where the location of expected maximum NO_2 concentration may occur, when evaluating a pool of candidate near-road monitoring sites. Further, EPA expects that modeling will be a tool used by states to assist in informing where near-road monitoring sites should go.

(7) *Comment:* The CASAC panel members who support the alternative approach, which is coupled to a monitoring network that includes only area-wide monitors, commented that diesel particle filters increase the fraction of NO_2 in NO_x and may lead to higher measured concentrations of NO_2 in places where vehicles are actually cleaner.

Response: EPA notes that the required near-road NO_2 monitors are to be sited in locations that are expected to measure maximum NO_2 concentrations. The issue of whether the fleet, or a component of the fleet, travelling on the target road is relatively dirty or clean is part of consideration of fleet mix that states are to consider when identifying near-road site locations.

(8) *Comment:* Many state and industry commenters (e.g., NACAA, NESCAUM, many states, Consumers Energy, EA, EEI, NAM) recommended that a near-road research monitoring program be implemented before a full-scale near-road monitoring network is required. Specifically, EA recommended that a near-road monitoring network not be required until enough near-road monitoring data was available to ensure that EPA's proposed NO_2 level is not set below background NO_2 levels.

Response: The EPA believes that is has sufficient understanding of the near-road environment from existing research to propose a near-road network that is appropriate for regulatory use. This issue is discussed in issue in section III.B.2 of the preamble to the final rule. In addition, as discussed in section II.F.4.d of the preamble to the final rule, the Administrator has set the level of the 1-hour standard at 100 ppb to protect public health with an adequate margin of safety. Her decision is based on consideration of available health evidence, exposure/risk information, the advice of CASAC, and input from the public.

D. Justification of meteorological measurements

Most commenters did not mention the issue of meteorological measurements but the comments received on the subject were unanimously against requiring monitoring stations to include three-dimensional anemometry equipment.

Comment: CASAC Panel members and a number of state commenters (e.g., AKDEC, NCDENR, SCDHEC, and WIDNR) questioned the need for meteorological measurements at the NO_2 monitoring sites. These commenters called into question the ability of three-dimensional anemometry to provide the microscale meteorological information EPA desires if the monitors are to be located close to the ground and other structures, and if they are averaging measurements over hour long periods of time. SCDHEC commented that the recording of air turbulence data at monitor stations ought to be encouraged but not required unless EPA were willing to fully fund the purchase, installation, and operation of the necessary equipment. These commenters concluded that the requirement to include equipment for measuring meteorological characteristics would be an unnecessary expense.

Response: EPA has chosen not to finalize a requirement for meteorological measurements, including three-dimensional anemometry, at near-road NO_2 monitoring stations, but does encourage states to perform meteorological monitoring to better characterize the behavior of NO2 cocentrations in the near-road environment. EPA discusses its rationale for this decision in section III.B.9 of the preamble to the final rule.

E. Monitoring technology

Commenters (CASAC Panel members, some state agencies, and some industry groups) who expressed an opinion regarding monitoring techniques generally agreed that the proposed chemiluminescence approach is appropriate. However, some groups (e.g., CASAC and industry) recommended that EPA promote the development of additional methods for measuring true NO_2 that would not be subject to positive interference.

(1) *Comment*: Several commenters (e.g., MODNR, SRNS, Teledyne API, and UARG) recommended that EPA encourage the development of alternative monitoring technologies, which includes the photolytic-chemiluminescence method or cavity ring-down spectroscopy, and to permit the use of these technologies for monitoring if the new technologies provide comparable or better monitoring results than existing FRM/FEM [Federal Reference Method/Federal Equivalent Method]. NCDENR urged EPA to maximize the flexibility in the choice of FRM and FEM technology available to demonstrate compliance so long as the technology provides comparable results.

Response: The FRM/FEM program ensures that only evaluated and approved methods may be used for comparison to the NAAQS (see 40 CFR Part 53). EPA only approves a particular method for use in measuring oxides of nitrogen once it has been shown to meet requirement set forth in 40 CFR Part 50 Appendix F, with testing and data provided usually provided by instrument vendors. The use of FRM/FEMs and furthering method technologies is discussed in section III.A.1 of the preamble to the final rule.

(2) *Comment*: One industry commenter, Aerodyne, expressed concern that current NO_2 monitoring equipment and siting protocols will not be suitable for use in near-road applications without proper reconfiguration. The commenter notes that the method by which the chemiluminescence FRM determines NO_2 concentrations, using alternating measurements of NO and NO_X and subsequently using the difference to indicate NO_2, may not be appropriate because this technique does not possess the time response required to accurately track the plumes of combustion gas emitted by passing vehicles. The commenter notes that these plumes "tend to be short-lived, with durations on the order of 3 to 30 seconds." As a result, the commenter asserts that the values reported by chemiluminescence FRMs "…can be quite inaccurate because of the inability of the alternating channel monitors to properly average these plumes." The commenter goes on to note that this issue "…begs the question of whether any of this affects reported 1 hour average NO_2 concentrations, the subject of the proposed regulations."

Response: The "alternating measurement" technique utilized by the chemiluminescence FRM is asserted by the commenter to cause variability in measuring short duration plumes or 'bursts' of NO_2. EPA believes this variability would be most apparent when there is only one plume, or a few individual plumes, that may pass the monitor for a short period of time, but is unlikely to cause a discernable effect in the 1-hour average. EPA believes that this particular characteristic of the chemiluminescence FRM does not warrant a new measurement approach for near-road monitors because the averaging time of the NAAQS is 1 hour. The NAAQS is a 1-hour standard, which EPA believes is a long enough averaging period where short-term variations, on the order of 3 to 30

seconds will be averaged out, an are not expected to have a discernible effect. The commenter states that "It has always been (rightly) assumed that when reporting 24 hour and /or yearly averages, the short term upsets observed in the NO2 data have no discernible effect." EPA notes that states calculate 24-hour and annual averages from the 1 hour averages they acquire each day.

The commenter suggests several alternatives to relying on a single chemiluminescence analyzer at near-road sites. EPA has expressed its desire to further the development of alternative methods in determining NO_2 concentrations, which is discussed in section III.A.1 of the preamble to the final rule, and also is open to alternative applications of existing methods, all of which would need to follow the process for submission and approval described in 40 CFR part 53.

(3) *Comment*: Some industry commenters expressed concern that open path monitors might not be appropriate for use in near-road applications.

Response: EPA notes that path integrated optical remote sensing techniques, also known as open-path methods, are not typically used by states at State and Local Ambient Monitoring Station (SLAMS) sites. However, there are approved open-path methods capable of providing hourly NO2 concentrations that can be compared to both the annual and 1-hour standard. EPA believes that an appropriate path length is between 50 meters to 300 meters, where 50 corresponds to the maximum distance away from the edge of the nearest traffic lane of a nearby road segment and 300 meters corresponds to the traditional maximum path length at micro- or middle scales site. EPA recognizes that if open path methods are going to be used in the near-road environment, issues regarding path orientation, safety, and optimal path length within the allowable range will likely be considered in the monitoring guidance that will need to be developed to assist states in the implementation of the network design.

(4) *Comment*: One industry commenter, AQRL, requested that EPA set guidelines for the maximum allowable inlet length and sample residence time.

Response: EPA has only chosen to set a maximum residence time of NO_2 in the sample line between the inlet probe and the analyzer of 20 seconds. EPA discusses this issue in section III.B.7 of the preamble to the final rule.

(5) *Comment*: API commented that, because state and local air monitoring agencies have little experience in near-road NO_2 monitoring, EPA needs to be prepared to support significant field validation and statistical analysis to assess monitor performance and dispersion and photochemical modeling analyses to assist in siting monitors.

Response: EPA believes it has systems in place that can provide "field validation and statistical analysis" of any ambient monitoring network. Field validation and statistical analysis starts with the initial testing of instruments to ensure that they are operating properly and providing precise and unbiased measurements before monitoring begins. All

monitoring organizations are required to have quality management plans and quality assurance project plans that provide the necessary elements to help in their achievement of the NO2 data quality goals. In addition, the quality assurance (QA) requirements in 40 CFR part 58 Appendix A provide the quality control samples, the auditing activities and the appropriate statistical analysis that monitoring organizations and EPA can use to judge whether the monitoring systems are under control from a data quality standpoint.

(6) *Comment*: Several state commenters (e.g., MODNR and NCDENR) suggest that the current bias measurement uncertainty criteria used for other NAAQS will be appropriate and acceptable for use with a 1-hr NO_2 standard.

Response: EPA is finalizing the approach to develop data quality objectives, and is changing the proposed goal for measurement uncertainty, to match those criteria of the NCore network and the historical approach for NO_2, where the goals for acceptable measurement uncertainty for NO_2 methods for precision is an upper 90 percent confidence limit for the coefficient of variation (CV) of 10 percent and for bias is an upper 95 percent confidence limit for the absolute bias of 15 percent.
This issue is discussed section III.C of the preamble to the final rule.

(7) *Comment*: A state commenter, IADNR, recommend allowing provisions for mobile monitoring to determine NO_2 exposure to motorists.

Response: The use of mobile monitoring may be a very beneficial tool to assist states in locating candidate near-road NO_2 sites; however, EPA does not believe that mobile monitoring is suitable for regulatory monitoring. The network design is predicated on placing monitors in the location of expected maximum concentration, which is inherently in a generally fixed location. Further, much consideration would have to be given to issues regarding the deviation from the standard practice of using fixed point (or fixed path-integrated) data for comparison to the NAAQS. Another issue that would arise would be regarding data completeness and representation, e.g. at what time and where the data are valid, and whether the data are representative of a given location. EPA is encouraged by the interest in mobile monitoring, but we believe that such monitoring is currently best suited for non-regulatory informational purposes.

F. Timing of monitor deployment

In general, the majority of comments about the timing of monitor deployment, State Implementation Plan (SIP) development, and determination of attainment were received from state agencies and industry groups recommending that EPA keep the proposed current implementation deadlines as proposed or extend the deadlines further. A few environment and public health groups provided comments urging EPA to move the implementation deadlines forward. [who were the commenters among the states, industry and enviros?]

Comment: A lage majority of state and industry groups who made comments on network implementation recommended that the deadline for installing near-road monitors remain January 1, 2013, or that EPA provide the maximum amount of time possible. They

claimed that the current January 1, 2013 deadline provides insufficient time to plan and implement such a complicated network of monitors. SJAQMD went further, recommending that EPA allow for schedule relief if a state can demonstrate that monitor installation delays are the result of delays in obtaining permits or rights-of-way for the near-road monitors. Conversely, the environmental and public health groups who made comments on network implementation recommended that urged "EPA to seek Congressional funding for an expanded network and to set a deadline for deployment of no later than January 1, 2012."

Response: EPA recognizes the need to aid state agencies in the network implementation process, particularly through guidance documentation that will be developed in partnership between EPA and various stakeholders including NACAA and the states. Further, EPA has modified the timelines for implementation by 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 from July 1, 2011 to July 1, 2012. However, 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. The basis and rationale for this decision is discussed in section III.B.5 of the preamble to the final rule.

G. Other monitoring issues

Many comments about the monitoring network associated with a one-hour standard were also submitted, including comments on what should be considered an exceptional event and the appropriate requirements for using data from monitors for evaluating attainment.

(1) *Comment:* Some commenters urged EPA to create criteria for defining exceptional events for near-road monitors that included events like road construction.

Response: The Exceptional Events Rule (EER) and the accompanying preamble (72 FR 13560, March 22, 2007) set forth and explain the criteria and procedures that must be used to determine whether an event qualifies as an exceptional event and the documentation that must be submitted to support an exceptional events claim. For an exceptional event claim to be approved and data affected by such an event to be excluded from consideration in any NAAQS attainment designations, the data would need to meet the criteria and procedures established in the rule. EPA believes that these criteria and procedures are sufficient to address any exceptional events claims that may arise for NO2 NAAQS. Additions or modifications to the EER are not needed for any exceptional events claims that may arise for NO2. In addition, the current exceptional event data flags available in the AQS--unique traffic disruption and other-- provide sufficient flexibility to address near-road exceptional events.

(2) *Comment:* One state commenter, NYSDOT, recommended (if EPA chose to finalize the two-tier network design which included near-road monitoring) that "EPA establish national guidance so there is reasonable uniformity among EPA regions in the implementation of these provisions."

Response: EPA notes that network consistency, from site to site, is achieved in ambient monitoring networks by the adherence to monitoring regulations and through the use of guidance. EPA has detailed siting criteria as specific as we believe is necessary and appropriate to develop a consistent monitoring network , while allowing some necessary flexibility for logistical considerations that will occur on a case-by-case basis. Further, EPA recognizes the need to aid state agencies in the network implementation process, particularly through guidance documentation that will be developed in partnership between EPA and various stakeholders including NACAA and the states. This issue is discussed in section III.B.5 of the preamble to the final rule.

(3) *Comment:* Some commenters recommended that the annual primary standard design value be calculated by averaging all 1-hour values for the year, while a third commenter recommended the design value be calculated by averaging within calendar quarters before averaging across calendar quarters.

Response: This issue is discussed in the final notice (Section IV.A).

(4) *Comment:* Several comments were made in regard to EPA's data completeness test. For example, three commenters agreed that the completeness test ought to stay at 75% for each quarter while a fourth commenter recommended the percentage be increased to 82%.

Response: This issue is discussed in the final notice (Section IV.B).

(5) *Comment:* A comment from a State agency noted that the proposed 75% capture requirement was inappropriate and should not be used for a 1-hr NO_2 standard.

Response: This issue is discussed in the final notice (Section IV.B).

(6) *Comment:* A commenter requested that EPA truncate NO_2 concentration measurements rather than rounding them.

Response: EPA agrees with this comment, as reflected in the final notice.

(7) *Comment:* An industry group requested that EPA further clarify the guidelines for situations where incomplete monitoring data could be considered valid.

Response: The rule text identifies factors for the administrator to consider in determining when to use such data. No further clarification is necessary because the variety and uniqueness of such situations require that they be treated on a case by case basis.

(8) Comment: One commenter expressed concern that the use of near-road monitoring would lead to near-source monitoring for other point sources of NO_2 and other pollutant emissions.

Response: EPA is establishing a two-tier monitoring network, which includes both near-road and area-wide monitoring, under this rule. EPA does not believe that near-road monitoring will directly result in non-near-road monitoring. However, EPA recognizes that in certain circumstances, there can be an area or areas of expected maximum concentrations of NO2 due to non-road, point, or area sources, that may not be monitored even though a state is fulfilling its minimum monitoring requirements. EPA has included a mechanism to deal with such circumstances by providing the Regional Administrator with the authority to require additional monitors above those minimally required. This issue is discussed in section III.B.4 of the preamble to the final rule.

(9) *Comment:* A State agency recommended that EPA allow averaging across monitors for design value calculations and substitution of values from additional monitors for the primary monitor, for example, if the primary monitor is taken offline for quality control (QC) during a high pollutant period.

Response: This issue is discussed in the final notice (Section IV.B).

VI. Air Quality Index

(1) *Comment:* Many State agency commenters discouraged the use of near-road concentrations in calculating the AQI since near-road NO_2 concentrations do not represent exposure of the general public to ambient NO_2. Several other commenters, including NACAA, expressed concern that using near-road monitors for calculating the AQI could diminish the value of the index as a metric for reporting air quality to the general public by making it sensitive to NO_2 concentrations that are present only in small areas. CASAC also raised questions about how the AQI would be affected by roadside monitors. An additional commenter noted that it would be difficult to forecast the AQI for regions where near-road monitoring stations existed, since near-road NO_2 concentrations are likely to be unpredictable.

Response: The response to this comment on the AQI is discussed in section VII of the final rule.

(2) *Comment:* The ALA, EJ, EDF, NRDC support setting the 100 level of the AQI at 50 ppb and the level of the "moderate" category well below 50 ppb (i.e., 25 ppb). These commenters disagree with EPA's proposal to maintain the breakpoints at the higher end of the AQI scale (i.e., 200 to 500). They note that the 500 level has not been changed in the last 22 years, and EPA cannot claim that it represents the most up-to-date scientific evidence without more extensive review. They also note that the proposed 200 level for NO_2 is too high, relative to the 100 level, given the relationship between these levels for other pollutants. As a result, these commenters recommend that EPA "establish a meaningful and practical scale of levels of concern and graduated cautionary statements for both sensitive groups as well as the general population" based on the current scientific evidence.

In addition, NACAA expressed support for the "EPA's proposed range of 0.040 to 0.053 ppm for the AQI value of 50 and 0.360 and 0.370 ppm for the AQI value of 150." But NACAA did express some concern that it might make for a "confusing outreach message if the AQI level of 50 is set below the annual standard of 0.053 ppm" since this would mean that state and local air agencies would "be forecasting moderate air quality even though an area is meeting the annual standard."

Response: With respect to an AQI value of 100, EPA has concluded that it is appropriate in this case to set this value at 100 ppb NO_2, 1-hour average, the level of the short-term standard. With respect to an AQI value of 50, EPA agrees with the NACAA comment which noted it might make for a confusing outreach message if this value is set below the level of the annual standard. This method of structuring the index is appropriate in the case where a short-term standard is set to protect against the health effects associated with short-term exposures and/or an annual standard is set to protect against health effects associated with long-term exposures. In such cases, the short-term standard in

effect defines a level of health protection provided against short-term risks and thus can be a useful benchmark against which to compare daily air quality concentrations.

With respect to the breakpoints at the higher end of the AQI scale (i.e., 200 to 500), EPA acknowledges that these breakpoints have been in place for a long period of time, and that an AQI value of 200 is higher for NO_2, relative to the 100 level, than it is for the other pollutants in the AQI. EPA does not agree that there is new health evidence that would provide support for changing these levels. The levels at the upper end of the AQI are linked to a related program designed to prevent air pollution emergencies. Some state and local air agencies are required to have plans to take actions at these levels, thus it is important to have a firm basis for revising these levels.

Significant harm levels (SHL) are those ambient concentrations of air pollutants that present an imminent and substantial endangerment to public health or welfare, or to the environment, as established in 40 CFR part 51.151. The SHL is typically set at the same ambient concentration of a pollutant as the AQI value of 500. Appendix L of 40 CFR part 51 includes example emergency episode plans as part of the Prevention of Air Pollution Emergency Episodes program. This program requires specified areas to have contingency plans in place and to implement these plans during episodes when high levels of air pollution, approaching the SHL, are in danger of being reached or have been reached. The Appendix L example links the AQI with emergency episodes. AQI values of 200, 300 and 400 are the basis for the example Alert, Warning and Emergency episode levels included in 40 CFR part 51, Appendix L. In this guidance, the Alert level corresponds to the breakpoint between the Unhealthy and Very Unhealthy categories, and the Warning level corresponds to the breakpoint between the Very Unhealthy and Hazardous categories. The Hazardous category ranges up to the SHL.

VII. Comments on the Process for Reviewing the NO_2 Primary NAAQS

A number of comments were received recommending changes to the current rulemaking process, either for NAAQS in general or the NO_2 NAAQS in particular.

(1) *Comment:* A number of industry groups and state agencies recommended that the proposed near-road monitoring network be considered in a separate rulemaking from the proposed new 1-hr NO_2 standard, because it represents a dramatic shift in the method of monitoring ambient air quality from previous NAAQS.

Response: EPA notes that separating the monitoring issues from the NAAQS revision is not consistent with recently finalized or planned NAAQS reviews. EPA has promulgated monitoring rules as part of, or simultaneously with the PM and Pb rules, and has proceeded to include the monitoring rule as part of this primary NO_2, as well as the primary SO_2, the secondary NOx/SOx, and CO revisions. Monitoring issues were handled separately from the 2008 ozone NAAQS revision, however EPA intends that future ozone NAAQS reviews will integrate monitoring into the action.

(2) *Comment:* Some commenters (e.g., NACAA, NESCAUM, Roger McClellan) noted that EPA had originally intended to publish an advance notice of proposed rulemaking (ANPR) and that because no ANPR was published, the public and CASAC had limited opportunity to comment on the range of available options. Other comments expressed disapproval with the limited amount of time for stakeholders to comment on EPA's ISA and REA; the late notifications that EPA provided when comment periods were extended; and the inclusion of new sections and studies in the final versions of the ISA and REA, which denied stakeholders the opportunity to comment on these additions.

Response: The Clean Air Act requires EPA to review and to revise, as appropriate, the NAAQS every five years. As a result of a lawsuit challenging EPA's failure to complete its review of the air quality criteria for NO_X and the NAAQS for NO_2, *inter alia*, EPA agreed in a consent decree to a schedule for this review of the NO_2 primary NAAQS. Pursuant to CAA § 113, EPA provided an opportunity for comment on the consent decree. This schedule was approved by the United States District Court for the District of Columbia.

We disagree that EPA's decision to not publish an ANPR limited the opportunity for meaningful comment on the rulemaking. EPA on occasion uses an ANPR to seeking input from stakeholders before issuing a proposed rule, but EPA is not required to publish an ANPR. Moreover, EPA provided for stakeholder comment throughout the review process, including 60 days of comment and held two public hearings on the proposed rule. To the extent that "new sections and studies" were added to the final version of the ISA and REA, stakeholders had the opportunity to comment on this material following the notice of proposed rulemaking.

(3) *Comment:* API commented that EPA did not not adequately address comments provided by other government agencies on the draft proposed rule.

Response: EPA engaged in extensive discussions with other agencies as part of the interagency review process prior to the publication of the proposed rule. Under section 307(d) of the CAA, EPA is under no obligation to provide written responses to comments provided by other agencies during the interagency review process. The scientific rationale for the standards is clearly provided in the record for the final rule.

(4) *Comment:* AASHTO requested that if EPA creates a 1-hr NO_2 standard more stringent than 80 ppb, an additional public comment period be created to allow stakeholders to comment directly on the specific standard level selected.

Response: As described in section II.F.4.d of the final rule, the Administrator has set the level of the 1-hour standard at 100 ppb.

(5) *Comment:* AGCA commented that EPA's Regulatory Impact Analysis (RIA) did not provide enough information to predict which areas of the country will not be in attainment with a new standard if the proposed near-road monitoring network is also included. This lack of information has the potential to negatively affect AGCA members because it prevents the organization from assessing the potential impact of a new near-road monitoring network on the road construction industry.

Response: We developed the best estimate we were able to develop of future design values at currently existing monitors, based on emission inventory projections for 2020, using the best available emission data and control strategy information. What we are not able to do is to credibly estimate specific design values at locations where monitors do not currently exist, but will in the future. States will determine where to place those monitors as they implement the NAAQS. In addition, we did not model near-roadway concentrations as a function of traffic density; this RIA is a national scale analysis.

VIII. Interpretation of the Clean Air Act

(1) *Comment:* Numerous comments were received from industry groups and state agencies expressing concern with EPA using near-road measurements of NO_2 concentrations to evaluate area-wide attainment with an NO_2 NAAQS. Many of the commenters note that EPA's proposed near-road monitoring network focuses on monitoring roadways likely to have high NO_2 concentrations without requiring any demonstration that large and adjacent populations are exposed to similarly high concentrations. Consequently, the commenters argue that EPA has proposed a monitoring network using rationale that does not reflect the purpose of the CAA and NAAQS, which is to protect the public from exposure to unhealthy concentrations of pollutants found within "ambient air" rather than just "air".

Response: We note that ambient air includes the outdoor air present around roads as well as the air that intrudes from outdoors into homes, buildings, or vehicles on/near those roads. As discussed in the final rule, people who spend time on or around major roads (e.g., because they live there, go to school there, or commute in vehicles on major roads) can be exposed to elevated concentrations of ambient NO_2.

(2) *Comment:* A number of industry groups provided comments maintaining that EPA may have overstepped its regulatory authority with its proposed 1-hr NO_2 standard. Comments included claims that the health effects from short-term exposure to high concentrations of NO_2 fail to constitute the "adverse health effects" called for in the CAA. Other comments noted that EPA is authorized by the CAA to set its NAAQS at levels intended to protect sensitive subpopulations, not the most sensitive individual. In addition, some commenters noted that NAAQS are not intended to eliminate all risks.

Response: The issues raised by these commenters are addressed in sections II.E.2, II.E.3, II.F.4 in the final rule.

(3) *Comment:* Roger McClellan provided some general comments on the role of CASAC and concluded that--

> In offering recommendations for a specific upper bound for the Standard, the Committee moved beyond advising on the science informing the policy judgments inherent in setting the Standard, to taking on a role reserved for the Administrator – the setting of the Standard. The Clean Air Act wisely delegates the setting of the Standard to the Administrator and calls for a Clean Air Scientific Advisory Committee, not a Clean Air Standard Setting Committee.

Response: Section 109(d)(2)(B) of the Clean Air Act, and the charter of CASAC, provide that CASAC shall review the air quality criteria and the NAAQS and "recommend to the Administrator any new national ambient air quality standards and

revisions of existing criteria and standards as may be appropriate." EPA believes that CASAC fulfilled this duty and provided helpful advice as a committee on the science issues raised by this review. Of course, the Administrator cannot, and did not, delegate the setting of the standard to CASAC.

(4) *Comment:* NPRA commented that EPA lacks the legal authority to withhold a designation of "attainment" from districts unless the districts cannot be classified on the basis of available information as meeting or not meeting the national air quality standard. The commenter argued that, at present, EPA cannot know whether it will lack the necessary information in 2012. According to NPRA, "it is clear from the statute that for NO_2 EPA must designate areas as in attainment that have attaining monitors absent an affirmative showing that such an area is contributing to downwind nonattainment in another area.." In addition, NPRA commented that section 107(d) of the CAA requires that EPA "consider the recommendations of States with regard to the designation of areas as attainment, nonattainment and unclassifiable."

One state agency agreed with EPA's proposal to designate all areas currently in attainment with the NO_2 standard as "unclassifiable" until a near-road network has been established and measurements have been evaluated.

Response: (Implementation group)

(5) *Comment:* Several environmental groups (e.g., ALA, EDF, EJ, NRDC) noted that the CAA requires that NAAQS be set to protect public health with an adequate margin of safety without consideration of cost and that, in setting the NAAQS, EPA must err on the side of protecting public health. These groups stated that this includes protecting sensitive subpopulations and guarding against "potential" health effects.

Response: EPA agrees that the NAAQS must be requisite (i.e., no less and no more stringent than necessary) to protect the public health, including the health of sensitive populations, with an adequate margin of safety. The Administrator's consideration of this issue in the current review is described in section II.F.4.d of the final rule.

IX. Comments on Implementation

(1) *Comment:* A minority of CASAC Panel members posed the question of what would be an effective control strategy to reduce NO_2 concentrations around major roads. A number of public commenters also expressed the concern that states have little ability to reduce on-road emissions from motor vehicles. Several went on to opine that it is the role of the federal government to reduce emissions from motor vehicles. One pointed out that their state has already implemented measures to reduce on-road emissions of NO_X as part of their plan to attain the ozone standard. One commenter opined that states have few options to reduce on-road emissions beyond federal requirements. Another commenter suggested that one option for states would be to adopt California's mobile source regulations including those that apply to non-road equipment. The commenter is concerned that adoption of California's non-road regulations would place a significant burden on the construction industry. The commenter is also concerned that states may attempt to reduce emissions from non-road equipment by imposing operating restrictions, requiring older equipment to be replaced or mandating retrofits for older equipment.

Response: EPA agrees that it is a federal responsibility to implement regulations that reduce emissions from new light- and heavy-duty vehicles. However, states have authority that can be used to reduce emissions from in-use light- and heavy-duty vehicles. For example, states can implement programs to retrofit heavy-duty diesel vehicles to reduce their NO_X emissions. States can implement regulations to reduce or eliminate long-duration idling of heavy-duty diesel vehicles. They can implement an inspection and maintenance program for light-duty vehicles. Additionally, states can implement a wide range of programs to improve travel efficiency. States can implement strategies such as congestion pricing, programs to reduce trips for commuting purposes, and measures to improve the operational efficiency of the transportation network. States can also work with freight shippers to improve the efficiency of goods movement in an area.

EPA agrees that a number of states have already implemented controls on on-road sources. The emissions reductions attributable to those measures will help such areas to attain the NO_2 NAAQS and can be included in a SIP for NO_2. If such an area was designated nonattainment for NO_2, EPA would expect the state to evaluate mobile source controls that it had not yet implemented and to evaluate the potential for controlling emissions from other sources that are contributing to the nonattainment problem.

With regard to the comments related to the adoption of California's on-road and non-road regulations by other states and the possibility that some states may choose to reduce NO_X emissions by requiring older non-road equipment to be replaced or equipped with retrofits or impose operating restrictions on non-road equipment, EPA expects each state with a designated NO_2 nonattainment area to develop a SIP that brings the area into attainment by the applicable deadline and that each state would evaluate the potential for controlling emissions from all sources that are contributing to the nonattainment problem. CAA section 177 allows states to adopt California's standards that apply to new motor vehicles or new motor vehicle engines and CAA section 209(e)(2)(B) allows states to

adopt California's standards that apply to new or used non-road engines and equipment. California, and therefore other states, are prohibited by CAA section 209(e)(1) from promulgating standards for new construction and farm equipment with engines smaller than 175 hp and from new locomotives and locomotive engines. It is possible that a state could choose to adopt California's standards that apply to new on-road and/or other non-road equipment in order to attain the NO_2 NAAQS. States may also choose to reduce emissions from non-road equipment through operating restrictions, or requiring older equipment to be replaced to the extent that such measures are not federally pre-empted. EPA would expect that before any state included any of these types of measures in a SIP for NO_2 the state would have evaluated a wide range of potential control measures and concluded that such measures are necessary to bring the area into attainment by the applicable deadline.

(2) *Comment:* Some commenters stated that modeling for permitting of the short term 1-hr NO_2 standard could likely show that stationary sources violate the standard as opposed to near-road mobile sources. Others requested that if EPA requires near-roadway monitoring for NO_2, it should provide clarifying guidance stating that near-road monitors would not be applicable for NSR or other point source permit applications.

Response: The permitting regulations for Prevention of Significant Deterioration of Air Quality (PSD) require applicants to provide 1 year of air quality data representative of the air quality in the area that the proposed new or modified source will impact. Typically, such monitoring data is used to represent background air quality levels that are considered along with modeled concentrations of a pollutant to show that the source's predicted impact will not cause or contribute to a violation of any NAAQS. We agree that the ambient data collected from near-road monitoring sites for NO_2 may not be representative of background air quality levels throughout the area of concern. However, if used correctly, such data could be useful in assessing the source's contribution in specific areas of potentially high ambient NO_2 concentrations largely attributable to near-road mobile source emissions. EPA will give further consideration to this comment as we evaluate any NSR guidance and regulations that may be needed to implement a 1-hour NO_2 NAAQS.

(3) *Comment:* API recommends that EPA update the Guidelines on Air Quality Models to address screening and refined models for modeling peak short-term concentrations in order to accurately predict short-term NO_2 concentrations in diverse environmental settings.

Response: The EPA agrees with this comment and intends to review the need to revise the Guideline on Air Quality Models to address issues associated with the promulgation of a short-term NO_2 NAAQS.

(4) *Comment:* API also recommends that EPA develop a database of NO_2 to NO_X emissions ratios for the variety of sources that would be affected by any new NO_2 standards. The database could also include methods to make use of data from existing ambient

monitoring networks to provide realistic background ozone and NO_2 concentrations required for the short-term NO_2 modeling framework.

Response: The EPA will review the need for the development of a database of NO_2 to NO_X emissions ratios sources following the promulgation of the NO_2 NAAQS.

(5) *Comment:* CAC disagrees 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 urges EPA to provide a graduated non-attainment classification system for the new standard. According to the Council, "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."

Response: 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. See the preamble to the final rule for consequences for areas failing to meet the attainment date. Once EPA makes a determination that an area has failed to meet its attainment date, the State will be requested to submit a SIP revision which must show that it can attain the standard as expeditiously as practicable, but no later than 5 years from the determination of failure to attain.

(6) *Comment:* One commenter opined that states that fail to develop SIPs or meet EPA's CAA deadlines would be subject to "numerous federal sanctions" including emissions caps, limiting economic development and the loss of federal highway transportation dollars. The commenter specifically states that a construction ban would impede projects that would improve municipal water supplies and wastewater treatment.

Response: CAA section 179 provides EPA with only two sanctions. These are the 2:1 offset sanction that applies to new or modified major stationary sources and the highway funding sanction. These sanctions are only applied in specific circumstances, such as when a state has failed to submit a required SIP or when a SIP revision is disapproved. The CAA no longer contains a sanction specifically aimed at limiting development. The CAA Amendments of 1990 do not include the construction ban that applied in certain situations under the 1977 CAA. Therefore, EPA disagrees that, if the available sanctions are imposed in an NO2 nonattainment area, they would result in a de facto construction ban and they would not delay municipal water or wastewater projects. It must be noted that there is no sanction for failing to reach attainment by the CAA deadline. For areas that fail to attain by the applicable deadline CAA section 179(d) requires that such areas submit a revised SIP within one year after EPA publishes a notice finding that the area failed to attain. In the case of NO2, this revised SIP would have to demonstrate

attainment as expeditiously as practicable, but no later than 5 years after the date of the Federal Register notice in which EPA made the finding that the area had failed to attain.

(7) *Comment:* One commenter pointed out that a new 1-hr standard for NO_2 will complicate permitting of small sources that may contribute to local NO_2 emissions.

Response: Section 110(a)(2)(C) of the CAA requires states to regulate the construction and modification of any stationary source as necessary to assure that NAAQS are achieved. Consequently, the addition of a 1-hour NO_2 NAAQS would require that the necessary consideration be given to preventing sources from violating a 1-hour NO_2 NAAQS. We do not, however, view this as a complication of the permitting process. In some instances, a modeling analysis may be required to make the necessary compliance demonstration, while in other cases modeling may not be required. Such decisions as to the level of analysis needed to make the necessary compliance demonstration must be made by the applicable state or local agency permitting authority.

(8) *Comment:* Several industry commenters requested that EPA slow the timeline for implementing a near-road monitoring network and designating roadway areas, because they believe EPA lacks significant information about the implementation and performance of a national, near-road monitoring network.

Response: EPA believes that there is sufficient information to implement a near-road NO_2 network and that the timeline for implementation will allow EPA to consult CASAC and collaborate with states in the development of guidance that will assist in the implementation of a network that is as consistent as possible. This issue is discussed in section III.B.5 of the preamble to the final rule.

(9) *Comment:* Numerous comments were received, primarily from state agencies, noting the significant cost of a near-road monitoring networks and requesting that the federal government pay for a large percentage of the network's cost by funding the monitors through Section 103 of the CAA, rather than section 105. Many commenters claimed that without federal funds, and because of the tight budgets faced by state governments presently, the funding of a near-road monitoring network would result in less spending on other valuable environmental programs.

Response: EPA understands the resource concerns of the states and intends to work with states in identifying available funds and assess the increased resource needs that may be needed for network implementation. This issue is discussed in section III.B.1 of the preamble to the final rule.

(10) Comment: Several commenters claim that EPA significantly underestimates the cost of near-road monitors for many locations where monitors are likely to be installed.

Response: EPA used direct quotes or its best estimate for the variety of capital and logistical costs that will be associated with implementing the network design. EPA must make its estimates as nationally applicable as possible, and cannot anticipate the

individual variations in resource needs, or in the actual costs themselves, that may occur from one location of the country to the next. EPA intends to work with states in identifying available funds and consider the increased resource needs that may be needed for network implementation.

(11) *Comment:* State agencies requested that EPA provide additional guidelines for the criteria that would be used by Regional Administrators in determining when additional near-road monitors would be required or when requests for additional monitors will be granted. An additional comment requested that EPA provide further guidance and oversight of Regional Administrators to ensure the consistent implementation of any near-road monitoring network across the country. State agencies also requested that the Regional Administrator be required to coordinate with the state government in deciding where near-road monitors would be placed.

Response: EPA has provided multiple examples of situations where Regional Administrator may use their discretion to require additional monitors above the minimum required in section III.B.4 of the preamble to the final rule. In particular, EPA notes that in situations where a Regional Administrator may consider the need for additional monitoring, EPA expects that the state and the Regional Administrator would work together to evaluate quantitative evidence that suggests an area may warrant additional monitoring.

(12) *Comment:* AASHTO recommended that state and local air monitoring agencies be required to coordinate with their respective DOTs when developing a near-road monitoring plan.

Response: Although can not require state and local air agencies to work with another state or local entity, EPA believes that state and local air monitoring agencies can greatly benefit from collaboration with their counterparts in state or local transportation authorities. Such collaboration may help in site identification, site access, and ensuring public and worker safety at near-road sites.

(13) *Comment:* Several State Agencies commented on the interaction between NO_X and O_3. For example, AASHTO requested that EPA clarify how areas can overcome potential negative impacts on ambient O_3 of increased control of NO_X emissions. In contrast, one State Agency (HCPHES) commented that a more stringent NO_2 standard will help them attain the O_3 NAAQS because NO_2 is a precursor to O_3.

Response: It has long been recognized that reducing NO_X emissions will result in lower concentrations of regional O_3 (National Research Council, 1991). This has been confirmed in numerous photochemical model simulations and assorted ambient data analyses over the past two decades (EPA 2005b; EPA, 2008d). As a result, efforts to reduce NO_X emissions are the foundation of Federal and State actions to attain the ozone NAAQS. However, because of the complex chemistry of ozone formation, there are some specific instances in which certain NO_X reductions can lead to localized ozone increases. In these areas, the local planning process will need to consider the

multipollutant aspects of air quality management and derive the most appropriate set of local control measures needed to attain multiple NAAQS simultaneously.

(15) *Comment:* One state agency recommended that state and local DOTs should be required to perform air quality impact analyses for NO_2 prior to road construction projects as well as conduct regular mobile monitor testing to demonstrate that the construction projects are not causing violations of the 1-hr NO_2 standard.

Response: Any such requirement for state and local DOT's to perform air quality impact analysis prior to road construction or to conduct any testing would have to be established and carried out under state or local authority.

(16) *Comment:* One commenter encouraged EPA to develop a 1-hr NO_2 significant impact level (SIL) without which, "any increase in NO_2 in a nonattainment area (or a near non-attainment area) could result in denial of the proposed permit, even if the increase is not significant or offset with offsite emission reduction credits" (CAAPCOA).

Response: This issue is discussed in section VI.D.2 of the preamble to the final rule.

(17) *Comment:* The North Carolina Department of Environment and Natural Resources (NCDENR) supports the use of a weighted annual mean (quarterly average) for the annual primary standard.

Response: This issue is discussed in the final notice (Section IV.A).

(18) *Comment:* SJVAPCD recommended that EPA include guidelines for near-road monitoring that allows for monitoring to stop at locations where sufficient data has been collected to conclude that measured concentrations of NO_2 are less than 85% of the standard level.

Response: 40 CFR § 58.14(c), explains the process by which states may request approval for discontinuing monitoring at an individual site. The discontinuation is subject to Regional Administrator approval, and requires the satisfaction of multiple requirements which are spelled out in the regulation text.

(19) *Comment:* CASAC Panel members who supported the alternative approach, as well as some public commenters (e.g., States) also raised questions related to how non-attainment areas would be designated if roadside monitors measure violations. For example, some commenters questioned whether an entire county could be out of attainment based on a roadside monitor.

Response: This comment is addressed in sections V.B and V.C of the final notice.

(20) *Comment:* The ALA, EJ, EDF, and NRDC also recommended that EPA "formulate a rational basis for re-designation based on limited monitoring data and available information on mobile source emissions from the relevant roadways." Under this approach, EPA is encouraged to "commit to designating near roadway areas no later than the end of 2013." These same groups also commented, "We believe it is reasonable to…promulgate a nonattainment SIP submittal deadline of no later than the end of 2015." Other environmental groups (e.g., CAC) also commented that the timing for designations should be accelerated.

Response: Section 110(d)(1)(B) of the CAA requires the EPA to designate areas as attainment, nonattainment or unclassifiable no later than 2 years following promulgation of a new or revised NAAQS (the CAA provides the Agency an additional third year from promulgation should there be insufficient information on which to make compliance determinations). The EPA intends to finalize initial designations for the revised NO2 NAAQS in January 2012.

A near-roadway monitoring network is not expected to be fully deployed until January 2013. For this reason, EPA will proceed with initial designations using air quality data from the existing, area-wide NO_2 monitoring network in order to complete designations by January 2012. Once the near-roadway network is fully deployed and 3 years of air quality data are available, the EPA intends to redesignate areas, as appropriate, based on the most recent air quality data from the new monitoring network. For both initial designations and redesignations, EPA will use monitoring data to identify violations of the standards. EPA would then consider a variety of other factors in determining which nearby areas contribute to a violation in setting the boundaries.

The response to commenters' requests that EPA both shorten and extend SIP and attainment deadlines is provided in the implementation section of the preamble.

(21) *Comment:* One commenter (City of NY) recommended that EPA should develop a screening approach to estimate short-term NO_2 concentrations, and provide source-type specific $N0_2/NO_X$ ratios with the NO_X emission factors.

Response: It is EPA's intention to utilize the current guidance and policies to implement the revised NAAQS for NO_2. However, we will be reviewing the need to provide additional technical as well as policy guidance following the promulgation of the NAAQS.

(22) *Comment:* API recommended that EPA "follow the precedent that was set for $PM_{2.5}$ by postponing the use of dispersion modeling to evaluate short-term ambient NO_2 concentrations until appropriate modeling tools are developed, evaluated, peer-reviewed, and subjected to public comment and review.

Response: It is EPA's intention to utilize the current guidance and policies to implement the revised NAAQS for NO_2. However, we will be reviewing the need to provide

additional technical as well as policy guidance following the promulgation of the NAAQS.

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