Responses to Significant Comments on the 1996 Proposed Rule on the National Ambient Air Quality Standards for Ozone

(December 13, 1996; 61 FR 65716)

Docket Number A-95-58

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List of Acronyms

The following acronyms have been used for the sake of brevity in this document:

Act	Clean Air Act
AQAP	air quality adjustment procedure
API	American Petroleum Institute
CASAC	Clean Air Scientific Advisory Committee
CI	credible interval
CMA	Chemical Manufacturers Association
EPA	Environmental Protection Agency
FEV_1	forced expiratory volume in 1 second
l/min	liters per minute
l/min-m^2	liters per minute per meter squared
NAAQS	national ambient air quality standards
NMOC	non-methane organic compounds
NO_X	nitrogen oxides
NO	nitric oxide
O_3	ozone
PEM	personal exposure monitor
PM	particulate matter
pNEM/O_3	probabilistic NAAQS Exposure Model for ozone
ppm	parts per million
ROM	Regional Oxidant Model
UV	ultra violet
VOC	volatile organic compounds

Frequently Cited Documents

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

Criteria Document:	U.S. Environmental Protection Agency (1996a) Air Quality Criteria for Ozone and Related Photochemical Oxidants. Research Triangle Park, NC: National Center for Environmental Assessment. Office of Research and Development. July 1996. EPA report no. EPA/600/P-93/004aF-cF.
Preamble to the final rule:	Preamble to the Final Rule on the Review of the National Ambient Air Quality Standards for Ozone; to be published in the *Federal Register* on July 18, 1997.
Proposal notice:	National Ambient Air Quality Standards for Ozone: Proposed Decision. 61 FR 65716, December 13, 1996.
Staff Paper:	U.S. Environmental Protection Agency (1996b) Review of the National Ambient Air Quality Standards for Ozone: Assessment of Scientific and Technical Information. OAQPS Staff Paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards. June 1996. EPA report no. EPA-452/R-96-007.
Summary of comments:	Abt Associates (1997) Final Summary of Significant Written Comments on the 1996 Ozone National Ambient Air Quality Standards Proposal: Issue Report; EPA Docket No. A-95-58.

Responses to Significant Comments on the 1996 Proposed Rule on the National Ambient Air Quality Standards for Ozone

I. INTRODUCTION

This document, together with the preamble to the final rule on the review of the national ambient air quality standards (NAAQS) for ozone (O_3) and several separate documents referred to below, present the responses of the Environmental Protection Agency (EPA) to the more than 50,000 public comments received on the 1996 O_3 NAAQS proposal notice. All significant issues raised in the public comments have been addressed.

As reflected in the table of contents for this document, responses are organized by topics, which correspond to specific sections of a companion document that has been placed in the docket, the *Summary of Significant Written Comments on the 1996 Ozone NAAQS Proposal -- Issue Report* (henceforth the "Summary of Comments"). Due to the large number of comments that addressed similar issues, as well as the sheer volume of the comments received, this response-to-comments document does not generally cross reference each response to the commenters 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. However, all commenters on a given topic are included in the Summary of Comments[1].

This document refers as appropriate to various support documents, available in the docket, that have been prepared to assist in presenting the more technical aspects of the Agency's responses. A complete list of references, including these support documents, is presented at the end of this document.

The responses presented in this document and in the separate documents referred to above are intended to augment the often extensive responses to comments that appear in the preamble to the final rule or to address comments not discussed in the preamble. Although portions of the preamble are paraphrased in this and other documents where useful to add clarity to responses, the preamble itself remains the definitive statement of the basic rationale for the revisions to the standards adopted in the final rule.

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[1]A separate summary document, the *Summary of Significant Written Comments on the 1996 Ozone NAAQS Proposal -- Author Report*, has also been placed in the docket to facilitate the review of the comment summaries by commenter as as as by issue.

In many instances, particular responses presented in the above documents include cross references to responses on related issues, either in those documents or in the preamble to the final rule[2]. In view of the large number of comments received, the cross references may not always reflect the extent to which information relevant to a particular comment is contained in responses to other comments. Accordingly, the above documents as a group, together with the preamble to the final rule, should be considered collectively as EPA's response to all of the comments submitted.

II. RESPONSES TO SIGNIFICANT COMMENTS ON PROPOSED O_3 STANDARDS

A. Primary O_3 Standard

1. General comments on proposed primary standard

A large number of comments on the proposed primary O_3 standard are very general in nature, basically expressing either 1) support for the proposed 8-hour 0.08 ppm standard, for one of the two alternative 8-hour standards on which comment was solicited in the proposal notice, or for an 8-hour standard that would be "equivalent" to the current 1-hour standard, or 2) expressing opposition to any revisions to the current 1-hour standard. Many of these commenters simply expressed their views without stating any rationale, while others stated general reasons for their views but without reference to the factual evidence or rationale presented in the proposal notice as a basis for the Agency's proposed decision. Such general comments specific to the O_3 proposal notice are summarized in section III.A.1 of the Summary of Comments, and general comments on both the O_3 and PM proposal notices are summarized in section I.A.

The Agency recognized in the proposal notice that there was a wide diversity of views as to whether revision of the current standard was appropriate in light of the available scientific evidence, and the range of general comments received reflect that diversity. The preamble to the final rule in its entirety presents the Agency's response to these general views. More specifically, section II.A of the preamble to the final rule responds to views that are generally health-based, including reasons related to 1) the nature of O_3-related health effects, 2) the strength of and uncertainties associated with the scientific evidence of these effects, 3) the appropriate and/or likely degree of public health protection to be afforded by the primary O_3 NAAQS, and 4) the nature of the advice from CASAC with regard to the adequacy of the scientific evidence available for making a decision on the standards and individual CASAC Panel members' personal views on the standard. Section IV of the preamble to the final rule responds to views that are based on reasons beyond the scope of those that the Administrator can consider in setting the standards, including those related to the costs and/or economic impacts of the

[2]The terminology used in the preamble to the final rule as it appears in the Federal Register refers to various named sections of the preamble as "units." This response to comments document refers to the units as "sections" of the preamble.

proposed standards. Sections IV, VII, and VIII of the preamble to the final rule respond to views based on reasons related to statutory interpretations and procedural issues.

2. Specific comments on proposed primary standard

A large number of comments addressed specific elements of the proposed primary O_3 standard, including the averaging time, level, and form of the standard, and on the interpretation of the standard as specified in proposed revisions to Appendix H (redesignated in the final rule as Appendix I). These comments are generally summarized in sections III.A.2.a,b,c,d of the Summary of Comments, and responses to the key issues raised in these comments are presented in sections II.B and VI of the preamble to the final. In some cases, more specific responses to the full range of significant issues raised in these comments are presented below.

a. Averaging time

This section addresses specific comments included in Section III.A.2(a) and elsewhere in the Summary of Comments concerning the averaging time of the primary O_3 standard.

Comments on the proposed change to the averaging time of the primary standard from 1 to 8 hours fall into two major categories. Those in the first group reflect broad support for the 8-hour averaging time, either as a replacement for or in addition to the current 1-hour standard. Support for the 8-hour standard was based on evidence of health effects reported in human studies of 6- to 8-hour exposure durations (but at lower O_3 levels than the 1- to 3-hour exposures), analyses indicating that an 8-hour standard would limit 1-hour and 8-hour exposures to O_3, and the unanimous recommendation of the CASAC members that the 1-hour standard be replaced by an 8-hour standard. Many who supported setting an 8-hour standard believed that increased health protection beyond that provided by the current standard was needed, while others suggested that health protection equivalent to that provided by the current standard was appropriate. Those in the second group did not believe there was sufficient justification for setting an 8-hour standard, or for making any changes in the current standard, by suggesting that the 1-hour standard, as currently being implemented, provides adequate public health protection from effects of exposure to O_3. Many of these commenters asserted that high costs and life style changes would result from programs designed to implement an 8-hour standard and/or referred to the conclusion of CASAC that there were not large differences (i.e., no “bright line”) in public health risk between any of the alternative 8-hour primary standards considered and the current 1-hour standard.

Section II.B. of the preamble to the final rule presents the key observations and conclusions that form the basis for the decision by the Administrator to select an 8-hour averaging time for the primary O_3 standard. Presented below is a Summary of Comments received and responses to various specific issues raised by commenters regarding averaging time. The responses below are intended to expand upon the discussion contained in the preamble to the final rule.

i. Lack of "bright line" effects threshold or acceptable risk

This section addresses comments included in section III.A.2(a) and elsewhere in the Summary of Comments that raise questions regarding threshold or acceptable risk related issues. Comments on these issues were received from AAMA (IV-D-2243) and others.

(1) *Comment:* The EPA ignored CASAC's view that there is no "bright line" or large differences in the degree of health risk or protection between any of the alternative 8-hour standards which were considered and the 1-hour standard set at 0.12 ppm.

Response: As discussed in the preamble to the final rule, commenters very frequently quoted from the CASAC closure letter (Wolff, 1995b) stating "that there is no 'bright line' which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health" and that "the selection of a specific level and number of allowable exceedances is a policy judgment." These commenters have variously interpreted these statements as a CASAC consensus that the differences in the public health protection afforded by any of the alternative standards were too small to be important from a public health perspective, not statistically significantly different, or simply not different at all. Based on these interpretations, the commenters argued that it is not appropriate to revise the standard in any way, because a revised standard would result in disruption to ongoing programs, additional planning requirements, and increased implementation costs, but would provide no or only very little improvement in public health protection.

The EPA believes that these commenters have misconstrued or too narrowly interpreted CASAC's advice to the Administrator by not considering the entire range of views and recommendations included in its closure letter. Specifically, CASAC began its summary of recommendations to the Administrator (Wolff, 1995b) by stating that "[t]he Panel was in unanimous agreement that the present 1-hour standard be eliminated and replaced with an 8-hour standard." This agreement was based on "the consensus of the Panel that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard." Thus, CASAC was unequivocal in its advice to the Administrator with regard to which averaging time the health effects evidence more strongly supports. While some commenters have also quoted statements by individual Panel members at CASAC meetings suggesting that choosing between a 1- or 8-hour averaging time is a "policy" choice, these individual statements during the course of CASAC's review do not contradict nor supersede the clear and unanimous agreement of CASAC on averaging time as conveyed to the Administrator in its closure letter.

In considering these comments, EPA also believes it is important to put into a public health perspective CASAC's observations about the differences among alternative standards in protecting the public from the health effects that were quantitatively estimated in EPA's risk assessment. In the closure letter (Wolff, 1995b), CASAC observed that “the differences in the percent of outdoor children . . . responding between the present standard and the most stringent proposal . . . are small and their ranges overlap for all health endpoints.” Most importantly, EPA notes that the primary standard would provide protection from a broader array of health effects than it was possible to consider in its quantitative risk assessment. This perspective is clearly shared in particular by those CASAC panel members who personally favored a level or range of levels that included the proposed level of 0.08 ppm, in that the closure letter characterizes their views as reflecting, in part, their “concern over the evidence for chronic deep lung inflammation from the controlled human and animal exposure studies.” While the risk of this effect, as well as other effects related to 6- to 8-hour exposures in the Criteria Document and Staff Paper (including increased airway responsiveness, impairment of host defenses suggesting an increased susceptibility to respiratory infection, and increased emergency room visits, doctor visits, and frequency of medication use by individuals with impaired respiratory systems) could not be quantitatively estimated in EPA’s risk assessment, EPA believes that consideration of these effects is nevertheless important in making public health policy judgments.

Further, in interpreting CASAC’s statements on EPA’s risk assessment report (Whitfield et al., 1996) that there is no “bright line” which distinguishes any of the standards as being “significantly” more protective, and that the “ranges overlap,” EPA notes that there are statistically significant differences in the estimated risks for the range of alternative standards analyzed. This information was presented to CASAC at its September 1995 meeting (CASAC meeting transcript, September 19-20, 1995, pp. 108-109). Further, EPA again notes that whether one judges the differences to be significant or small can depend on whether one focuses on percentages, as CASAC’s letter did, or on total numbers of times that children or other at-risk individuals experience such effects. The overlap in the ranges of risk referred to in the CASAC letter reflect differences among urban areas used in EPA’s risk analysis (e.g., air quality, exposure patterns, environmental factors), not random uncertainties in risk estimates within any given urban area. Thus, the fact that the ranges overlap does not mean that there are no real or statistically significant differences in protection among alternative standards. To the extent that the quoted statements from CASAC’s closure letter are read as implying that CASAC considered the differences not to be statistically significant (or that there are no differences at all in the protection afforded by the alternative standards), EPA disagrees with that reading.

(2) *Specific Comment (American Automobile Manufacturers Association, IV-D 2243):* Since a 1-hour standard can provide protection against high 8-hour levels, there is no need to change to an 8-hour standard. Also, the air is getting cleaner, and changing the standard now would provoke only chaos, not cleaner air, because it would disrupt ongoing control programs.

Response: As discussed in the preamble to the final rule, EPA agrees that air quality trends are improving as a consequence of ongoing control programs designed to attain the current NAAQS. The EPA does not, however, believe that these trends relieve the Agency of its statutory mandate to review and, if appropriate, revise the NAAQS on the basis of the best available scientific evidence to establish standards that protect public health with an adequate margin of safety. The fact that current control programs are resulting in progress toward improving air quality suggests that it is important to ensure that such progress is maintained during any transition to a revised standard. The EPA believes that issues associated with maintaining progress in air quality management programs are appropriately addressed in the development of implementation strategies rather than in the setting of the NAAQS itself.

ii. Relationship between 1- and 8-hour air quality standards

This section addresses comments included in section III.A.2(a) and elsewhere in the Summary of Comments that raise questions regarding relationships between 1- and 8-hour air quality standards. Comments on these issues were received from Wolff (IV-D-2334) and others.

(1) *Comment:* Commenters supported the 8-hour primary O_3 standard because it will provide health protection which is more consistent with new health effects information published in recent years and supported by CASAC. Commenters argue that there will be an improvement in public health protection that will result from replacing the existing 1-hour standard, which they believe does not adequately protect public health, with an 8-hour standard, which they believe will improve longer-term air quality and increase public health protection.

Response: As discussed in the preamble to the final rule, EPA agrees with the considerations raised by those commenters who favor an 8-hour standard. In considering the appropriateness of an 8-hour standard as compared to a 1-hour standard, EPA also notes the results of its exposure and risk assessments which show variability across the nine urban areas analyzed with regard to the extent to which the current 1-hour standard, and alternative 8-hour standards, limit 8-hour exposures of concern and associated risks of adverse health effects. As noted in the proposal notice and in the supplemental risk assessment, there is much greater variability across urban areas, particularly in looking at the seven current nonattainment areas examined, in the extent to which the current 1-hour standard limits such exposures of concern and risks than for the alternative 8-hour standards. For example, the updated assessment estimates that the current 1-hour standard results in 8-hour exposures of concern at and above 0.08 ppm that vary by almost two orders of magnitude across all nine urban areas. In contrast, the alternative 8-hour standards at the proposed level of 0.08 ppm result in estimated 8-hour exposures of concern and risks that are much more consistent. In EPA's view, the fact that an averaging time of 8 hours results in a significantly more uniformly protective national standard than the current 1-hour standard is an important public health policy consideration that supports the selection of an 8-hour averaging time.

(2) *Specific Comment (George Wolff, IV-D-2334):* Commenter's personal recommendation with regard to averaging time is to set a new 8-hour O_3 primary standard in place of the 1-hour standard. The commenter asserts that although the CASAC Panel favored the 8-hour standard, and it was the consensus of the Panel that there be only one O_3 primary NAAQS, the CASAC Panel recognized that the same degree of health protection could be achieved with either an 8-hour or a 1-hour NAAQS at the appropriate levels.

Response: EPA agrees that a new 8-hour O_3 primary standard should be set in place of the 1-hour standard, because the 8-hour standard more appropriately directs control programs to reduce the risk of exposures of most concern. EPA also agrees with the commenter that it is possible for either a 1-hour standard or an 8-hour standard, at appropriate levels, to provide roughly "equivalent" public health protection nationwide (in terms of total population protected or aggregate risk), although EPA notes that any such 1-hour and 8-hour standards would not be truly equivalent since different areas would be protected under 1- or 8-hour standards with levels that result in roughly equivalent protection nationwide.

(3) *Comment:* EPA should retain the current 1-hour standard to protect against short-term exposures to O_3 and set an 8-hour standard to provide protection against the prolonged 6- to 8-hour exposures to O_3. A greater degree of health protection than that afforded by either standard alone is warranted, and both a 1- and 8-hour standard are needed to provide the requisite protection from exposures of concern.

Response: As stated in the preamble to the final rule, while EPA agrees that it is possible that an 8-hour standard alone could allow for high 1-hour exposures of concern (at and above 0.12 ppm), EPA's exposure assessments estimate that alternative 8-hour standards at the level of 0.08 ppm, but with different forms, would be very effective in limiting 1-hour exposures, and generally even more effective in limiting 1-hour exposures of concern than is the current 1-hour standard. More specifically, the updated assessment estimates that upon attainment of alternative 8-hour 0.08 ppm standards (with forms ranging up to the 5th highest concentration form), less than 0.1% of outdoor children are likely to experience any 1-hour exposures greater than 0.12 ppm while at heavy exertion levels in four to seven of the nine urban areas analyzed, whereas this is true for only two of the nine urban areas upon attainment of the current 1-hour standard. In all nine urban areas both the current and alternative 8-hour standards are estimated to limit such exposures to less than 1% of the outdoor children. Thus, EPA concludes that an 8-hour 0.08 ppm averaging time does effectively limit both 1- and 8-hour exposures of concern.

iii. Air quality trends

This section addresses comments included in section III.A.1(c) and elsewhere in the Summary of Comments that raise air quality trends related issues. The comments on recent air quality trends were received from numerous commenters representing industry, trade associations (NMA, IV-D-2247), (CMA, IV-D-2249), (AAMA, IV-D-2243), and others.

(1) *Comment:* Commenters stated that national air quality trends do not support the need for a revision to the NAAQS for O_3. Levels of O_3 and emissions of O_3 precursors such as VOCs have been consistently declining for the past ten years. The commenters also noted that the Agency's own National Air Quality and Emissions Trends Report, 1995 shows that over the past 25 years emissions and ambient concentrations of the 6 criteria pollutants have decreased nationally by almost 30%. Further, the commenters said that the significant reduction in the number of nonattainment areas, the decline in emissions and ambient levels from current and prospective CAA programs, and EPA's forecast of continued reductions in O_3 precursor emissions strongly suggest that there is no need for EPA to adopt more stringent NAAQS.

Response: The Administrator, in her November 1996 press conference announcing the findings of the 1995 Trends Report, said that the trends showed continued air quality improvement during the past 10 years for all six criteria pollutants. These air quality improvements are especially encouraging given the economic growth that has occurred in this country during the past 25 years. However, the fact that air quality is improving does not mean that EPA should not establish a new O_3 air quality standard that better reflects human exposure and risk. As the Administrator stated in her press release, "Today's report underscores the effectiveness of strong, protective air pollution standards and the continuing need for such standards to protect public health. As science provides us with new information about the health risks of air pollution, EPA must continually review and update our national standards to ensure that they protect the public." For the reasons noted in the preamble to the final rule, the Administrator has decided to replace the current 1-hour O_3 standard with an 8-hour O_3 standard to protect public health.

b. Level of 8-hour standard

This section addresses specific comments included in Section III.A.2.b and elsewhere in the Summary of Comments concerning the level of the 8-hour primary O_3 standard.

As discussed in the preamble to the final rule, many public commenters supported EPA's proposed level of 0.08 ppm for an 8-hour standard, including most public health associations and groups of medical professionals, many citizens, and some States and regional associations. There were also large numbers of commenters who expressed strong views in opposition to the proposed level. Of those who did not support the proposed 8-hour level, including many local governmental groups and private citizens, some States, and almost all commenters representing businesses and industry associations, either supported no change to the current standard or, if EPA were to replace the current 1-hour standard with an 8-hour standard, supported a level of 0.09 ppm directly or simply one that would be “equivalent” to the current standard. On the other hand, environmental groups, many citizens, and some medical professionals and researchers supported a level of 0.07 ppm for an 8-hour standard.

In general, the issues raised by these groups of commenters can be addressed in three categories: (1) comments on the strength and adequacy of the health effects evidence upon which the proposed decision was based, (2) comments on the quantitative exposure and risk assessments and the extent to which the assessments either over- or under-predict exposures and risks among sensitive populations, and (3) judgments as to whether the differences in public health protection provided by alternative standards are significant from a public health perspective. Each of these categories of key issues is discussed below.

With regard to the first category of comments, on the strength and adequacy of the health effects evidence, commenters who did not support the need for any increased protection beyond that provided by the current standard questioned the adequacy or highlighted the limitations of the various types of health effects studies that have related O_3 exposures to adverse effects. For example, some commenters questioned the controlled human exposure studies, arguing that: (1) many such studies used patterns of exposures and exercise levels that are not representative of normal population exposures to ambient O_3, (2) some exposure chambers using artificially generated O_3 may have been contaminated with other pollutants that could have accounted for some of the observed effects, and (3) responses to elevated O_3 levels were compared to responses to air with essentially no O_3 rather than to background levels typical of ambient air. Some commenters argued that these flaws in the study designs would result in overestimating responses to non-background levels of ambient O_3 or in erroneous findings of statistical significance. In contrast, others commented that because the chambers did not contain other pollutants and natural pulmonary irritants (e.g., pollens, dust) or a full range of environmental conditions (e.g., high temperatures and humidity) typical of ambient air, the results may underestimate the true impact of O_3 in the ambient air.

Some commenters also questioned the summer camp and other field studies and epidemiological studies reporting increased hospital admissions and emergency room visits, arguing that: (1) the responses in these studies were inherently confounded by exposures to other pollutants, (2) the camp studies did not differentiate activity levels of the participants, and (3) linear regression down to or below background levels was unjustifiably used to analyze the results of the hospital admission studies. These commenters expressed the view that these and other flaws call into question any conclusions about whether the reported associations are causal. In contrast, other comments argued that the hospital admissions reported in these studies are indicative of a pyramid of adverse health effects, including increased mortality, increased visits to emergency and outpatient departments and physicians, increased numbers of asthma attacks resulting in increased medication use, and increased numbers of restricted activity days and acute respiratory symptom days, that EPA has not adequately taken into account. The EPA notes that these comments are consistent with statistics published by the U.S. Department of Health and Human Services, which indicate that for every hospital admission of an individual with asthma for respiratory causes, there are more than five emergency and outpatient department visits and more than 20 office-based physician visits (U.S. DHHS, 1996).

With regard to studies related to pulmonary inflammation and chronic respiratory damage, some commenters argued that the linkage between repeated inflammatory responses and chronic respiratory damage was merely speculation, and, therefore, should not to be considered as part of the basis for decisions on the primary standard. In contrast, others commented that animal studies had demonstrated that repeated pulmonary inflammation leads to degenerative or irreversible lung damage, that these studies are consistent with observations in human exposure studies, and, therefore, that they should be considered in decisions on the standard.

The EPA notes that many of these comments did not reflect an integrative assessment of the evidence--the approach CASAC has historically urged EPA to follow--but rather a piecemeal look at each individual study or type of study, which tends to miss the strength of the entire body of evidence taken together. Other commenters did consider the body of evidence in a more integrative manner, and many of these commenters expressed the view that the body of evidence as a whole provided clear evidence of O_3-related effects at and below O_3 concentrations allowed by the current standard. Some commenters highlighted the large number of studies that demonstrate evidence of effects for prolonged exposures at and below 0.08 ppm, and criticized EPA for giving too little weight to those studies which reported serious effects, but for which the data were not sufficient to do quantitative risk assessments.

With regard to the second category of comments, on the exposure and risk assessments, a number of commenters raised concerns about key aspects of the assessments including: the exposure model, the development of concentration-response functions, the application of the risk model, and the measures of risk used to characterize the results of the assessments. With regard to the exposure model, a number of commenters claimed that: (1) the model overestimates the exertion level that can be achieved by most children and outdoor workers and the fraction of time that these groups spend in moderate or heavy exertion, (2) the model overestimates outdoor ambient exposures because fixed-site monitors overestimate outdoor personal exposures, and (3) the air quality adjustment procedures used to simulate attainment of the standards are inappropriate or highly uncertain. Other commenters expressed concern that the exposure model may be significantly underestimating exposures for children and outdoor workers who repeatedly exercise due to limitations in the available human activity pattern data.

As discussed in the proposal, EPA recognizes that the exposure model necessarily contains many sources of uncertainty, although every effort has been made to account for such uncertainties to the extent possible. In particular, the model incorporates and is sensitive to analytical procedures used to simulate spatial and temporal distributions of O_3 concentrations that would occur as a result of an area just attaining any of the alternative standards addressed in the exposure assessment. These air quality adjustment procedures are based on generalized models intended to reflect the patterns of changes in distributions of O_3 concentrations that have historically been observed in areas implementing control programs designed to attain the O_3 NAAQS. The EPA recognizes that future changes in air quality distributions are area-specific, and will be affected by whatever specific control strategies are implemented in the future to attain the revised NAAQS. Thus, generalized models are expected to be more uncertain for any given area than when exposure results are aggregated across many areas (as was done across the nine urban areas analyzed in EPA's exposure assessment).

Some commenters questioned the specific air quality adjustment procedures used in the initial and supplemental assessments[3], and a few of these commenters recommended revisions or alternative procedures that they believed would be more representative of historical or projected future air quality patterns. As discussed in more detail in the Response to Comments, EPA acknowledges that both procedures used in the assessments result in projections of air quality that deviate to some degree from historical patterns of air quality changes observed in specific urban areas, and that other procedures may be more representative of air quality patterns in specific areas. While EPA will take these comments into account as future refinements are made to the air quality adjustment procedures used in the exposure model, EPA believes, and CASAC concurred, that the procedures used in the assessments conducted as part of this review are reasonable given the uncertainties inherent in projecting future changes in air quality patterns.

In commenting on the air quality adjustment procedure used in the supplemental assessment, some commenters particularly focused on the results for two of the nine areas analyzed in which, contrary to results from the initial assessment, lower risks were estimated for the current standard as compared to the proposed standard. As discussed more fully in the Response to Comments, EPA believes that these results for each area can not be distinguished within the sensitivity of the alternative air quality adjustment procedures used in the initial and supplemental assessments. Further, EPA notes that these two areas have much higher ratios of peak 1-hour to 8-hour O_3 concentrations than the vast majority of areas in which O_3 is monitored[4], and it is thus reasonable to expect that generalized air quality adjustment procedures would be particularly uncertain for such areas.

Comments focusing on the development of concentration-response functions for use in the risk model have claimed that: (1) EPA inappropriately selected studies for developing the functions by excluding studies that reported lower response rates and by using only studies conducted by EPA

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[3]The initial risk assessment used both "Weibull" and "proportional" air quality adjustment procedures, whereas the supplemental risk assessment used a "proportional" air quality adjustment procedure for all nine urban areas. In responding to comments on the air quality adjustment procedures, EPA also evaluated an alternative "quadratic" procedure (as discussed in the Response to Comments), which generally resulted in risk estimates between those from the Weibull and proportional procedures.

[4]The two areas are Houston and Los Angeles, which are two of only six areas nationwide with peak 1- to 8-hour design value ratios greater than 1.5.

scientists, (2) contaminants in the controlled exposure chambers may be responsible for some of the effects incorporated into the concentration-response functions for O_3, (3) it was inappropriate to extrapolate the concentration-response functions to background levels, and (4) it was inappropriate to develop concentration-response functions for symptomatic responses in children based on studies of such responses in adults.

Of the comments focusing on the application of the risk model, some commenters claimed that the aggregate risk results were overstated because of: (1) many of the methodological problems noted in the above Summary of Comments, (2) the failure to take into account the known attenuation of effects, and (3) the assumption of an inappropriately low background concentration in calculating risks attributable to non-background sources of O_3. On the other hand, other commenters claimed that aggregate risk results were understated because of: (1) methodological problems, noted above, that underestimate exposures, (2) limiting the analyses to only a subset of adverse health effects rather than estimating the full range of effects that have been attributed to O_3, and (3) by focusing only on nine urban areas rather than projecting risk reductions from alternative standards nationally.

While EPA has responded more fully to these comments elsewhere in this document, EPA notes here that most of the issues and concerns raised by commenters concerning the health effects evidence and the methods used in the exposure and risk assessments are essentially restatements of concerns raised during the review of the Criteria Document and the development and review of these quantitative assessments as part of the preparation and review of the Staff Paper. EPA presented and the CASAC reviewed in detail the approaches used to assess exposure and health risk, the studies and health effect categories selected for which concentration-response functions were estimated, and the presentation of the exposure and risk results summarized in the Staff Paper. As stated in the proposal notice, EPA believes and CASAC concurred, that the general models selected to estimate exposure and risk are appropriate and that the methods used to conduct the exposure and risk assessments represent the state of the art. EPA does not believe that the exposure or risk assessments are fundamentally biased in one direction or the other as claimed in some of the comments.

The Administrator and CASAC have recognized, however, that there are many uncertainties inherent in such assessments and that the resulting ranges of quantitative risk estimates do not reflect all of the uncertainties associated with the numerous assumptions inherent in such analyses (Wolff, 1995). In the proposal notice EPA summarized some of the most important caveats and limitations concerning both the exposure analyses and the risk assessments for lung function changes, respiratory symptoms, and hospital admissions. A more complete discussion of assumptions and uncertainties is contained in the Staff Paper and technical support documents (Johnson et al., 1996 a,b; Whitfield et al., 1996; Richmond, 1997).

With regard to the third category of comments, reflecting commenters' judgments as to whether the differences in public health protection of alternative standards are significant from a public health perspective, EPA notes that highly divergent judgments were expressed by different groups of commenters. A large number of commenters who expressed the view that the differences in public health protection were not significant or important enough to warrant any standard more stringent than the current standard used CASAC as the basis for their position. Others cited small percentages of outdoor children and other sensitive groups likely to be affected based on EPA's assessment, or even smaller percentages as modified by analyses conducted by the commenter to correct perceived errors in the analyses. In contrast, other commenters cited large total numbers of children likely to be affected, not only for the subset of O_3-related effects and the nine areas analyzed in EPA's assessments, but also for a broader array of related effects projected nationally.

See section II.B of the preamble to the final rule for further response to comments on the level of the primary standard.

(1) *Specific Comment (Clean Air Network, IV-D-2301):* The commenter asserted that an 8-hour standard of 0.07 ppm is necessary to protect public health and can be defended with sound science. Further, the commenter asserted that tens of thousands of hospital admissions would be prevented by a tighter 8-hour standard.

Response: The O_3 primary standard published in the preamble to the final rule is based on extensive scientific and technical review of O_3 health effects information. Based on that review, it is the conclusion of the Agency that the standard, as published, provides protection of public health from exposure to ambient concentrations of O_3 with an adequate margin of safety. See also Section II.B of the preamble.

(2) *Specific Comment (NESCAUM, IV-D-2169):* The NESCAUM States support the proposed primary standard and are comforted by the fact that the process by which EPA has developed the primary standard has produced a standard which is adequately protective of public health. Reliance on CASAC and extensive peer review of the best available science reviewed by a committee of national experts from academia and industry demonstrates that EPA's proposal is appropriate.

Response: The EPA agrees that the air quality criteria review process has provided a strong scientific basis for this rulemaking. The Agency believes that the primary O_3 standard, as published in the preamble to the final rule, is based on the best available science and protects of public health with an adequate margin of safety.

(3) *Specific Comment (UARG, IV-D-2253):* Commenter supports 0.09 ppm only if standard must be revised to an 8-hour averaging period, because it would be the only level of the options in proposal that would be equivalent to the current standard.

Response: The Agency's decision, as published in the preamble to the final rule, is that the O_3 primary standard should be set with an 8-hour averaging period and at 0.08 ppm, a level at which numerous controlled-exposure human studies have reported health effects such as lung function decrements, respiratory symptoms, and indicators of inflammation. The decision to set the 8-hour primary standard level at 0.08 ppm is based upon the review of scientific literature contained in the O_3 Criteria Document and O_3 Staff Paper and the extensive scientific review of that information by CASAC and the public.

c. Form of 8-hour standard

A number of comments were received on the form of the standard in general, and on a number of specific issues including: the use of a concentration-based form, considerations with regard to the stability of alternative forms, spatial averaging across monitors, and considerations with the use of a too-close-to-call concept for determining compliance with the standard. These comments are included in section III.A.2(c) and elsewhere in the Summary of Comments document. Responses to these comments in general are discussed in section II.B.3 of the preamble to the final rule; the more specific issues are discussed further below.

i. Concentration-based vs. exceedance-based forms

Comment: Ford Motor Company (Ford, O_3, IV-D-5323) is concerned about the conversion from the exceedance form to the concentration-based form. Ford believes that the corresponding concentration-based form for three allowed exceedances per year should be the annual fourth-highest value, averaged over three years. Similarly, Ford said that the current one-exceedance form has always been translated into requiring the annual second highest value not to exceed the level of the standard, or the fourth highest value in three years not to exceed the level of the standard. With the above conventional definition, Ford believes that the proposed form of the annual third-highest value is not consistent with the intended choice of three allowed exceedances per year.

Response: The preamble to the final rule described the Administrator's rationale for selecting a concentration-based form for the O_3 NAAQS, and clearly stated that the decision was not made by merely "converting the exceedance form." The commenter has ignored the differences between exceedance-based standards that place a "cap" on the total number of exceedances in a three year period, and the average 'nth max' form that does not limit the number of exceedances in a single year. An average 2nd max concentration design value is not the same as the 4th highest day. For example, with the current one-exceedance per year standard, once four exceedances are recorded, even in the first year of three, the standard is not met, regardless of the number of exceedances in succeeding years. EPA performed analyses of air quality relationships for both concentration-based and exceedance-based forms which were cited in the proposal notice (EPA, 1996). While a three exceedance per year standard limits the total number of exceedances in a 3-year period to 9 exceedances, based on air quality data, 5 percent of sites just attaining an average annual 3rd highest concentration standard had 7 or more exceedances of 0.08 ppm, compared to 6 exceedances for the three exceedances form. The worst site for the concentration-based form had 12 exceedances in the worst year of 3 years, whereas the worst site attaining a 3 exceedances per year standard recorded 8 exceedances in the worst year of three.

ii. Stability considerations

This section addresses comments included in section III.A.2(c) of the Summary of Comments and elsewhere on stability considerations for the form of the standard. Numerous commenters expressed support for the concentration-based form because they stated that it would be more robust than the exceedance-based form of the current standard. Ford Motor Company (Ford, IV-D-5323) expressed concerns about the stability of the proposed form of the new concentration-based standard and provided supplemental data analyses with their comments. Other commenters that expressed concerns about stability either cited the Ford comments or made general statements.

Comment: Ford noted that meteorology fluctuates from year to year and so does the O_3 concentration, being substantially influenced by meteorology. In the absence of a statistical attainment test, to avoid flip-flops and secure a long-term attainment status, Ford believes that an area must effectively lower the design value well below the level of the standard to make room for this fluctuation. The long-term mean of the design value below which no violation of a given standard will occur can be determined from the data. For the form of the proposed standard, Ford estimated the "effective" design value at 78 ppb for the proposed concentration-based standard. Ford also provided a chart listed as Figure 1, "Number of counties not meeting the different forms of the O_3 air quality standard" (Ford, IV-D-5323) which Ford said showed similar year-to-year changes in the number of areas failing to meet alternative standards.

Response: Clearly, the proposed concentration-based annual average 3rd highest concentration form is more stable than the current one exceedance per year form. EPA's annual Trends Reports have long documented the greater year to year variability in the number of exceedances of the standard level than in peak concentrations. Further, the analysis provided by Ford shows that the long-term mean design value for the current 1-hour standard of 0.12 ppm is 108 ppb, while the long-term design value is 78 ppb for the 0.08 ppm standard given the standard rounding conventions. Thus, to ensure long-term compliance with the standard, the long-term design value for the current 1-hour standard must be at least 12 ppb lower than the level of the 1-hour standard, while it need be only 2 ppb lower for the average annual 3rd maximum concentration-based 8-hour standard. EPA expects similar results for the final average annual 4th maximum 8-hour concentration-based standard. Finally, Ford's Figure 1, "Number of counties not meeting the different forms of the O_3 air quality standard" (Ford, IV-D-5323) clearly shows that there are smaller year to year differences for the proposed 8-hour concentration-based form than for the current 1-hour exceedance-based O_3 standard.

iii. Spatial Averaging

This section responds to comments regarding the use of spatially-averaged air quality data versus the use of data from the highest monitor in the area to judge compliance with the standard. These comments are primarily contained in sections I.B.8. and III.A.2(c)3 of the Summary of Comments, but may be in other sections as well.

Comment: Commenters from business and industry associations frequently supported the use of spatially-averaged data, as did a small number of States, principally because it would provide a more stable air quality indicator. Two industry commenters, the American Automobile Manufacturers Association, and the American Petroleum Institute, provided highly specific comments that included the following representative arguments regarding the advantages of spatial averaging, 1) it would better represent population exposure and risk, 2) it would be consistent with the use of risk assessment as a policy tool, 3) it would produce a more representative measure of overall air quality, and 4) it was proposed in the rulemaking for PM. In sharp contrast, environmental associations, public health professionals, most States, and many individuals voiced strong concerns that the use of spatially-averaged data would routinely allow individuals who live or work in an area with consistently higher O_3 levels to be exposed to concentrations of concern. Many commenters raised the issue of environmental equity, expressing the view that areas with consistently higher O_3 concentrations typically are composed predominately of individuals of lower socioeconomic status, or are composed of a predominately minority population. Some commenters raised concerns with about the complexity and burdens associated with redesigning existing monitoring networks.

Response: The issues raised with respect to the use of spatially-averaged air quality data to judge compliance with the standard are addressed within the preamble to the final rule, prinicipally in Section II.B.

iv. Too-close-to-call concept

This section addresses comments included in section III.A.2.d(4) and elsewhere in the Summary of Comments that raise issues concerning the use of statistical attainment to determine compliance with the standard. Specific supporting information was submitted by two commenters, Ford Motor Company (Ford, IV-D-5327) and the American Automobile Manufacturers Association (AAMA, IV-D-2243). The Vermont Air Pollution Control Division (VT, IV-D-9696) offered general support for a "too-close-to-call" concept or some other measure to minimize "flip-flops."

(1) *Comment:* The commenters stated that it is absolutely necessary that a statistical attainment test be used to determine compliance; such a statistical test will generate a "too-close-to-call" interval that will change according to fluctuations in measured ambient O_3 concentrations.

Response: EPA does not believe that it is appropriate to implement a "too-close-to-call" category as part of the O_3 NAAQS. As noted in the preamble to the final rule and elsewhere in this response to comments document, the new concentration-based form of the O_3 NAAQS is more stable than the current one exceedance per year standard. However, EPA is exploring this issue and other implementation issues with its State partners and other stakeholders as part of the Federal Advisory Committee Act (FACA) process addressing implementation issues for the new standard.

While the use of a confidence interval approach can reduce the misclassification rate (i.e., cases where truly attainment areas are classified as nonattainment, and vice versa), it can also delay the implementation of needed controls, or conversely, the redesignation of an area from nonattainment to attainment.

(2) *Comment:* Commenters said that currently, areas that may otherwise be in attainment often get pushed into nonattainment due to one hot year, since O_3 concentrations fluctuate from year to year due to meteorology.

Response: Numerous comments were received strongly supporting the change from an exceedance-based to a concentration-based form for the standard. One of the reasons most often cited was that the concentration-based standard, the 3-year averages of the annual 3rd-highest-concentration form (or higher nth max forms such as the 4th or 5th max), is more stable than the current one exceedance per year form. EPA's annual Trends Reports have long documented the greater year to year variability in the number of exceedances of the standard level than in peak concentrations. The number of exceedances of the level of the standard is more sensitive to year-to-year changes in meteorology than are peak concentrations. Figure 1, "Number of counties not meeting the different forms of the O_3 air quality standard" (Ford, IV-D-5323) shows smaller year to year differences for the proposed concentration-based form versus the current 1-hour exceedance-based form. The exceedance-based form limits the total number of exceedances that can occur during the entire 3-year compliance period. Thus, a single hot summer could cause an area to change from attainment to nonattainment with the exceedance-based form. However, with the concentration-based form, there is no cap on peak concentrations and a single year doesn't automatically place an area into noncompliance since other lower years are averaged in with the peak year.

(3) *Comment:* Ford, and others, said that to avoid attainment flip-flops all areas must have an effective design value that is much lower than the level of the standard.

Response: The analysis provided by Ford (Ford, IV-D-5323) shows that the long-term mean design value needed to ensure continuous attainment for the current 1-hour standard of 0.12 ppm is 108 ppb, while the long-term design value is 78 ppb for the 0.08 ppm standard given the standard rounding conventions. Thus, to ensure long-term compliance with the standard, the long-term design value for the current 1-hour standard must be at least 12 ppb lower than the level of the 1-hour standard, and only 2 ppb lower than the level of the standard for the average annual 3rd max concentration-based standard. EPA expects similar results for the 4th max concentration-based form.

(4) *Comment:* Ford recommends the use of a T-test to create a statistical attainment test that provides for a "too-close-to-call' category.

Response: Various statistical methods, including a T-test, could be devised to include a "too-close-to-call" category. For the current exceedance-based form of the 1-hour standard, for example, EPA could designate an exceedance rate above 1 so that sites with an expected exceedance rate between 1 and that value would be regarded as too-close-to-call, and sites above that rate would be designated as nonattainment. For concentration-based standards, the design value could be used to define a "too-close-to-call" category based on a confidence interval. A T-test is not the only statistical approach available, and its assumptions would have to be assessed for such small sample size (i.e., 3 annual peaks). Other statistical approaches include nonparametric methods, and parametric approaches, such as the California Air Resources Board current approach which involves fitting a tail-exponential distribution. Before a statistical confidence interval approach could be considered, one issue that would need to be addressed is the issue of how to handle missing or incomplete data. Minimum data completeness requirements might be needed to limit the problem that if there is a lot of missing data, then the confidence intervals would be wider and the "too-close-to-call" category would be more likely.

d. Revisions to Appendix H

As explained in the Preamble to the Final Rule, because the revocation of the current 1-hour standard will become effective at a later date, EPA has decided to retain the existing Appendix H in its current form. A new Appendix I applies to the new 8-hour NAAQS. The discussion below sometimes refers to the contents of the new Appendix I as revisions to Appendix H, so as to highlight how the new Appendix I differs from the current Appendix H.

i. <u>Data completeness and missing data adjustment</u>

This section addresses comments included in section III.A.2.d (1) and elsewhere in the Summary of Comments that raise issues concerning the data completeness requirements and missing data adjustment procedures of the proposed revisions to Appendix H as included in the new Appendix I.

(1) *Comment:* Several commenters from the environmental community suggested that the standard created an incentive for monitoring agencies to "throw out valid data showing exceedances."

Response: EPA disagrees with the contention that the changes reflected in new Appendix I create an incentive for throwing out valid data. Part 58 to 40 CFR contains specific requirements for monitor siting and quality assurance procedures that are followed by the state and local agencies who operate the individual monitoring networks throughout this nation. One of those requirements is the annual certification by the senior air pollution official of the operating agency that the data were collected in a manner that conformed to the applicable quality assurance, air monitoring methodology, and probe siting criteria of Part 58.

(2) *Comment:* Numerous commenters, including most states, supported dropping the current approach of adjusting the exceedance rate for missing data and replacing that approach by raising the data completeness requirements.

Response: As noted above, Section II.B.3 of the preamble to the final rule contains an extensive discussion of the rationale for changing the form of the standard from an exceedance-based standard to a concentration-based standard and those issues are not addressed here. For the concentration-based standard, there is no numerical adjustment to the average fourth-highest concentration to account for missing data. In its place, the new Appendix I states that for a site to demonstrate attainment with the standards, the site must average 90 percent data completeness for the 3-year compliance period, with no single year having less than 75 percent.

(3) *Comment:* The Northeast States for Coordinated Air Use Management (NESCAUM) commented that EPA should exercise caution when relying on automated procedures in EPA's Aerometric Information Retrieval System (AIRS) to compute whether the data completeness requirement has been met at a monitoring site (NESCAUM, IV-D-2169) .

Response: EPA has continued to work with the data reporting agencies, both the state and local agencies, to ensure that the O_3 season is updated correctly in AIRS.

(4) *Comment:* EPA received a comment from Governor James Hunt of North Carolina (NC, IV-D-7003) that the State believed that the 90 percent data completeness requirement was too stringent. NC stated that they believed that a minimum requirement of 75 percent data completeness was more reasonable.

Response: EPA established the minimum data completeness requirement, average data completeness of 90 percent with no single year less than 75 percent, after reviewing historical data completeness for monitoring sites reporting ambient data to EPA's Aerometric Information

Reporting System (AIRS). During 1993-95, sites that operated continuously during that 3-year period averaged greater than 90 percent data completeness for a daily maximum 8-hour average standard. The results by category averaged across all states were 97% data completeness for sites designated as National Air Monitoring Stations (NAMS), 96% for sites designated as State and Local Air Monitoring Stations (SLAMS), 92% for Special Purpose Monitoring sites (SPMs) and 95% for privately operated sites. The specific results for sites in North Carolina were 98 percent data completeness for NAMS, 95 percent for SLAMS and 89 percent for SPMs. These results demonstrate that the minimum data completeness requirements in the new Appendix I are reasonable.

(5) *Comment:* Several States expressed concern that they would be penalized for hours missing due to routine calibration procedures.

Response: EPA believes that individual hours that are lost when calibrating the instrument will not negatively impact the data completeness calculation for two reasons. First, data completeness is computed on the basis of the number of days with valid 8-hour daily maxima, not hours. Second, a single missing hour will not cause an 8-hour period to be counted as missing.

(6) *Comment:* Two commenters stated that servicing and quality assurance checks of monitors should occur outside of the typical peak O_3 period of 9:00 am to 9:00 pm. Missing an hour or more out of this peak diurnal period should be counted as 1 of the 36 days per year that EPA allows for monitoring equipment malfunction.

Response: The number of days to meet the completeness requirement under the proposed rule is not 90 % of the days in a year (365 days). To demonstrate attainment, 90 % of days in the O_3 season within a three year period are to be valid, with at least 75 % of the days in the O_3 season per year. However a nonattainment designation under the proposed rule may also use data from incomplete years and days if the concentrations exceed the level of the standard. The quality assurance guidelines are intended to make sure that servicing and calibration activities do not impact the daily maximum concentrations. If other data are missing at random, and if the peak is sufficiently sharp, then the missing hours would be more likely to increase the daily maximum 8-hour average concentration than to decrease the daily maximum, because the missing hours are less likely to occur at the peak hours. If there is concern about the possibility of peak hours being deliberately excluded by some counties, then one can examine the data for patterns in the missing hours. Note however that if a county really wanted to fix the data to avoid a nonattainment designation, then a more rigorous completeness requirement could just as easily be circumvented by reducing the measured peak concentrations. The deliberate removal or reduction of measured concentrations is prohibited by the monitoring regulations set forth in 40 CFR Part 58.

ii. Consideration of meteorological conditions to identify missing days assumed to be less than the level of the standard

This section addresses comments summarized in section III.A.2.d.1 and other sections of the Summary of Comments on the use of data on meteorological conditions to identify missing days when meteorological conditions are not conducive to peak O_3 formation. In the proposal, the EPA specifically requested comment on the appropriateness of using data on meteorological conditions, as well as on other information that would permit better definition of those necessary conditions likely to result in peak 8-hour O_3 concentrations in the ranges of concern.

Comment: Most commenters expressing an opinion supported the use of meteorological data, as well as ambient data from nearby monitoring sites to establish that missing hours could be assumed less than the level of the standard. Commenters stated that days assumed less than the level of the standard should be counted as non-missing when computing whether the data completeness requirements have been met at the site.

Response: As noted in the Preamble to the Final Rule, EPA took these comments into account and decided to include procedures in the new Appendix I to count missing days assumed less than the standard when computing data completeness. EPA will develop guidance on methodologies necessary for using meteorological data and ambient measurements to make such determinations.

iii. Consideration of stratospheric O_3 intrusion

This section addresses comments included in section III.2.d(2) and elsewhere in the Summary of Comments that raised issues on whether peak O_3 concentrations resulting from stratospheric O_3 intrusion should be excluded when judging compliance with the standard.

Comment: Several commenters stated that stratospheric O_3 intrusion could lead to high peak concentrations at a monitoring site which would cause an area to be declared in nonattainment for the standard.

Response: EPA addressed this concern in the preamble to the final rule. Documented events of stratospheric O_3 intrusion may be flagged as uncontrollable natural events and excluded from compliance calculations following procedures specified in the new Appendix I to Part 50.

iv. Data handling and rounding conventions

This section addresses comments included in section III.A.d(2) on data handling and rounding issues, in section III.A.d(3) on quality assurance issues, and elsewhere in the Summary of Comments which raise issues on data handling conventions, rounding conventions and quality assurance procedures.

(1) *Comment:* Several comments were received, including a comment from the NESCAUM states (NESCAUM, IV-D-2169), that supported substituting values, such as background, zero, etc., for missing data in those 8-hour periods that recorded less than 6 hours of data. The NESCAUM states were concerned that sites not be rewarded for missing data. In the proposal notice, EPA specified that 8-hour periods with less than 6 hours of data would be treated as missing.

Response: EPA responded to these comments in the preamble to the final rule by modifying the data handling procedures in the new Appendix I for 8-hour periods with less than 6 valid hours. In the new Appendix I, eight-hour periods with three or more missing hours are not ignored if, after substituting one-half of the minimum detectable value for that instrument, the resulting 8-hour average concentration is greater than the level of the standard.

(2) *Comment:* Several commenters recommended changes to the computation procedures for daily maximum 8-hour average concentrations to limit possible double counting of 8-hour exceedances. Ford Motor Company (Ford, IV-D-5323) commented that the running 8-hour average concentration should be assigned to the "mid-point" of the 8-hour period to minimize overlap of hours across days.

Response: EPA believes that the change from an exceedance-based standard to the concentration-based form should minimize this concern since exceedances are not counted. EPA examined typical diurnal patterns in hourly O_3 concentrations and discussed these results on pages A-6 through A-8 of the Ozone Staff Paper (EPA, 1996). It should be noted that there is no "mid-point" hour for an 8-hour average. The average concentration would have to be assigned to either the 4th or 5th hour of the 8-hour period. In response to these specific comments, EPA conducted an analysis of the frequency of occurrence of the start-hour for the annual 4th highest daily maximum 8-hour O_3 concentration. Based on all O_3 sites reporting data to AIRS for 1993, 98 percent of the annual 4th highest 8-hour daily maximum concentrations have all 8 hours within the calendar day. Based on these results, and for the reasons stated in the preamble to the final rule, EPA has not changed the computation of the 8-hour average daily maximum concentration and of the annual 4th highest 8-hour average daily maximum concentration.

(3) *Comment:* The standard should be stated to three decimal digits.

Response: For the reasons cited in the preamble to the final rule, EPA has retained the proposed two decimal rounding conventions in the new Appendix I.

The following specific comments on rounding, instrument precision and accuracy and data handling procedures were characterized in comments and analyses submitted by Ms. Antoinette Stein (Stein, IV-D-2342) and cited in comments by the American Lung Association (ALA, IV-D-2339) and others.

(4) *Comment:* Eight hour averaging significantly improves the measurement precision and supports stating the level of the standard to three decimal digits.

Response: An analysis conducted for EPA by Systems Applications, International described in "Determination of a reasonable systematic error estimate for O_3 monitors" (SAI, 1997) estimated the imprecision in an 8-hour O_3 measurement due to instrumental variation. This error is in two parts, systematic and random error. Systematic errors cannot be reduced by averaging and includes errors due to drift, detector non-linearity, precision error, instrument calibration error, NIST standard calibration error, and cross section uncertainty, in the case of UV O_3 measuring instruments. Random errors are due to random fluctuations in the measured signal strength, and can be reduced by internal or external averaging. Internal averaging is performed automatically by instruments, which use averages over a user-specified time frame to compute the reported hourly concentration. External averaging computes eight hour averages from the reported hourly averages. The SAI analysis estimated that the imprecision of an eight hour average due to systematic errors is about 4 ppb, which can be interpreted as the standard deviation of the errors from a collection of monitors, or from the same monitor evaluated at random times.

As discussed above, and elsewhere in an analysis prepared for EPA (SAI, 1997), averaging can at best reduce the effects of random errors but cannot reduce the effects of systematic errors. For example, if the instrumental drift and non-linearity at the beginning of an eight hour period are such that the O_3 concentrations are underestimated by 5 ppb, then the same will essentially be true throughout the eight hour period so that the eight hour average will also be underestimated by 5 ppb. (This simplified argument ignores the fact that measurement precision varies with the measured concentration and ignores changes in systematic errors over a short time span.)

Another issue not previously discussed is that the Stein calculations assume that the random errors in each of the assumed 480 one minute measurements are statistically independent, which may well not be a valid assumption. In principle, one should expect the consecutive measurement errors to be correlated, although the size of that correlation will be very hard to estimate in any given situation.

(5) *Comment*: The health effects evidence from the chamber studies considered in setting the proposed standard has at least 3 decimal places of precision and accuracy, and since today's

monitoring instruments have precision of 0.001 ppm, the standard should also be expressed to three decimal places.

Response: First, there is a major question about whether or not chamber studies like the Folinsbee, Hortsman, and McDonnell studies represent the real world situation better than the epidemiological studies that the Administrator also considered. In a chamber study, the O_3 concentration is carefully controlled, and so the fluctuations in the concentration over space and time are probably much less than in the real world. For example, the Folinsbee study was designed to keep O_3 fixed at 0.12 ppm for 6.6 hours. Second, CASAC reviewed the health effects data and recommended a range of levels expressed to two decimal places rather than three. CASAC assessed all the health effects evidence, including not only the relatively tightly controlled chamber studies, but also numerous epidemiological studies discussed in the Criteria Document. It seems clear from their recommendations that the committee would not agree with Stein's assertion that the clinical evidence shows an O_3 effect to three decimal places of precision and accuracy.

(To clarify the next points, "worse" precision or accuracy than 0.001 ppm means that the results are not as accurate, e.g. the precision and accuracy might be to two decimal places rather than three. If the precision and accuracy is worse, then the measured precision and accuracy value (e.g. standard deviation of the measurement error) will be numerically higher.)

Third, it should be noted that the precision and accuracy of the O_3 concentrations in the chamber studies may have been overstated by Stein, and were worse than in Steins' report. For example, the Folinsbee article states that the O_3 levels averaged 0.120 ± 0.002 but two minute averages ranged from 0.092 to 0.141. It is not clear from the text whether the 0.002 is the standard deviation of the data or the standard error of the mean, although the wide range suggests that the reported value represents the standard deviation of the mean, so that the O_3 concentration precision (as defined by the standard deviation of the data) was actually much worse than 3 decimal places for this study. Furthermore, even if the measured O_3 concentrations were reported to 3 decimal places, analyses have suggested that those reported values could have had systematic errors on the order of 4 ppb.

(6) *Comment:* A commenter said that the paper by Curran and Suggs (1979) showed peak statistics were overestimated due to imprecision in the data. Based on new simulations conducted by the commenter, with different assumptions from Curran and Suggs, the commenter believes that the rounding convention may not prevent misclassifications of nonattainment, and can result in misclassifications as attainment. The commenter suggests that the Curran and Suggs results motivated the selection of the rounding convention.

Response: The comments on the Curran and Suggs paper are interesting, but this paper did not play any role in the Administrator's decision on setting the level of the standard and the rounding convention. (See response to specific comment 5 on p. 41 of this response-to-comment document.) However, given the obvious effort expended in commenting on the paper, EPA will respond to the major technical comments. The paper by Curran and Suggs (1979) showed that peak statistics would be overestimated (on average) due to measurement imprecision, and that the effect of the 20 % measurement imprecision in the Quality Assurance Guidelines could be counteracted by the bias of the rounding convention (for the current O_3 standard).

One general point that is not discussed by commenters is that the proposed standard is based on the third highest daily maximum eight hour average, and the fourth highest in the final rule, rather than the peak. All of the simulations are for the peak value. The Curran and Suggs effect on the third highest, and the fourth highest, value will be smaller.

(7) *Comment:* At a precision less than (i.e. more accurate than) 20 %, the rounding convention will lead to misclassification of an area as in attainment at some values above the standard.

Response: This simplistic, intuitive argument does not define the statistical issues associated with attainment misclassification, and ignores the variability in the O_3 data and in the Curran and Suggs overestimation. Any attempt to properly define these terms and determine whether the rounding convention has caused a misclassification soon leads to complexities.

Consider the Stein example of a 4 % precision, corresponding to an average overestimation of about 1 % for the maximum concentration, and the current 0.12 standard. Suppose a measured value is 0.122 ppm. Although this value is above 0.120, the monitor could easily be in attainment (with no misclassification) according to the current Appendix H rules, partly because the rounding conventions in Appendix H define attainment in terms of the expected exceedances of 0.125 ppm (> 0.122), and partly because the expected exceedances per year might easily be less than or equal to one. To avoid a circular discussion, the "true" attainment designation could be defined by whether or not the underlying expected value of the maximum value, as measured by a perfect instrument, exceeds 0.120, and the observed attainment designation could be redefined by whether or not the observed maximum exceeds 0.125 (hence allowing for rounding). As argued by Stein, if the observed maximum is 0.122 ppm, this is consistent with having 0.121 ppm as the value that would have been measured by a perfect monitor, due to the Curran and Suggs effect. However, the measured value from this hypothetical instrument could be lower or higher than this number. Classical statistical arguments cannot properly be applied in this case to evaluate the probability of a misclassification based on the observed value, since the true value is a fixed, but unknown, parameter of the distribution.

Absent any information on prior probabilities, it is more correct to use the classical statistical paradigm and argue the other way round, starting with the assumed parameter values. If the expected maximum measured by a perfect instrument is just above 0.12, but below 0.124, then an instrument with 4 % precision will on average have an expected maximum below 0.125, and the observed maximum has a certain probability of also being below 0.125, corresponding to a misclassification of attainment (relative to the underlying, unknown "true" designation). In this sense, the rounding convention increases the probability of misclassification of attainment and the Curran and Suggs effect decreases the misclassification probability. However, since maximum O_3 concentration distributions have a heavy tail, the variability in the observed maximum about its mean will likely be greater than the 0.005 rounding convention. In such a case the misclassification probability will be high, regardless of the rounding convention and/or the Curran and Suggs effect.

(8) *Comment:* The Curran and Suggs argument ignores site to site variability in the form and parameters of the underlying O_3 distribution.

Response: The size of the Curran and Suggs effect (i.e. overestimation of peak values due to measurement imprecision) will indeed depend upon the underlying distribution. The tendency of measurement imprecision to increase peak values follows regardless of the underlying distribution if it is assumed that the measurement errors are relative, rather than absolute. Under that assumption, the instrumental precision is, on average, a percentage of the measured value, and so has a larger impact on the higher values.

Stein made a critical error in the choice of alternative distributions to be evaluated. Since the Curran and Suggs effect is extremely unlikely to change the attainment classification for sites that are not borderline (the impact on the peak statistics will be small compared to the difference between the design value and the standard), the analysis should only be carried out for distributions where the design value is close to the standard, e.g., the 364/365 quantile equals 0.12 for the current standard, or equals 0.08 for the proposed standard.

(9) *Comment:* The Curran and Suggs argument ignores year to year variability in the overestimation and therefore overstates the impact on misclassification rates.

Response: The year to year variability is indeed an important consideration when evaluating the impact on misclassification rates. Stein appears to have incorrectly evaluated the effect on the misclassification rates by not excluding simulated years that are not borderline. Suppose the overall distribution has a design value at or just above the level of the current 0.12 standard. If a simulated year has a design value sufficiently above or below 0.12, then the measurement imprecision for that design value is unlikely to change the designation. If the underlying design value is equal to or less than 0.12, but the simulated year has a design value well above 0.125, then the year will be misclassified regardless of the rounding convention. In many cases the rounding and measurement imprecision effects will not affect the classification, but those cases should be excluded when comparing the impacts of the rounding convention and the Curran and Suggs effect.

(10) *Comment:* The discussion of the air quality design value should not be "nested" in the discussion of rounding. Nonattainment classifications should be included in Part 51, since the public has been informed that the standard is under revision, not the design value.

Response: The commenter has failed to recognize the distinction between the "definition" of the design value, which is a function of the form of the standard, and nonattainment classifications based on the" level" of the design value which are specified in the Clean Air Act Amendments of 1990. The air quality design value at a monitoring site is defined as that concentration that when reduced to the level of the standard ensures that the site meets the standard. Thus, whenever the form of the air quality standard is changed, then the definition of the design value must also change.

In specific response to this comment, in the final rule EPA moved the design value discussion to a separate section, Section 3 of the new Appendix I. For a concentration-based standard, the air quality design value is simply the standard-related compliance test statistic, because when the concentration equals the level of the standard the standard is attained. Thus, for the primary and secondary O_3 standards, the 3-year average of the annual fourth-highest daily maximum 8-hour average O_3 concentration is both the attainment test statistic and the air quality design value at a monitoring site.

v. <u>Uncertainty in data (QA procedures)</u>

Comment: The EPA should review and update 40 CFR, Part 53, Subpart B which deals with the testing and performance characteristics of automated measurement methods. More specifically, EPA should tighten the requirements for noise, lower detectable limit, interference equivalent, zero drift, span drift, lag time, rise time, fall time and precision for automated O_3 analyzers.

Response: While at this time EPA is not aware of strong evidence that the performance specifications for reference and equivalent monitoring methods for O_3 are seriously deficient, updating of these specifications to better reflect current method capabilities may be appropriate. Considerable study of the specifications would be required to determine the need and extent of any appropriate changes. Any changes in the performance specifications identified in this process would of course need to be proposed for public comment.

vi. <u>3-Year Compliance Period</u>

This section addresses comments included in section III.A.2.c.2 and other sections of the Summary of Comments that raised issues on use of a 3-year compliance period for judging attainment with the standard.

(1) *Comment:* EPA received comments from more than 40 individuals and organizations supporting the use of a 3-year period for judging compliance with the standard. A few additional comments were received supporting the use of 5-year averaging for judging compliance with the standard. The primary rationale given for supporting multi-year averaging was that it would be more stable and it would be less likely that rare meteorological events would cause an area to flip in and out of nonattainment status. Several comments were also received opposing multi-year averaging for judging compliance with the standard. The commenters expressed environmental justice and health concerns.

Response: EPA believes that use of a 3-year averaging period for judging compliance with the standard provides the proper balance between the need for adequate health protection and the desire to provide a stable compliance target. EPA based this decision on the results of the exposure and risk assessments and with the support of CASAC. A longer compliance period, although increasing temporal stability, will at the same time not respond as quickly to real changes in the underlying air quality status of the area. A longer compliance period also means a longer lag before an area can change from nonattainment to attainment status.

(2) *Comment:* Several commenters representing state and local air pollution control agencies stated that the proposed compliance form is not a real ambient air quality data point associated with an air pollution episode, but a derived value and, as such, is impractical to recreate for air quality modeling purposes.

Response: Unlike the current 1-hour expected exceedance form which is a derived value, the design value for the 8-hour concentration-based standard is based on three actual air quality data values, which come from a specific air quality episode in each of the three years. Yes, the actual design value is an average, but one can simply model the three individual episodes that compose the 3-year average concentration.

(3) *Comment:* One commenter stated that the sanction for not having complete data at a monitoring site should not be a determination that the site is in nonattainment of the standard.

Response: The requirement in the proposed revisions to Appendix H to not ignore years failing to meet the minimum data completeness requirement of 75 percent data capture if the annual 3rd maximum concentration is greater than the level of the standard is not a “sanction” for years with less than complete data. Given the 4th maximum form of the new concentration-based standard, the 4th maximum concentration can *only increase* with additional data, never decrease. Additional data will only cause the degree of noncompliance to increase. Thus, in the new Appendix I, EPA has decided not to ignore 3-year periods which fail to meet the standard, even if they have less than complete monitoring data.

3. Specific scientific/technical comments

a. Health effects evidence

This section addresses comments included in Sections III.A.3.a. and III.A.3.c. and elsewhere in the Summary of Comments concerning the health effects evidence which EPA considered in making the decision on the proposed primary O_3 standard.

Comments on health effects evidence used as the scientific basis for the proposed primary O_3 standard fall into two general categories. Those in the first group, for a variety of reasons (e.g., large number of scientific studies demonstrating effects at lower O_3 levels, severity of effects associated with O_3 exposures, concern for sensitive populations), contended that the scientific evidence is compelling in demonstrating the need for setting a primary O_3 standard which is more protective than the standard proposed. Commenters in this group assert that the assessment of scientific information contained in the Criteria Document and new information published since completion of the air quality criteria review support replacement of the current 1-hour standard set at 0.12 ppm with an 8-hour standard in the lower range of 0.07 to 0.08 ppm (i.e., the lower end of the range under consideration). In contrast, those in the second group assert that the scientific evidence upon which the proposed standard is based is flawed, contains numerous errors, and is far too unreliable to be used for setting a new standard as stringent as that proposed by EPA. Commenters in this group encouraged EPA either to reaffirm the current 1-hour O_3 standard or, if EPA does replace the 1-hour with an 8-hour standard, to set a standard level and form equivalent in stringency to the 1-hour standard of 0.12 ppm.

Section II.A. of the preamble to the final rule provides an overview of the health effects information used by the Administrator to inform judgments about the extent to which exposure to ambient O_3 results in adverse health effects for exposed individuals. The discussion of scientific information contained in this section of the preamble, together with Chapter 9 of the Criteria Document and Chapter V of the Staff Paper, uses an integrative approach to address the entire body of health effects evidence, considering limitations and uncertainties in the evidence and the diversity of views relative to interpretation of scientific evidence. As discussed in the proposal notice and in the preamble to the final rule, EPA recognizes the contrasting views on the issues raised and is aware of the limitations that must be considered in interpreting the scientific evidence. Presented below is a summary of significant comments received and responses to various specific issues on each of the different types of health effects studies considered in the air quality criteria review. This is intended to expand upon the discussion contained in the preamble to the final rule.

i. <u>Controlled human exposure studies</u>

This section addresses comments included in Sections III.A.3.a(1), IV.A.3.c(1), and IV.A.3.c(2) and elsewhere in the Summary of Comments concerning the health effects evidence from chamber studies which was considered as part of the basis for the decision on the proposed primary O_3 standard.

A number of issues were raised by commenters primarily dealing with elements of the study designs that may have introduced significant uncertainty in the results or may have produced responses that are either over- or under-estimated relative to those likely to occur under ambient exposure conditions, as discussed below. In addition, a number of issues were raised about how these studies were used in EPA's exposure and risk assessments, and these issues are addressed in Sections II.A.3.d and II.A.3.e of this document.

(1) *Comment:* EPA has ignored negative or non-significant scientific information in considering the body of controlled human exposure studies, thereby emphasizing only those results which justify or support the proposal for a more stringent standard.

Response: EPA has reviewed the peer-reviewed scientific information from controlled human exposure studies on O_3, regardless of the statistical outcome, that was available for inclusion in the air quality criteria. Description of individual studies and discussion of the results is presented in the text and tables of the Criteria Document. Emphasis has been placed on the relevant newer literature in Section 7.2 of the Criteria Document; however, the older literature is summarized in tables, and specific key studies that were the basis for the current O_3 NAAQS are discussed briefly. More extensive discussion of the older literature is presented in the previous 1986 Criteria Document (U.S. EPA, 1986). These discussions in the 1986 Criteria Document, including the selection of key studies (e.g., McDonnell et al., 1983; Avol et al., 1984; Kulle et al, 1985), were thoroughly reviewed by the public and the CASAC.

(2) *Comment:* EPA inappropriately relied heavily on studies conducted by EPA researchers in Chapel Hill that were possibly biased by the location of the studies and the presence of contaminants in the study chambers in Chapel Hill due to the method used for artificially generating O_3. Lung function decrements observed in these chamber studies are substantially higher, with lower effect thresholds, than those reported by other investigators.

Response: EPA believes that differences in responses observed in various controlled human exposure studies are appropriately explained by factors other than the potential comtaminants from the method used to artificially generate O_3 in the Chapel Hill studies. For example, the large intersubject variability in response to O_3, with at least a 10-fold difference between the most and least responsive individuals, would far outweigh other potential differences associated with the types and low concentration levels of the contaminants, or artifacts, from the O_3 generation method used. Controlled human studies from areas like Los Angeles, with higher average ambient O_3 levels, also suggest a seasonal variability in response that may be attributed

to increased exposures during the summer months. Historically, studies with subjects drawn from the population of Los Angeles have reported a reduced response to O_3, possibly due to prior attenuation of response, compared to nonresidents.
Based on public and CASAC review of these studies, as characterized and evaluated in the Criteria Document, it is clear that the chamber studies conducted by EPA are comparable to those conducted by other clinical research labs and that the extremely low concentrations of contaminants which have been found in the EPA chambers are well below the levels which might reasonably be anticipated to have any substantial impact on lung function of individuals tested.

More specifically, the importance of other respiratory irritants in relation to controlled O_3 exposures has been of interest since the late 1970's when investigators at the Rancho Los Amigos Laboratory in California started a series of studies comparing the responses of human subjects exposed to ambient air and to filtered ambient air containing UV-generated O_3. These studies are briefly summarized in Section 7.3.1 of the 1996 Criteria Document and are discussed in more detail in Section 11.2.1 of the 1986 Criteria Document. UV ozonation of filtered ambient air can produce elevated hydroxyl radicals, leading to increased carbonyl concentrations (e.g., aldehydes and ketones). Despite the potential for these artificially-induced chamber irritants, the exposures to unaltered ambient air containing O_3 produced the same response in healthy adult subjects as the controlled-exposures to UV-generated O_3.

EPA has been aware of the potential for “artifacts” in the O_3 exposure chambers used for controlled human studies where charcoal-filtered ambient air has been used as the air stream source for production of O_3 by mercury vapor lamps. Ozonation of residual VOCs in this filtered ambient air can produce a net increase in total NMOCs and carbonyls in the exposure chamber, when compared to outside air samples. The hydrocarbon and carbonyl measurements in the EPA exposure facility were made over a 9-year period as part of a quality assurance check. Increased levels of carbonyls in the chambers measured by a DNPH-coated silica gel cartridge/HPLC method range from 10 to 50 ppb as a function of O_3 concentrations from 120 to 500 ppb. There has been no further attempt to speciate the carbonyls, making any possible toxicological evaluation highly speculative.

Interpretation of the carbonyl measurements is complicated by the potential for both positive and negative measurement errors. In general, however, the DNPH/HPLC methods for carbonyl identification would most likely yield the highest peaks for aldehydes and ketones in the presence of O_3. The most common aldehydes found in ambient air, formaldehyde and acetaldehyde, occur at average concentrations of 10 to 20 ppb and 1 to 2 ppb, respectively. If aldehydes are the predominant contaminant in the chamber, then potential human effects are linked to (1) the type of aldehyde (e.g., formaldehyde, acetaldehyde) based on the carbon chain length, and (2) known (or anticipated) health effects associated with the aldehyde. The only aldehyde with a sufficient data base to judge potential effects is formaldehyde.

EPA has reviewed the available published scientific literature on aldehydes and found that no significant effects of formaldehyde were reported in humans at concentrations lower than 50 ppb. Objective measures (e.g., optical chronaxy, EEG) were reported at levels >50 ppb without symptoms, but more often at levels \$1500 ppb (1.5 ppm). The principle effect of low concentrations of formaldehyde observed in humans is irritation of the eyes and mucous membranes; none of these effects, however, were observed in the chamber studies with O_3. Also, no measurable pulmonary function effects have been demonstrated in controlled studies of human subjects at rest at formaldehyde concentrations ranging from 0.5 to 3.0 ppm. The irritant properties of formaldehyde may be accentuated when mixed with other gases; however, there are no known lung irritant studies in humans of interaction between O_3 and formaldehyde at the chamber concentrations identified.

(3) *Comment:* Many of the controlled human studies may present erroneous findings of statistical significance due to using O_3-free air as the control against which O_3-related responses were compared instead of using an ambient background level of O_3 as the control.

Response: Consistent with the purpose of characterizing health effects related to O_3, exposure to O_3-free air has been used for controlled-exposure conditions in almost every human-exposure chamber study of O_3 health effects. It is necessary to remove other contaminants from the air and to control other environmental factors (e.g., temperature, humidity) in order to assess the health impact on subjects of varying O_3 concentrations and exercise levels of subjects. Studies which investigated the health impact of controlled exposures to O_3 were considered acceptable for inclusion in the O_3 Criteria Document and O_3 Staff Paper. Based on conclusions drawn by EPA during the public review of these documents by the CASAC, the use of O_3-free air as the control does not invalidate the usefulness of these studies as part of the scientific basis for the O_3 primary standards.

(4) *Comment:* Conditions within the exposure chambers were not representative of ambient exposures. Heat and humidity were kept unchanged throughout controlled-exposure studies and maintained at relatively moderate levels, unlike conditions commonly found in the ambient air. Some commenters suggested that this may have resulted in over-estimating the responses which would be likely to occur under ambient conditions, while other suggested that the results may have under-estimated responses.

Response: Most of the controlled-exposure chamber studies considered relevant during review of the O_3 primary standard were not designed to address the effects of heat and humidity, or other environmental variables. Because high heat and humidity can exacerbate respiratory dysfunction, environmental conditions such as these are often kept at moderate levels during controlled O_3-exposure studies in order to eliminate them as experimental variables. However, as discussed in Section 7.4.1.2 of the Criteria Document, several studies have incorporated concurrent heat exposure with the experimental design and have determined that combined O_3

and heat exposure is similar to O_3 exposures alone for effects on lung function. Environmental conditions typically encountered in the summertime when ambient O_3 levels are highest may possibly add to respiratory demands which could contribute to slightly greater functional and respiratory symptom effects than would be expected under the conditions maintained in many controlled-exposure chamber studies. It is likely that on days when heat and humidity are very high, some individuals may be expected to reduce the intensity of outdoor activity, thereby reducing exposures that would result in adverse health effects. However, in contrast, in the summer when O_3 levels are high, there also tend to be more people outdoors, particularly children who are out of school, than during other seasons of the year (McCurdy, 1994), which increases the potential for adverse health effects. See Sections II.A.3.d for further discussion of consideration of meteorological variables in the O_3 exposure analyses.

ii. Summer camp and other field studies

This section addresses comments included in section III.A.3.a(2), sections III.A.3.c(1) and III.A.3c(2), and elsewhere in the Summary of Comments concerning the health effects evidence from summer camp and other field studies which was considered as part of the basis for the decision on the proposed primary O_3 standard.

(1) *Comment:* The multi-week, summer camp studies of children demonstrate a large (seven fold) spread of sensitivities, suggesting confounding by other pollutants or variables. Some commenters suggest that these variables may result in unacceptable inconsistencies which make the data from summer camp studies uninterpretable, while other commenters point to the fact that the results of the summer camp and field studies are very consistent among locations along the east and west coast.

Response: The conclusions drawn in the Criteria Document, following review by the public and CASAC, are that qualitatively the types of responses in summer camp and field studies are similar and quantitatively the ranges of responses are comparable. When results from the six available summer camp studies of children and adolescents were pooled for presentation in the Criteria Document (see the discussion in Section 7.4 of the Criteria Document), a slope of -0.5 mL/ppb (range -0.19 to -1.29 mL/ppb) was observed for changes in lung function associated with O_3 exposure. The lowest individual, study-specific slope was not significant and the highest slope was much larger than the rest, possibly due to greater subject activity levels or confounding by other environmental agents (e.g., acid aerosols, airborne allergens). Despite the camp-to-camp variability, the Criteria Document, as reviewed by CASAC, concluded that results are consistent across the six studies in six different geographical locations by three different investigative groups. Although direct comparisons cannot be made because of differences in experimental design and analytical approach, the range of response in lung function was comparable to the range of response seen in the controlled, chamber studies at low O_3 concentrations, as discussed in Section 7.4 of the Criteria Document.

EPA encouraged the authors responsible for pooling the summer camp studies in the Criteria Document to submit their analysis to a peer-reviewed journal for publication. The final paper (Kinney et al., 1996), which was based on the analysis presented in the Criteria Document and reviewed by the CASAC, was published after completion of the Criteria Document. In the published version, the authors looked at potential factors across studies that might have been responsible for variations in the individual, study-specific, lung function slopes. Lack of sufficient data made it hard to determine the influence of variations in activity levels or confounding by other pollutants and environmental factors. Inclusion of variables accounting for temporal trends in lung function reduced, but did not eliminate, the relationship of lung function with O_3.

(2) *Specific Comment (Dunn-Edwards Corporation, IV-D-2252):* The commenter observes that O_3 has a stronger effect in New Jersey than in Southern California, and suggests that either other pollutants are causing the reactions seen in New Jersey or that there is an adaptive mechanism.

Response: EPA does not agree that there is a general difference between studies conducted on the East and West coasts. The recent summer camp studies are summarized in the Criteria Document (pp. 7-96 to 7-104), and results for one lung function parameter, FEV_1, are summarized in Table 7-16. The average decrease in FEV_1 per ppb O_3 was -0.50 $\pm$ 0.16, and the FEV_1 changes found in the two California studies were -0.32 $\pm$ 0.13 and -0.84 $\pm$ 0.20. From the two studies conducted in New Jersey, the FEV_1 changes were -0.50 $\pm$ 0.16 and -1.29 $\pm$ 0.27. As observed by EPA in the Criteria Document, one New Jersey study (Spektor et al., 1991; Spektor and Lippman, 1991) yielded a larger slope than the other studies and a number of possible explanations (greater subject activity levels or confounding by other environmental agents such as acid aerosols or airborne allergens) were considered. The authors of this study found no correlation between the regression residuals and temperature-humidity index or acid aerosol concentrations, indicating that there was no remaining effect of these variables with lung function after accounting for O_3, but multiple pollutant models were not used in the study. The authors of the San Bernadino study (Higgins et al., 1990; Gross et al., 1991) note that most subjects resided in the Los Angeles basin, and were likely to have been exposed to high O_3 levels prior to attendance at camp. However, the change in FEV_1 found in this study (-0.84 $\pm$ 0.20) was actually larger than in most other studies. While there are some differences in results between the studies, EPA believes that the consistency of findings from one study to another are evidence that O_3 exposure can result in decreased lung function.

(3) *Specific Comment (Air Quality Standards Coalition, IV-D-2580):* The results of camp studies in New Jersey, New York and California failed to address confounding factors that could significantly alter conclusions drawn from them. The commenters cite, specifically, weather factors, pollens and organic compounds and other pollutants.

Response: EPA believes that it is unlikely that the consistent findings of reduced lung function in the summer camp studies are due to confounding by some other factor in each of the studies. Some, but not all, of the summer camp studies evaluated the effects of other pollutants as well as O_3. In two New Jersey studies (Spektor et al., 1988; Spektor et al., 1991) data were obtained for acid aerosol, PM, temperature and humidity, and no associations were found with acid aerosols or PM. In the San Bernadino study (Higgins et al., 1990), levels of nitrogen dioxide and sulfur dioxide were very low, often at the limit of detection, and when O_3, PM, temperature and relative humidity were combined in a model, the PM effect was not significant while the O_3 effect remained significant and the coefficient increased somewhat in magnitude. Conversely, Raizenne et al. (1987) found significant associations between FVC and sulfates, $PM_{2.5}$ and temperature. As outlined in more detail in the responses regarding hospitalization studies, the key issue in attempting to distinguish the adverse health effects of one pollutant from potential effects of other pollutants in ambient air is to compare studies conducted in different locations with varying meteorology, climate or pollution sources. In so doing, it is clear that studies conducted in New Jersey, Ontario and California show some consistent adverse effects of O_3 on lung function in children.

(4) *Comment:* Training effects have been observed in summer camp studies and may influence the results of those studies by making it appear that effects are greater than they would be otherwise.

Response: EPA has looked at training effects in individual-level epidemiology studies, and concluded that there may be potential effects of time trends resulting in overestimating lung function effects by looking at early results. In the available studies reviewed by EPA, as discussed in Section 7.4.1.2 of the Criteria Document, average measures of lung function (e.g., FEV_1) have been observed to first decline and then stabilize over time. However, time trends will result in confounding of O_3 effects only if, by chance, the trend correlates with temporal variations in O_3 concentration. Such chance correlations would be more important for studies where all subjects begin the study simultaneously, and with little follow-up measurement, and less important for studies that focus on daily changes in lung function. The summer camp studies considered as part of the basis for the primary standard focus on daily changes in lung function and the subjects do not begin the study at the same time. In the published analysis of six summer camp studies, Kinney et al. (1996) [see comment (1) earlier in the section] found that the pooled slope of FEV1 on O_3 was reduced in magnitude, but remained statistically significant, when time trends due to training effects were considered. Therefore, the role of training effects is not considered a significant problem for the summer camp studies.

(5) *Comment:* Children do not report respiratory symptoms as do adults when they are exposed to O_3 in controlled laboratory studies; therefore, children may not experience respiratory symptoms due to O_3 exposure.

Response: Despite similarities in lung function decrements, children and adolescents exposed to O_3 do not appear to report the respiratory symptoms reported by adults (e.g., cough, PDI, SB). The reasons for this observed difference are not clear, but relatively few controlled laboratory studies have been performed with children and adolescents to adequately address this question (as discussed in Sections 7.2.1.3 & 7.3.1 of the Criteria Document). In these studies, symptom questionnaires were administered before, during, and following exposure; however, there were no significant differences in symptom scores between O_3 exposures and controls. The researchers involved in studies of children and adolescents speculate that young people may be inherently less able than adults to detect the irritating effects of O_3 on the respiratory tract. Alternate explanations are that children and adolescents either did not adequately comprehend the symptom questionnaire, or they experienced symptoms but were reluctant to report them.

(6) *Comment:* Associations between ambient O_3 levels and acute respiratory signs and symptoms have been shown in children and adults spending time outdoors (e.g., summer camps, hiking, cycling, jogging). Some commenters suggest that uncontrolled variables in outdoor studies may contribute to acute respiratory symptoms and lung function changes, while others note that the magnitude of the lung function change is comparable to that found in the controlled-exposure chamber studies.

Response: EPA believes that the associations found in the summer camp and field studies are supported by the chamber studies. Adult asthmatics and nonasthmatics not only have qualitatively similar responses among these field studies but they also report effects comparable to results reported in chamber studies. Acute respiratory symptoms, however, have not been reported in children in these field studies.

In both chamber and field studies, the lung function responses of healthy children to acute O_3 exposure are similar to those seen in adults. Lung function decrements of children and adolescents exposed to O_3 at summer camps are qualitatively similar to those found in individuals exposed to O_3 under controlled experimental conditions. Although direct quantitative comparisons cannot be made because of differences in experimental design and analytical approach, the range of response is comparable. A more detailed discussion of these comparisons is found in Section 9.3.1.2 of the Criteria Document.

In asthmatic children, results of exercise and daily-life epidemiology studies are consistent with the camp studies and support a consistent relationship between ambient O_3/oxidant exposure and acute respiratory morbidity in the population. Temperature, particles, aeroallergens, and asthma severity or medication status, however, may also contribute as independent or modifying factors in these studies.

iii. <u>Hospital admissions and other epidemiological studies</u>

This section addresses comments included in sections III.A.3.a(3) and III.A.3.c(3) and elsewhere in the Summary of Comments concerning the health effects evidence from hospital admissions and other epidemiological studies which were considered as part of the basis for the decision on the proposed primary O_3 standard.

(1) *Comment:* The hospital admissions data are seriously flawed and do not establish a link between O_3 and increased admissions. For example, the New York study fails to account for the effects of the many other pollutants which exist, especially sulfates and other particles, thereby overestimating personal exposure in an area that does not attain the current standard. Other commenters, however, contend that as levels of O_3 increase, so do hospital admissions, emergency department visits, and other measures of morbidity in individuals with existing respiratory disease. These commenters believe the newly published studies indicate that the frequency of asthma emergency department visits increases 20 to 30%, even at O_3 concentrations below the level of the current standard. In addition, they also state that hospital admissions and visits, by themselves, undercount by almost an order of magnitude the health impact of a given O_3 episode because they do not account for those individuals suffering from asthma attacks who seek help from their private physicians or do not otherwise document their suffering.

Response: EPA has indicated that the strongest and most consistent evidence of O_3 effects in the population is provided by the multiple epidemiologic, time-series studies that have been conducted over the last decade on summertime daily hospital admissions for respiratory causes in various geographical locations in eastern North America (e.g., Birmingham, Buffalo, Detroit, Minneapolis - St. Paul, Montreal, New York City, southern Ontario including Toronto). Collectively, these studies consistently have shown that O_3 air pollution is associated with a small, but statistically significant, increased incidence of admissions. The association has been shown to remain significant even after controlling for the possible confounding effects of temperature and humidity, as well as when considering only days having 1-hour average maximum O_3 concentrations below 0.12 ppm (the current standard). The scientific basis and rationale for this conclusion is discussed more completely in Sections 7.4.1.3 and 9.3.2 of the Criteria Document. EPA agrees with those commenters who noted that estimates of excess hospital admissions attributable to O_3 do not include those individuals suffering from asthma attacks who seek help from private physicians or fail to seek medical assistance.

EPA continues to believe that there is a substantive and convincing body of evidence, particularly among the studies of hospitalization or emergency room admissions for respiratory causes, that O_3 at levels found in many communities is causing adverse health effects.

EPA does not agree that the hospital admission epidemiological studies included in the air quality criteria review fail to control for such factors as seasonality or the presence of confounders. Many of the time series studies control for extraneous cycles in the data that are unrelated to air pollution through the use of non-parametric smoothing for long-term trends, parametric models for time trends, seasonal adjustments by Fourier series, stratification by season, or dummy variables for year, season, day-of-week or holidays. Some examples of trends that are common and require control in many epidemiologic studies of hospital admissions are the increase in hospitalization for respiratory causes that often occurs in winter, and a day-of-week effect where admissions are higher on Monday and lower on Saturday or Sunday. Other environmental variables that change on a time scale similar to the time scale for air pollution changes, such as weather variables, are adjusted by non-parametric smoothing, parametric models or dummy variables. Typical weather variables that are used in air pollution epidemiology are temperature and humidity. In some studies, information is available on individual characteristics such as age, race, gender, location of residence, etc., and these may be used as stratifying factors or added as indicator variables to the models.

Collinearity between air pollutants can make it difficult to determine whether there are relationships between individual air pollutants and health effects. As described in the Criteria Document, some researchers have used multiple pollutant models to investigate the impact of including additional air pollutants on an association seen with O_3, and many studies have indicated that O_3 associations remain significant in multi-pollutant models (i.e. Thurston et al., 1994; Burnett et al., 1994). However, even where the effects of individual pollutants cannot be distinguished, EPA notes that the relationships found for O_3 have been consistent from one location to another.

The hospital admission studies included in the Criteria Document have, in general, incorporated modelling strategies to address seasonality or other trends in the data, and to address confounding variables, as needed. EPA was aware of these issues and, in evaluating the epidemiological studies, noted the presence of methodological deficiencies of this nature, and did not include in the final review of the literature any studies that were deemed to have serious methodological flaws.

EPA observes that, after controlling for confounders, seasonality and other factors, the hospital admission studies nearly always found significant relationships between O_3 and adverse respiratory effects. The most convincing evidence for the presence of an association between O_3 and respiratory health effects is that different studies with different model-building strategies have found small but quantitatively similar increases in adverse health effects with increased O_3 concentration. While it may be difficult to distinguish the effects of O_3 from one or more other pollutants in certain locations, depending on local geography, meteorology, climate and types of pollution sources, it is much more difficult to believe that there are some hypothetical, but as of yet unidentified or substantiated, confounder that can account for the O_3 associations in each study. For example, in this scenario, comments might argue that the apparent O_3 effect is actually due to confounding by PM in one location, but in another location the alleged confounder might be NO_2. If levels of all other pollutants were low, the confounders might be temperature or humidity or pollen count. It is unrealistic for such a diverse array of alleged confounders to result in O_3 effects of approximately the same magnitude in each of these locations.

(2) *Specific Comment (Chemical Manufacturers Association, IV-D-2249):* Commenter cites specific concerns with the use of the study by Thurston et al. (1992). Specifically, the commenter argues: (1) that the study did not obtain personal exposure data; (2) had inconsistencies between urban areas; (3) did not control for seasonal confounders; (4) did not consider other confounders. The other confounders of concern include pollutants (acid aerosols and sulfates) and lifestyle factors (smoking, indoor air quality, occupational exposure to respiratory factors, genetic disposition, pulmonary function and pre-existing disease).

Response: EPA does not agree with the commenter's criticism of this study. As discussed in the following response, EPA does not agree that data from personal monitors is necessary to adequately describe community O_3 exposures. With regard to the comment that the differences between communities regarding asthma admissions were not explained, EPA notes that the authors describe analyses using data on socioeconomic and other factors that were intended to address this issue. An additional concern raised by the commenter is potential confounding by indoor environmental factors, and EPA notes that these factors cannot be considered to be confounders of a relationship between O_3 and hospitalization; this issue is further discussed in the following response.

With regard to adjustment for seasonality and confounders, EPA believes that Thurston and colleagues did appropriately consider these issues. Seasonality was addressed by restricting the analysis to data collected during June through August. The data were prefiltered to adjust for long-wave autocorrelation, day-to-day variations during the summers, and day-of-week patterns in hospitalization. The prefiltering included sine and cosine terms for a one-year cycle and dummy variables to control for day-of-week effects. Maximum daily temperature was included in the models, and each of the three pollutants (O_3, acid aerosol, sulfates) was added individually. The authors state that multiple pollutant models were not used because the three pollutants were highly intercorrelated. The authors found significant associations between respiratory hospital admissions and each of the three pollutants. As observed in the Criteria Document, adjustments for day-of-week and long-wave cycles improved the pollution correlations with admissions.

The commenter notes that Thurston et al. (1992) did not address the issue of multi-pollutant effects; as observed previously, the authors chose not to use multi-pollutant models due to intercorrelation between the pollutants. Interestingly, in a similar study in Toronto (Thurston et al., 1994), additional analysis was done for two-pollutant models. In this study, the effect estimate for the relationship between O_3 and hospitalization was relatively unchanged by the addition of another pollutant (particulate matter or a PM component), and the magnitude of the effect (21% increase in respiratory admissions as a mean effect) was similar to those found for the New York communities in the earlier study.

The commenter also raises the issue of addressing lifestyle factors or occupational exposures as confounders. As for indoor environmental exposures, it is unlikely that lifestyle factors or occupational exposures can be true confounders in a time series analysis of the relationship between O_3 and hospitalization. Thurston and colleagues obtained city-specific information regarding socioeconomic status, but this data is also of little relevance to a study of daily changes in health with daily changes in pollution level. Occupational exposures, as well, may alter an individual's health status or susceptibility to air pollution effects, but they would be unlikely to confound a day-to-day relationship between O_3 and risk of hospitalization.

(3) *Specific Comment (UARG, IV-D-2253):* Commenter observes that "At least one study that did address seasonal cycles, however, reported no significant association between emergency disease hospital admissions and O_3 when temperature was used in the equation."

Response: Apparently the commenters refer to the study conducted in Montreal by Delfino and colleagues (1994), in which a positive association was found between admissions and O_3 concentrations when analyzing data from July-August, but the association lost statistical significance with the addition of temperature to the model. EPA describes the results of this study in further detail in the Criteria Document (p. 7-132). EPA notes that the O_3 concentrations used in this study were quite low, with a seasonal mean of 82.5 ug/m^3 (42 ppb) for data collected during the months of July and August, 1984-1988 (1-hour maximum O_3 concentration); the 90th percentile O_3 concentration was only 129.1 ug/m^3 (66 ppb). EPA believes that these findings support the decision to set a more stringent O_3 standard. This study finds evidence for a positive association with hospitalization with O_3, but the relationship is not significant at these low levels, which are well below the EPA's proposed standard of 80 ppb.

(4) *Specific Comment (UARG, IV-D-253, Roth Associates, Inc.):* Roth Associates, Inc. present critiques of ten epidemiological studies (Schwartz, 1994 -Birmingham; Schwartz, 1994 - Detroit; Burnett et al., 1994; Burnett et al., 1992; Ponka, 1991; Cody et al., 1992; Weisel et al., 1994; White et al., 1994; Thurston et al., 1992; Thurston et al., 1994; Xu et al., 1994), which were included in the air quality criteria reviews for either O_3 or particulate matter.

Response: EPA has reviewed Roth's critiques and finds little new information; some of the observations about potential flaws in the studies were also observed by EPA in the Criteria Document or by the original authors. Many criticisms are vague, unsupported statements such as the following regarding Thurston et al. (1992): "The 1989 data did not support the validity of the pollutant regression results." No support for this statement, or others like it, is offered. More importantly, what is important is the overall weight of evidence on adverse health effect associations with O_3 exposure. Every individual study will have strong and weak points, and simply highlighting potential weaknesses in the studies is of little value. EPA remains convinced that the overall body of scientific evidence clearly indicates that adverse health effects are occurring at O_3 levels below the current NAAQS.

(5) *Comment:* Some commenters contend that as levels of O_3 increase, so do hospital admissions, emergency department visits, and other measures of morbidity in individuals with existing respiratory disease. These commenters argue that newly published studies indicate that the frequency of asthma emergency department visits increases 20 to 30%, even at O_3 concentrations below the level of the current standard. For example, the American Lung Association (IV-D-2339) urges the EPA to set a more stringent standard for O_3, citing as evidence of increases in hospitalization with O_3 exposure a number of studies included in the Criteria Document along with some new studies (Delfino et al., 1997; Stieb et al., 1997).

Response: In accordance with EPA's long-standing interpretation of the Act, the Administrator bases her NAAQS decisions on studies and related information included in the pertinent air quality criteria and available for CASAC review.[5] Thus, the Administrator has not considered the findings of more recent studies in her final decision on the O_3 standards. Nevertheless, the Administrator has conducted a provisional examination of more recent studies raised by commenters to assess their general consistency with the much larger body of literature evaluated in the Criteria Document and Staff Paper.[6]

Assuming the results of the new papers cited by the commenters were sustained following a full review in the criteria and CASAC process, they would generally support EPA's conclusion that

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[5]Since the 1970 amendments, the EPA has interpreted the Act as requiring that NAAQS decisions be based on scientific studies that have been assessed in air quality criteria. See e.g., 36 FR 8186 (April 30, 1971) (EPA based original NAAQS for six pollutants on scientific studies discussed in the air quality criteria and limited consideration of comments to those concerning validity of scientific basis); 38 FR 25678, 25679-80 (September 14, 1973) (EPA revised air quality criteria for sulfur oxides to provide basis for reevaluation of secondary NAAQS). This long-standing interpretation was strengthened by new legislative requirements enacted in 1977 (section 109(d)(2) of the Clean Air Act; section 8(c) of the Environmental Research, Development, and Demonstration Authorization Act of 1978) for CASAC review of air quality criteria and reaffirmed in EPA's decision not to revise the O_3 standards in 1993. 58 FR 13008, 13013-14 (Mar. 9, 1993).

[6]As discussed in EPA's 1993 decision not to revise the NAAQS for O_3, new studies may sometimes be of such significance that it is appropriate to delay a decision on revision of NAAQS and to supplement the pertinent air quality criteria so the new studies can be taken into account. 58 FR at 13014. In the present case, EPA's provisional examination of recent studies suggests that reopening the air quality criteria review is not warranted. Accordingly, EPA believes that the appropriate course of action is to consider the newly published studies during the next periodic review cycle.

increased hospital admissions are associated with O_3 levels below the current 1-hour standard. In Delfino et al. (1997), the maximum O_3 concentrations (1-hour maximum) for 1992 and 1993 were, respectively, 79 and 67 ppb in Montreal, Quebec. Emergency room visits for respiratory illness were reported to be significantly associated with O_3 concentration in elderly patients (>64 years of age), with an estimated increase of approximately 20% in admissions for a mean increase in O_3 (31 ppb for 8-hour, and 36 ppb increase in 1-hour O_3 concentration) using 1993 data. Similarly, Stieb et al. (1997) reported a maximum O_3 concentration of 160 ppb in Saint John, New Brunswick, Canada, and reported that emergency department visits for asthma were predicted to increase by 33% when the 1-hour maximum concentration of O_3 exceeded 75 ppb. Thus, Stieb et al. (1997) is generally supportive of the standard that is adopted today while Delfino et al. (1997) appear to have found effects of O_3 at lower levels.

(6) *Specific Comment (Electric Power Research Institute, IV-D-2330):* The commenter submitted a preliminary report from a study of the relationship between emergency room visits for asthma with ambient air pollutant concentrations. The commenter observed that, though positive associations are found for both O_3 and PM_{10}, both associations lose statistical significance when multi-pollutants models are considered; the commenter states that this is likely due to collinearity between pollutants.

Response: As stated in the preceding response, EPA has not considered studies that have not been through the extensive review process entailed in preparing the air quality criteria. Further, the report submitted by the commenter has not been published as a peer-reviewed journal article. However, EPA notes that the study's findings are generally consistent with those presented in the Criteria Document and Staff Paper. As presented in the report, the likelihood of presenting to the emergency room for asthma is significantly increased with a 20 ppb increase in O_3 (OR 1.045, 95% CI 1.016-1.076) and the magnitude of the association is increased when spatial autocorrelation of exposure is accomodated through a kriging process. The authors also report an association of borderline significance when comparing admissions at O_3 exposure levels of 70-79 ppb with those at levels below 50 ppb. The association between O_3 and emergency room admissions becomes nonsignificant in a model with PM_{10} (OR 1.025, 95% CI 0.983-1.069) which may be due, as the authors state, to the high degree of correlation that was found for the two pollutants. The authors discuss some additional analyses that are being conducted with the data from this study, and EPA encourages the authors to submit the final results for publication for use in future evaluations of the O_3 standard. As stated in the response to the general comment on confounding and related issues in epidemiological studies, EPA believes that comparing results from studies conducted in locations with differing climates and pollution sources is an appropriate means of distinguishing the effects of one pollutant from another. The studies outlined in the Criteria Document indicate that the effects seen for O_3 are consistent from one study to another, and the EPA remains convinced that health effects occur at O_3 concentrations below the current 1-hour standard of 120 ppb.

(7) *Comment:* Several commenters state that hospital admissions and visits, by themselves, undercount by almost an order of magnitude the health impact of a given O_3 episode because they do not account for those individuals suffering from asthma attacks who seek help from their private physicians or do not otherwise document their suffering.

Response: EPA recognizes that the different health endpoints used in epidemiological studies -- mortality, hospitalization, outpatient visits, reduced lung function, increased symptoms, lost workdays, etc. -- mark varying levels of severity of adverse health effects. The "pyramid of effects" is characterized by increasing numbers of individuals being affected as the relative severity decreases from mortality down to small changes in lung function. EPA considered each type of health effect in making its decision on the proposed level of the O_3 standard, as described in the Staff Paper (pp. 149-154 and p. 166) and proposal notice. While hospitalization studies are a key component of the basis for the O_3 standard, the final decision on the level of the standard, as published in the preamble to the final decision, was determined using a weight-of-evidence approach and considered all of the scientific evidence as outlined in the air quality criteria.

(8) *Comment:* Some commenters contend that asthma admissions are correlated with ambient O_3 because some of the same meteorological conditions that cause high O_3 levels (e.g., high temperature and humidity) also cause increased exposures indoors to environmental agents that trigger asthma attacks (e.g., dust mites, cockroaches, molds and mildew, pet dander, tobacco smoke) as a result of mitigating behavior of individuals avoiding outdoor exposures. These commenters contend that the increase in incidence of asthma may in fact be caused by factors other than ambient O_3 levels. Others have suggested that exposure to elevated ambient O_3 levels may exacerbate asthma attacks which are induced by these other environmental agents and result in increased rates of hospital admissions and emergency room visits.

Response: Although it is true that meteorological conditions which produce high O_3 levels can also cause individual indoor exposures to increase with resultant increased exposures to other environmental agents that trigger asthma attacks, the time individuals spend outdoors when ambient O_3 levels are elevated can increase the likelihood that those asthma attacks will occur and that they will be more severe. This is in part because some O_3 exposures induce or add to an (existing) inflammatory response which can predispose some sensitive individuals to be more susceptible to asthma attacks and other respiratory problems. Because there is a consistent association between ambient O_3 levels and increased hospital admissions, even in cities such as Vancouver where the temperature and humidity are typically moderate, the scientific evidence supports the conclusion that the association reflects an O_3 response rather than a response to increased indoor exposures.

To be a true confounder, a factor must be related both to the exposure and to the health effect under study. In time series studies, researchers examine changes over time of the health status of a population in response to changes over time in the air pollution exposure of that population. Indoor exposures to environmental agents such as dust mites, cockroaches, molds and mildew, pet dander and tobacco smoke cannot be considered to be confounders in an O_3/health effect association unless there is some evidence that there are daily changes in the indoor exposure that are linked to daily changes in O_3 concentration. For example, while the presence of tobacco smoke in the home may be associated with respiratory health problems, it has never been found that exposure to tobacco smoke in the home increases or decreases correspondingly with changes in ambient O_3 concentration. Therefore, EPA cannot agree that indoor environmental exposures are confounding the relationship seen between respiratory admissions and ambient O_3 concentration.

In addition, commenters raise the question over whether individuals may have increased exposure to indoor environmental factors during the time periods when temperature and humidity are high, which is also when O_3 concentrations are likely to be greatest. The commenters present no scientific evidence to support this claim, and there are a number of reasons to discredit this hypothesis. While it is true that individuals may spend more time indoors during the warmer season, it is also true that people are likely to spend more time indoors during the coldest months, when O_3 concentrations are expected to be low. In most parts of the U.S., air conditioners are used during the warm season, while heating systems would be used in the cooler months. During both of these periods, exposure to indoor pollutants might be higher than periods of mild temperatures when people may have windows open and spend more time outdoors. The abundance of dust mites and molds or mildews in residences has been found to be higher in communities with a more humid climate, but the adverse effects found with O_3 exposure have been consistent from one location to another, despite climatic, geographic or meteorologic differences among the communities. The use of air conditioning in warmer climates may also reduce indoor exposures to dust mites, molds and mildews, by reducing levels of indoor humidity. EPA does not agree that indoor environmental factors can be credited as the true causative agent behind the associations found between hospitalization and ambient O_3 concentrations. In fact, EPA believes that it is more likely that indoor exposures to environmental agents might mask an association with ambient pollutants than that they are producing a false signal that appears to be an O_3 association.

(9) *Specific Comment (American Lung Association, IV-D-2339):* The commenter asserts that exposure to elevated ambient O_3 levels may exacerbate asthma attacks which are induced by other environmental agents and result in increased rates of hospital admissions and emergency room visits and cites studies that show increased allergic responses in asthmatic subjects after exposure to O_3 than after exposure to air.

Response: EPA agrees that there is evidence for heightened responses to allergens following O_3 exposure. As described in the Criteria Document, Staff Paper and proposal, O_3 exposure has been found to result in inflammatory changes in the lung. Some researchers have found increased bronchial responsiveness to allergen with O_3 exposure (for example, Molfino et al., 1991), but some researchers have failed to find increased responses to nasal challenge with antigen following exposure to O_3 (for example, Bascom et al., 1994). The O_3 exposure levels in the studies mentioned here, and in similar studies, are generally above 120 ppb for 1 hour or more. EPA believes that the O_3 standard being established today is appropriate for the protection of public health regarding this potential O_3 health effect.

(10) *Comment:* Some commenters suggest that because estimates of exposure to O_3 are not based on personal monitoring data but rather rely on centralized O_3 monitors to estimate individual O_3 exposures, there is great uncertainty regarding the role that O_3 plays in contributing to increased hospital admissions for respiratory causes. Others point out that associations between ambient O_3 concentrations and increased hospital admissions for respiratory causes are consistently found in numerous studies despite the uncertainties associated with personal exposures.

Response: The EPA recognizes that there is uncertainty regarding personal exposure in any epidemiological study which must be taken into account before drawing conclusions. The hospital admissions and exposure data upon which estimates of increased hospital admissions and emergency room visits are based have been published in peer-review journals and reviewed by the CASAC. The associations reported between ambient O_3 concentrations and increased hospital admissions and emergency room visits for respiratory causes is consistently statistically significant despite numerous potential confounding factors.

EPA does not agree that the use of data from central monitoring stations to determine O_3 exposure levels is inappropriate. EPA has concluded that O_3 concentrations from ambient monitoring stations are appropriately used to describe community O_3 exposures. The key question is <u>not</u> whether the central monitoring site measurements contain a signal reflecting actual exposure to O_3 <u>from all sources</u> at the individual level. Rather, the ultimate question is whether the central monitoring site measurements contain a signal reflecting average population exposure to <u>ambient O_3</u>, including both exposure to ambient O_3 while outdoors and to O_3 that has filtered indoors. Particularly for a pollutant such as O_3, which is primarily generated outdoors and levels are often greatly diminished inside buildings, it is likely that the O_3 concentration measured at a central monitoring site is a good indicator of community exposures to O_3.

(11) *Comment:* The low O_3 concentrations associated with hospital admissions would be extremely unlikely to send anyone to the emergency room, based on the scientific evidence available from controlled human exposure and field studies.

Response: Controlled human studies on subjects with mild asthma have not generally shown an enhanced responsiveness to O_3 exposure relative to healthy individuals, as measured by changes in lung function. However, most asthmatic individuals have lower baseline lung function than individuals without asthma. This means that for a given decrease in lung function the impact will be greater for those with mild asthma and even more substantial for those with moderate or severe asthma. Chapter 9 of the Criteria Document and Section V.F. of the Staff Paper discuss adverse respiratory effects of O_3 exposure for those with preexisting respiratory disease and provides a table of individual responses to short-term O_3 exposures ranging from functional and symptomatic responses to interference with normal activity and seeking medical treatment. This table shows that increasing lung function decrements and increasing symptomatic responses to O_3 exposure will result in greater interference with normal activity and increases in medical treatment sought by individuals with preexisting respiratory disease. These interferences potentially can become sufficiently severe to cause disruption or cessation of activity for the affected individuals.

Hospital admissions often are a result of many different physiological and symptomatic responses which don't necessarily correlate well with lung function decrements. The differences in results reported in epidemiologic studies reporting asthma and hospital admissions and controlled-exposure chamber studies might be explained if the increased summertime hospital asthma admissions primarily involved people with moderate or severe asthma. Clinical studies generally included only mild asthmatics because of concern for subject safety; however, in one study, moderate asthmatics had a more severe lung function and symptomatic response to O_3 than healthy individuals. Even if the lung function decrements induced in asthmatics by O_3 are similar to those experienced by healthy subjects, they nevertheless represent a further decline in lung volumes and flows that are already diminished in asthmatics.

Ozone may also exacerbate asthma attacks by increasing response to allergens. Controlled human studies have indicated that allergic asthmatics have a stronger than usual reaction to inhaled allergens after they were previously exposed to O_3. One possible explanation is that O_3 may cause a greater inflammatory response in asthmatics, who typically have an ongoing lung inflammation.

Thus, in summary, based on the scientific evidence gathered on moderate or severe asthmatics, it is clear that O_3 can induce responses which may result in some asthmatic individuals seeking treatment at emergency rooms and/or being hospitalized.

(12) *Specific Comment (Private Citizen, IV-D-8890):* This comment included a portion of a report prepared by Haluk Ozkaynak et al. (1996), which is cited by the commenter, and observes that there is an inverse relationship between hospital admissions and O_3 concentration.

Response: Simply plotting the temporal distribution of a health effect and a pollutant may not indicate the presence of a true relationship. The graph submitted by the commenter indicates that hospital admissions for respiratory causes are highest in the winter months, and lowest in the summer months. This is a well-known phenomenon. During the winter months, there is a marked increase in respiratory disease admissions due to infectious diseases, and it is important to control for this increase when evaluating relationships with pollutants. Epidemiological studies are designed to control for long-term trends, seasonal trends, influenza epidemics, day-of-week differences, and other such factors, as needed in the individual study. The commenter did not submit the full report from which this graph was drawn, so EPA cannot offer a specific response on the statistical model that was used by Ozkaynak et al. (1996), which is not included in the air quality criteria review. However, in the studies evaluated in developing the Criteria Document, careful attention was paid to the modelling strategy, and studies were not used in the decision making process if there were serious inadequacies in such factors as controlling for other causative factors or confounders.

iv. Studies of inflammation, host defense mechanisms, and chronic respiratory damage

This section addresses comments included in section III.A.3.c(4) and elsewhere in the Summary of Comments concerning health effects evidence from studies of inflammation, host defense mechanisms, and chronic respiratory damage which was considered as part of the basis for the decision on the proposed primary O_3 standard.

Comment: A number of commenters have asserted that the linkages between repeated inflammation and chronic lung damage are highly speculative and too uncertain to consider as a basis for the standard. These commenters contend that insufficient work has been conducted to extrapolate from the effects reported in animal toxicology studies to the potential health effects which may or may not occur in humans. In sharp contrast, other commenters have asserted that animal studies are consistent with the observations in humans; that, in fact, inflammation of the respiratory tract after O_3 exposure occurs in all species that have been studied. These commenters suggest that, despite similarities with human exposure to O_3, the Administrator has ignored or assigned minimal weight to the animal studies. They feel that the potential for chronic lung disease with protracted exposure to O_3 is a compelling reason for the most protective standard option.

Response: The effect of long-term O_3 exposure in humans remains a key scientific and regulatory issue. Epidemiologic studies that are primarily cross-sectional in nature (i.e., a snap shot in time) have not provided compelling evidence that health effects are occurring in populations exposed to O_3 for long periods of time. However, controlled studies in which laboratory animals have been exposed to O_3 for up to two years (i.e., the lifetime of rodents) provide a warning that long-term O_3 exposure may have some lasting effects. For example, there is general agreement that the main effect of these exposures on laboratory animals is a structural alteration in the centriacinar region of the lung in which airway epithelium of the conducting airways extends into the gas exchange region. This is accompanied by a (smoldering) inflammatory lesion characterized by infiltration of mononuclear cells and remodeling of epithelial and underlying connective tissue. These effects are reminiscent of the earliest lesions found in respiratory bronchiolitis in laboratory animals, some of which may progress to fibrotic lung disease.

The collective data on long-term O_3 exposure garnered from animal toxicologic and human population studies have some ambiguities. What is clear is that the distribution of the O_3 lesions is roughly similar across species; is, in part, concentration dependent and most likely exposure-pattern dependent; and, under certain conditions, has irreversible structural attributes. What is unclear is whether ambient exposure scenarios encountered by humans result in similar lesions and whether there are resultant functional or impaired health outcomes. These data do not drive EPA to conclude that these effects would occur at levels associated with attainment of the 8-hour standard proposed; however, they still provide reason for concern for public health which EPA believes should be considered in the final decision on the standard. As explained in the preamble to the final rule, EPA has concluded that the standard promulgated does provide an adequate margin of safety considering the potential for O_3-induced long-term adverse health effects in humans.

v. Mortality studies

This section addresses comments included in section III.A.3.c(5) and elsewhere in the Summary of Comments concerning the health effects evidence from studies of mortality effects, which evidence was not considered as part of the basis for the decision on the proposed primary O_3 standard. Based on the fact that many of the studies published to date regarding associations between ambient O_3 levels and mortality were not published in time for inclusion in the air quality criteria review, premature mortality associated with O_3 was not given substantial consideration during this review of the O_3 primary NAAQS. Because some of the new studies were considered in the Regulatory Impact Analysis, some commenters may have believed mistakenly that they were considered in review of the NAAQS. Only a small number of studies on premature mortality associated with O_3 were included in the air quality criteria and considered by EPA in developing the proposal, and EPA did not give significant weight to that mortality evidence.

Comment: A number of commenters referenced newly published community population studies that report an association between daily human mortality and ambient O_3 concentrations. Many such commenters assert that, unlike previous studies, the new ones account for potential confounding factors, indicate the need for a new O_3 standard set at the lowest level under consideration, and require EPA to substantially fund new research to establish this association. Other commenters assert, however, that the newer studies add more confusion to this issue because each study used a different model for examination of the O_3 mortality relationship and this relationship varied among different models used and the number and type of copollutants included, and, thus that these studies can't be used in any decision on the O_3 primary standard.

Response: Many of the early time-series epidemiology studies looking for associations between O_3 or oxidant exposure and daily human mortality have been difficult to interpret because of methodological or statistical weaknesses, including the failure to account for other pollutant and environmental effects. One of the two most useful studies on O_3-mortality reviewed in the Criteria Document found a small but statistically significant association in Los Angeles where peak 1-hour maximum O_3 concentrations reached concentrations greater than 0.2 ppm during the study period (Kinney and Ozkaynak, 1991). The second study in regions with lower (#0.15 ppm) maximum 1-hour O_3 concentrations (St. Louis, MO, and Kingston-Harriman, TN) did not detect a significant O_3 association with mortality (Dockery et al., 1992).

Since publication of the Criteria Document, Kinney et al. (1995) published the results of PM-associated daily mortality in a newly developed data set from Los Angeles County for the period 1985-1990. This analysis was included prepublication in the Criteria Document and reviewed by the CASAC. Kinney et al. (1995) reported a relative risk of 1.05 associated with a 100 $\mu g/m^3$ increase in PM_{10}; however, more importantly, the multivariate analysis of mortality data that included both PM_{10} and O_3 resulted in a relative risk of 1.00, suggesting that the O_3 effect on mortality, if any, is weaker than that of PM_{10}. Other studies on O_3-associated daily mortality have been published recently showing the importance of not only using appropriate controls for seasonal, day-of-week, and heat (e.g., temperature-humidity) influences, problems that plagued the early studies, but also being able to account for the effects of other pollutants, especially particulate matter, and exploring the potential associations of mortality with prior pollutant exposure (i.e., lagged data). In one recent review of these newer time-series studies, Thurston (1997) concludes that when appropriately analyzed, a small, but statistically significant, effect of O_3 (on the order of a relative risk of 1.06 per 100 ppb increase in the 1-hour daily maximum concentration) can be found on the incidence of acute total human mortality. EPA cannot consider the new studies since they were not included in the criteria review (see response to comment (5) in section II.A.3.a.iii of this document). Based on a preliminary review, however, EPA believes that they may provide increased support for the epidemiological observation that O_3 exposures may be associated with increased mortality and should be considered in the next review of the O_3 primary standard.

vi. Relationship between increasing asthma incidence rates and decreasing O_3 trends

This section addresses comments included in sections III.A.1., III.A.3.a., III.A.3.c., and elsewhere in the Summary of Comments regarding studies of asthma incidence..

Comment: Asthma incidence in the U.S. has been increasing in recent years despite the fact that O_3 levels have been decreasing. This would be inconsistent if O_3 is a cause of asthma.

Response: It is not believed, based on current evidence, that ambient O_3 exposure causes asthma. There is evidence, however, that air pollutants, including O_3, are involved in exacerbating asthma. Therefore, EPA has considerable interest in asthma as a public health and as an environmental health issue.

Controlled human exposure studies on asthmatics indicate that although symptom and volume-related responses to O_3 are similar to those of nonasthmatics, airway resistance increases relatively more, from an already higher baseline, in asthmatics exposed to O_3. There is no evidence at this time that O_3 causes a persistent increase in airway responsiveness, but there is evidence that O_3 exposure accentuates the airway response to allergens that cause asthma symptoms and functional exacerbations. Additional symptom responses have also been reported in asthmatics exposed to O_3. In contrast to nonasthmatics, wheezing, a typical symptom in asthma, is prevalent in O_3 chamber studies in addition to the cough, chest tightness, and shortness of breath that are reported by subjects without asthma. Epidemiological research described in the Criteria Document also has provided evidence that chronic O_3 exposure contributes to an increase in 10-year cumulative incidence of asthma and an increase in asthma severity. The studies on a large population of Seventh Day Adventists in California have provided the most refined measures of chronic O_3 exposure to date. Overall, the aggregate population time series studies considered in Chapter 7 of the Criteria Document provide the strongest evidence that ambient exposures to O_3 can cause significant exacerbations of preexisting respiratory disease, resulting in increased hospital visits and admissions, in the general public, at concentrations below 0.12 ppm for short-term exposures.

b. Definition of sensitive populations

This section addresses comments included in Section III.A.3.b and elsewhere in the Summary of Comments concerning the definition of sensitive populations used in developing a basis for the decision on the proposed primary O_3 standard.

In the proposal notice, EPA stated that groups at increased risk of experiencing health effects from O_3 exposure include active children and outdoor workers who regularly engage in outdoor activities that involve heavy levels of exertion during short-term periods of elevated ambient O_3 levels or moderate levels of exertion during prolonged periods of elevated ambient O_3 levels. Also, individuals characterized as having preexisting respiratory disease (e.g., asthma or chronic obstructive lung disease) may be at increased risk. Further, it is recognized that some individuals are unusually responsive to O_3 relative to other individuals with similar levels of activity or with similar health status and may experience much greater functional and symptomatic effects from exposure to O_3 than the average individual.

(1) *Specific Comment (Nucor Corp., IV-D-2231):* EPA is focusing on sensitive individuals, not sensitive populations.

Response: EPA disagrees. EPA's exposure and risk assessments are tools designed to look at the exposure and risk to two population groups--outdoor children and outdoor workers.

(2) *Specific Comment (American Lung Association, IV-D-2339):* The proposal quotes the CAA as requiring the Administrator to set a primary standard at a level “requisite to protect the public health” not only of the general public but also of sensitive groups within the population (e.g., asthmatics). The Administrator’s decision excludes from risk calculation those with asthma, who account for roughly 10% of the population, and the “responders,” who account for 5 to 30 % of the population. Exclusion of these two groups from consideration in setting standard is unwarranted and inconsistent with requirements of law.

Response: EPA acknowledges that primary standards must be set at a level which protects public health of sensitive groups as well as that of the general population. The exposure and health risk assessments conducted by EPA offer analytical evidence that groups at higher risk to O_3 exposure and thus more likely to be adversely affected will be afforded protection by the standard published in the preamble to the final rule. The standard selected fell within the range of the options presented in the Staff Paper and discussed with CASAC. The CASAC, by consensus, concluded that the Staff Paper provides an adequate scientific basis for making regulatory decisions concerning a primary O_3 standard and supported selection of a standard within the range of options as being appropriate.

c. Adversity of effects

As discussed in the preamble to the final rule, EPA’s consideration of O_3 health effects information necessarily included judgments with respect to when physiological effects become so significant that they should be regarded as adverse to the health of individuals experiencing the effects. The proposal notice summarized the criteria and reasoning for EPA’s judgments on this issue, upon which the CASAC panel expressed a consensus view that these "criteria for the determination of an adverse physiological response was reasonable" (Wolff, 1995b). The criteria take into account the degree of severity of the effects; the likelihood that the effects would interfere with normal activity for individuals with impaired respiratory systems or active healthy individuals; the likelihood that the effects would result in additional or more frequent use of medication, medical treatment, or emergency room visits for individuals with impaired respiratory systems; and the implications of single or repeated occurrences of the effects in an individual.

Some commenters raised concerns regarding the criteria used by EPA to make determinations as to when effects become adverse, citing CASAC’s closure letter (Wolff, 1995b) stating that “there was considerable concern that the criteria for grading physiological and clinical responses to O_3 was confusing if not misleading.” These concerns were discussed at length during a public CASAC meeting, resulting in very specific agreements as to how to revise the draft criteria so as to be consistent with CASAC’s advice (Transcript of CASAC meeting, September 19-20, 1995, pp. 242-248). Having reached such specific agreements, CASAC advised that further review of the final version of these criteria, subsequently incorporated in both the final Criteria Document and Staff Paper, was unnecessary.

Other commenters have questioned whether judgments made in this review are consistent with those made in the last review with regard to when physiological and clinical effects become adverse to individuals experiencing such effects. Specifically, the commenters focused on the judgment stated in the 1993 final decision notice (58 FR 13008, March 9, 1993) that "lesser effects associated with [1- to 3-hour] exposure to O_3 in the range of 0.12 ppm to 0.15 ppm observed in the controlled human studies did not constitute adverse effects for purposes of section 109 of the Act." The "lesser effects" referred to in that notice involved responses of a maximum decrease in lung function [as measured by forced expiratory volume in 1 second (FEV_1)] of from 9% to 16% for the most sensitive individuals exposed in this range, with few, if any, symptoms. The EPA notes that this judgment is, in fact, consistent with judgments presented in the 1996 proposal notice, which identify moderate and large lung function decrements (as reflected in EPA's risk assessment by FEV_1 decreases of $\geq$15% and $\geq$20%, respectively, with the most sensitive individuals experiencing FEV_1 decreases as large as 40% to 50% at 6- to 8-hour exposures in the range of 0.08 ppm to 0.10 ppm in controlled human studies), and moderate to severe symptoms as being adverse.

(1) *Specific comment (General Motors Corporation, IV-D-2694):* EPA has presented no credible evidence of adverse health effects produced by O_3 below the present 0.12 ppm 1-hour standard level. Misapplication by EPA of the American Thoracic Society guidelines has led to inappropriate conclusions regarding what constitutes an adverse health effect. Not all physiological changes are necessarily adverse.

Response: EPA agrees that not all physiological changes are adverse. The EPA staff provided a detailed discussion and tables of what constitutes an adverse health effect induced by O_3 exposure in the O_3 Staff Paper. This was presented for review to CASAC panel members, who concluded that ". . . the Agency's criteria for the determination of an adverse physiological response was reasonable (Wolff, 1995)." The Administrator took this information into account in drawing conclusions regarding what constitutes an adverse health effect for purposes of setting the primary O_3 standard. See section II of the preamble to the final rule.

(2) *Specific Comment (American Lung Association, IV-D-2339):* Statistically significant, progressive decrements in FEV_1 have been demonstrated in healthy young men exposed for 6.6 hours to as little as 0.08 ppm O_3 during exercise. Average lung function and other decrements understate the true magnitude of health injuries. Other studies of school children, hikers and cyclists show lung function changes to be significantly associated with ambient O_3 levels. These lung function decrements are adverse and should be considered in setting primary O_3 standard.

Response: The information cited by the commenter was included in the criteria and taken into consideration in setting the primary O_3 standard. EPA recognizes that effects have been reported at the level and averaging time of exposure of the primary standard published in the preamble to the final rule. However, health effects of the magnitude reported at that level would occur in most individuals without adversely affecting them. More generally, in the absence of a discernible threshold for health effects, it is not possible to eliminate all risks of such effects for all individuals, and the Administrator’s task is to select a standard level which, in her judgment, will reduce risks sufficiently to protect public health with an adequate margin of safety. See the preamble to the final rule.

d. Exposure analyses

i. Comments about general methodology

This section addresses comments included in section III.A.3.d.(1) and elsewhere in the Summary of Comments that raise general methodology issues concerning the exposure analyses. Comments on the exposure analyses can generally be divided into two groups. One group of commenters claimed that: 1) the model overestimates the exertion level that can be achieved by most children and outdoor workers and the fraction of time that these groups spend in moderate or heavy exertion, 2) the model overestimates outdoor ambient exposures because fixed-site monitors overestimate outdoor personal exposures, and 3) the air quality adjustment procedures used to simulate attainment of the standards are inappropriate or highly uncertain. The second group of commenters expressed concern that the exposure model may be significantly underestimating exposures for children and outdoor workers who repeatedly exercise due to limitations in the available human activity pattern data.

As discussed in the proposal notice, EPA recognizes that the exposure model necessarily contains many sources of uncertainty, although every effort has been made to account for such uncertainties to the extent possible. EPA notes here that most of the issues and concerns raised by commenters concerning the methods used in the exposure analyses are essentially restatements of concerns raised during the development and review of these quantitative assessments as part of the preparation and review of the Staff Paper. EPA presented and the CASAC reviewed in detail the approaches used to assess exposure and the presentation of the exposure results summarized in the Staff Paper. As stated in the proposal notice, EPA believes and CASAC concurred, that the models selected to estimate exposure are appropriate and that the methods used to conduct the exposure analyses represent the state of the art. EPA does not believe that the exposure analyses are fundamentally biased in one direction or the other as claimed in some of the comments.

Presented below is a Summary of Comments received and responses to various specific issues related to the exposure analyses considered in developing the proposed rule. This section is intended to expand upon the discussion of the exposure analyses contained in the Preamble to the final rule.

Specific Comment (Asphalt Institute, IV-D-2282): EPA relied on estimates derived from exposure models that have not been properly validated.

Response: It should be recognized that predictive exposure models that simulate attainment of alternative standards can never be fully "validated" because they are predictions or simulations of a condition that will occur in the future based on the best information available currently. Rather, one can *evaluate* models to see how they perform under baseline or "as is" conditions. However, even these evaluations depend on the availability of personal exposure databases for O_3 which are extremely limited. Section 7 in Johnson et al. (1996d), which is available in the docket, discusses initial efforts to validate the pNEM/O3 model using the only data set available at the time that included personal exposure monitoring for O_3.

ii. Air quality adjustment procedures

This section addresses comments on the air quality adjustment procedures used in exposure analyses that are primarily summarized in section III.A.3.d.(1)(a) of the Summary of Comments.

(1) *Comment:* EPA should revise rollback method because the Weibull approach over predicts median values by typically 50% (cites Johnson, 1995 evaluation letter report) and it is highly unlikely that the same general shape and timing of O_3 concentration and frequency at a given monitoring site would be maintained as assumed in model.

Response: The exposure model incorporates and is sensitive to analytical procedures used to simulate spatial and temporal distributions of O_3 concentrations that would occur as a result of an area just attaining any of the alternative standards addressed in the exposure assessment. These air quality adjustment procedures are based on generalized models intended to reflect the patterns of changes in distributions of O_3 concentrations that have historically been observed in areas implementing control programs designed to attain the O_3 NAAQS. The EPA recognizes that future changes in air quality distributions are area-specific, and will be affected by whatever specific control strategies are implemented in the future to attain the revised NAAQS. Thus, generalized models are expected to be more uncertain for any given area than when exposure results are aggregated across many areas (as was done across the nine urban areas analyzed in EPA's exposure assessment).

The original adjustment procedure was developed and tested with a focus on the tail of the 1-hr and 8-hr air quality distributions. Therefore, there is more uncertainty about how well the adjustment procedure characterizes the 1-hr and 8-hr daily maximum values that are in the middle of the distribution. The exposure analysis cited in the 1996 OAQPS Staff Paper was based on using two types of AQAPs: for six of the nine areas the approach involved fitting parameters of the Weibull distribution and for the other three areas that were close to attaining the alternative standards under consideration the approach involved a proportional adjustment. A limited evaluation of the adjustment procedure (Johnson, 1995) suggests that the Weibull approach provided reasonable estimates of the upper 10% of the distribution of hourly O_3 values, the region that determines the O_3 exposures of most concern in pNEM/O_3 analyses, based on an empirical analysis of six of the nine urban areas included in the exposure analysis. The results also showed that the Weibull AQAP may significantly over-estimate O_3 concentrations in the lower portions of the distribution. For this reason, EPA used the proportional AQAP in all nine urban areas in carrying out the supplemental exposure and health risk analyses (Johnson et al., 1997; Whitfield, 1997a), which were made available in the docket during the comment period (see 62 FR 77431, February 20, 1997). In response to comments, EPA also has carried out a sensitivity study for six of the nine urban areas to examine the sensitivity of the exposure and risk estimates to alternative AQAP's, including the proportional, Weibull, and quadratic approaches (Johnson, 1997; Whitfield, 1997b). The quadratic approach, like the Weibull approach, reduces the peak or upper end of the air quality distribution by a greater amount than the lower and middle portions of the distribution.

EPA recognizes that additional research is required to better characterize how the spatial and temporal pattern of O_3 air quality distributions will change as a function of control strategies adopted to attain the O_3 NAAQS in the future. See response to specific comment by CMA below (II.A.3.d.ii.(6)) for more concerning this issue.

(2) *Comment:* The unexpected result that Denver and Miami have maximum O_3 levels higher than current levels upon attaining alternative standards raises concerns about the air quality adjustment procedure.

Response: For purposes of evaluating the health protection associated with possible alternative primary standards, EPA believes it is appropriate to estimate the exposure and health risks that would occur if an area was just attaining each alternative standard. In some cases, such as for Miami and Denver, this involves adjusting the air quality from current levels upward so that they just attain a given standard. The exposure and risk estimates obtained are not predictions of what will occur in any given year, but rather what level of exposure and risk would occur if an area just attained a given standard. EPA prepares a separate regulatory impact analysis which deals with projections of future air quality under alternative standards and control strategies. As stated in the O_3 Staff Paper (p.88), "For the O_3 exposure analyses conducted to support the decisions on the NAAQS, it is sufficient to simulate the just-attaining situation without being concerned about how, when, or even if that situation will occur."

(3) *Specific Comment* (Krupnick, IV-D-2100): The effects of major assumptions were not tested through sensitivity analysis; EPA should have examined 2 bounding assumptions for air quality adjustment: proportional and "clipping" off of the high end of the distribution since actual exposure reduction probably lies between these two assumptions.

Response: A recent letter report by Johnson (1997a), which was conducted in response to comments and has been placed in the rulemaking docket, provides a comparison of exposure estimates obtained from three different air quality adjustment procedures (i.e., proportional, Weibull, and quadratic). This report indicates that the Weibull and quadratic approaches reduce the high end of the distribution more than the lower and middle parts of the O_3 distribution, while the proportional approach reduces all parts of the distribution by the same percentage. For purposes of this rulemaking, EPA is relying on those exposure estimates which use the AQAPs which were placed in the docket prior to the close of the comment period (including Weibull and proportional analyses).

EPA has examined how air quality has historically improved over the last 25 years. Based on this review, somewhat larger reductions in the high end of the O_3 distribution compared to the middle or lower end of the O_3 air quality distribution typically have occurred. However, EPA finds no evidence based on how O_3 levels have historically been reduced to support the proposition that only the high end of the distribution would be "clipped off" in the future.

(4) *Specific Comment* (Krupnick, IV-D-2100): It appears that the city-wide air quality adjustment method used in the supplemental exposure and risk analyses (i.e., the proportional procedure) didn't assume a background of 0.04 ppm and allowed rollbacks to bring concentration reductions below "background" levels.

Response: The assumption that there is a lower bound to the O_3 concentrations that may be measured in an urban area (the "background" concentration) applies to peak O_3 concentrations, not to the entire distribution of O_3 concentrations. One-hour O_3 concentrations below 0.04 ppm are routinely measured at monitoring sites under baseline ("as is") conditions. Application of the proportional adjustment procedure to the one-hour data reported by a particular monitor will increase the number of one-hour values below 0.04 ppm, but the peak one-hour value will typically remain far above 0.04 ppm.

(5) *Specific Comment* (Krupnick, IV-D-2100): Suggest sensitivity analyses should be done with background subtracted out of entire distribution, then calculating adjustment based on residual values so that no credit taken for reductions that are unlikely to occur.

Response: As indicated above, a background concentration serves as the lower limit for the peak value in the distribution of one-hour concentrations, not all values. Note that subtraction of 0.04 ppm from each one-hour value in distribution will produce negative values when the one-hour value is less than 0.04 ppm.

(6) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): Achievement of any of the proposed O_3 standards in a current non-attainment area would undoubtably shift both the location and timing of the maximum O_3 concentrations in an urban area, and it is highly unlikely that the same general shape and timing of the O_3 concentration frequency at any given monitoring location would be maintained, as assumed in the pNEM/O_3 methodology.

Response: In evaluating alternative forms of the NAAQS for O_3, EPA uses pNEM/O_3 to estimate the number of people exposed to O_3 in selected urban areas. In a typical pNEM/O_3 analysis, ten or more fixed-site monitors are selected to provide ambient O_3 concentrations across an urban area. The data reported by these monitors for a particular year are considered to represent "as is" or baseline conditions. An air quality adjustment procedure (AQAP) is applied to the baseline data to produce O_3 data representative of "attainment" conditions -- the conditions expected when the urban area just attains a specified O_3 NAAQS. Reviewers have suggested that this procedure may not adequately account for the change in the O_3 production rate which occurs as an area moves into attainment. A change in the O_3 production rate could result in peak O_3 levels occurring in a geographic area and/or at a time of day that differs from that predicted by the AQAP.

As the majority of urban areas to which the AQAP has been applied have never achieved the specified attainment conditions, researchers have found it difficult to validate the AQAP used in pNEM/O_3 directly. EPA conducted a limited evaluation of the air quality changes resulting from the AQAP in the exposure model using the Regional Oxidant Model (ROM). ROM is the only available tool that estimates O_3 concentrations over a significant portion of the O_3 season that explicitly takes into account spatial and temporal patterns in meteorology and O_3 precursors. EPA has placed a report (Johnson and Weaver, 1996), Comparison of Temporal and Spatial Patterns in Ambient Ozone Concentrations Estimated by pNEM/O_3 and the Regional Oxidant Model (ROM), in the rulemaking docket that provides a detailed description of this assessment.

Johnson and Weaver (1996) presents the results of statistical analyses in which researchers examined temporal and spatial patterns in estimates of O_3 concentrations obtained from the AQAP and from ROM. Shifts in peak O_3 levels with respect to time of day and geographic location were quantified for each of six urban areas (Chicago, Houston, New York, Philadelphia, St. Louis, and Washington, DC) which have been used in past pNEM/O_3 exposure analyses. In each case, the shift observed in the estimates obtained from the pNEM/O_3 air quality adjustment procedure was compared to the corresponding shift in estimates obtained from ROM.

The analyses of temporal shifts support the following two general conclusions:

- pNEM/O_3 and ROM produce similar diurnal patterns for baseline and attainment conditions, and

- the peak in the diurnal pattern of O_3 concentrations (1 hour or 8 hour) under attainment conditions tends to occur slightly earlier (one hour or less) than the peak for baseline conditions, regardless of model.

In summary, pNEM/O_3 and ROM produce comparable results with respect to temporal shift.

The analyses of spatial shifts support the following general conclusions:

- Considered separately, the ROM and pNEM/O_3 procedures each produced high baseline-to-attainment correlations for site rankings for most cities. The baseline-to-attainment change in rankings produced by ROM for New York and Philadelphia was not observed in the pNEM/O_3 results. The cause of the ranking change in these two cities with respect to ROM is not known.

- When matched for baseline and attainment conditions, correlations between pNEM/O_3 and ROM site rankings were generally low. However, when city-wide patterns in O_3 levels were represented by O_3-weighted centroids, the locations of the pNEM/O_3 and ROM centroids were approximately the same when matched for baseline and attainment conditions.

Overall, the results suggest that the pNEM/O_3 and ROM modeling approaches will produce significant differences in the rankings of individual sites but similar large-scale, city-wide patterns.

The conclusions presented above with respect to temporal and spatial shifts presume that the pNEM/O_3 and ROM data sets are generally comparable. Although an attempt was made to select modeled days which exhibited high O_3 levels across most of the six urban areas, the resulting pNEM/O_3 and ROM data sets represented different calendar years (1987 versus 1990/91) and, thus may have been affected by differing meteorological conditions. In addition, the ROM attainment data were based on a particular emission control scenario selected by EPA as appropriate for the analysis. Use of another, equally plausible, control scenario to achieve attainment conditions may produce different patterns in the ROM O_3 estimates. Since the exact mix of control measures to attain a new 8-hour O_3 standard is not known at this time, there is uncertainty about whether the spatial pattern of O_3 concentrations will shift in the future.

The results of this limited evaluation using the ROM do not suggest that the temporal and spatial patterns of O_3 will change significantly upon attainment of alternative standards. Given the relatively small differences in temporal and spatial patterns observed in the evaluation, EPA continues to believe that the approach taken in adjusting air quality within the exposure model was appropriate.

(7) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): For some of the regulatory standard scenarios adjusted maximum O_3 levels for Miami and Denver were actually higher than monitored values in the base year (in spite of the fact that O_3 concentrations in these cities

are currently below some of the proposed standards). Thus, the pNEM/O_3 model predicts that O_3 exposures for some regulatory scenarios would be higher than the actual current exposures in Miami and Denver (p. 74).

Response: In the pNEM/O_3 analyses developed for the review of the standard, analysts have assumed that O_3 levels in a city will move up or down from the base year to exactly meet the stated attainment conditions. In cases where O_3 levels are currently below the specified standard (e.g., Miami and Denver), this assumption accounts for the possibility that future growth in emissions may increase O_3 levels to the point where the city just attains the standard.

iii. Activity patterns and exertion levels

This section addresses comments primarily contained in section III.A.3.d.(1)b) of the Summary of Comments that raise issues related to how human activity patterns were used in the exposure analyses.

(1) *Comment:* The activity pattern data used in the exposure analyses are inadequate and/or are not representative of patterns for children and outdoor workers nationwide.

Response: For both the outdoor children and outdoor worker versions of pNEM/O_3, EPA included all of the available, peer-reviewed human activity pattern data that was suitable for estimating exposures. The studies included were summarized in the OAQPS Staff Paper and in the exposure analysis technical reports (Johnson et al., 1996a,b). In the proposal, EPA acknowledged that there are uncertainties in the exposure analysis; however, the analysis was used following review by CASAC and with the support of CASAC.

(2) *Comment:* EPA exposure analyses overestimate exposure because: (1) activity pattern used in chamber studies is not representative of daily activity patterns of sensitive populations targeted.

Response: The controlled 6.6-hr human clinical studies involved 50 minutes of exercise and 10 minutes of rest for each of 3 consecutive hours, then a 45 minute lunch break and then another 3 hours of 50 minutes exercise and 10 minutes rest each hour. For the exposure analysis and risk assessment of outdoor children and outdoor workers, EPA has estimated 8-hr exposures under moderate exertion for the range of equivalent ventilation rate (EVR) observed in the clinical studies over the 6.6 hr period (i.e., 90% of the subjects in the clinical studies had an average 6.6 hr EVR in the range 13-27 l/min-m^2). EPA recognizes that activity patterns in the real world generally do not follow the simple pattern employed in the clinical studies. Nevertheless, the elevated ventilation (i.e., breathing) rates achieved by the experimental protocol are not atypical for some children actively engaged in outdoor play (e.g., running, sports, etc.) or some outdoor workers engaged in physical labor (e.g., construction work, loading/unloading vehicles, etc.). Ventilation rate is a key factor that determines the durations and concentrations of O_3 exposure that will be effective in causing human health effects. Simply put, the higher the ventilation rate, the shorter the duration and the lower the concentration of O_3 that will cause lung function decrements and/or respiratory symptoms. On balance, EPA believes that the exposure estimates used in the exposure analysis are appropriate.

(3) *Comment:* Exposure model fails to consider the role of temperature and humidity, that may dramatically reduce a person's outdoor activities and exertion level.

Response: See response to the specific comment below by CMA.

(4) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): In the presence of high relative humidity under ambient summertime conditions, the general population would probably decrease their exercise level and/or spend more time indoors in order to decrease their discomfort. Both of these changes in activity patterns would decrease the exposure to O_3 for a given ambient air concentration. In general, pNEM/O_3 fails to consider the role of increased temperature and humidity that may dramatically reduce a person's outdoor activities and exertion level (p. 78).

Response: As the outdoor children report (Johnson et al., 1996a) clearly indicates, the pNEM/O_3 model estimates activity location (indoors/outdoors) and breathing rate category (slow, medium, fast) directly from human diary data which have been matched to the modeled day by demographic group, season, day of the week, and <u>temperature range</u>. As temperature is explicitly considered in matching activity data to modeled days, the resulting activity patterns for high-temperature days should be reasonably representative of people's activities on high temperature days. If humidity is high on a high-temperature day, the commenter is correct in stating that the procedure may over-estimate the occurrence of strenuous outdoor activities. However, the procedure may <u>under-estimate</u> the occurrence of strenuous outdoor activities when temperature is high but humidity is low. These potential biases would appear to balance with respect to their effect on the estimated exposures for an entire O_3 season, as the commenter states that "humidity ... has little effect on O_3 formation" (i.e., high O_3 does not tend to occur more frequently when humidity is high).

The commenter states that the algorithm that determines window status (open or closed) is not defined. This statement is incorrect, as there is a detailed description of this algorithm on pages 47 through 50 of the outdoor children report [Johnson et al. (1996a)].

(5) *Comment:* Use of human activity diary subjects mostly from California and Cincinnati in EPA's exposure analyses may not be representative of other locations in U.S.

Response: Addressed by response below to specific comment by CMA.

(6) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): Human activity diary subjects are mostly from California and Cincinnati and may not be representative of other locations in U.S. (p. 99). The proportions of time that individuals from different areas spend in different microenvironments and their levels of exertion may differ significantly. Johnson et al. (1993) estimated that adult subjects in Los Angeles and Cincinnati engaged in more activities per hour than subjects in Denver and Washington. Beside temperature, time/activity patterns are likely to be affected by a variety of local factors, including topography, land-use, traffic patterns, mass transit systems, and recreational opportunities.

Response: The pNEM/O_3 analysis of outdoor children included data from seven diary studies and included every usable diary record then available. The procedure which pNEM/O_3 uses to construct activity patterns attempts to adjust for the effects of demographic group, temperature, season, and day of the week on activity patterns. The commenter is correct in stating that the procedure does not explicitly account for local factors (topography, land-use, etc.). However, the differences in activities per hour among adult subjects in Los Angeles and Cincinnati and adult subjects in Denver and Washington may be due to the fact that the Denver and Washington, D.C. diary studies were conducted only during the winter, while the Cincinnati study included diary data only for March and August. Individuals are likely to engage in more activities per hour during periods when the weather is more conducive to outdoor activities. McCurdy (1994) has shown in his review of activity diary data for children, that more time is spent outdoors during the summer season than in the winter. Johnson et al. (1993) also suggest that the cited differences in activities per hour may be the result of differences in study protocols (e.g., different diary formats) rather than differences in the location of the study subjects. While admittedly not perfect, the diary data used were the best available and EPA believes that the uncertainties balance sufficiently to make reliance on the data appropriate.

(7) *Comment:* Use of small number of days (<3) to construct entire O_3 season may not be representative. Some commenters expressed concern that approach used may underestimate exposures for children attending residential summer camps because this type of activity pattern was not included in data base. Other commenters expressed concern that approach used would result in overestimating exposures for outdoor children.

Response: The concern about possible underestimation of exposure for children attending summer camps is addressed in the response below to a specific comment by CMA. The concern that the exposure model overestimates outdoor exposure for children is addressed here. In the pNEM/O3 analysis of outdoor children, analysts constructed a special time/activity database containing diary data obtained from a group of children identified as "outdoor children." Each member of this group reported from one to three days of diary data, all of which were used in constructing the special database. The criteria used to select the outdoor children group are spelled out on p. 82 and 85 of the Staff Paper. This procedure produced a pool of 479 outdoor children with 792 person-days of activity data. When pNEM/O3 constructs exposure event sequences for outdoor children, the sequencing algorithm draws from all 792 days and, thus includes days with varying periods of outdoor activities. Of the 479 children selected 323 provided a single day of data. As each of these days must have met the stated requirements for inclusion, each was an “outdoor day.” The remaining 156 children provided two or three days of data, of which at least one day was an outdoor day. Consequently, a minimum of 60.5 percent (479/792) of the selected person-days were outdoor days. If activity patterns were randomly constructed from the pool of 792 person-days, then a minimum of 60.5 percent of the days in each activity pattern would be outdoor days. The pNEM/O3 model constructs activity patterns by sequencing person-days according to demographic group (6 to 13 years, 14 to 18 years), season (winter, summer), day type (weekday, weekend), and range of daily maximum temperature (winter: < 55, 55+EF.; summer: < 84, 84+EF.). To evaluate the effects of the selection procedure, EPA’s contractor, IT-AQS, created two data files listing number of minutes spent outdoors by person-day. The data set designated “All” contained all person-days for children obtained from the diary studies; data set “OC” contained only the person-days that were selected for the outdoor children analysis. Table 1 provides selected statistics (arithmetic mean, standard deviation, quartiles) for the number of minutes spent outdoors per day broken down by data set, demographic group, and season. Table 2 provides arithmetic means by data set for a more detailed breakdown of the data by demographic group, season, day type, and temperature range. Table 2 also lists the difference between means for each data subset. The differences range from 54 minutes (6 - 13 years, winter, weekday, 55+EF.) to 210 minutes (14 - 18 years, summer, weekend, < 84EF.).

A spread sheet program was set up which provides an estimate of the number of minutes over the O_3 season that the pNEM/O3 sequencer subroutine would assign a child to outdoor locations. The program assumes that the mean value for outdoor time per day for each combination of season, day type, and temperature range is equal to the applicable value listed in Table 2. It was assumed that the weekday/weekend split was 5/2 and that the two temperature ranges occurred with equal frequency within each season. These assumptions yielded the following values for mean number of minutes spent outdoors per day based on an <u>O_3 season of 366 days</u>.

Demographic group	All	OC	Difference
Children 6 - 13	160	244	84
Children 14 -18	113	211	98

Table 1. Descriptive Statistics by Demographic Group and Season for Time Spent Outdoors Based on Data Sets for All Children and for Outdoor Children Only.

Classification variables		Data set[a]	Number of days	Time spent outdoors per day, minutes				
Demographic group	Season			Mean	Std. dev.	25th pct.	50th pct.	75th pct.
6 - 13 years	Winter	All	638	165	190	54	122	209
		OC	340	256	220	142	202	295
	Summer	All	443	242	196	95	205	335
		OC	234	352	204	266	325	451
14 - 18 years	Winter	All	407	101	126	16	60	140
		OC	172	182	156	84	152	239
	Summer	All	183	170	169	29	122	242
		OC	64	324	185	216	313	449

[a]All: all children, OC: outdoor children

Table 2. Means by Four Classification Variables for Time Spent Outdoors Based on Data Sets for All Children and for Outdoor Children Only.

Classification variables				Number of days: all/OC	Time spent outdoors per day, minutes		
Demographic group	Season	Day type[a]	Temp. range, EF.		Mean for all children	Mean for outdoor children	Difference = OC - all
6 -13	Winter	WD	< 55	88/38	102	170	68
			55+	289/174	140	194	54
			All	377/212	131	190	59
		WE	< 55	47/13	81	145	64
			55+	214/115	245	392	147
			All	261/128	215	367	152
		All	All	638/340	165	256	91
	Summer	WD	< 84	196/112	249	347	98
			84+	130/62	242	373	131
			All	326/174	246	356	110
		WE	< 84	44/24	247	351	104
			84+	73/36	219	333	114
			All	117/60	230	340	110
		All	All	443/234	242	352	110
	All	All	All	1081/574	197	295	98
14 - 18	Winter	WD	< 55	111/37	76	166	90
			55+	158/61	99	181	82
			All	269/98	90	176	86
		WE	< 55	32/14	86	143	57
			55+	106/60	135	200	65
			All	138/74	124	189	65
		All	All	407/172	101	182	81
14 - 18 (cont.)	Summer	WD	< 84	84/27	168	320	152
			85+	37/12	159	305	146
			All	121/39	166	315	149
		WE	< 84	25/8	188	398	210
			85+	37/17	172	309	137
			All	62/25	179	338	159
		All	All	183/64	170	324	154

Classification variables				Number of days: all/OC	Time spent outdoors per day, minutes		
Demographic group	Season	Day type[a]	Temp. range, EF.		Mean for all children	Mean for outdoor children	Difference = OC - all
	All	All	All	590/236	123	220	97
All	All	All	All	1671/810	171	273	102

[a]WD: weekday, WE: weekend.

Note that the results labeled “all” are expected when the sequencer uses all available diary data for children, whereas the “OC” results represent results expected when the special outdoor children data set is used. The following results were obtained using an O_3 season of 210 days (seven months).

Demographic group	All	OC	Difference
Children 6 - 13	181	272	91
Children 14 -18	127	239	112

Depending on the demographic group and the assumed O_3 season, the differences range from 84 to 112 minutes.

McCurdy (1994) (included as Appendix A of this response-to-comments document) summarizes time spent by children in the outdoor microenvironment based on data from 10 human activity surveys. From Table 2 of this memo, the mean hours/day spent in the outdoor microenvironment during the July-September or “non-school” days ranged from 1.1 to 4.7 hours/day for children in seven different studies. Four of the seven studies had mean times of at least 4.0 hours/day outdoors. Given that the pNEM/O_3 outdoor children estimates are only applied to 47 percent of preteens and 31 percent of teenagers, EPA believes that the estimates of time spent outdoors for outdoor children resulting from the modeling approach are reasonable and, in fact, may underestimate exposure, as discussed in the next response. Furthermore, the approach is responsive to CASAC recommendations made at public meetings held on September 19-20, 1995 that EPA attempt to estimate exposures for children whose repetitive day-to-day activities were likely to place them outdoors more often than the average child..

(8) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): The procedure used to construct each activity pattern may not account for the day-to-day repetition of activities common to individual children. Consequently, pNEM/O_3 may tend to under-estimate the number of people, particularly outdoor children, who experience multiple occurrences of exposure while engaged in moderate or heavy exertion. For example, the outdoor children analysis does not adequately reflect exposures for children attending residential summer camp because this type of activity pattern is not included in human activity pattern data base used in the outdoor children exposure analysis (p. 99).

Response: The commenter is correct in stating that the procedure used to construct activity patterns for outdoor children may under-estimate the effects of repetitive activities and this caveat has been noted in the OAQPS Staff Paper discussion of the exposure analysis and in the exposure technical reports. The statement that the outdoor children database does not include summer camp patterns is incorrect. Several of the Los Angeles subjects attended summer camp on days included in the outdoor children database. However, whether or not the activity data base used for the exposure analysis includes the same proportion of "summer camp" activity patterns as exists in the nine cities included in the analysis is unknown. EPA has attempted to obtain information on attendance at summer residential and non-residential camps, but has not found any national or regional data base with this type of information. While there are limits to the data available to EPA, the Agency believes that, on balance, the exposure analyses are a valuable tool. (See preamble for further discussion.)

iv. Estimation of ventilation rates

This section addresses comments primarily contained in section III.A.3.d.(1)c) of the Summary of Comments that raise questions as to how equivalent ventilation (EVR) rates were estimated in the exposure analyses.

(1) *Comment:* EVR estimates used in pNEM are too high and should be revised based on new field studies. Additional concerns raised suggesting EVR estimates used in pNEM are too high include:

-- Exposure model inappropriately assumes that 100% of people are "motivated exercisers" thus only fraction of projected risk likely to occur; cites USHHS (1996) to support comment that less than half of population fit or willing to maintain relatively high breathing rates, even if motivated;

-- EVR estimates used by EPA don't correct for arm movement and increase in temperature; and

-- Calibration of heart rate (HR) and ventilation rate (VR) cited in exposure analyses done primarily with leg exercise, whereas most recreational exercise and occupational endeavors involve both arm and leg exercise; overestimation of VR by about 5-8% for lower ranges of HR (Adams et al., 1995).

Response: EPA does not agree that the EVR estimates used in pNEM are too high. EPA has reviewed the literature addressing children's breathing-rate capabilities and compared it with pNEM/O_3 outputs (see McCurdy, 1997 included as Appendix B to this document). McCurdy (1997), an analysis which was conducted in response to comments and is available in the docket, describes an analysis that is based on values from the exercise physiology literature on the distribution of maximal oxygen uptake in healthy boys and girls, combined with information from the literature on the distribution of height and body mass to generate distributions of ventilation rates for children approximately 11 years old. These distributions were then compared with actual pNEM/O_3 results (see Table 2 of McCurdy (1997). While the comparison only involves one run of the pNEM model for one cohort, and is, thus a limited comparison, the variability in pNEM/O_3 is not large for ventilation estimates in any one urban area for a given time period. The maximum possible ventilation rate for normal girls is 80 L/min for a 1-hr period and 40 L/min for an 8-hr period based on values obtained from the exercise physiology literature. For boys -- trained or not -- it is 95 L/min and 55 L/min, respectively. The maximum ventilation rate modeled in pNEM (EVR * 1.23) is around 58 L/min for 1-hr for both the all children and outdoor children pNEM runs examined, considerably lower than the maximum ventilation rate estimates that are possible based on the exercise physiology literature. Thus, there is no problem with pNEM/O_3 modeling too high a maximum ventilation rate or EVR, even if the EVR-limiting algorithm used in the model is too high for most children. This point is reinforced by the second section of Table 2 of McCurdy (1997). The capability of the 6-13 year old group to exercise at the 1-hr motivated level of 59 l/min used in the pNEM work is around 12% for boys and 3% for girls. In the pNEM runs analyzed, however, this level is reached only 1-hr per year, less than 1% of the total population-hours modeled. For 8-hrs, the literature indicates that 8-13% boys can sustain a maximum ventilation rate of 31 l/min, as can 3% of girls. In the all-children pNEM/O_3 run analyzed, no one experiences a breathing rate level of 31 l/min for 8-hrs. The outdoor children run was not analyzed because there was little difference in the 1-hr maximum ventilation rate averages between the two groups.

Finally, McCurdy (1997) provides a comparison to determine what percentage of children 6-13 can exercise at the 1-hr, 20-37 l/min and 8-hr 16-33 l/min "moderate " levels used in pNEM/O_3. The literature indicates that almost all children (93-97%) can sustain the 1-hr, 20 l/min breathing rate, whereas only about 7% of the children-hours in pNEM are at that level. The corresponding values for the 1-hr, 37 l/min level is 39-68% of the population versus < 1% of the pNEM population. There is less difference in the 8-hr estimates, but the pNEM runs are still significantly below those sustainable based on the exercise physiology literature.

In sum, there is no indication that the pNEM/O_3 model produces extreme breathing-rate estimates due to the motivated exerciser concept. In fact, pNEM modeled estimates are well below those based on measured breathing rates studied in many laboratories over many years.

(2) *Comment:* EPA's exposure model tends to over predict occurrence of high EVR values within each demographic group because EVR limit based on subset of specified cohort (e.g., 11 year old males used for 6-13 group and 15 year old males used for 14-18 group).

Response: The Staff Paper (Section V.G.2, p.90) and outdoor children exposure report (Johnson et al., 1996a, p.27) acknowledge that the parameter values for certain physiological characteristics used in the algorithm for determining the EVR upper limit are based on a subset of the specified demographic group (e.g., males aged 11 used for the 6-13 age group) and that this will tend to over predict the occurrence of high EVR values within each demographic group. However, the analysis done by McCurdy (1997), as discussed in the response to comment II.A.3.d.iv(1) above, suggests that any potential bias introduced by the upper limit EVR approach used in pNEM is minimal. The pNEM modeled estimates are well below those based on measured breathing rates studied in many laboratories over many years. Also, while the EVR **limit** was calculated using the body surface area for males aged 11 for the 6-13 age group, the EVR values were sampled from distributions obtained directly from field studies in which the body surface area varied with the subject.

v. Ambient concentrations vs. personal exposure levels

This section addresses comments primarily contained in section III.A.3.d.(1)d) of the Summary of Comments that raise questions as to how the exposure model estimates exposures for outdoor microenvironments based on fixed-site ambient concentrations, and how these estimates compare with concentrations estimated using personal exposure monitors (PEMs).

(1) *Comment:* Personal exposure is substantially overestimated based on research (Johnson et al., 1996c) indicating actual exposure averaged only 50-60% of that predicted by EPA's exposure model.

Response: Addressed by response below to specific comment by CMA.

(2) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): The Johnson et al. (1996c) study contradicts the Contant et al. (1987) results in that the Johnson study reports PEM concentrations substantially lower than fixed-site values in all microenvironments. This is particularly the case for indoors and in vehicle microenvironments, but also for outdoor microenvironments. The mean Los Angeles PEM results indicate 40% reduction compared to fixed-site values.

Response: In the API-sponsored study by Johnson et al. (1996c), there apparently was no side-by-side evaluation of the performance of the PEM device with the fixed-site monitor devices. Therefore, it is possible that the PEM devices may be biased low. Past research with PEM devices has shown that orientation of PEMs often influences the magnitude of concentrations observed. Until the potential bias in the Johnson study's Los Angeles PEM measurements is resolved, EPA believes that it is reasonable to assume that outdoor personal exposures are approximately equal to fixed-site concentrations.

(3) *Comment:* Use of only 1 study to relate personal outdoor exposure to fixed-site monitors in exposure analyses raises concerns about accuracy and reproducibility. A recent study by Johnson (1996c) contradicts Contant et al. (1987) results. The differences in these 2 studies may be due to effect of monitor inlet height (3-5 m) vs. PEM height of 1-2 m or due to scavenging of local sources by NOX near highway or power plant plumes.

Response: The Contant et al. (1987) study was the only applicable personal monitoring study available at the time analysts developed the relationship between outdoor exposure and fixed-site O_3 measurements for pNEM/O_3, a model of which CASAC approved. See above response for concerns EPA has about the relevance and validity of the PEM results from the Los Angeles study. See the response below to the specific comment by API addressing monitoring inlet height and scavenging by NOX.

(4) *Specific Comment* (API, IV-D-2242): Current EPA ambient monitoring siting guidance may also contribute to overestimates of personal O_3 exposure. Present guidelines direct that O_3 monitor inlets be installed 3 to 15 meters above grade. Recent studies of vertical O_3 gradients indicate that O_3 concentrations frequently increase with height above ground (Trotter et al., 1996), due perhaps to O_3 surface deposition and emissions of O_3 scavengers such as isoprene (e.g., human breath and vegetation) and NO (e.g., soil, human breath, and auto exhaust) near the surface. Recently measured increments in O_3 levels between 2 and 10 meters averaged 13% (Wisbith et al., 1996). The current pNEM/O_3 model does not correct for this effect and so may overpredict O_3 exposure accordingly.

Response: EPA cannot consider the studies cited in this comment because they appeared in the literature after completion of the criteria review. (See response to comment (5) in section II.A.3.a.iii of this document.) Nevertheless, EPA has provisionally examined the new studies cited in this comment. In the Trotter study, researchers measured vertical profiles of O_3 in the eastern ridge-and-valley region of Tennessee. According to the study, the area is a "region of complex terrain consisting mostly of parallel ridges and valleys running from southwest to northeast ... highly corrugated ... regional surface cover is mostly deciduous forest." The paper provides vertical profiles for morning and evening time periods. The profiles extend from 0 to 700 meters with generally poor spatial resolution in the range of interest (0 to 10 m). Although most of the graphs show an increase in O_3 concentration with height, a few graphs (e.g., Figures 2-C and 3-B) show O_3 levels decreasing with increasing height below about 20 m. In general, it is difficult to relate the Trotter results for eastern Tennessee to the urban areas analyzed by pNEM/O_3 because of the differences in terrain and ground cover.

In the Wisbith et al. (1996) study, researchers used an abandoned radio tower to measure O_3 levels at 2, 10, 20, 40, and 80 meters above a grassy field located 20 miles north of downtown Cincinnati. O_3 measurements made during the study at a height of 10 meters over-predicted the 2-meter concentrations by an average of 17.5 percent, based on the median ratio of 10 m O_3 to 2 m O_3 (1.175) calculated from six sets of measurements. This value is actually higher than the value (1.15) cited by the commenter. Wisbith et al. (1996) note that the results may not be generally applicable, as the data were collected at a single location during a single day.

Johnson (1997b), in a study prepared for the American Petroleum Institute and not cited in the Criteria Document, has used the results of Wisbith et al. (1996) to develop a procedure for adjusting monitoring data to account for probe inlet height. When this procedure was applied to fixed-site monitoring data used in a pNEM/O_3 analysis of exposures of outdoor workers in Los Angeles, the resulting exposure estimates for outdoor workers in Los Angeles showed relatively small decreases (0 to 2 percent) when compared to estimates obtained from unadjusted data. The potential bias suggested by the commenter does not appear to be large enough to warrant further analysis at this time.

(5) *Comment:* The 5.6% average difference between PEM and fixed-site monitors in Contant et al. (1987) may be due to differences in measurement technique (PEM used chemiluminescent and fixed site used UV absorption).

Response: Addressed by response below to specific comment by API (II.A.3.d.v.(6)).

(6) *Specific Comment* (API, IV-D-2242): The 5.6% average difference between PEM and fixed-site monitors in Contant et al. (1987) may be due to differences in measurement technique (PEM used chemiluminescence and fixed-site monitors used UV absorption). The PEMs used by Contant also exhibited positive baseline drift.

Response: Difference in measurement technique is a possible explanation for the 5.6% difference, although research by Leston and Ollison (1993), a study cited by the commenter, suggests that a UV monitor would typically report higher concentrations than a chemiluminescent monitor when both instruments are temperature controlled. As the PEM was not temperature controlled, it is possible that baseline drift contributed to the 5.6% difference between chemiluminescent PEM and UV fixed-site monitor. If this is the case, then it is possible that the 1.056 multiplier should be replaced by a factor of 1.000. However, EPA does not expect that this small difference would have a significant impact on the exposure or health risk estimates. Also, since it is not certain that baseline drift contributed to the difference, EPA believes it is reasonable to maintain the current approach of using the 1.056 multiplier in the exposure analyses supporting the current review.

(7) *Comment:* Failure to correct other modeling uncertainties and assumptions (e.g., reduction of O_3 in near roadway and in-vehicle microenvironments due to reaction of NO from car exhaust) results in pNEM model overestimating exposures.

Response: Addressed by response below to specific comment by API (II.A.3.d.v.(8)).

(8) Specific Comment (API, IV-D-2242): Reductions of O_3 in near-road and in-vehicle microenvironments from the reaction of O_3 with nitric oxide (NO) emitted by automobile exhaust are ignored in the current EPA exposure model.

Response: This comment is based on the fact that the algorithms which estimate O_3 exposures in the near-road and in-vehicle microenvironments assume that outdoor O_3 concentrations in and near roadways are approximately equal to O_3 concentrations measured outdoors by fixed-site monitors located away from roadways. In pNEM/O_3, the outdoor O_3 concentration is adjusted by a mass balance equation to determine O_3 concentrations in the "in-vehicle"

microenvironment. No adjustment is applied to the outdoor concentration to determine O_3 concentrations in the near-road microenvironment.
With respect to the in-vehicle microenvironment, the mass balance equation produces an average value of about 0.352 (0.333 x 1.056) for the ratio of in-vehicle O_3 to O_3 at the nearest fixed-site monitor. This value can be compared to empirical data obtained from a recent field study conducted in Cincinnati (Johnson et al., 1995) in which researchers measured O_3 concentrations inside vehicles under a variety of conditions. An analysis of these data by (Johnson, 1997b), was not included in the review of the air quality criteria, and therefore cannot be relied on in this rulemaking (see response to comment (5) in section II.A.3.a.iii of this document). Nevertheless, EPA has examined this study provisionally to see what implications it might have on the issue raised. The Johnson (1997b) analysis produced distributions of values for

$$\text{IMRATIO} = (\text{in vehicle } O_3)/(\text{nearest fixed-site } O_3)$$

which varied with vehicle speed, ventilation conditions, traffic density, road type, and time of day. The analysis suggested that 0.180 was a reasonable average value for IMRATIO and that 0.378 was a reasonable upper bound representing "worst-case" conditions. The pNEM/O_3 ratio of 0.352 is approximately double the empirically-derived average value of 0.18, but falls below the suggested upper limit of 0.378. This conservatism in the pNEM/O_3 algorithm is justified, however, as the Cincinnati results represent a single city and this study was not included in the air quality criteria review.

With respect to the near-road microenvironment, algorithms in pNEM/O_3 yield an average value of 1.056 for the ratio of O_3 concentration in this microenvironment to the O_3 concentration at the nearest fixed-site monitor. This ratio can also be compared with recent field data from Cincinnati summarized in Section 2 of a report by Johnson et al.. (1997b). Again, this new report cannot be relied upon because it has not been through the extensive review process entailed in preparing the air quality criteria. Nevertheless, a provisional look at the study reveals that researchers measured O_3 at various distances from selected roadways in Cincinnati. Based on measurements made during 1994 at a height of 2 meters, Johnson proposed that 0.65 would be a reasonable estimate for the ratio of downwind O_3 concentrations near a roadway to O_3 at a distant location (e.g., a fixed-site monitor). Assuming that 50 percent of the exposures in the near-road microenvironment occur upwind where the ratio is 1.00, the combined near-road ratio would be (0.5)(0.65 + 1.00) or 0.83. This ratio is about 20 percent less than the 1.056 ratio used in pNEM/O_3.

This same report, Johnson (1997b), that was prepared for the American Petroleum Institute and submitted to EPA as part of API's public comments, carried out sensitivity analyses of pNEM/O_3 applied to outdoor workers under "as is" air quality for Los Angeles. In this sensitivity analysis the 0.18 ratio was used for the in-vehicle microenvironment and a randomly selected value of 0.65 or 1.00 was used for the near-road microenvironment. Collectively, these two alterations produced a reduction in the O_3 exposures of interest of only 3 to 7 percent (Johnson, 1997b). While none of these more recent studies may be considered in this rulemaking, because they were published since completion of the CASAC and public review of the air quality criteria, it is interesting to note that should they merit inclusion in a future criteria review, they would suggest only a relatively small change in EPA's estimated O_3 exposures (i.e., only a 3 to 7 percent reduction).

vi. Indoor exposures

This section addresses comments primarily contained in section III.A.3.d.(1)f) of the Summary of Comments that raise questions as to how the exposure model estimates exposures for indoor and inside vehicle microenvironments.

(1) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): The air exchange rate for motor vehicles is a point estimate based on data for a single vehicle.

Response: This comment is true and has been included in the discussion of caveats and uncertainties related to the O_3 exposure analysis in both the OAQPS Staff Paper and technical support documents describing the exposure model and results. This was the only value available at the time of the outdoor children and outdoor worker exposure analyses. As EPA updates the exposure model for future standards reviews, it will review the scientific literature again to determine if additional information is available that is relevant to this component of the model.

(2) *Specific Comment* (CMA, App. A, Gradient, IV-D-2249): Uncertainties about O_3 indoor levels should not have a significant impact on exposure estimates at moderate and high exertion where exposure levels exceed 0.08 ppm because indoor levels are unlikely to reach 0.08 ppm.

Response: This statement is probably true for one-hour exposures above 0.08 ppm. Eight-hour exposures above 0.08 ppm which combine indoor and outdoor exposures may be affected by uncertainties concerning indoor levels of O_3. The EPA took account of the uncertainties in proposing the 8-hour 0.08 ppm standard.

vii. Characterization of uncertainties

This section addresses comments primarily contained in section III.A.3.d.(1)e) of the Summary of Comments raising questions as to how the exposure model characterizes uncertainties.

(1) *Comment*: EPA has not included all significant uncertainties in its exposure model and, thus, large uncertainties remain. Given the large uncertainties in exposure estimates, EPA should not revise the standard.

Response: EPA has attempted to include in its exposure model all significant uncertainties in estimating O_3 exposures using the techniques of Monte Carlo simulation to represent variability and uncertainty. Furthermore, EPA has presented the range of uncertainty in the estimates contained in the Staff Paper and in the technical support documents. In addition, EPA has described qualitatively in the Staff Paper and in the technical support documents the limitations, uncertainties, and caveats that were not addressed quantitatively. The approach to characterizing uncertainty, the format of the results, and the various qualitative limitations and discussion of uncertainties that are not quantified were all presented to the CASAC at public CASAC meetings in March 1994, March 1995, and as part of the Staff Paper review in September 1995. In its closure letter (Wolff, 1995), the CASAC concurred with EPA "that the models selected to estimate exposure and risk are appropriate models." The CASAC also stated that "because of the myriad of assumptions that are made to estimate population exposure and risk, large uncertainties exist in these estimates." Despite these "large uncertainties", CASAC also stated in its closure letter that "EPA's risk assessments must play a central role in identifying an appropriate level." As noted above, EPA has consistently acknowledged the various uncertainties, both those which it quantitatively addressed as well as others that were addressed qualitatively, in its technical support documents, the Staff Paper, the proposal notice, and in the Preamble to the final rule. EPA does not agree with those commenters who suggest that because there are significant uncertainties, EPA should not consider the results of these analyses in its final decision. In accordance with CASAC's advice, EPA has carefully considered the exposure and health risk assessments, along with their associated uncertainties, in reaching its proposed and final decision.

(2) *Specific Comment* (API, IV-D-2242): API modification of model, in coordination with OAQPS staff (Johnson, 1997b) indicates exposures may be overestimated several-fold.

Response: The Johnson (1997b) analysis submitted to EPA by API relies on new research, has not been published in the peer-reviewed literature, and has not been considered or reviewed by the CASAC. Accordingly, EPA cannot consider this research in this NAAQS review. (See response to specific comment 5 on p. 41 of this response-to-comment document.) Nevertheless, EPA has made a provisional examination of the study here. In Johnson (1997b) a number of the algorithms in pNEM/O_3 were altered to test the effect of using alternative assumptions in the model. The purpose of the study was to determine how sensitive the exposure model estimates were to the various inputs to the model, not to determine which alternative assumptions or inputs were appropriate. The implication that OAQPS staff agreed to any specific modifications to update the exposure model used in the current O_3 NAAQS review is not correct. The resulting special versions of pNEM/O_3 were used by

Johnson (1997b) to estimate exposures of outdoor workers, rather than outdoor children, under "as is" air quality for Los Angeles. When applied to motivated exercisers, a modified version which combined the alternative assumptions produced 1-hour exposures 20-30% below those obtained from the standard (unaltered) version of pNEM/O_3 and 8-hour exposures 60% below the standard version. The commenter asserts that application of the modified versions would produce comparable results for outdoor children. Although this assertion is unsupported, it is likely that the modified versions of pNEM/O_3 would produce some degree of reduction in the exposure estimates of outdoor children. However, in EPA's judgment the proposed alterations do not represent a balanced, comprehensive assessment of potential changes that will improve the model.

(3) *Specific Comment* (Krupnick, IV-D-2100): The term "aggregate" still needs to be defined. The commenter also questions use of only 10 runs in model simulations for exposure analysis.

Response: The term "aggregate" in the context of the exposure analysis results refers to the sum of the exposure estimates for the 9 urban study areas included in the analysis. Consistent with previous exposure analysis work for the carbon monoxide NAAQS review, EPA has used 10 runs (realizations) for each air quality scenario for each version (i.e., outdoor worker, outdoor children, general population) of pNEM/O_3. While it would be desirable to have a large number of runs, resource and time limitations preclude running the exposure model for hundreds of runs. Based on an analysis described in McCurdy (1993) which examined sets of 10-run results versus a 108-run result, EPA believes that the results from only 10 runs of the model adequately predict the mean and variance observed in 100 or more runs of pNEM/O_3. EPA does recognize that increasing the number of runs would increase the range of possible outcomes for exposure estimates. EPA reviewed the approach of using 10 runs for each air quality scenario with the CASAC and there were no significant objections raised by the CASAC.

viii. Supplemental exposure analyses

This section addresses comments primarily contained in section III.A.3.d. of the Summary of Comments raising issues about the supplemental exposure analysis (Johnson et al., 1997a) placed in the rulemaking docket in February 1997.

Comment: The supplemental analysis shows a higher percentage of outdoor children exposed to levels at or above 0.08 ppm under moderate exertion upon attainment of the proposed 8-hr standard than under the current 1-hr standard.

Response: The commenter refers to the results for Houston and Los Angeles, two of the nine urban areas studied. EPA believes that these results for each area can not be distinguished within the sensitivity of the alternative air quality adjustment procedures used in the initial and supplemental analyses. Further, EPA notes that these two areas, Houston and Los Angeles, are two of only six areas nationwide with peak 1- to 8-hour design value ratios greater than 1.5. Thus, these two areas have much higher ratios of peak 1-hour to 8-hour O_3 concentrations than the vast majority of areas in which O_3 is monitored, and it is therefore reasonable to expect that generalized air quality adjustment procedures would be particularly uncertain for such areas.

e. Health risk assessments

This section addresses comments included in section III.A.3.e. and elsewhere in the Summary of Comments concerning the health risk assessments which were considered in the decision on the proposed primary O_3 standard.

Comments on the exposure and health risk assessments considered as part of the basis for the proposed primary O_3 standard fall into two general categories. Those in the first group, for a variety of reasons (e.g., methodological problems that underestimate exposures, limiting the analyses to only a subset of adverse health effects rather than estimating the full range of effects that have been attributed to O_3, and focusing only on nine urban areas rather than projecting risk reductions for alternative standards on a national basis), contend that EPA has understated the aggregate lung function and respiratory symptoms and hospital admission risks associated with the proposed 8-hour standard. In contrast, those in the second group assert that the aggregate lung function and respiratory symptoms and hospital admission risk estimates are overstated for a variety of reasons including: methodological problems in the exposure model resulting in overestimates of exposure, the failure to take into account attenuation of health effects for lung function and respiratory symptom responses, inappropriate selection of studies used to develop concentration-response relationships, inappropriate extrapolation of concentration-response relationships to a background level of 0.04 ppm, and the use of a background O_3 level that is too low.

Section II.A.3. of the Preamble to the final rule provides an overview of the exposure and risk assessment information used by the Administrator to inform judgments about exposure and health risk estimates associated with attainment of alternative standards. EPA notes here that most of the issues and concerns raised by commenters concerning the health effects evidence and the methods used in the exposure and risk assessments are essentially restatements of concerns raised during the review of the Criteria Document and the development and review of these quantitative assessments as part of the preparation and review of the Staff Paper. EPA presented and the CASAC reviewed in detail the approaches used to assess exposure and health risk, the studies and health effect categories selected for which concentration-response functions were estimated, and the presentation of the exposure and risk results summarized in the Staff Paper. As stated in the proposal notice, EPA believes and CASAC concurred, that the general models selected to estimate exposure and risk are appropriate and that the methods used to conduct the exposure and risk assessments represent the state of the art. EPA does not believe that the exposure or risk assessments are fundamentally biased in one direction or the other as claimed in some of the comments.

The Administrator and CASAC have recognized, however, that there are many uncertainties inherent in such assessments and that the resulting ranges of quantitative risk estimates do not reflect all of the uncertainties associated with the numerous assumptions inherent in such analyses (Wolff, 1995b). In the proposal notice EPA summarized some of the most important caveats and limitations concerning both the exposure analyses and the risk assessments for lung function changes, respiratory symptoms, and hospital admissions. A more complete discussion of assumptions and uncertainties is contained in the Staff Paper and technical support documents (Johnson et al., 1996 a,b; Whitfield et al., 1996; Richmond, 1997). Presented below is a summary of comments received and responses to various specific issues related to the health risk assessments considered in the final rule. This is intended to expand upon the discussion contained in the preamble to the final rule.

i. Use of exposure estimates in 9-city risk assessment

This section addresses comments primarily contained in section III.A.3.e.(1)a) of the Summary of Comments that question the use of the exposure estimates in the health risk analyses.

Comment: The exposure analysis overestimates how many children are outdoors and how many are at moderate exertion and, therefore, the risk assessment overestimates how many children would experience lung function and respiratory symptoms.

Response: EPA does not agree that the exposure model overestimates how many children are outdoors or how many are at moderate exertion. See responses to comments above in Sections II.A.3.d.iii(7) and II.A.3.d.iv(1).

ii. Selection of studies used in risk assessment

This section addresses comments primarily contained in section III.A.3.e.(1)d) of the Summary of Comments that raise questions regarding the selection of studies used in the risk assessment.

(1) *Comment:* EPA's risk assessment relies heavily on studies conducted in EPA's chamber facilities and results from other studies (e.g., Horvath et al. and Linn et al.) show less response for lung function and symptoms. Commenters questioned why Linn et al. (1986) was excluded for 1-hr risks and why Linn et al.(1984) was excluded for 8-hr risks. Commenters also stated that greater response observed in EPA's chamber studies may have been due to artifacts in these chambers.

Response: EPA acknowledged in the Staff Paper (Section V.H.2, p.111) that the magnitude of the O_3 responses in healthy subjects used for risk assessment was somewhat lower in some of the studies, especially the Linn et al. (1994) and Horvath et al. (1991) studies conducted in California, when compared to the studies completed by the EPA in North Carolina. The differences, however, are more likely due to subject response variability caused by differences in experimental design (e.g., subject number, exercise level and duration), subject age (e.g., greater number of older subjects), pre-study O_3 exposure history, or heretofore unexplained biological variability (e.g., genetic differences). The magnitude of the O_3 responses in subjects with asthma was more comparable across studies.

The rationale for selection of studies was stated in the Staff Paper (Section V.H.2., p.111): "These additional studies [including Linn et al., 1994 and Horvath et al, 1991] were not included in developing the estimated exposure-response relationships because they each involved a single exposure level and differences in study protocols precluded pooling the data from these studies with the Chapel Hill studies. The magnitude of the responses was somewhat lower in some of these studies, specifically the Linn et al. (1994) and Horvath et al. (1991), compared to the three Chapel Hill studies used in the risk assessment. However, this may have been due to use of a lower ventilation rate and attenuation due to previous exposure in Los Angeles for the Linn et al. (1994) study and the use of older, less sensitive subjects in the case of the Horvath et al. (1991) study. The responses of asthmatics in the Linn et al. (1994) and the Horstman et al. (1995) studies is more comparable to the level of responses seen in the three Chapel Hill studies used in the risk assessment."

See also response to comment II.A.3.a.i(2) and II.A.3.a.i(3) concerning contention that artifacts may be responsible for large response in chamber studies included in EPA's risk assessment.

(2) *Comment:* Studies used in EPA's risk assessment to estimate lung function and respiratory symptom responses fail to account for attenuation of response upon repeated exposures and consecutive day episodes result in less response than do single exposures. Therefore, response is overestimated in EPA's risk assessment.

Response: As explained in the Staff Paper (Section V.H.6., p.132) in a discussion of assumptions and limitations associated with the risk assessment, "For the acute health endpoints, the risk assessment assumes that the O_3-induced response in any particular hour is not affected by previous O_3 exposure history. The extent of attenuation and/or enhancement of O_3-induced responses due to previous O_3 exposures cannot be addressed quantitatively and must be regarded as an additional uncertainty in interpreting risk estimates." For the lung function and respiratory symptom effects associated with 1-hr exposures, studies have shown an enhanced response on the second day of exposure to O_3. Generally, attenuation of response for 1-3 hour exposures is not observed until after 2 days of exposure to elevated O_3 levels. Therefore, repeated days of exposure may lead to either increased or decreased response depending on the level and duration of O_3 exposures. Further, as stated in the

Criteria Document (Section 7.2.4.2) based on both animal studies and a recent controlled human exposure study it appears that certain biochemical changes and markers such as LDH and elastase "never show attenuation indicating that tissue damage may continue to occur during repeated exposure." On balance, EPA does not believe that the risk assessment is biased so as to overestimate response.

(3) *Comment:* Other studies (cites Kulle et al., 1985; Avol et al., 1984, and McDonnell et al., 1983 results) report lower response rates (often zero) at lower concentrations and higher ventilation rates than studies used in the risk assessment for moderate or severe pain on deep inspiration (PDI) (Seal et al., 1993)

Response: EPA has presented risk estimates for heavy exertion based on concentration-response relationships developed using data from McDonnell et al. (1983) in the Staff Paper (see Section V.H.4.) and specifically notes in a footnote on p.122 of the Staff Paper that additional risk estimates for heavy exertion based on other studies (e.g., Kulle et al., 1985; Avol et al., 1984) are presented in technical support documents (Whitfield et al., 1996). Thus, EPA has analyzed risk from the various studies with sufficient information to estimate concentration-response relationships under conditions of heavy exertion. The differences in response rates between these studies are most likely due to subject response variability caused by differences in experimental design (e.g., subject number, exercise level and duration) and pre-study O_3 exposure history, or heretofore unexplained biological variability (e.g., genetic differences). The technical support documents also compared Avol's and Kulle's studies to that of Seal et al. (1993), which was used in the risk assessment for moderate or severe PDI. Based on Table 11 (p.30 of Whitfield et al., 1996), the response rate for moderate or severe pain on deep inspiration, corrected for exercise effect in clean air, is lower at 3 of the 4 concentrations tested (e.g., at 0.12 ppm 2/60 = 0.033 response rate for the Seal et al., 1993 study) under moderate exertion compared to 1.94/21 = 0.092 for the McDonnell et al. (1983) under heavy exertion. At the remaining concentration level, the response rates were very similar comparing these same two studies. Thus, the assertion by the commenters that the response rates for Seal et al. (1993) were higher than other studies involving heavy exertion is not true in all cases.

(4) *Comment:* EPA's risk assessment only captures the "tip of the iceberg" in terms of effects included in the assessment. The risk assessment fails to estimate risks for increased medication usage, asthma attacks, emergency room visits, doctors visits, increased inflammation, increased infections, etc.

Response: EPA has consistently stated in the Staff Paper, technical support documents, and in the proposal notice that the risk assessment addresses only those health effects for which studies were available that allow for a determination of how the percentages of individuals likely to experience such effects vary as a function of the O3 concentrations to which they are exposed. The proposal notice (61 FR 65729) discusses EPA's concern about other health effects (e.g., nonspecific bronchial responsiveness, inflammation of the lungs) not addressed explicitly in the risk assessment. See also the responses to comments Sections II.A.3.a.iv and II.A.3.c.iv, and Section II.B.1. of the Preamble to the final rule.

iii. Concentration-response relationships for lung function and respiratory symptoms

This section addresses comments primarily contained in section III.A.3.e.(1)c) of the Summary of Comments that raise issues concerning estimating concentration-response relationships for lung function and respiratory symptom effects associated with O_3 exposures.

(1) *Comment:* Contaminants in the controlled exposure chambers conducted in Chapel Hill may be responsible for some of the effects incorporated into the concentration-response functions for O_3.

Response: See response to comment in Sections II.A.3.a.i(2) and II.A.3.a.i(3).

(2) *Comment:* EPA's risk assessment has not factored in adaptation and should include concentration-response relationships from studies showing adaptation. EPA should conduct sensitivity analysis with and without adaptation factored in for Los Angeles.

Response: See response to comment about attenuation in previous section. Also, there is insufficient concentration-response data from studies showing attenuation to conduct a risk assessment. Every study examining the issue of attenuation has been conducted at a single O_3 exposure level.

(3) *Comment:* EPA's risk assessment inappropriately uses concentration-response relationships from clinical studies involving adults to estimate symptom responses in children (6-18) even though symptoms were not observed in studies involving children.

Response: Despite similarities in lung function decrements, children and adolescents exposed to O_3 do not report the respiratory symptoms reported by adults (e.g., cough, pain on deep inspiration, shortness of breath). The reasons for this observed difference are not clear, but relatively few controlled laboratory studies have been performed with children and adolescents to adequately address this question (as discussed in Sections 7.2.1.3 & 7.3.1 of the Criteria Document). In these studies, symptom questionnaires were administered before, during, and following exposure; however, there were no significant differences in symptom scores between O_3 exposures and controls. The researchers involved in studies of children and adolescents speculate that young people may be inherently less able than adults to detect the irritating effects of O_3 on the respiratory tract. Alternative explanations are that children and adolescents either did not adequately comprehend the symptom questionnaire, or they experienced symptoms but were reluctant to report them. EPA acknowledged in the Criteria Document, the Staff Paper (Section V.H.6., p.132), and in the risk assessment technical support document (Whitfield et al., 1996) that controlled human exposure and field epidemiology studies in children have reported pulmonary function, but not symptomatic, effects for O_3 exposures. As stated in Chapter V of the Staff Paper, "Therefore, the headcount symptomatic effects estimates which rely on population exposures that include children may overstate symptom headcount risk estimates. Pulmonary function risk estimates are not affected, and the lack of apparent symptoms does not mean that biological processes associated with O_3 symptoms in adults are not also present in children." Furthermore, EPA has presented the approach of using adult studies to estimate symptoms for children to the CASAC and there were no objections from the CASAC to this approach as long as appropriate caveats were included. As noted above, these caveats have been included in both the Staff Paper and technical support document.

(4) Comment: There is no scientific basis for extrapolating exposure-response relationships below 0.08 ppm to a background level of 0.04 ppm. There may be a threshold since other studies not used by EPA in the risk assessment report lower response rates or zero response at lower concentrations.

Response: The approach used in the risk assessment of extrapolating concentration-response relationships down to background was presented to the CASAC at several meetings in March 1994 and March 1995. CASAC members generally endorsed the approach used in the risk assessment and encouraged EPA to use a linear relationship down to a background level of 0.04 ppm, unless there was sufficient data to justify another choice. Furthermore, the CASAC addressed the issue of whether biological thresholds were likely to exist in its closure letter on the Staff Paper (Wolff, 1995b), "The Panel felt that the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to O_3 above background concentrations. Based on information now available, it appears that O_3 may elicit a continuum of biological responses down to background concentrations."

(5) *Specific Comment* (Gradient for CMA, IV-D-2249): Based on review of 9 health endpoints in Whitfield et al. (1995), the population response rate approaches 0 at 0.08 ppm for 8-hr exposures for virtually all cases and this suggests a threshold exists below which there is no effect.

Response: The statement that "the population response rates approach 0 at 0.08 ppm for 8-hr exposures for virtually all cases" is not accurate. In fact, for three (moderate-to-severe cough after 1-hr exposures at heavy exertion; FEV_1 decrements \$15% and \$20 after 8-hr exposures at moderate exertion) of the four endpoints that are the subject of most of the detailed analyses, the median response rates at 0.08 ppm are 10%, 18%, and 10%, respectively, and the 0.05-

fractile response rates are 2%, 10%, and 4%, respectively. In addition, the response rates at 0.07 ppm are only slightly less than these values.

(6) *Specific comment* (Gradient for CMA, IV-D-2249): EPA should have used logistic regression to estimate concentration-response relationships and uncertainties in these relationships. Also, the commenter questions the choice for the number of subjects (N) that is used to calculate uncertainties at concentrations for which there is no experimental data.

Response: EPA questions the appropriateness of using logistic regression to model the controlled human exposure data that form the basis of the risk analysis. Logistic regression is designed to predict a quantitative variable from a number of binary variables, each of which is scored 0 or 1, which clearly is a different set of conditions. For example, social scientists use logistic regression to predict the number of social services an elderly couple uses based on race (African-American or Caucasian), gender of the care giver (male or female), status of the care giver (healthy or not), etc. The approach used in the risk assessment has been described several times to CASAC and CASAC has accepted the approach as reasonable. The approach used in the risk assessment requires one regression to develop an exposure-response relationship and results in relationships that are similar to those involving a regression for each fractile (21 in our case). The advantage of the current approach is that it avoids numerous logical inconsistencies (viz, fractile relationships that intersect), which would require extensive analyst "intervention" to resolve. The current approach is consistent with CASAC's encouragement to choose modeling methods that minimize the need for analyst intervention.

The question about the proper value of N (number of subjects) that should be used at locations (i.e., ppm levels) for which there are no experimental data is a good one. The risk assessment generally used the value of N at the lowest O_3 level for which there were data (i.e., 0.08 ppm) to calculate uncertainty at O_3 levels < 0.08 ppm. To use a substantially smaller value of N at, say, 0.07 ppm would result in a logical inconsistency that higher response rates are more likely at 0.07 ppm than at 0.08 ppm. Besides, since EPA is only interested in O_3-induced responses, the response rates must, by definition, be 0 at for 0 ppm (or, in some cases, considerably higher than 0 ppm). Furthermore, all fractiles must show 0 response at 0 ppm, and possibly at an O_3 level > 0 ppm.

(7) *Comment:* Exposure scenarios used in the clinical studies which are the basis for concentration-response relationships in the risk assessment are unrealistic because human exposure is interrupted by different activity levels, movement, and time spent indoors, as well as by changes in seasons and weather conditions.

Response: EPA recognizes that activity patterns in the real world generally do not follow the simple pattern employed in the clinical studies. However, there is little data allowing an assessment of how different activity patterns that result in the same average EVR over a 6-8 hr period would affect exposure-response relationships. As discussed in Section 7.2.1.1 of the Criteria Document, McKittrick and Adams (1994) has reported that O_3-induced lung function responses were very similar for subjects either exposed continuously exercising for 1-hr or exposed for 2-hr with intermittent exercise, where the equivalent dose was delivered during the two different types of exposures. This suggests that the details of the pattern of human activity may not be a significant factor in influencing the nature and magnitude of the exposure-response relationships for lung function and respiratory symptom responses. No evidence is offered in the comments about the extent to which other factors, such as temperature or humidity, or whether an individual is exposed to O_3 indoors or outside, influence the nature or magnitude of the exposure-response relationships for lung function or respiratory symptoms.

(8) *Specific Comment* (Gradient for CMA, IV-D-2249): To the extent that high humidity results in decreased activity level from that observed in chamber studies, then exposure-response will be overestimated and headcount risk will be overestimated.

Response: See response to comment II.A.3.d.iii(4).

(9) *Specific Comment* (API, IV-D-2242): Approximation using single breathing rate to estimate risk for a range of rates "grossly overestimates projected risks", since modeled EVR distributions are strongly peaked at low EVR levels and response rates are decreased at lower ventilation rates.

Response: EPA has examined this issue (see McDonnell, 1997 included as Appendix D to this document) and does not agree that the approach used in the risk assessment grossly overestimates risk. The risk assessment matched the concentration-response relationship estimated from the controlled chamber studies with population exposures for the range of exertion observed in the chamber studies. For example, for the 8-hr health risk assessment the range (based on being within 2 standard deviations of the mean) of EVRs observed in the subjects who participated in the study was 13-27 liters per minute per meter squared (l/min-m^2). The concentration-response relationship for the combined 8-hr data set was matched with exposure estimates for outdoor children engaged in moderate exertion (i.e., having an EVR in the range of 13-27 l/min-m^2) over an 8-hr period. EPA recognizes that the characteristics of the O_3 concentration-response relationship are a function of EVR and that application of a concentration-response relationship calculated for a particular EVR will overestimate response for individuals with a lower EVR and underestimate response for individuals with a higher EVR. The relevant question is how strongly related is the concentration-response curve to EVR under these conditions. The API comments present data at one concentration (0.12 pp) from two of the three published 6.6 hour studies that EPA used to develop risk estimates for 8-hr exposures. While the data presented by API show a relationship between FEV_1 response at EVR at this single concentration, the trend is not statistically significant. Furthermore, if one examines the data for all concentrations from all three studies upon which EPA's 8-hr risk assessment is based, one finds that the picture is not so clear. Based on this more complete data set, there is a nonsignificant positive trend between FEV_1 response and EVR at 0.12 ppm. At 0.10 ppm, there is a marginally significant positive trend, but at 0.08 ppm, there is a slightly negative (almost zero) and nonsignificant relationship between FEV_1 response and EVR. These seemingly contradictory results are a function of two things. First, there is a large amount of individual variability in response to O_3 and any single analysis based upon a relatively small number of observations is likely to give results which are not very precise. Second, the effect of EVR upon the concentration-response relationship may get smaller at lower O_3 concentrations. These considerations suggest that it is inappropriate to select a small amount of data at the highest O_3 concentration tested and to use only these data as the basis for predicting risk at much lower concentrations. In light of the essentially nonexistent relationship between FEV_1 response and EVR at 0.08 ppm in these particular data, it appears that the API analysis significantly overstates the magnitude of any error which might be introduced by the approach used in EPA's risk assessment. EPA continues to believe that the approach used in the risk assessment is appropriate and does not introduce any significant bias in the risk estimates.

(10) *Specific Comment* (CMA, IV-D2249): EPA should consider using separate exposure-response for sedentary people and one for those who regularly exercise.

Response: EPA's risk assessments focused on estimating risk for sensitive and at risk population groups, such as outdoor children and outdoor workers, at moderate or heavy exertion levels. This approach accords with the Clean Air Act's directive to set the NAAQS at a level that protects public health with an ample margin of safety. A separate analysis using exposure-response relationship for sedentary people is not needed because these individuals would be expected to be at less risk for O_3-induced health effects, given their sedentary habits, than the population groups included in the risk assessments.

iv. Hospital admission risk methodology issues

(1) *Comment:* EPA's risk assessment improperly assumes a linear concentration-response relationship and extrapolates down to background level of 0.04 ppm without any scientific basis.

Response: There is clear evidence from hospital admission studies that effects may continue down to background. This was discussed with the CASAC panel members who agreed that it is reasonable to assume that there is an association between O_3 and hospital admissions in the range of concentrations down to background for purposes of estimating O_3-induced effects based on the hospital admission studies. Although associations between ambient O_3 levels and hospital admissions are more uncertain at lower ambient levels, there is a consistency between studies which supports the association at all levels studied.

(2) *Comment:* EPA's risk assessment inappropriately extrapolates the results from Thurston et al. (1992) which was based on 90 days in the year of highest O_3 levels in a decade to a full 214 day O_3 season. Also, the risk assessment focuses only on data from 1988, a very high O_3 year, while Thurston et al. (1992) found less of a response for the summer of 1989.

Response: Thurston et al. (1992) presents data for both 1988 and 1989 but the authors focused their analyses on the summer of 1988 in the Buffalo and NYC metropolitan areas where the cross-correlations indicated that the pollution associations are mostly clearly discernable. The following paragraph from p.446 of the paper contrasts the 1988 and 1989 data for those two cities.

"Comparisons of the presented 1988 Buffalo and NYC results with analogous 1989 summer results is also informative. It was expected from the cross-correlations results that the 1989 pollutant regression coefficients would be less significant, though the coefficient values should be similar to the 1988 results. In fact, though not always significant, the 1989 summer pollutant coefficients (not presented) were all positive (as was the case for the 1988 coefficients). Moreover, the 1989 pollutant coefficients in these cities were not statistically different from the 1988 values for 10 of the 12 regressions considered in Table 6. Thus, while the mean effects and RR estimates are usually lower (due to generally lower pollution during the summer of 1989), the 1989 regression coefficients did support the validity of the pollutant regression coefficients, mean effects, and RR estimates reported here for the summer of 1988."

As indicated by Thurston et al., the 1989 data generally support the relationships observed in the 1988 data. Since the risk assessment is applying the coefficient which is expressed as an increase in hospital admissions per change in the hourly daily maximum O_3 concentration on a daily basis and combining this relationship with daily maximum O_3 levels, there is no problem or bias introduced in the risk assessment when the analysis is extended to the entire O_3 season. The Thurston et al. study simply provides the relationship between O_3 levels and increased hospital admissions. EPA believes it is reasonable to apply this same relationship to other days in the O_3 season, beyond the 90 days included in the study, since there is no reason to believe that these same effects would not occur on other days when O_3 concentrations were elevated. EPA acknowledges that there is some additional uncertainty introduced when one applies these relationships to the remainder of the O_3 season because of possible differences in exposure patterns and differences in other factors (e.g., pollen levels) that also contribute to hospital admissions.

(3) *Specific comment:* (Gradient for CMA, IV-D-2249): EPA should have used logistic regression approach to estimate concentration-response relationships rather than linear relationship.

Response: CASAC reviewed the modeling approach employed in the hospital admissions risk assessment at meetings in March 1994 and March 1995 and expressed general support for the techniques used.

v. <u>Calculation of excess risk relative to background O_3 levels</u>

This section addresses comments primarily contained in section III.A.3.e.(1)b) of the Summary of Comments that raise questions about the numerical value assumed to represent background O_3 concentrations used in the risk assessment, and the approach used in the risk assessment to estimate risks in excess of background levels of O_3.

Comment: Use of 0.04 ppm for estimated background level in EPA's risk assessment is too low. If the assumed background level were higher, then risk estimates in excess of background would be lower than estimated by EPA. Analysis of data from remote areas suggests background may be as high as 0.06-0.08 ppm.

Response: The numerical estimates of "natural" background levels of O_3 were carefully assessed during the development of the proposal. At the 1995 CASAC meeting, Dr. George Wolff, CASAC chairman, stated that "the background ... averages about 0.04 [ppm] ... anything above 0.04 is assumed that would be due to anthropogenic additions to it that are not part of background" (9/19/95 transcript, 308:19-25, 309:1-8) While background concentrations of O_3 can be as high as 0.05 ppm, unless O_3 concentrations are affected by anthropogenic VOC and/or NOx emissions, 8-hr O_3 background concentrations will typically be much lower than 0.05 ppm. A reasonable estimate of the 8-hr daily maximum O_3 background during the summer season is 0.03-0.05 ppm. Summertime maximum O_3 concentrations of less than 0.03 ppm have been observed due to precipitation scavenging.

It is true that at remote or rural sites O_3 concentrations can exceed 0.07 ppm. However, the Staff Paper makes it clear that the component consisting of background O_3 is only a fraction of rural O_3 concentrations, which are clearly increased by human activities throughout the U.S. The magnitude of the natural background component of O_3 concentrations at remote or rural sites cannot be precisely determined because of the role of long-range transport of anthropogenic precursors and /or O_3.

For the purposes of estimating risk in excess of background, the relevant statistic is what is the typical contribution to observed O_3 levels due to background since risk estimates are calculated for each day of the O_3 season, not just the peak or maximum level days. The range of 0.03-0.05 ppm is given in the Criteria Document for the typical summertime contribution due to background. The CASAC supported EPA's decision to use 0.04 ppm as a central estimate of background for the purposes of calculating risk in excess of background over an entire O_3 season. As discussed further in Section II.A.3.f.(2) of this document, the decision to use 0.04

ppm as a central estimate for typical daily maximum 8-hour O_3 background also is supported by EPA's analysis of air quality data for 11 remote rural sites. This air quality analysis indicates that the annual (O_3 season) 50th percentile daily maximum 8-hour O_3 concentration averaged across all eleven sites was 0.038 ppm (38 ppb) and the majority of the median values were below 0.04 ppm (40 ppb).

vi. Characterization of uncertainties

This section addresses comments primarily contained in section III.A.3.e.(1)e) of the Summary of Comments that raise issues about how uncertainties were calculated and presented in the health risk assessment. The EPA believes, and CASAC concurred, that the models selected to estimate exposure and risk were appropriate and that the methods used to conduct the health risk assessment for adverse lung function and respiratory symptom responses represent the state of the art. Nevertheless, the Administrator and CASAC recognized that there are many uncertainties inherent in such analyses, and that not all uncertainties inherent in such analyses could be quantified and reflected in ranges of risk estimates (Wolff, 1995b), as discussed in the proposal notice and the referenced technical support documents.

(1) *Comment:* The confidence intervals used for exposure-response relationships presented in EPA's risk assessment are narrower because of methods used and EPA should have used an alternative approach (involving logistic regression), which results in same central tendency estimate but wider confidence intervals in the vicinity of 0.07 ppm. Commenter suggests that "correct" treatment would result in response rates above 0.08 ppm that are more certain and response rates below 0.08 ppm would be highly uncertain.

Response: See response to specific comment by CMA/Gradient above (II.A.3.e.iv.(6))

(2) Comment: Ranges presented in risk assessment don't represent all of the uncertainties and the uncertainties are much larger than stated in EPA's risk assessment.

Response: EPA has repeatedly stated in the Staff Paper, proposal notice, and in the technical support documents that not all uncertainties are captured in the risk assessment. For example, Section V.H.6 (pp. 129-133) of the Staff paper discusses a number of factors and limitations that contribute to additional uncertainty about the risk estimates. EPA acknowledges that all uncertainties are not included, but there is nothing provided by the commenter to demonstrate that the uncertainties are much larger than stated by EPA.

(3) *Specific Comment* (Krupnick, IV-D-2100): The "statistically significant" differences in health protection afforded by lowering the primary standard stem only from EPA's own result-oriented statistical analysis, which EPA improperly performed with different assumptions to

decrease variability in random number sequences used to address variability in such factors as air conditioning and activity patterns.

Response: Although it is true that the risk distributions for the various air quality scenarios, when plotted as probability density functions, overlap considerably (in part due to the general practice of showing 90% CIs), the majority of the sets of 10 medians (and means) of the risk distributions that are available for each air quality scenario are statistically significantly different (Kolomogorov-Smirnoff test). Most notably, those sets of medians associated with 8-hr, 0.08 ppm standards tend to be significantly different from those associated with the current 1-hr, 1 expected exceedance, 0.12 ppm standard. In the supplemental exposure and risk assessment EPA chose to use a common set of random number generator seeds for a set of 10 pNEM/O_3 runs for every air quality scenario to allow a better comparison of the differences in exposure and risk protection afforded by alternative standards. This approach allows one to examine the impact that changes in air quality will have on exposure and risk, rather than masking the differences due to variability and random noise introduced by other factors (e.g., human activity patterns, fraction of homes with air conditioning) that should not change as alternative air quality standards are analyzed.

vii. Supplemental risk assessment

This section addresses comments primarily contained in section III.A.3.e.(2) of the Summary of Comments concerning the supplemental risk assessment (Richmond, 1997) as compared to the initial assessments cited in the proposal notice.

(1) *Comment:* EPA's supplemental risk assessment shows reduced risks providing even less justification for a more stringent 8-hr standard.

Response: See Preamble to the final rule, Sections II.B.1, II.B.2, and II.B.3. for rationale as to why EPA, after considering the supplemental risk assessment, remains convinced that a more stringent 8-hr standard than the current 1-hr standard is appropriate.

(2) *Comment:* EPA's supplemental risk assessment suggests that the proposed 8-hr standard will provide less protection for Houston and Los Angeles than the current 1-hr standard.

Response: EPA believes that the results for each of these two areas can not be distinguished within the sensitivity of the alternative air quality adjustment procedures used in the initial and supplemental assessments. EPA has carried out a sensitivity study for six of the nine urban areas to examine the sensitivity of the exposure and risk estimates to alternative AQAP's, including the proportional, Weibull, and quadratic approaches (Johnson, 1997; Whitfield, 1997b). These analyses were carried out in response to comments, and while the Agency is not relying on them in the final decision, they have been made available in the docket. The quadratic approach, like the Weibull approach, reduces the peak or upper end of the air quality distribution by a greater amount than the lower and middle portions of the distribution. When the Weibull or quadratic AQAP's are applied for the two areas, Houston and Los Angeles, the proposed 8-hr standard provides greater protection than the current 1-hr standard. Only when the proportional AQAP is used do the estimates show less protection for Houston and Los Angeles than the current 1-hr standard. Further, EPA notes that these two areas, Houston and Los Angeles, are two of only six areas nationwide with peak 1- to 8-hour design value ratios greater than 1.5. Thus, these two areas have much higher ratios of peak 1-hour to 8-hour O_3 concentrations than the vast majority of areas in which O_3 is monitored, and it is thus reasonable to expect that results using generalized air quality adjustment procedures would be particularly uncertain for such areas.

(3) *Specific Comment* (AAMA, IV-D2243): EPA's risk assessment supplement has not been evaluated by CASAC, therefore, EPA can't use it to support the O_3 standard.

Response: The exposure and risk assessment methods used by EPA were reviewed prior to proposal at several CASAC meetings. These include public meetings held in December 1994, March 1995, July 1995, and September 1995. The supplemental assessment, placed in the public docket in February 1997, generally applies the exposure and risk assessment methods previously reviewed by CASAC to the proposed standard and other alternative standards for which the Agency solicited public comment. There were some refinements to the methods which are fully described in Richmond (1997) and the attachments to that memorandum. EPA does not believe that the technical changes made to the methodology for the risk assessment supplement were significant enough to warrant additional CASAC review.

viii. Public health implications of risk assessments

This section addresses comments primarily contained in section III.A.3.e.(3) and elsewhere in the Summary of Comments related to the public health implications of the risk assessments. EPA notes that highly divergent judgments were expressed by different groups of commenters concerning the public health implications of the risk assessments conducted as part of the O3 NAAQS review. A large number of commenters who expressed the view that the differences in public health protection were not significant or important enough to warrant any standard more stringent than the current standard used CASAC as the basis for their position. Others cited small percentages of outdoor children and other sensitive groups likely to be affected based on EPA's assessment, or even smaller percentages as modified by analyses conducted by the commenter to correct perceived errors in the analyses. In contrast, other commenters cited large total numbers of children likely to be affected, not only for the subset of O_3-related effects and the nine areas analyzed in EPA's assessments, but also for a broader array of related effects projected nationally.

EPA clearly recognizes that for nonthreshold pollutants, such as O_3, no standard can be risk-free. The Administrator's task is to select a standard level that will reduce risks sufficiently to protect public health with an adequate margin of safety, since a zero-risk standard is neither possible nor required by the Clean Air Act. As the CASAC recognized, "the selection of a specific level ... is a policy judgment" (Wolff, 1995b).

Section II.B.2 of the Preamble to the final rule discusses the risks to public health that can be quantified as well as those for which quantitative risk information is more limited and focuses on comparisons between the degree of health protection likely to be afforded by the proposed 0.08 ppm, 8-hour standard and alternative 8-hour standard levels of 0.07 ppm and 0.09 ppm. Presented below is a summary of comments received and responses to various specific issues related to the public health implications of the health risk assessments considered in the proposal. The responses below expand as appropriate upon the discussion contained in the Preamble to the final rule.

(1) *Comment:* Risks attributable to O_3 are small compared to other factors which cause these same effects. The estimated reduction in hospital admissions associated with the proposed 8-hour proposed standard is very small.

Response: See Preamble to the final rule (Section II.B.2).

(2) *Comment:* The broader array of O_3-related effects (e.g., increased medication usage by asthmatics, increased doctors visits, increased infections, increased occurrences of inflammation) are not included in the risk assessment, thus the health risks associated with the proposed standard are greater than indicated by EPA's assessments.

Response: See response to comments in Section II.A.3.c.iv. and the Preamble to the final rule (Section II.B.1 and II.B.2).

(3) *Comment:* The risk assessment was limited to 9 urban areas and, thus underestimates the national risk reduction that would be associated with attainment of the proposed standard.

Response: EPA agrees that the risk estimates for the 9 urban areas underestimate the national risk reduction associated with attainment of the proposed standard. While EPA did not conduct a national risk assessment, the Preamble to the final rule notes that nationally approximately 46 million more people, including approximately 13 million more children and 3 million more asthmatics live in areas that would not attain the proposed 0.08 ppm, 8-hr standard compared to a 0.09 ppm standard. EPA recognizes that while it does not have specific risk estimates for all of these areas, this broader population would breathe cleaner air as a direct result of control measures designed to bring areas into attainment with an 8-hour standard of 0.08 ppm.

(4) *Comment:* The risk assessment doesn't fairly characterize equivalency of standards because it is limited to 9 urban areas. Based on air quality information a 0.08, average 5th maximum, 8-hr standard would provide greater health protection than the current 1-hr standard, even though the risk assessment suggest that the 0.08 ppm/avg 5th is roughly equivalent to the current standard.

Response: EPA agrees that the risk assessment does not address equivalency of standards on a national basis, but rather only for the aggregate risk estimates reflecting the nine urban areas examined.

(5) *Specific Comment* (Krupnick, IV-D-2100): EPA should have compared multiple policy options using "change in risk from baseline (attainment of current standard)" which should be shown as "best estimate, with error bars representing clearly defined measure of confidence in the point estimate ..."

Response: Recent analyses (Whitfield, 1997a), available in the docket, have presented a comparison of policy options in the format suggested. Tabulated results present:

- Median risk estimates for the current standard and three 8-hr, 0.08 ppm standards of the n^{th} highest average daily maximum form (for n = 3, 5, and 7).
- Central 90% credible intervals (CIs) about the median values.
- Reductions from the current standard (i.e., the current standard is, as Krupnick suggests, a "baseline" against which the other options are compared).
- The 90% CIs address the "best estimate with error bars" and the "confidence intervals" that Krupnick suggests should be provided. (Note: Our results usually include a representation of the uncertainty about estimates. See, for example, figures of risk results in Whitfield et al. [1996]. Rarely does EPA give point estimates without an indication of uncertainty about the estimate.)
- Results in Whitfield et al. (1996) include a table and a figure that show the most detailed level of risk results that are available. Because the amount of risk results is very large, it is not practical to document all results at such a level of detail. Instead, "representative risk distributions" and "Tukey box plots" were constructed to capture the essence of the detailed results, which include 10 risk distributions based on 10 pNEM/O_3 runs available for each air quality scenario that was investigated. Each risk distribution incorporates uncertainties about human activity, O_3 concentrations in various microenvironments, exertion level, and population response to specific O_3 exposures during specific time intervals.

f. Characterization of background O_3 concentrations

This section responds to comments regarding the relationship between the primary O_3 standard and background O_3 concentrations. These comments are primarily contained in Sections III.A.1, III.A.2.b, III.A.3 and III.A.3.e.(1)b) of the Summary of Comments, but may be in other sections as well. The rationale for the decision on the level of the standard, in Section II.B.2 of the preamble to the final rule, contains a discussion of background O_3 concentrations. The responses to other specific comments regarding stratospheric O_3 intrusion and revisions to Appendix H (now designated as Appendix I) are in Section III.A.2.d of this document, and comments regarding the choice of a background O_3 level for determining excess risk are in Section III.A.3.e of this document. Attainability of the revised O_3 NAAQS is addressed elsewhere in this document in section IV.A.1.

Comments regarding EPA's estimation of background O_3 concentrations were received primarily from commenters representing business and industry associations, but also some State and local agencies. Several industry commenters expressed the view that EPA mischaracterized aspects of background O_3 concentrations and ignored high O_3 concentrations recorded at remote or rural sites. Many industry commenters and a few State and local agencies commented that the proposed standard would be difficult to attain due to high background O_3 concentrations. Some State and local agencies expressed concern about attaining the standard based on high upwind O_3 concentrations, without specifying the origin of the O_3.

(1) *Comment:* A representative comment from the General Motors Corporation (IV-D-2694) noted that EPA's definition of background O_3 in the Staff Paper is incorrect for two reasons. First, the Staff Paper defines background O_3 as the absence of biogenic as well as anthropogenic emissions, which clearly underestimates the true background. Second, the definition also refers to the absence of emissions in North America, rather than the U.S., and to the extent that Canadian and Mexican emissions influence ambient O_3 concentrations in the U.S., this will underestimate U.S. background O_3.

Response: The EPA recognizes that an inadvertent error was made in the definition of O_3 background as stated in the Staff Paper. The correct definition is: "Background O_3 is defined as the O_3 concentrations that would be observed in the U.S. in the absence of anthropogenic emissions of VOCs and NOx in North America." The EPA intends to make available, after the publication of the final rule, a corrigenda to the Staff Paper that will incorporate this change.

Part of this background is due to long-range transport of anthropogenic or biogenic emissions from outside North America, over which the U.S. government can have no control. In response to the commenter's second reason, EPA notes that CASAC agreed with the exclusion of anthropogenic emissions in North America because the U.S. government has influence over the emissions at our borders that affect ambient concentrations of O_3 and/or O_3 precursors entering the U.S. from Canada and Mexico.

(2) *Comment:* The American Petroleum Institute (IV-D-2242), along with others, asserted that the Staff Paper estimate of the 8-hr maximum daily background O_3 concentration (30-50 ppb) is too low. More specificallyl, some commenters asserted that the level of the proposed

standard (80 ppb) approaches peak 8-hr concentrations observed in clean sites in the U.S. and other areas in the world. These peak levels can be higher than 60 ppb in the summertime. The commenter stated that regional background in and around nonattainment areas can be close to 80 ppb. To support this range of background O_3 concentrations, the American Petroleum Institute cited three different references: 1) a 1996 presentation indicated that the percent of 8-hr daily maximum concentrations greater than or equal to 40 ppb for 3 clean sites is generally greater than 50%, and that the 3rd highest 8-hr daily maximum concentrations averaged over 3 years (1993-1995) for six clean sites in the U.S. had values which ranged from 45-61 ppb; 2) a paper by Altshuller and Lefohn (1996), using hourly data from remote sites in the western U.S. and Canada, reported that current background levels at inland sites were in the range of 50-98 ppb for the April through October period, with coastal sites ranging from 44-80 ppb; and 3) in testimony submitted to CASAC, Lefohn (1994) presented a table summarizing the top 10 8-hr daily maximum values for clean sites described in the Criteria Document, which resulted in a range of 55-69 ppb. The commenters asserted that these levels of background O_3 suggest that in some areas very substantial anthropogenic emissions reductions will be needed to attain and maintain the proposed standard, and in other areas the proposed standard will be unattainable.

Response: In the general response to the commenter, EPA notes that background concentrations of O_3 originate from 3 sources: stratospheric O_3 which is transported down to the troposphere, called stratospheric intrusion, O_3 formed from the photochemically-initiated oxidation of biogenic and geogenic methane and carbon monoxide, and the photochemically-initiated oxidation of biogenic VOCs. The magnitude of this natural part cannot be precisely determined for two reasons. First, the part due to anthropogenic precursor emissions in other non-North American parts of the Northern Hemisphere is not known. Second, NO_x plays an important role in the oxidation of naturally generated methane, carbon monoxide and biogenic VOCs, and it is not possible to determine the amounts of O_3 that would have been formed just due to natural NO_x emissions. However, some estimates can be made. On the basis of O_3 data from isolated monitoring sites, a reasonable estimate of the O_3 background concentration near sea level in the U.S. for an annual average is 0.020-0.035 ppm (20-35 ppb). This includes a 0.010 to 0.015 ppm (10-15 ppb) contribution (averaged over time) from stratospheric intrusions into the troposphere and a 0.01 ppm (1 ppb) contribution from photochemically-initiated oxidation of methane and carbon monoxide. The remainder is due to the photochemically-initiated oxidation of biogenic VOCs and long-range transport. Based on diurnal profiles presented for O_3 at rural sites in Kelly et al. (1982, 1984), it is reasonable to estimate that the 8-hr daily maximum O_3 during the summer is in the range of 0.03 to 0.05 ppm (30-50 ppb). (Staff Paper, p.20-21; Wolff letter, dated April 11, 1995, Docket No. NCEA-CD-92-0746, IIAF-025). The numerical estimate of background levels of O_3 was carefully assessed during the development of the proposal. At the 1995 CASAC meeting, Dr. George Wolff stated that "the background.....averages about 0.04 [ppm].....anything above 0.04 is assumed that it would be due to anthropogenic additions to it that are not part of background" (Transcript of September 19, 1995 meeting, 308:19-25, 309:1-8).

Background O_3 concentrations will vary by geographic location, altitude and season. Monitoring data from rural or remote sites is often used to characterize O_3 background. Rural sites are closer to urban areas and therefore well within the distance that anthropogenically produced precursors and/or O_3 can be transported. Concentrations at remote sites are less likely to be impacted by anthropogenically produced precursors and/or O_3. Ozone concentrations measured at remote or rural sites generally consist of locally produced or transported background O_3, combined with O_3 produced elsewhere from anthropogenic sources and transported into the area, and/or O_3 produced within the area from unreacted precursors transported into the area. Also, O_3 precursors from anthropogenic and natural sources can interact within rural areas to form locally-produced O_3. Unless O_3 concentrations are affected by anthropogenic VOCs and/or NO_x emissions, 8-hr O_3 background concentrations will typically be much lower than 0.05 ppm (50 ppb). It is true that at remote or rural sites peak O_3 concentrations can exceed 0.06 ppm (60 ppb), as illustrated in the table below. The Staff Paper makes it clear that the component consisting of natural background O_3 is only a fraction of rural O_3 concentrations, which are clearly increased by human activity throughout the U.S. The magnitude of the natural background component of O_3 concentrations at remote or rural sites cannot be precisely determined because of the role of long-range transport of anthropogenic precursors and/or O_3.

In response to the comments made based on the first reference cited in the comment, the table below lists the median and annual fourth highest 8-hour daily maximum O_3 concentrations for the three most recent years of data available for the sites listed in references 1 and 2, except Custer National Forest. Custer National Forest was omitted because monitoring data were available only for the years 1978 to 1983. The compliance test statistic for the 8-hour standard is the average fourth highest daily maximum 8-hour average O_3 concentration. This average is computed for the three most recent, consecutive calendar years of monitoring data. For the eleven sites in the table below, the annual 4th highest 8-hour daily maximum O_3 concentration ranges from a low of 0.042 ppm (42 ppb) at Olympic NP, WA to a high of 0.075 ppm (75 ppb) at Quachita NF, AR. The annual 4th highest 8-hour daily maximum O_3 concentration averaged across all eleven sites is 0.054 ppm (54 ppb). Approximately 75% of the annual 4th highest values are less than 0.06 ppm (60 ppb). The annual 50th percentile 8-hour daily maximum O_3 concentration varies from a low of 0.023 ppm (23 ppb) at Olympic NP, WA to a high of 0.054 ppm (54 ppb) at Arches NP, UT. The annual 50th percentile daily maximum 8-hour O_3 concentration averaged across all eleven sites is 0.038 ppm (38 ppb). The majority of the median values are below 0.04 ppm (40 ppb). These data do not suggest that background concentrations of O_3 will cause an area to fail to meet the standard.

In response to the points made by the commenters based on the second reference cited in the comment, EPA recognizes that at rural or elevated remote sites 1-hour O_3 concentrations have been reported that exceed 0.070 ppm (70 ppb) on peak days within the O_3 season. Most of the highest reported values were associated with forest fires, while other values may result from occasional atmospheric conditions that are conducive to intrusion of stratospheric O_3 into the troposphere. In the paper by Altshuller and Lefohn (1996), almost all of the high hourly O_3 concentrations (17 out of 20 hours) were associated with the massive fires during 1988 at Yellowstone National Park. High concentrations from events such as these are not representative of background levels. Even considering these peak concentrations at selected remote sites, the 3-year average of the 4th highest maximum O_3 concentrations at these sites was well below the proposed standard level of 0.08 ppm as seen in the table below. However, in recognition of the occurrence of such uncontrollable natural events that can contribute to atypically high O_3 concentrations, EPA has decided to include provisions in the new Appendix I to Part 50 to exclude peak O_3 concentrations that are associated with either stratospheric O_3 intrusion or other natural events, such as forest fires. See the preamble to the final rule and elsewhere in this document for further discussion of this point.

Further, with the exception of the 5 years of monitoring data from Denali National Park, which contained the lowest measured O_3 concentrations of any site listed on Table 2 of Altshuller and Lefohn (1996), the ambient O_3 monitoring data listed on Table 2 are wholly captured in Table 4-6 (page 4-30) of the Criteria Document. Clearly, these ambient concentrations were part of the discussion of O_3 background in the Criteria Document, and taken into account in the estimate of O_3 background in the Staff Paper, which was subsequently endorsed by CASAC.

In response to the range of the ten highest 8-hr daily maximum values presented in the third reference cited in the comment, this comment contained in Lefohn (1994), does not contradict the rationale presented above. Further, these comments were made to CASAC, and were taken into account in the development of the estimate of background in the Staff Paper which was subsequently endorsed by CASAC.

Distribution of Median and Annual Fourth Highest 8-Hour Daily Maximum Ozone Concentrations at "Background" Sites in the United States.

Monitoring Site Location	Year	4th Highest 8-hr Daily Max Concentration (ppm)	50th Percentile 8-hr Daily Max Concentration (ppm)
Denali NP, AK	1993	0.048	0.032
	1994	0.049	0.031
	1995	0.054	0.039
Quachita NF, AR	1993	0.061	0.036
	1994	0.063	0.039
	1995	0.075	0.043
Redwood NP, CA	1992	0.045	0.028
	1993	0.043	0.029
	1994	0.046	0.030
Point Reyes NP, CA	1990	0.055	0.031
	1991	0.052	0.033
	1992	0.052	0.032
Glacier NP, MT	1993	0.045	0.030
	1994	0.055	0.041
	1995	0.045	0.034
San Dunes NM, CO	1989	0.057	0.046
	1990	0.061	0.047
	1991	0.063	0.048
Theod. Roos. NP, ND	1993	0.056	0.038
	1994	0.058	0.045
	1995	0.058	0.044
Badlands NP, SD	1990	0.055	0.040
	1991	0.056	0.043
	1992	0.053	0.038
Arches NP, UT	1988	0.063	0.050
	1989	0.062	0.054
	1990	0.044	0.033
Olympic NP, WA	1993	0.042	0.023
	1994	0.042	0.026
	1995	0.049	0.035
Yellowstone NP, WY	1992	0.064	0.042
	1993	0.054	0.044

	1994	0.062	0.049

g. Communication of public health information

The EPA received a large number of comments from a wide variety of commenters strongly endorsing the usefulness of both an expanded health advisory system and the forecasting of 8-hour O_3 concentrations. These comments are primarily found in Section III.A.3.g of the comment summary document, and have been discussed extensively in Section II.C of the preamble to the final rule. The EPA expects to propose revisions to the Pollutant Standard Index (40 CFR 58.50) and significant harm level program (40 CFR 51.16), most likely in conjunction with Phase II of the Integrated Implementation Strategy for the revised O_3 and PM NAAQS, and will take all of these comments into account when developing this proposal.

B. Secondary O_3 Standard

1. General comments on proposed alternative secondary standards

A number of comments on the proposed secondary O_3 standard are very general in nature, basically expressing either 1) support for one of the two alternative proposed revisions to the secondary standard on which comment was solicited in the proposal notice, or 2) expressing opposition to any revisions to the current 1-hour standard. Many of these commenters simply expressed their views without stating any rationale, while others stated general reasons for their views but without reference to the factual evidence or rationale presented in the proposal notice as a basis for the Agency's proposed decision. These comments are mainly summarized in section III.B.1. through III.B.1.b. (2) of the Summary of Comments document. A few comments, however, are summarized in sections III.B.1.d.(1), III.B.1.d.(2), III.B.3., III.B.3.b.- c., and III.B.3.f.(3) of the Summary of Comments document.

In addition to the responses below, the preamble to the final rule in its entirety presents the Agency's response to these general views. More specifically, section III. of the preamble to the final rule responds to views that are related to 1) the nature of O3 related welfare effects, 2) the strength of and uncertainties associated with the scientific evidence of these effects, 3) the appropriate and/or likely degree of public welfare protection to be afforded by the current secondary O3 NAAQS and alternatives, and 4) the nature of the advice from CASAC with regard to the adequacy of the scientific evidence available for making a decision on the secondary standard. Section IV.A. of the preamble to the final rule responds to views that are based on reasons beyond the scope of those that the Administrator can consider in revising the standard, including those related to the costs of implementing a revised standard. Sections IV and VIII of the preamble to the final rule respond to views related to statutory interpretations and procedural issues.

(1) *Comment*: The secondary should be equal to the primary. Primary will adequately address non-health effects.

Response: EPA recognizes that the degree of public welfare protection provided by any standard is a function of the form, level, and averaging time. The Administrator's selection of a primary 8-hour, 0.08 ppm standard, using the form of the 4th highest daily maximum value averaged over three years, will provide a significant level of additional protection from the effects of O_3 on vegetation and the Administrator has decided to set the secondary standard identical to the primary standard in all respects (see Section III. of the preamble to the final rule for a discussion of the Administrator's rationale). However, EPA does not agree that a primary standard would always adequately address welfare effects of concern.

(2) *Comment*: Secondary should be set equal to an 8-hour, 0.09 ppm primary standard.

Response: See response to comment (1) under this section.

(3) *Comment*: Secondary should be set equal to an 8-hour, 0.07 ppm primary standard.

Response: See response to comment (1) under this section.

(4) *Comment*: This commenter recommended withdrawing the secondary standard proposal.

Response: CASAC Panel members all agreed that "damage is occurring to vegetation and natural resources at concentrations below the present 1-hour national ambient air quality standard (NAAQS) of 0.12 ppm, ..." and that "a secondary NAAQS, more stringent than the present primary standard, was necessary to protect vegetation from ozone..." Taking no action to mitigate these effects would not fulfill the requirements of the CAA that a secondary standard shall be set at a level that "is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air."

(5) *Comment:* The secondary standard should not be more stringent than the current primary. There should be no backsliding but there is no need for more protection.

Response: See the response to comment (4) above.

(6) *Comment*: A number of commenters state that the scientific basis for a revised, more stringent secondary standard is insufficient.

Response: EPA disagrees that the science is insufficient to support a decision to revise the secondary standard. EPA refers the commenter to the discussions in section III. of the preamble to the final rule, as well as chapter V. in the Criteria Document, chapter VII. in the

Staff Paper and section IV. of the proposal notice, which set forth the scientific basis for EPA's decisions to propose and finalize a more stringent secondary standard.

(7) *Comment*: One commenter (Private Citizen, IV-D-9611) stated that four major gaps exist in the "biologically relevant database": 1) limited information on the effects of O_3 on endangered and threatened species; 2) limited information on the effects of chronic O_3 exposure on productivity; 3) limited ability to evaluate actual O_3 uptake rates; and 4) difficulty in comparing of data sets because of lack of an accepted standard methodology or protocol. Similarly, another commenter (Dupont SHE Excellence Center, IV-D-11389) makes the observation that the inability to determine the amount of O_3 entering the leaves complicates the assessment of plant response to O_3.

Response: EPA agrees that additional research in each of these areas is appropriate, and identified these limitations in the data throughout its discussions in the Criteria Document and Staff Paper. EPA refers the commenter to section VII.F.2. of the Staff Paper for discussion of what is known about O_3 effects on endangered plant species. While the available information has limitations, the Administrator has decided there is sufficient information to merit the establishment of a more stringent secondary standard (see section III. of the preamble to the final rule).

(8) *Comment*: Secondary standards should be generally less burdensome than primary standards, since protection of visibility and material/vegetation damage should not be elevated to the same level as protection of human health. Additionally, EPA should only recommend use of a secondary standard, not force states to use it where welfare benefits are questionable.

Response: The commenter has failed to offer any statutory basis for its views, and EPA finds no support in the Clean Air Act for such views.

2. Specific comments on proposed seasonal standard

EPA received a number of comments either in support of or in opposition to the seasonal secondary alternative. These comments are mainly found in sections III.B.1.b.(3), III.B.1.c., and III.B.2. (all subsections) of the Summary of Comments document. However, a few comments are also found in sections III.B.1.- III.B.1.b.(2), III.B.3.c., III.B.3.d.(2), and III.B.3.e.(2). The Agency's reasons for not adopting a seasonal standard at this time are found in section III. of the preamble to the final rule. A few comments discussed issues that played a key role in the Administrator's rationale for her decision not to adopt a seasonal secondary standard. These comments will be responded to in more detail below, to the extent they are not addressed in the preamble to the final rule. Other commenters raised issues regarding the specific form and level of a seasonal standard.

(1) *Comment (Private Citizen, IV-D-11008)*: One commenter recommended a different air quality index for the secondary standard. He states that an Integrated Ozone Index (IOI) is a valid indicator for ecological effects and crop losses as it closely relates to biological and air quality aspects of O_3 exposure. Further, it is more robust than the current form of the NAAQS since it is less influenced by meteorological conditions.

Response: EPA was unaware of the existence of this index and would want to review it closely and consult with CASAC to determine its appropriateness for consideration as a form for a seasonal secondary O_3 national ambient air quality standard.

(2) *Comment*: Several commenters stated that a seasonal secondary would be inappropriate at this time due to the fact that there is no agreement in the scientific community over the biologically relevant dose (e.g., questions remain as to whether peaks or mid-range concentrations are more important). Additionally, other commenters pointed out that there is "disagreement among CASAC's plant experts whether the SUM06 formula is the best for a cumulative standard to protect vegetation from O_3."

Response: The Administrator cited these uncertainties as one of the key factors in her decision to make the secondary identical to the primary standard at this time (see section III.B. in the preamble to the final rule).

(3) *Comment*: Several commenters stated that either the SUM06 has no biological basis, or the threshold level of 0.06 ppm has no biological basis.

Response: See section VII.E. of the Staff Paper and section IV.B. of the proposal notice for EPA's discussion of the biological threshold issue and the characteristics of a biologically-relevant index.

(4) *Comment*: Several commenters made the statement that SUM06 is unnecessarily complicated and difficult to explain to the public.

Response: EPA disagrees. Summing the hourly O_3 concentrations above 0.06 ppm for each 12 hour period per day (8 am to 8 pm), for the 3 highest consecutive months during the O_3 season, is not a difficult concept. The total of this summation would then be compared to the level of the standard (e.g., 25 ppm-hrs.).

(5) *Comment*: One commenter (API, IV-D-2233) asked what is the scientific justification for using a cumulative 12 hrs., while the actual day length during summer months is greater than that value at most sites and times, and concentrations above 0.06 ppm sometimes occur at night? A second commenter (Private Citizen, IV-D-9611) recommended using the diurnal window of 7

am to 7 pm because according to the commenter the proposed 8 am to 8 pm biases toward the later hours, particularly during the late summer.

Response: EPA's rationale for selecting the 12 hour period (8am to 8pm) is described in the Staff Paper, section VII.E.1., and section IV.B in the proposal notice. In light of the Administrator's decision not to set a seasonal secondary standard at this time, EPA did not explore the merits of the commenter's concerns.

(6) *Comment (Cowling, VI-D-8824)*: One commenter submitted a comment in support of the seasonal form of the secondary standard because it would provide an additional measure of protection for ecosystems and crops. In support of his comment, he attached an article which he co-authored with Walter Heck, titled "The Need for a Long-Term Cumulative Secondary Standard- An Ecological Perspective", published in EM, 1997. This article presented the outcome of a workshop sponsored by the Southern Oxidants Study (SOS) and held in Raleigh, NC, attended by sixteen scientists.

Response: See the discussion of the article and workshop in section III.B. in the preamble to the final rule. See also the response to comment (7) below.

(7) *Comment*: Numerous commenters recommended EPA set a seasonal secondary standard in the form of SUM06 at a level or range of levels below the 25 ppm-hr level proposed by EPA in the proposal notice. Most of these commenters cited the conclusions from the SOS workshop (see comment 6). Those comments consistently expressed concern that the SUM06 level proposed (25 ppm-hr) would not provide adequate protection to vegetation for a variety of O_3 effects.

Response: As explained in more detail in the preamble to the final rule, the Administrator has decided that it is not appropriate to move forward with a seasonal secondary standard at this time. In coming to this decision, the Administrator specifically considered the significant welfare benefits that are expected to be afforded by the new 8-hour primary standard with respect to increased protection of public welfare, as well as the value of obtaining additional information to better characterize O_3-related effects on vegetation under field conditions. The uncertainties described in the preamble to the final rule regarding the incremental benefits of a seasonal secondary standard apply to a seasonal standard in the 8-20 ppm-hr. range as well as the proposed seasonal standard level of 25 ppm-hrs. Also, see response to comment (6).

(8) *Comment*: Several commenters stated that EPA should select a SUM06 level higher than the proposed 25 ppm-hr level. The recommended levels included 30 ppm-hrs and 38 ppm-hrs. Additionally, one commenter stated that the 10% yield loss level is inappropriate due to uncertainties in the NCLAN analyses. Therefore, the 20% effects level should be used.

Response: See response to comment (7) above.

Further, the uncertainties described in the preamble to the final rule regarding the benefits of a separate seasonal secondary standard in lieu of a secondary standard identical to the primary standard apply to a seasonal standard in the 30-38 ppm-hr. range recommended by commenters, as well as at the 25 ppm-hr level proposed.

Also, EPA notes that it evaluated the degree of protection afforded by different levels of a seasonal secondary within the range of 25-38 ppm-hrs. for a variety of O_3 effects on vegetation as discussed in the Staff Paper, not just crop yield loss.

(9) *Comment*: Some commenters recommended some combination of a cumulative, seasonal form with a second component that would take into account either high nighttime values due to transport (e.g., a supplemental 24-hr secondary standard) or the number of hours above 0.10 ppm. Several commenters pointed out that NCLAN exposures which produced crop yield losses contained numerous concentrations above 0.10 ppm and asserted that unless the peaks are included in the proposed seasonal form, sites with high SUM06's but few or no peaks above 0.10 ppm could be overestimating vegetation impacts.

Response: Because of a lack of information on vegetation response to O_3 at night it is not yet known whether there is a need for a separate standard to protect against nighttime exposures. Further, as discussed in section VII.E.1. of the Staff Paper and section IV.B. in the proposal notice, the timing of the exposure may be just as important as the concentration level. Because of the uncertainties that still remain with respect to O_3 exposure dynamics and the differential effect of various concentration levels on plants at different points in time, additional research would need to be done to ascertain the relevance of these different options. EPA is fully aware of the uncertainties associated with the NCLAN exposure regimes and discusses them in Section VII.D.2. of the Staff Paper and sections IV.A.2 and IV.B. of the proposal notice.

(10) *Comment*: Several comments were received that discussed comparisons between the different cumulative indices evaluated in the Staff Paper. One commenter (AAMA, VI-D-2243) states that EPA does not adequately characterize distributions of O_3 concentrations for any of the metrics being considered for the secondary standard and how they will vary seasonally, and recommends using the AOT06 index form because it is less confounded by background than the SUM06. Another commenter (API, IV-D-2233), stated that, contrary to what the Staff Paper concludes, the W126 index is not more influenced by background than the SUM06 index.

Response: EPA refers the commenters to pg. 226 to 227 and Appendix F of the Staff Paper which address how the three different exposure indices (AOT06, W126, and SUM06) differentially weight peak, mid-range and low O_3 concentrations for various ambient air quality scenarios from several NCLAN studies and air quality distributions produced from AIRS database for a variety of selected monitored locations. This information can be used to determine the relative impact on air quality distributions that each metric would have if it were the form of the standard or how changing air quality distributions would be reflected by each metric.

(11) *Comment (UARG, IV-D-2253)*: Much of the data EPA is using to justify setting a seasonal standard is based on O_3 levels which will not occur once the current primary ambient standards are attained. The proposal notice has not demonstrated that after the current primary is attained, O_3 will have an adverse impact on the public welfare. Since EPA associates damage with O_3 concentrations exceeding 0.10 ppm, it must show that there are significant areas for which a 0.12 ppm standard would not be controlling but that numerous concentrations above 0.10 ppm would occur. Using data from 64 rural monitoring stations (SON network) only a few sites have these characteristics. Therefore, data is inadequate to demonstrate that damage is occurring.

Response: EPA refers the commenter to sections VIII.C. of the Staff Paper and IV.D in the proposal notice where EPA discusses the adverse effects of O_3 on vegetation at various concentration ranges. The Administrator judges effects occurring at concentrations below 0.10 ppm as adverse, and both EPA and CASAC agree that "a secondary NAAQS, more stringent than the present primary standard, is necessary to protect vegetation from ozone."

(12) Comment: Two commenters stated that the proposed secondary standard is three times as stringent as the proposed (0.08 ppm) primary standard and should be reconsidered.

Response: EPA proposed two options for the secondary standard. One option was to set the secondary equal to the proposed primary. The alternative option was to set a seasonal standard at 25 ppm-hrs using a SUM06 index. The Agency does not understand the basis for commenter's opinion that either of the proposed secondary standards would be three times more stringent than the proposed primary standard. Obviously, a secondary standard identical to the primary standard would be equally as stringent as the primary standard. With respect to the proposed seasonal standard, the Administrator at no time indicated such a large difference in stringency between the two proposed secondary standards. See also section IV.C.3. of the proposal notice and section III of the preamble to the final rule, in which the Administrator explains the potential for incremental benefits from the seasonal standard alternative compared to a secondary standard set identical to the primary standard.

3. Specific scientific/technical comments

This section includes comments that cover a broad range of technical issues, including those that deal with the completeness, accuracy, representativeness, and limitations to interpretation or extrapolation of either the underlying scientific database or the results of analyses conducted by EPA. Because the comments in this section are found in numerous sections within the Summary of Comments document, the appropriate sections in the Summary of Comments document in which these comments are found will be identified separately for each subheading below.

a. Strength of effects evidence

i. Limited air quality monitoring data

Comments concerning the impact of limited rural air quality monitoring data are scattered throughout the Summary of Comments document, specifically in sections III.B.1.a., III.B.2.a.(1), III.B.3.b., III.B.3.c., and III.B.4.

(1) *Comment*: Many commenters stated that very little monitoring data is available in rural areas to support the proposed decision on the secondary O_3 standard.

Response: The proposed decision on the secondary O_3 standard involves two separate questions. The first question is whether the current standard protects public welfare against known or anticipated adverse effects. When the answer to the first question is no, the second question is what standard would protect public welfare against such effects. In answering the first question, EPA reviewed the science contained in the criteria describing the effects of O_3 on vegetation and the levels of exposure at which such effects occur. This information clearly demonstrated that a standard set at 0.12 ppm, 1-hour does not protect vegetation from acute foliar injury responses, crop yield loss and reduced biomass production associated with O_3 concentrations less than 0.12 but greater than or equal to 0.10 ppm nor chronic stress to vegetation resulting in reduced plant growth and yield, shifts in competitive advantages in mixed populations, decreased vigor leading to diminished resistance to pests, pathogens, injury from other environmental stresses, and foliar injury in some sensitive species associated with O_3 concentrations within the range of 0.05 to 0.09 ppm (see section VIII.C. of the Staff Paper, section IV.D. of the proposal notice, and section III.A. in the preamble to the final rule for a discussion of these conclusions). Additionally, these effects have been documented at several ambient air sites. Thus, EPA found and CASAC concurred, that the current secondary standard did not adequately protect vegetation. However, in order to answer the second question of what standard would adequately protect the public welfare against these adverse effects, EPA needed to be able to characterize O_3 air quality in rural and remote sites. Because of the limitations on the monitoring data available in rural areas, EPA conducted a national analysis using a geographic information systems (GIS). The large and unquantifiable uncertainties in the GIS exposure and risk estimates, as discussed in the Criteria Document, Staff Paper, the proposal notice, and by CASAC, affected EPA's decision at proposal and in the final rule regarding what level of revised standard would protect public welfare. As explained more fully in section III of the preamble to the final rule, EPA decided not to move forward with a seasonal secondary standard in part due to the limits of the rural air quality data. Also, the Administrator reaffirmed her commitment, described in the proposal notice, to pursue expansion of the existing rural monitoring network.

(2) *Comment (West Virginia Manufacturers Association, IV-D-2222)*: One commenter states that there is no evidence to support a secondary standard because all the monitoring data is from non-attainment areas.

Response: There is monitoring data from O_3 attainment areas, including sites located in Class I areas, and EPA has considered that data (see chapter 5, section 5.7 in the Criteria Document and section VII.F. in the Staff Paper). One example is a study by Neufeld, et al., 1992 which measured O_3 concentrations at three sites for the years 1987 through 1990 in the Great Smoky Mountains National Park.

(3) *Comment*: EPA should postpone its decision until it has sufficient monitored data. There are not an adequate number of O_3 monitors or monitoring data in National Forests or in the typical agricultural crop growing areas to make a sound scientific judgment on the impacts of changing the standard.

Response: See response to comment (1) above.

(4) *Comment*: Because of serious deficiencies in monitoring site distribution, accurate assessment of O_3 damage to crops is not possible.

Response: EPA agrees that without additional monitors in areas of agricultural importance, projected yield loss in crops from O_3 cannot be verified with precision. See also section III. in the preamble to the final rule.

ii. <u>Agricultural crop studies</u>

The majority of comments addressing different technical aspects of the NCLAN crop studies are summarized in sections III.B.3.d.(1- 4) of the Summary of Comments document. Other comments related to this topic are scattered among sections III.B.3.b., III.B.3.b.(1), III.B.3.c., and III.B.3.d. of the Summary of Comments document.

(1) *Comment*: [Note: Many commenters raised issues related to open top chambers (OTC). The more detailed comments have been blended together into one comment and EPA's response is intended to address both the more general and specific comments.] Commenters asserted that OTC microclimate conditions (temperature, radiation and moisture) can differ substantially from ambient conditions, magnifying some effects and mitigating others. The design and execution of OTC overestimate O_3 effects on plant yield, and/or do not have a consistent effect on yield

response, thus making extrapolation to the real world problematic. The effect of some other parameters (e.g., pathogens) were not measured. It is therefore not clear whether the reported crop effects are attributable to O_3 or to one of the other parameters. Commenters asserted that these factors were not considered in proposing a secondary standard.

Response: Both the Criteria Document (Section 5.2.1.1.) and Staff Paper (Section VII.D.2) discuss the implications of the chamber effects. Both documents conclude after reviewing a number of studies that conducted exhaustive comparisons between plants grown in carbon-filtered chambers, non-filtered chambers and ambient air plots, that the only consistently different variable between ambient air plots and non-filtered chambers was plant height. Studies that were performed to specifically examine the relationship between chambers and O_3 effects found no evidence of a large effect of chambers on plant response to O_3. The plant experts on CASAC had different views on the importance of the chamber effect. The CASAC closure letter states "two of the plant experts said that the open-top chamber experiments by their very design and execution produced results that overestimated the effects of O_3 on plant yield. The other two experts agreed that the open-top chambers do alter the environment in the chamber with respect to ambient field conditions but did not agree with there being a positive bias." Because the significance of the chamber effects has not yet been firmly established, EPA has continued to include caveats with any discussion of OTC data recognizing the existence of some uncertainties associated with the chamber effect. However, in EPA's judgement, based on the studies discussed in the Criteria Document and Staff Paper, these uncertainties are not of such great degree as to weaken the findings of NCLAN in any significant way. Indeed, the CASAC went on to recognize that "research has not yet provided methods that are clearly better than open-top chambers for establishing O_3 dose-response relationships for a wide variety of crops." Thus, EPA considers the use of OTC data appropriate as a basis for standard setting.

(2) *Comment*: NCLAN uses comparisons of crop yields grown using charcoal filtered air (25 ppb), which is "cleaner" than typical background O_3 levels, with crop yields in the field exposed to ambient air. As a result, NCLAN overstates the effects of anthropogenic O_3. EPA should reanalyze NCLAN using a baseline of at least 0.04 ppm to be consistent with human health baseline.

Response: The NCLAN studies were conducted at a variety of sites representing a variety of different ambient O_3 air quality profiles. The charcoal-filtered (CF) chambers represented the study's control and were not intended to represent background O_3 levels at each site. Exposure levels in the chambers were described as using the 7-hour seasonal mean. A seasonal mean value is not very descriptive because it does not reveal hourly or daily fluctuations and can, therefore, not be interpreted to mean a flat, hourly exposure level of 25 ppb, as the commenter has done. The charcoal filtered chambers reached O_3 concentrations that were 20 to 50% of ambient O_3 inside the chambers, which included O_3 influx through the open top (Heck, et al., 1982). Some of the 7-hour seasonal means in the CF chambers for different crop studies (table III., Heck, et al., 1982) fall between 0.03 to 0.05 ppm, which is stated in the Staff Paper and closed on by CASAC as the appropriate range for background summertime 8-hr daily seasonal average. A composite response function was developed by EPA's Office of Research and Development for all crop species which was able to handle the range of values in the (CF) controls. It is this composite function that was used to develop predictions of 10, 20,or 30% yield loss for different percentages of the NCLAN crops as a whole at different ambient O_3 concentrations (see chapter 5, section 5.6 of the Criteria Document). Thus, the baseline O_3 concentrations were not consistently below acceptable values for background and as a result, yield loss estimates are not universally overstated. Until additional monitoring is conducted in agricultural areas to better characterize existing O_3 levels and transport, EPA does not agree that a different baseline should be selected and NCLAN reanalyzed on that basis. The EPA has discussed this source of uncertainty in the Staff Paper in section VII.D.2. and in the proposal notice under section IV.A.2. Based on the variability in CF concentrations described by Heck, et al. (1982), EPA feels that a 7-hr seasonal mean (CF) value of 25 ppb is reasonably representative of the average (CF) 7-hr. seasonal means seen in the NCLAN studies.

(3) *Comment*: Some commenters asserted that NCLAN results were biased by atypical O_3 air quality (e.g., contained numerous high peaks), and that O_3 exposure regimes do not take into account that plants can recover from episodic exposures.

Response: EPA recognized that O_3 exposures used in NCLAN contained more peak concentrations than would be found in ambient air and has discussed this source of uncertainty in the Staff Paper in section VII.D.2 and in the proposal notice under section IV.A.2. The NCLAN studies were not designed to evaluate the potential for recovery from O_3 episodes since these were annual, not perennial, crops that were being studied to determine the cumulative effects of exposure to O_3 over the entire growing season.

(4) *Comment*: NCLAN plants may have actually been affected by exposures occurring after 12 hr. exposure period, thus overestimating the impact of 25 ppm-hrs during a 12 hr. period.

Response: EPA believes the potential for significant effects of O_3 on NCLAN crop yields after the 12 hr. daylight period is very low, and refers the commenter to the discussions of this issue in section VII.E. of the Staff Paper.

(5) *Comment (UARG, IV-D-2253)*: One commenter in particular raised several different points related to the statistical analyses of the NCLAN database. These comments are as follows: 1) Ozone exposures are not normally distributed and therefore, it is not statistically appropriate to use arithmetic means. 2) The Weibull model used to characterize exposure-response functions may not be appropriate because it: a) has no biological or mechanistic basis; b) is ecologically

unrealistic; c) can only identify states not rates of change; d) NCLAN data are so few and widespread that major regions of change in yield response exist between data points; e) the Weibull performed differently at different sites and years; f) the Weibull cannot show yield stimulation at low O_3 exposures; g) the Weibull model has not been validated. 3) Statistical analysis of NCLAN data fail to establish a quantitative linkage between crop effects and O_3. EPA should have done further tests to show that the statistical analysis was physiologically valid. 4) NCLAN's results are unreliable because they are based on very few data points and as a result downplay interspecies, cultivar and annual variability. NCLAN cannot be used to forecast crop response under complex real world situations when other factors are varying.

Response:

1) Analyses using the arithmetic mean are not invalid. The assumptions of least squares were evaluated and justified for each NCLAN study (Lesser, et al., 1990).

2.a-c) NCLAN specifically selected the Weibull model to represent the O_3 dose-crop yield response relationship since it was biologically realistic. Also, EPA notes that other researchers have used the Weibull model in modeling toxic effects in aquatic ecosystems (Christensen and Nyholm, 1984) and modeling plant disease progression (Pennypacker et al., 1980).

2.d) The plot of response means against the dose-metric shows a continuous response curve which was well captured by either a polynomial or the Weibull model. The NCLAN studies were designed so that O_3 treatments were allocated across a range of continuous response in order to approximate the response curve with a statistical model. No evidence of a discontinuous response appeared in the NCLAN data. Lack-of-fit tests to assess appropriateness to the Weibull model were made to each of the NCLAN studies.

2.e) The Weibull model was expected to perform differently at various sites and years. This was one of the reasons the Weibull model was adopted since it was flexible enough to accommodate the various types of response found across the sites and species. It was desirable to have a common model that could be used to characterize all dose-response data sets.

2.f) NCLAN scientists recognized that the Weibull model cannot show yield stimulation at low O_3 exposures. However, other mathematical models, such as the quadratic model, tend to predict higher false peaks of yield performance at low doses of O_3. Many species showed a plateau-like response, which could be better modeled by the Weibull, rather than the quadratic model. Since only a few studies in the NCLAN program did show a slight yield increase at low O_3 exposures, which may be due to just random variation, overall the Weibull model tended to reflect a better goodness of fit than the polynomial models (Rawlings et al., 1988).

2.g) Rawlings and Cure (1985) and Rawlings et al. (1988) investigated linear and nonlinear models to determine the most flexible and appropriate empirical model to represent the dose-response functions. Their conclusions were that the Weibull model was the most useful model for characterizing the effects of O_3 on crop yield. Other investigators from other disciplines, phytopathology and civil engineering, have adopted the Weibull model to model biological response (see response to 2(a-c)).

3) The NCLAN data clearly show a quantitative relationship between crop yield and O_3. This can be seen in scatterplots of yield and O_3 in the NCLAN data. Regression analysis describes statistical relationships between variables. Assumptions of the statistical analyses were checked and justified for each analysis (Lesser et al., 1990). Estimates of standard error provided with each Weibull model provide estimates of variability associated with the fitted model.

4) The statistical analysis based on the regression results make it possible to draw inferences about the mean response for any value of O_3 within the observational range studied. NCLAN results are reliable for those species, cultivars, and other factors which may alter plant response to O_3, such as sulfur dioxide or moisture stress, that were studied with the NCLAN program (Lesser et al., 1990). Variables that were not included are not important unless they are known to affect plant response to O_3 since yield estimates are on a relative basis.

(6) *Comment* (American Farm Bureau Federation, IV-D-2588): One commenter stated that before any new rules come out, EPA should wait to consider the results of research on agriculture's contribution to ambient air quality currently being conducted at Texas A&M and the University of California at Davis.

Response: EPA has already completed the criteria review which establishes the scientific base for the current NAAQS review. See response to comment (5) in section II.A.3.a.iii of this document. Any studies published after that date, assuming their results are accepted following a full review in the criteria and CASAC process, will become part of the criteria used to support the next NAAQS review.

(7) *Comment*: NCLAN data do not cover enough species and do not define physiological processes well enough to support a secondary.

Response: Fifteen species (corn, soybean, wheat, alfalfa, clover, fescue, tobacco, sorghum, cotton, barley, peanuts, dry beans, potato, lettuce and turnip) and 38 cultivars were studied under NCLAN and they represented greater than 85% of the U.S. agricultural acreage planted at that time. However, in its development of recommendations on a secondary standard, EPA did not limit the species considered to those included in the NCLAN studies. EPA also considered information from 11 different tree seedlings in the Hogsett, et al., 1995 studies, as well as information on numerous other species (see Table VII-3 in the Staff Paper and all of Chapter 5 in the Criteria Document). Plants representing a variety of growth strategies and physiological processes are included in the studies included in the Criteria Document and Staff Paper. While EPA recognizes that the information evaluated represents only a small fraction of all the plant species found in the United States, EPA believes, and CASAC concurred, that the large database that exists on O_3 effects on vegetation covers enough species and physiological processes to serve as the basis for determining that adverse effects are occurring to vegetation at levels of O_3 found in the ambient air and further, that a more stringent secondary standard is needed to provide adequate protection to public welfare.

(8) *Comment*: EPA's discussion of vegetation loss does not describe what percentage of crops were studied, what kinds of crops were studied, etc.

Response: See response to previous comment, section VII.D.2 in the Staff Paper, and section IV.C. in the proposal notice.

(9) *Comment*: The commenter questions whether EPA has fairly characterized the current or continuing vegetative damage patterns since it is using older studies as its basis. Specifically, it points to studies and data analyses conducted in the West for the years 1980 through 1988 and from 1988 to 1992, and questions the legitimacy of drawing parallels between "such older scientific efforts and the present situation, as well as, the applicability of studies in the West and other geographically limited areas to the entire nation...." Additionally, the commenter points to the decision in the recent NO2 review where "given the multiple causes and regional character of these problems, the Administrator also concludes that adoption of a nationally-uniform secondary standard would not be an effective approach to addressing them." (61 FR 52855) and questions why EPA has taken a different approach in the current O_3 review.

Response: EPA disagrees with the commenter's view that the studies serving as a basis for this review are out of date. The commenter failed to identify any newer studies that it would recommend for consideration. With respect to the commenter's concern that regional findings in the scientific literature are being inappropriately interpreted to apply to the entire U.S., EPA refers the commenter to comment (2) under section II.B.3.a.iv. below. Finally, EPA notes that a single excerpted sentence from the 1996 NO_2 NAAQS review, 61 FR 52852 (October 4, 1996), cannot fairly characterize the basis for the Administrator's decision on the NO_2 NAAQS. That NAAQS rulemaking should be viewed in its entirety, as should this rulemaking regarding O_3. See response to III.B.7(3) in this document. When viewed from the proper perspective, EPA believes that both the NO_2 decision in 1996 and the O_3 decision today are appropriate.

iii. <u>Tree seedling studies</u>

All comments under this section are found in section III.B.3.d.(4) of the Summary of Comments document.

(1) *Comment*: Seedling studies by Hogsett, et al. (1995) report a ten-fold range in seedling sensitivities to O_3. Any attempt to extract a secondary ambient standard from this wide variation would be at best, subjective. EPA should reconsider these data to determine the validity of the sensitivity estimates in view of the following sources of uncertainty: a) extrapolating from OTC to real world; b) using a low charcoal filtered baseline concentration overestimates the effect of anthropogenic O_3 on tree growth in the ambient air; c) extrapolating from seedlings to mature trees is not possible; d) extrapolating from study concentrations to other ambient concentrations is not appropriate since the shape of the exposure-response relationship between experimental and control O_3 concentrations is not known.

Response: Many studies have documented a wide range of sensitivity within tree species (e.g., white pine) and among tree species. A finding of a high or low degree of variability is not in and of itself either good or bad. If it can be supported by sound science, it is useful in informing the Administrator's judgement on the nature of the entities she is trying to protect. Thus, EPA disagrees that the proposal of a secondary standard that would be protective of tree seedlings is made subjective due to the finding of a high degree of variability in the seedling studies. Secondly, with respect to the sources of uncertainty identified in the comment above, the uncertainties associated with the experimental protocols used in the Hogsett et al., 1995 study have been acknowledged and addressed in numerous places in the Staff Paper and proposal notice. (See also the response to comments under section 3.a.ii. on uncertainties associated with OTC and NCLAN methodologies above). Further, EPA did not extrapolate from seedlings to mature trees. All discussion or depictions of seedling data have been heavily caveated so that there could be no misinterpretation of this point. (See section VII.F.2 in the Staff Paper and section IV.A.3. in the proposal notice.)

(2) *Comment (UARG, IV-D-2253)*: The commenter stated that Pye (1988) reviewed data from 25 experiments and discovered that the problems associated with each study precluded the development of definitive relationships between O_3 and tree growth, tree height, or photosynthesis. There are still large uncertainties in going from seedling to mature tree and mature tree to stand level competition.

Response: EPA agrees that the studies reviewed by Pye, 1988, had limitations. Most of these studies were included in the 1986 Criteria Document and served as the basis for the recommendations put forth in the 1989 Staff Paper. In spite of the studies'shortcomings, Pye (1988), states in his concluding paragraph that "seedling experiments have provided convincing evidence of short-term effects of O_3 on growth." Fortunately, as a result Pye's review, many of the studies on trees and tree seedlings published since Pye, 1988, have addressed some of the limitations which he pointed out. For example, Pye recommends that in place of the more commonly used exposure methods of the day, open top chambers (OTC) should be used because they "currently provide the most realistic data on yield response." Further, Pye points out that the most common exposure statistic of the day, the daily 7-hr mean, averaged over the growing season, obscured the smaller temporal and spatial patterns of O_3 exposures. According to Pye, "ideally, exposure-response studies should include treatments representing four or more concentrations of O_3 that span the range of control scenarios under policy consideration, allowing nonlinear regression analysis of impacts." Additional suggestions by Pye for improving the predictive power of seeding studies were to look at below ground impacts and impacts over multiple rather than single years. At the time of Pye, 1988, very little research had examined the question of whether O_3 damage would be greater under variable or constant O_3 exposures, given the same seasonal mean. All of the concerns identified in Pye, 1988, with respect to tree seedling studies have been addressed by more recent tree seedling studies, including Hogsett, et al., 1995. Since most of these studies were included in the 1996 Criteria Document and Staff Paper and formed part of the basis for the proposal of a new secondary standard, EPA refers the commenter to the discussions in these two documents that describe these new studies.

In spite of the advances in seedling research methodologies, EPA also agrees that there are still large uncertainties in extrapolating from seedlings to mature trees and from trees to stands. Pye, 1988, recognized the role that modeling will have to play in order to be able to extrapolate from seedlings to trees to stands. Since that time, several new models (e.g., TREGRO and ZELIG) have been developed. TREGRO models whole tree or seedling growth and simulates multi year O_3 effects while providing a basis for incorporating environmental and size/age influence (e.g., water availability) on growth response. ZELIG models the competition for resources that occurs between four individuals of the same or different species in a stand. Such modeling studies are expected to lead to a better understanding of O_3 effects on mature trees and forests in the future.

iv. <u>Natural forests and ecosystems</u>

Comments under this section are summarized in sections III.B.3. and III.B.3.b.(4) in the Summary of Comments document.

One commenter (UARG, IV-D-2253) provided a series of comments on the data regarding non-commercial forest systems and the usefulness of this database as support for a seasonal secondary standard. These comments were discussed in greater detail in Attachment 6 which accompanied the UARG comment.

(1) *Comment*: It is not possible to predict the forest response to O_3 concentrations occurring after attainment of the current primary standard because the majority of non-commercial forest data occurs at concentrations above or well above ambient concentrations that will occur after

attainment of the current primary standard. Therefore, the non-commercial forest data is irrelevant to the standard-setting process.

Response: Contrary to the commenter's assertions, visible foliar injury and growth effects have been documented for several tree species (black cherry, red oak, red maple, yellow poplar, aspen, and paper birch) at O_3 levels that never exceeded 0.08 ppm (Table 5-27 in the Criteria Document). Therefore, EPA disagrees that the non-commercial forest data is irrelevant to this rulemaking.

(2) *Comment*: The San Bernardino exposures are unrepresentative of other parts of the country and the original study did not consider the complex interactions of other environmental factors.

Response: EPA agrees that the San Bernardino ecosystem is unique and that subsequent research has and is uncovering additional layers of complexity in the pollutant/plant response equation. However, the uniqueness of San Bernardino does not nullify its usefulness as evidence of forest-scale damage at high O_3 levels. Every ecosystem, whether in the East or West, has a unique set of characteristics, species, and complex environmental stressors and no one system can represent them all. By comparing and contrasting different systems, much can be learned. EPA recognizes that the original study on the San Bernardino forests did not include certain other environmental factors (e.g., nitrogen deposition) that have since been shown to have played a role in the decline of the ponderosa and Jeffrey pine in the San Bernardino forests. Again, however, the importance of these new findings does not change the fact that O_3 was and continues to be a significant stressor to this system. By learning more about the interactions of O_3 with other stressors, we will be able to better characterize future risks to other forested systems. Section 5.7.4.2 in the Criteria Document and section VII.D.4. of the Staff Paper discuss in greater depth the differences between the forests of the West and the East.

(3) *Comment (UARG, IV-D-2253)*: Dendrochronological and dendroecological studies (e.g., tree ring analysis) for ponderosa, Jeffrey, and white pine did not employ standard dendroecological techniques and thus cannot be used to develop reliable exposure response relationships. Thus, it is difficult to determine if any observed decreasing trend in radial growth is real or an artifact of the averaging process. Studies that hypothesize an O_3 effect on tree growth must be reconciled with the Hornbeck et al. (1988) study which shows increasing growth alongside increasing O_3 exposures .

Response: The commenter is incorrect in its statement that "Dendrochronological and dendroecological studies (e.g., tree ring analysis) for ponderosa, Jeffrey, and white pine did not employ standard dendroecological techniques." Many of the studies referred to by the commenter (e.g., Peterson et al., 1987; Peterson and Arbaugh, 1988, 1992; Peterson et al., 1991) used these techniques, (e.g., cross-dating, variance filters, etc.), and took into account variables such as age, size, precipitation, and temperature. EPA refers the commenter to the

"Sampling and Statistical Analysis" sections of each of these papers. EPA is aware of the numerous environmental factors that can affect plant response and discusses them in great detail in both the Criteria Document (section 5. 4) and in the Staff Paper (section VII.C.). EPA is also aware of the limitations associated with findings of O_3 effects on mature trees growing in the field and has included caveats when discussing the findings of these studies in both the Criteria Document (section 5.7) and the Staff Paper (section VII.D). In contrast, the study identified by the commenter (Hornbeck et al., 1988) does not employ these same techniques, does not provide any quantitative data about levels of exposure to specific air pollutants (e.g., O_3), and does not distinguish air pollution effects from the other factors that have potentially influenced tree growth. Instead, Hornbeck, et al., 1988 compared regional growth rates for 10 species in the Northeast for the period 1950 to 1980 to determine whether any of these species were showing trends of decreased growth in order to identify which if any of these species should receive priority in future research on forest health. Thus, Hornbeck et al., 1988 cannot serve as a valid basis of comparison or rebuttal of other O_3 forest effects research.

(4) *Comment*: There is no documentation to support the suggestion that O_3 was responsible for the dieback of high elevation forests, especially with respect to red spruce forests.

Response: EPA has not made such a claim. In eastern forests, however, red spruce and Fraser fir are often found growing together. The Criteria Document does discuss several studies (e.g., Hain and Arthur, 1985; Aneja et al., 1992) which focus on the death of Fraser fir on Mt. Mitchell, suggesting that gaseous air pollutants, particularly O_3, and cloud water deposition of acidic substances are among possible stresses that have increased host susceptibility to attack by the balsam wooly adelgid insect. Since the Criteria Document has described the antagonistic and synergistic relationship between obligate and facultative pathogens, respectively, and O_3 injured plants and studies where insect larva seemed to prefer O_3 injured leaves over non-injured leaves in some species, EPA believes this theory may be plausible. EPA refers the commenter to sections VII.D.4. and VII.F.2. in the Staff Paper and sections IV.A.4. and IV.C.2. of the proposal notice where EPA discusses the issue of forest dieback. In these sections, EPA simply points out that an interaction between O_3 and vegetation and insect attack did occur in the San Bernardino forest and could possibly occur again somewhere else. Thus, EPA has not overstated the possible risks of dieback to high elevation forest species.

(5) *Comment (Sierra Club, Virginia Chapter, Air Quality Chair, IV-D-10663)*: The commenter sent information on the effects of O_3 and acid ion deposition on the decline and increased mortality of oaks and hickories in the eastern U.S. This material is currently being prepared for submission to a peer-reviewed journal.

Response: See response to comment (1) under section II.B.3.a.ii.3. of this document.

(6) *Comment*: Three commenters provided information in support of findings that O_3 damage is occurring to vegetation at levels present in the ambient air. One commenter stated that controlled field studies indicate symptoms (e.g., premature leaf drop, declining vigor and higher rates of mortality) in Northeast high elevation forests. A second commenter presents evidence from Great Smoky Mountains National Park regarding visible foliar injury to black cherry at O_3 levels ranging from 14.2 -17.6 ppm-hrs. The third commenter stated that adverse effects have been observed in Vermont at levels half the level of the proposed SUM06 standard.

Response: None of these commenters provided any references to published literature as documentation of these findings. To the extent this information is already published in the peer-reviewed literature that was incorporated in the criteria, it has been considered as part of this review. See also response to (5).

b. Interpretation of vegetation effects evidence

Comments relating to this section have already been addressed in sections II.B.3.a. (i.-iv).

c. Exposure analyses

Comments addressed in this section are summarized in the Summary of Comments document primarily in sections III.B.3.d.(1), III.B.3.d.(2), III.B.3.d.(4), and III.B.3.e.(1). Additional comments are found in sections III.B.3., and III.B.1.a.

i. General Methodologies

(1) *Comment*: Exposure estimates were based on an empirical model not subject to peer-review or any performance evaluation. The system for extrapolating results for the entire US is based on an unpublished internal EPA memorandum which contains insufficient details to adequately evaluate its appropriateness. Computations for effects of background conditions are insupportable.

Response: As stated in the proposal notice, section IV.C.1., "a description of the GIS and air quality adjustment methodologies used, as well as the associated uncertainties, are discussed in the Staff Paper and related technical support documents (Horst and Duff, 1995a,b,; Lee and Hogsett, 1996; Rodecap et al., 1995)." EPA refers commenters to these technical documents in the docket which support these analyses. While EPA did not publish its memorandum, it did submit the GIS methodology to CASAC for review. In its discussions of uncertainties, described in the proposal, the CASAC panel members expressed concerns about the use of the GIS methodology to project national O_3 air quality and exposures of O_3 sensitive species. Though EPA and CASAC recognized that the uncertainties in the exposure and risk estimates derived from the GIS methodology are large and unquantifiable, as noted in the Staff Paper and proposal notice, they also recognized that the method provides useful information that is appropriate to consider in comparing the relative protection afforded by alternative standards. Thus, EPA feels that the peer-review and documentation of this methodology is sufficient for the purposes of this standard review.

(2) *Comment*: The GIS is overly simplistic in dealing with O_3 formation (e.g., uses NO_X to substitute for O_3, rather than joint NO_X /VOC; uses a universal decay curve which might not be relevant in all cases; combines all meteorologic information together in a way that doesn't allow for consideration of the joint probability of the various factors occurring at the same time).

Response: The nature of a model is that it simplifies complex systems. EPA is aware of the simplifying assumptions that were used to estimate O_3 exposure potentials across the U.S. These assumptions were thoroughly documented in (Horst and Duff, 1995a,b, Lee and Hogsett, 1996; Rodecap et al., 1995). Furthermore, given the very limited rural O_3 monitoring network, large uncertainties would exist in any prediction of rural air quality using any different interpolation technique. EPA chose to use a GIS-based approach which predicts O_3 exposures base on factors known to influence O_3 air quality assimilated on a 10-km grid, rather than assuming a smoothly changing surface between monitored sites as traditional interpolation techniques do (e.g., krieging). Thus, EPA feels that the results of the GIS-based risk assessment were useful in informing the Administrator about relative risks to vegetation under different standard alternatives, while acknowledging that the results are limited by substantial uncertainties.

(3) *Comment (Dupont SHE Excellence Center, IV-D-11389)*: One commenter stated that gaps in the understanding of measurement methodologies calls into question the regulatory relevance of the vegetation evidence.

Response: EPA recognizes and has discussed the uncertainties associated with the methodologies used in both the OTC's and the GIS (see sections II.B.3.a.ii. and II.B.3.c.i., respectively, of this document). However, EPA and CASAC did not feel that these uncertainties were great enough to negate the overwhelming evidence of the phytotoxic effects of O_3 on vegetation. Thus, CASAC concluded in its closure letter to the Administrator (Wolff, 1996) that "...damage is occurring to vegetation and natural resources at concentrations below the present 1-hour national ambient air quality standard (NAAQS) of 0.12 ppm.... Further, it was agreed that a secondary NAAQS, more stringent than the present primary standard, was necessary to protect vegetation from ozone."

ii. Characterization of uncertainties

The comments and responses that address uncertainties in the exposure analyses are included under sections II.B.3.c.i. and II.B.3.d.i. - ii.

d. Risk assessments

Comments under this section are found in the Summary to Comments document sections III.B.3., III.B.3.e., and III.B.4. Comments under this section are associated with the completeness of the risk assessment and EPA's ability to validate its results.

i. General Methodologies

(1) *Comment*: EPA's risk assessment methodology uses quadratic rollback on wind and emission data that has not been validated for this purpose and which does not take into account episodic variations in background levels which can mask the effect of emissions reductions on vegetation.

Response: The rollback methodology was not used directly on wind and emission data. The wind and emission data was used to develop the O_3 potential exposure surface (PES). The rollback procedure was used on the actual monitoring sites data. Then, this rolled back monitor data was used with the PES to estimate concentrations in non-monitored areas. The quadratic rollback equation was designed to have proportionally greater rollback of higher concentrations such that concentrations below 0.045 ppm are largely unaffected. The quadratic equation did not greatly affect concentrations below 0.06 ppm because these concentrations do not contribute to the SUM06 index.

(2) *Comment*: EPA's risk assessment is completely inaccurate.

Response: EPA recognizes that there are large uncertainties associated with the risk assessment. These uncertainties have been discussed in numerous places, including the Staff Paper and proposal notice. However, consistent with advice from CASAC, the Administrator concludes that the risk assessment is still useful in providing information on the relative impacts across the range of standard options considered.

ii. Characterization of uncertainties

(1) *Comment (AAMA, IV-D-2243)*: One commenter stated that major discrepancies found in a comparison of Figure IV-5 Staff Paper with Figure 11 of the June 29, 1995 Agency memo suggests that there is a reason to be concerned about the GIS methodology.

Response: Figure IV-5 of the Staff Paper is a set of histograms showing an example of O_3 hourly frequency distributions at four different sites. Each histogram represents the maximum 3 months of O_3 during the O_3 season selected from the highest year for each site within the 3 year period (1991-1993). Since the highest O_3 year for one city may be different from that for another city, each city may depict a different year's air quality. This Figure was developed to show the variability between sites in the number of hours which have O_3 concentrations in a given concentration category and how the way these concentrations are distributed affects the relative values of each of three different indices (AOT, W126, and SUM06). Figure 11 in the Agency memo (also known as "Methodology for Calculating Inputs for Ozone Secondary Benefits Analysis Report dated June 29, 1995") is a map of a single year's PES (potential exposure surface). The memo states that "the PES values are unitless qualitative values that depict the estimated relative potential for O_3 exposure at each 10 km cell...." In other words, these qualitative values have not yet been related to any concrete numbers which could then be used for comparison. Since the histograms for the cities come from more than one year, and the PES was developed for a year different from any of the histograms, there can be no comparison of the two figures. However, as stated in section VII.F.2. of the Staff Paper, EPA did conduct a visual comparison of the map of 1990 estimated Max. 3 months 12-hr, SUM06 exposures (Figure VII-10 in Staff Paper) predicted using GIS to the 1990 map of monitored SUM06 values greater than 25 ppm-hrs by county (Figure IV-4 in Staff Paper) and found that the areas of predicted violations in the GIS map corresponded well to the areas of measured concentrations.

(2) *Comment*: EPA's risk assessment cannot be validated due to limited monitoring data and therefore cannot be used to justify the expense of a comprehensive air quality management program.

Response: EPA's risk assessment is included as part of the informational base used by the Administrator to inform her decision on the appropriate form and level of a secondary standard necessary to protect the public welfare from the adverse effects of O_3 present in the ambient air. Thus, the risk assessment is only intended for use in the decision-making process on the form and level of the standard and does not bear the burden of having to justify any form of air quality management program. See the response to comment (1) under section II.B.3.a.i. and comment (2) under II.B.3.c.i. in this response to comments document.

(3) *Comment*: EPA ignores important welfare effects that will be negatively impacted by O_3.

Response: Because the commenter failed to identify the type of welfare effects which it thinks EPA ignored, EPA cannot respond with any specificity. See proposal notice at 65735 for an explanation why EPA's review of the secondary standard focused on the O_3 effects on vegetation.

e. Benefits assessments

The majority of comments on the benefits assessment are found in sections III.B.3.f. (All subsections except III.B.3.f.(3)) of the Summary of Comments document. A few other comments are found in sections III.B.3., III.B.3.b.(1) and III.B.3.d.(4) of the Summary of Comments document.

Comments regarding cost considerations are addressed in Section IV.A. of the preamble to the O_3 NAAQS final rule and will not be addressed specifically in this document. Comments regarding the Regulatory Impact Analysis (RIA) are addressed both in section IV.A and in section VII of the preamble to the O_3 NAAQS final rule.

(1) *Comment* (Sinclair Oil Corporation, IV-D-7011): Agricultural benefits claimed by EPA not substantiated by USDA.

Response: The economic models used to estimate agricultural benefits utilize USDA-published data for yield per acre, acres harvested, production costs, and model farms. In addition, the economic analysis is based on field level research regarding O_3 concentrations and yield effects. This research was carried out at several land grant universities by USDA and university researchers.

(2) *Comment* (American Farm Bureau Federation, IV-D-2588; George Mason University, IV-D-2227; American Iron and Steel Institute, IV-D-2579; API, IV-D-2233): EPA's concern of "ozone-caused crop damage ... is unfounded". Cites CASAC finding that "absolute values of the numbers in Tables VII-5a-VII-7 are highly uncertain estimates of crop losses and are a result of a propagation of uncertainties. They are rough estimates..."; Cites CASAC finding that EPA's crop loss estimates are uncertain. Economic models add layers of uncertainty.

Response: All CASAC Panel members agreed that damage is occurring to vegetation and natural resources at concentrations below the present 0.12 ppm, 1-hr NAAQS. The CASAC experts further agreed that vegetation appears to be more sensitive to O_3 than humans and that a secondary NAAQS more stringent than the present NAAQS is necessary. In the proposal and supporting documents, EPA acknowledges the uncertainties of the economic analysis and presents the results as rough approximations that provide useful insights for comparing the relative benefits of alternative regulatory scenarios. Also, EPA acknowledges the uncertainties of the economic models which were available and used for the analysis. EPA notes, however, that these economic models have appeared in the peer-reviewed literature and were reviewed by CASAC.

(3) *Comment* (AAMA, IV-D-2243): EPA must know what O_3 exposures are in rural areas before it can draw any conclusions regarding benefits of a separate seasonal secondary. Not considering costs could lead to the illogical result of $1B in cost to avoid $1M in crop losses.

Response: EPA acknowledges the uncertainties in the aerometric projections of rural air quality to estimate crop yield benefits. However, all CASAC Panel members agreed that damage is occurring to vegetation and natural resources at concentrations below the present 0.12 ppm, 1-hr NAAQS. The CASAC experts further agreed that vegetation appears to be more sensitive to O_3 than humans and that a secondary NAAQS more stringent than the present NAAQS is necessary. If a stricter standard will protect vegetation (which includes crops), then realization of economic benefits can be expected. Although there are insufficient O_3 rural monitors to allow a firm and faithful exposure assessment where damage is observed, some next-best estimate is appropriate to assess the acknowledged plant damage. See the discussion in section IV.A. of the preamble to the final rule for a discussion on cost considerations. See also previous response.

(4) *Comment* (CMA, IV-D-2249): Given the current limited understanding and uncertainties, it is extremely important that any proposed secondary standard be based on a proven net benefit to the environment.

Response: See the discussion in section IV.A. of the preamble to the final rule and in section III of this Response To Comment document regarding cost considerations.

(5) *Comment* (UARG, IV-D-2253): The commenter noted that the U.S. has a crop surplus, and, thus O_3 reductions and any associated yield increases would reduce producers' overhead of current production levels (increased yield results in fewer acres planted and cost savings); this would be an avoidance of adverse effects on public welfare and remediable under Section 109(b)(2). The commenter questioned whether "overhead" adverse effect should be mitigated with improved ambient air quality.

The commenter further asserted that the Staff Paper does not establish that an incremental secondary standard for O_3 would produce economic benefits from crop yield improvements, and listed the following concerns:

- Economic analyses must account for relationships between crop yield
- Economic analyses based on rejected W126 index
- Economic benefits based on NCLAN
- Economic analysis depends on maps on Appendix E
- Incremental analysis vanishingly small compared to agricultural industry total
- Benefits don't outweigh costs; costs and number of new N/A areas would be high

In addition, the commenter asserted the same concerns with regard to effects on forests.

Response: The issue of potential crop surplus is addressed in the structure of the underlying economic model and the staff paper analysis itself. From a legal and peer reviewed perspective of theoretical and applied welfare economics, the subject analysis is appropriate. The uncertainties regarding the data inputs and models are addressed in the analysis. See also discussion of cost considerations in section IV.A of the preamble to the final rule. Economic benefits were not assessed for commercial or non-commercial forests so the commenter's reference to forests does not apply to commenter's concerns about crops.

(6) *Comment* (Sierra Club National Committee, IV-D-2067; *AAMA*, IV-D-2243): The first commenter said that economic assessment of crop loss across U.S. for corn, soybean, cotton, wheat and peanuts were valued at a net loss of $5.2B (1987 $) if O_3 concentrations are reduced to 0.08 ppm per 8-hr period. Bringing O_3 down to 0.025 ppm for the season would boost wheat production by 8%, soybean by 17%, corn by 3%, and peanut by 30%. This assessment in 1987 dollars must be updated to show the true depth of the destruction of crops by O_3. The other commenter said that NCLAN 0.025 ppm background is too low and overestimates crop damage and benefits of control.

Response: The first commenter asserts a loss estimate which is inconsistent with that contained in the Staff Paper. The commenter argues for estimating the total crop loss damages to O_3 by taking observed, modeled, and calculated concentrations down to a specified level of 0.025 ppm for naturally occurring O_3 (background). Chapter IV of the Staff Paper states that it is reasonable to estimate O_3 background levels in the range of 0.03 to 0.05 ppm and for this reason, the Staff Paper also states that crop yield losses based on a background level concentration of 0.025 ppm will result in a directional overestimation of the benefits.

(7) *Comment* (UARG, IV-D-2253): From attachment 5: Overall conclusion of this section is that EPA does not have a sound scientific basis for concluding that reductions in O_3 exposure will have a significant effect on agricultural economics.

Response: All CASAC Panel members agreed that damage is occurring to vegetation and natural resources at concentrations below the present 0.12 ppm, 1hr NAAQS. The CASAC experts further agreed that vegetation appears to be more sensitive to O_3 than humans and that a secondary NAAQS more stringent than the present primary is necessary. If a stricter standard will protect vegetation (which includes crops), then realization of some economic benefits can be expected. Therefore, the commenter's conclusion that estimated economic effects are not significant from a scientific perspective is not supported by empirical analysis nor the view of CASAC experts.

(8) *Comment* (American Iron and Steel Institute, IV-D-2579): Tenuous benefits cannot be justified by the costs of attainment of a new standard.

Response: See the discussion in section IV.A. of the preamble to the final rule and section III of this Response To Comment document regarding cost considerations.

(9) *Comment* (UARG, IV-D-2253): EPA's recommendation that the nonquantifiable information be weighed in considering to what extent the secondary should be precautionary in nature is inconsistent with the CAA provision that EPA take into account only those adverse effects which are "known or anticipated" and "demonstrable or predictable". Thus EPA may not rely upon the non-quantifiable plant data cited in final SP.

Response: See response to comment III.B.5. of this response to comment document. EPA disagrees with the commenter's contention that qualitative data is to play no role in determining an appropriate level for a secondary standard. Under the Clean Air Act, EPA is to consider all relevant information, both quantitative and qualitative, in the air quality criteria. See sections 108(a)(2) and 109(b)(2). Also, non-quantifiable plant data is not necessarily un-demonstrable or unpredictable. Research efforts conducted over a number of years provide conclusive evidence that O_3 causes injury to forest trees (O_3 causes discernable effects on photosynthesis and other physiological processes that directly impact on tree growth).

f. Monitoring Issues

Comments on monitoring are found mainly in sections III.B.2.a. and III.B.4 of the Summary of Comments document. One other comment is found in section III.B.2.b.(2) of the Summary of Comments document. Comments on monitoring fall under two categories: 1) The need for an expanded rural monitoring network and 2) the appropriateness of spatial averaging for a seasonal secondary standard.

i. Expansion of monitoring network

Comment: Several comments were received on the appropriate spatial scale for an expanded rural monitoring network.

Response: EPA appreciates all comments received pertaining to the appropriate spatial scale for an expanded rural monitoring network and will take them into account as it moves toward meeting the Administrator's goal, as described in the proposal notice and preamble to the final rule, to develop a monitoring network that will provide better coverage in rural areas of agricultural or ecological importance

ii. Consideration of spatial averaging

Comment: Several comments were received either in favor of or opposed to spatial averaging for a seasonal secondary standard.

Response: EPA's response to these comments is found in section III.C. of the preamble to the final rule.

III. RESPONSE TO COMMENTS ON LEGAL, ADMINISTRATIVE, AND PROCEDURAL ISSUES RELATED TO THE REVIEW OF THE O_3 NAAQS

A. Introduction

These responses address comments summarized in section IV and elsewhere in the Summary of Comments. Because of the emphasis public commenters placed on certain issues, EPA responded directly to them in sections IV and VII of the preamble to the final rule. Section IV of the preamble addresses the following legal and procedural issues: (1) whether EPA must give consideration to costs and similar factors in setting NAAQS; (2) whether EPA erred in its selection of a methodology for determining the level of a NAAQS that protects public health with an adequate margin of safety; (3) whether EPA committed a procedural error by not extending the comment period; and (4) whether the 1990 amendments to the Act preclude EPA from revising the O_3 NAAQS to establish a new 8-hour standard. Section VII of the preamble addresses issues raised in public comments with respect to EPA's obligations under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), and the Unfunded Mandates Reform Act.

As discussed in section VII.B of the preamble, EPA convened outreach meetings modeled on the SBREFA panel process to solicit and convey small entities' concerns with the proposed NAAQS. Summaries of comments received at these meetings and written comments submitted in connection with them, together with EPA's responses, have been prepared and entered separately into the docket. Similarly, as discussed in Section VII.D, a summary of the key issues raised at outreach meetings with State and local government officials and EPA's evaluation of those issues has been prepared and entered separately into the docket.

Given the extensive response to public comments on legal and procedural issues in the preamble to the final rule, the following responses serve to augment those discussions or to address other comments not discussed in the preamble. Therefore, responses to comments presented in the preamble, the separate responses to issues raised in outreach meetings, and the responses to comments discussed below collectively constitute EPA's response to comments on legal and procedural issues.

B. General Issues

1. Cost Considerations

This section addresses comments that EPA erred in not considering costs or other societal impacts in establishing NAAQS, particularly for non-threshold pollutants or in light of uncertain health effects information. Some commenters also maintained that costs should be considered in setting secondary NAAQS.

(1) *Comment*: EPA is not precluded from considering costs; among other things, the judicial decisions relied upon by EPA as precluding consideration of such factors rest on faulty analysis that predates and cannot survive scrutiny under <u>Chevron</u>, <u>U.S.A.</u> v. <u>Natural Resources Defense Council</u>, 467 U.S. 837 (1984) (API, IV-D-2233; GM, IV-D-2694;

ATA, IV-D-2245; UARG, IV-D-2253; AISI, IV-D-2242 in comment on the PM proposal).

Response: Post-Chevron decisions have confirmed that costs and similar factors may not be considered in setting NAAQS. See section IV.A of the preamble to the final rule.

(2) *Comment*: Section 109 of the Act does not preclude consideration of cost/benefit analysis when read in pari materia with sections 108(a) and 302(h) (GM, IV-D-2694).

Response: See section IV.A of the preamble to the final rule. Reading section 109(b) together with sections 108(a) and 302(h) does not alter the conclusion that consideration of costs and similar factors is precluded in setting NAAQS. Section 109(b) provides that NAAQS are to be based on air quality criteria issued under section 108(a)(2). As the commenter indicates, section 108(a)(2) provides that information on welfare effects, as well as health effects, is to be included in the air quality criteria. That information, however, does not include costs and similar factors resulting from efforts to attain or maintain the NAAQS. Although section 302(h) defines "welfare" as including "effects on economic values," this phrase refers to the economic costs of pollution, not to the costs of controlling pollution. Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1148 n.36 (D.C. Cir. 1980). Cf. Natural Resources Defense Council v. Administrator, 902 F.2d 962, 972-73 (D.C. Cir. 1990).

(3) *Comment*: Section 109(d)(2)(c)(iv) requires EPA to consider the advice of its independent science advisors on any "adverse public health, welfare, social, economic, or energy effects" that might arise from implementing revised standards when establishing them (UARG, IV-D-2253).

Response: See section IV.A of the preamble to the final rule.

(4) *Comment*: If Congress intended to forbid consideration of costs and benefits under section 109, it would have enacted a preclusive section 302 definition of "health effect" or "margin of safety" similar to the section 302(h) definition of welfare effect (GM, IV-D-2694).

Response: Such a definition was unnecessary in view of other indicia of congressional intent discussed in section IV.A of the preamble to the final rule. See, e.g., Natural

Resources Defense Council v. EPA, 824 F.2d 1146, 1157-59 (D.C. Cir. 1987).

(5) *Comment*: Selection of a level for the O_3 NAAQS is a policy decision that must reflect costs, particularly when there is no "bright line" between several alternatives under consideration (AAMA, IV-D-2243).

Response: See sections IV.A and IV.B of the preamble to the final rule.

(6) *Comment*: The Act prohibits consideration of non-health matters in setting standards; the place to consider costs is in the development and adoption of State implementation plans (ALA, IV-D-2339; NESCAUM, IV-D-2169).

Response: EPA agrees.

(7) *Comment*: In selecting among alternative secondary standards that provide a safe environment, the purposes of the Act (section 101(b)(1)) require EPA to conduct a holistic inquiry into all effects on the public welfare to ensure that its standard-setting will actually advance the public welfare. In doing so, EPA must take into account adverse social and economic effects that might result from implementing a secondary standard, as evidenced by the requirement (section 109(d)(2)(c)(iv)) that CASAC advise EPA on such effects. EPA's legal analysis misapplies Lead Industries since that case only addressed primary standards (language regarding secondary standards is only dicta), and EPA ignores the Vinyl Chloride and NRDC cases, which call for a bifurcated assessment of risk in cases such as this. Once a safe level is established, the determination of how far below that level a standard should be set is a policy choice, calling for a comprehensive assessment of all effects on public welfare as described above, regardless of whether EPA is setting an ample margin of safety under § 112, setting an adequate margin of safety for a primary standard, or determining a demonstrated level of adverse effects on public welfare for a secondary standard (UARG, IV-D-2253).

Response: The comment is flawed in several respects. First, it appears to assume that proposal of alternative standards amounts to a finding that any of the alternatives would provide adequate protection of public welfare under section 109(b). This is incorrect; proposal of alternative standards (primary or secondary) reflects the Administrator's awareness that there may be a range of views on the scientific information on which NAAQS are to be based, as well as on how the information should be used in making the policy judgments required for the final choice of a standard. Only the Administrator's final decision on a standard, taking into account public comments on the proposal, can be said to represent her determination of what standard meets the statutory criteria.

Second, the purposes of the Act are stated in general terms and are, at best, only a general guide to decisions under specific sections of the Act. To the extent they appear to conflict with more specific decision criteria stated in the statutory provision at issue, the more specific criteria are controlling. Under the decision criteria stated in section 109(b), consideration of costs and similar factors is precluded in setting NAAQS, and CASAC's responsibility to advise EPA on adverse effects that might result from implementation of standards does not alter that conclusion. See section IV.A of the preamble to the final rule.

Finally, although the statements of that principle in Lead Industries and other judicial decisions are technically dicta as to secondary standards, the commenter presents no persuasive reason, based on indicia of congressional intent, the pertinent caselaw, or even policy considerations, for concluding that costs and similar factors may be considered in setting secondary NAAQS though not in setting primary NAAQS. The commenter also mistakes the meaning of the Vinyl Chloride and NRDC decisions, which do not call for bifurcated assessments of risks in NAAQS decisions. See sections IV.A and IV.B of the preamble to the final rule.

2. Margin of Safety

This section addresses comments on the approach used by the Administrator in specifying an O_3 standard that protects public health with an adequate margin of safety.

Comment: In setting a NAAQS with an adequate margin of safety, EPA must define what constitutes "acceptable risk" for present and future rulemakings. In reaching such a determination, EPA must consider among other factors the results of cost-benefit analyses, the acceptability of risk judged in a "real world" context, and any adverse public health effects that might result from implementation of alternative standards. In other words, EPA must adopt a specific approach for specifying a standard that protects public health with an adequate margin of safety, and that approach must consider costs and other societal impacts. (UARG, IV-D-2253; GM, IV-D-2694; ATA, IV-D-2245).

Response: See sections IV.A and IV.B of the preamble to the final rule.

3. Comment Period

This section addresses comments on the adequacy of the public comment period.

Comment: A large number of commenters requested an extension of the public comment period for periods of time ranging from 60 days up to 1 year. These commenters in seeking an extension cited among other things the complexity of the issues involved, the fact four other notices (NPRM for the PM NAAQS, NPRM for reference and equivalent methods and $PM_{2.5}$ monitoring requirements, ANPRM on implementation of O_3 and PM NAAQS, and a notice seeking comment on the Interim Implementation Policy for O_3 and PM) were issued at the same time, and that it was not necessary for the O_3 NAAQS review to be on the same schedule as the PM NAAQS review because it was not under court order. One commenter (API, IV-D-2233) sought an extension because the availability of certain O_3 exposure/risk analyses was not announced in the Federal Register until February 20, 1997. This same commenter also sought an extension because of the delay in placing the transcripts from the public hearings into the dockets (API, IV-D-8155).

Response: See section IV.C of the preamble to the final rule. Also, the Act specifies no minimum time period from docketing hearing transcripts to the close of the comment period. See 42 USC § 7607(d). In any event, EPA notes that the extension of the comment period provided ample opportunity for the review of public hearing transcripts since the transcripts for the Chicago and Salt Lake hearings were docketed on February 6, 1997, and the transcripts for the Boston and Durham hearings were docketed on February 13, 1997, giving the public approximately 30 days to review them before the close of the comment period on March 12, 1997.

4. 1990 Act Amendments

This section addresses comments that the 1990 amendments to the Act that specified comprehensive control strategy requirements for O_3 prohibit EPA from revising the 1-hour primary standard or from simultaneously implementing the present standard and a new 8-hour standard.

Comment: The 1990 amendments that enacted the provisions of subpart 2 of part D of title I of the Act preclude EPA from revising the existing 1-hour standard for O_3. Alternatively, EPA cannot implement a revised standard so long as the existing 1-hour standard remains in effect (GM, IV-D-2694; UARG, IV-D-2253; API, IV-D-2233).

Response: See section IV.D of the preamble to the final rule.

5. Linkage of O_3 and PM Reviews

This section addresses comments that the O_3 and PM NAAQS reviews should be decoupled.

(1) *Comment*: EPA failed to adequately explain the basis for linking the O_3 and PM NAAQS reviews (GM, IV-D-2222; CSMA, IV-D-2530; Kalamazoo, Michigan Chamber of Commerce, IV-D-2186; GM, IV-D-2694).

Response: The June 12, 1996 advance notice of proposed rulemaking (61 FR 29719) as well as the O_3 proposal notice (61 FR 65718) explained in some detail the EPA's reasons, both in terms of common linkages with regard to observed health effects and common linkages in the formation of O_3 and fine particles in the atmosphere, for conducting the reviews of O_3 and PM NAAQS on the same schedule. The EPA believes that explanations in these two notices are adequate.

(2) *Comment*: The O_3 and PM reviews should be decoupled to provide adequate time for public comment on the O_3 proposal (UARG, IV-D-2253; API, IV-D-2233).

Response: See section IV.C of the preamble to the final rule.

(3) *Comment*: EPA linked the O_3 and PM NAAQS in order to hide the negative economic impacts of the O_3 proposal behind the more positive economic impacts associated with the proposed PM NAAQS; linking the two proposals will not reduce regulatory burdens (Sterling Chemicals, IV-D-2038; ESI, IV-D-2187).

Response: As discussed in section IV.A of the preamble to the final rule, EPA is precluded from considering costs or economic impacts in setting NAAQS.

6. Consideration of Disbenefits

Comment: One commenter argued that reductions in tropospheric O_3 associated with the proposed standards would result in adverse effects from increased UV_b radiation such as skin cancer, cataracts, and immunosuppression. Commenter notes that a class of compounds called chloroflourocarbons (CFCs) can deplete O_3, particularly in the stratosphere, and as a result

EPA has adopted regulations to phase-out CFC's and led international efforts to freeze and phase-out the use of O_3 -depleting CFC's. Commenter claims the disbenefits associated with reducing tropospheric O_3 levels to comply with the current O_3 NAAQS or attain the proposed standard may be similar in magnitude to the respiratory-related health benefits associated with such an O_3 reduction. Finally, commenter asserts that EPA was arbitrary and capricious in not considering disbenefits associated with decreases in tropospheric O_3 as a result of UV_b radiation during the Criteria Document and Staff Paper reviews and during the development of the proposed standards (GM, IV-D-2684). This same commenter submitted similar comments in regard to the PM NAAQS proposal.

Response: EPA strongly disagrees with this commenter's suggestion that such "disbenefits"of tighter standards can and should be considered in reviewing and revising NAAQS, because it is inconsistent with the Clean Air Act and ill advised from an environmental management policy perspective. Furthermore, the evidence the commenter submits to support these claims is based on unfounded and erroneous assumptions that greatly overstate the potential effects and relies on very uncertain approaches. Each of EPA's reasons is discussed more fully below.

The clear intent of Congress in enacting the NAAQS provisions of the Clean Air Act prohibits EPA from considering in this rulemaking any health "disbenefits" that may result from the implementation of a new, more stringent NAAQS. Where the intent of Congress on a specific issue is clear, as determined by traditional tools of statutory construction, it must be given effect by the implementing agency and the courts. Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837, 842-45 (1984). As described below, Congress clearly intended to limit EPA's consideration in developing criteria and in setting NAAQS to the adverse health effects caused by the presence in the ambient air of the pollutant in question. Accordingly, EPA is not considering in this rulemaking the alleged health "disbenefits" from implementation which have been raised by commenters, and EPA did not include them in the discussion of the air quality criteria.

The NAAQS provisions of the Act are set forth in sections 108 and 109 and were first enacted in 1970. In that year, Congress set up a three-step process for the development of NAAQS -- first, EPA must prepare a list of air pollutants meeting certain requirements; second, EPA must develop criteria for the listed pollutants; and third, EPA must establish NAAQS for the pollutants based on the criteria. See 42 U.S.C. sections 7408, 7409. At each step, there is evidence that Congress intended the Agency to consider only the adverse health effects caused by the presence in the ambient air of the pollutant at issue.

As the initial step, Congress directed EPA in 1970 to list "each air pollutant - (A) which in his judgment has an adverse effect on public health or welfare; (B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and (C) for which . . . he plans to issue air quality criteria . . . ." 42 U.S.C. section 7408(a)(1). In paragraph (A), Congress expressly focused the entire NAAQS process on pollutants that have an adverse or harmful effect on public health.

In the second step, EPA must develop air quality criteria for each listed pollutant. Section 108(a)(2) states that the "criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air." Read out of context, the phrase "all identifiable effects" might be deemed sufficiently broad to encompass any health effect, whether positive or negative. But the phrase can clearly be read as meaning only harmful effects, and it is only part of a larger body of statutory language that evidences Congress' intent with respect to the NAAQS. Other language in sections 108 and 109 indicates that Congress had harmful effects of a pollutant in mind when it directed EPA to examine "all identifiable effects." Indeed, the immediately following sentence in section 108(a)(2) specifies three factors that the Agency must include in the criteria, and two of those three factors expressly direct EPA to focus on "adverse" effects to health and/or welfare.[7] Similarly, the listing process in section 108(a)(1)(A) in 1970 required the Administrator to list for criteria and NAAQS development each air pollutant "which in his judgment has an adverse effect on public health or welfare . . . ."[8] Together, these statutory excerpts (with the provisions of section 109, discussed below) evidence Congress' clear intent for EPA to focus on the harmful effects of a pollutant in developing the air quality criteria.

Also, the express language of section 108(a)(2) limits the scope of causality which it is appropriate for EPA to consider. The language directs EPA to focus on "effects that may be expected from the presence of the pollutant in the ambient air." This language parallels that in the listing process, which directs EPA to list pollutants "the presence of which in the ambient

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[7]The three factors are: "A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant; (B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and (C) any known or anticipated adverse effects on welfare." 42 U.S.C. 7408(a)(2)(A)-(C).

[8] In 1977, Congress amended the language in subsection 108(a)(1)(A). As revised, the subsection directs the Administrator to list each air pollutant "(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare...." The legislative history shows that Congress inserted this revised language into the Clean Air Act in several sections to clarify that proof of actual harm was not necessary under section 108 or the other revised provisions of the Act, and to create a uniform test for regulation to protect public health and welfare. See, e.g., H.R. Rep. 95-294, at 43-51 (1977). The statutory language ("endanger") and the legislative history make it clear that Congress remained focused on the adverse effects of pollution. See id.

air" results from numerous or diverse mobile or stationary sources (section 108(a)(1)(B)). In both provisions, Congress limited the causality consideration to the effects caused by the emitted pollutant's presence in the ambient air. There is no language to support the idea that Congress intended to focus on the indirect effects of implementation efforts to reduce pollution following the establishment of a NAAQS. Indeed, such considerations would be premature at this point in the process, when the Agency is focusing on the criteria that will form the basis for setting the NAAQS.

In the third and final step, section 109 directs EPA to set the NAAQS based on the air quality criteria issued under subsection 108(a)(2). 42 U.S.C. 7409(b)(1)-(2). The case law on considering cost in NAAQS reviews confirms that Congress limited the Agency's consideration to the factors specified in section 108(a)(2). See section IV.A of the preamble to the final rule. Further, the 1970 Senate report evinces Congress' intent to focus on adverse health effects when setting primary standards. The report emphasizes that the Agency should protect the health of particularly sensitive citizens such as asthmatics, and declares that a NAAQS will be sufficient to protect the health of sensitive individuals "whenever there is *an absence of adverse effect* on the health of" an appropriate sample of such persons. S. Rep. No. 91-1196, at 10 (1970) (emphasis added).

Thus, it is clear from the language and legislative history of the 1970 amendments alone that Congress intended to limit EPA's focus to the adverse effects of a pollutant's presence in the ambient air. The repeated references to "adverse" effects, and Congress' focus on the effects caused by an emitted pollutant's presence in the ambient air, indicate that Congress did not want EPA to weigh the potential health "disbenefits" of pollution control against the adverse health effects from a pollutant's presence in the ambient air.

The 1977 and 1990 amendments to the Clean Air Act offer additional evidence confirming this conclusion.[9] In 1977 Congress made some significant changes to sections 108 and 109 but did not change its substantive instructions for setting NAAQS by amending subsections 108(a)(2) or 109(b). In new subsection 109(d), Congress directed EPA to review existing NAAQS periodically and established CASAC as a special advisory committee to advise the Administrator in such reviews. Congress expressly directed that both EPA's decisions and CASAC's recommendations on revisions of existing NAAQS be made in accordance with existing section 108 and subsection 109(b). 42 U.S.C. 7409(d)(1), (2)(A)-(B). As a separate task, Congress directed CASAC to offer advice to the Administrator in several areas, including

[9] Even if doubt were to remain about Congress' intent after review of the 1970, 1977, and 1990 amendments, EPA's longstanding interpretation of the statutory language is clearly reasonable, for the reasons discussed above. Moreover, EPA's interpretation is supported by the policy reasons set forth later in this response.

any "adverse public health . . . effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards." 42 U.S.C. 7409(d)(2)(C). This language specifically addresses the potential for health "disbenefits" from implementation. It shows that Congress was aware of the potential for such effects, yet declined to include them among the section 108 factors to be considered in setting a NAAQS. Instead, Congress directed CASAC to offer advice on the potential health effects of implementation separately from its involvement in the establishment and revision of the NAAQS. The legislative history confirms that such advice was intended for the benefit of the States and Congress who might wish to use it in developing implementation strategies or in fashioning future legislation. See H.R. Rep. No. 95-294, at 183 (1977).[10]

In 1990, Congress again amended the Clean Air Act substantially without changing the basis for setting NAAQS. At the same time, Congress expressly addressed the issues of stratospheric O_3 depletion and global warming that are the proximate causes of the health effects raised by commenters. Congress enacted Title VI (sections 601-618) to address stratospheric O_3 depletion[11] and directed EPA in section 602(e) to consider the global warming potential of potential substitutes for stratospheric O_3 depleting substances. These provisions demonstrate that Congress was aware of the potential environmental hazards of stratospheric O_3 depletion and global warming but chose to address them separately from the process for setting and revising NAAQS. At the same time, other amendments show that Congress was aware EPA might revise the then existing NAAQS. For example, section 172(a)(1) expressly contemplates that EPA may revise a NAAQS in effect at the time of enactment of the 1990 Amendments.

The D.C. Circuit's decision in the <u>PM_{10}</u> case further supports the conclusion that Congress did not intend EPA to consider the implications for global warming and UV_b exposure from implementing strategies to reduce O_3 and PM in accordance with the new NAAQS. In that litigation, AISI argued that EPA should have considered the potential human health effects of unemployment that might result from implementing the PM_{10} NAAQS. EPA had interpreted the statute as prohibiting the agency from considering such potential health effects of implementation in setting or revising a NAAQS. The court upheld EPA's conclusion, quoting subsection 108(a)(2) and stating that "it is only *health effects relating to pollutants in the air* that EPA may consider." <u>Natural Resources Defense Council v. Administrator</u> ("<u>PM_{10}</u>"), 902 F.2d 962, 972-73 (D.C. Cir. 1990) (emphasis in original).

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[10] In 1977, Congress also added provisions to address stratospheric O_3 depletion and the increase in UVb radiation exposure that it causes. P.L. 95-95, sections 150-159 (1977).

[11] Title VI replaced the provisions regarding stratospheric O_3 depletion enacted in 1977. P.L. 101-549, section 601 (1990).

As pertinent here, the potential health effects of UV_b radiation or global warming, like the potential health effects of unemployment, would not result from air pollution but from the implementation of pollution control. Like the potential health effects of unemployment, the potential health effects of both global warming and UV_b increases would not be caused by the presence of the applicable pollutant in the ambient air. In each case, there is an independent, intervening cause (unemployment, stratospheric O_3 depletion, atmospheric increases in greenhouse gases) of the potential harmful effect. In each case, the argument for considering the potential effect is that implementing a new, tighter standard would "cause" an increase in the effect, but in each case the effect is actually a result of the intervening cause. In other words, without these intervening causes, there would be no health "disbenefit" to implementing the new NAAQS. In all three circumstances, the fact that the potential "disbenefit" would result from implementing the new NAAQS, rather than from the presence of the relevant pollutant in the air, means that EPA is prohibited from considering such effects.

The scenarios suggested by the commenter do differ from the unemployment concerns presented in the PM10 litigation in one respect, and that difference argues yet more strongly against EPA's consideration of such concerns. In the PM10 litigation, AISI alleged that pollution control efforts would cause unemployment, which in turn would cause the harm to public health. In contrast, there is no causal connection whatsoever between O_3 or PM reduction and either the buildup of greenhouse gases or stratospheric O_3 depletion. Both of the environmental hazards cited by the commenter (and the health effects they potentially cause) would occur whether or not efforts were made to control PM or tropospheric O_3. All that this commenter alleges is that PM and tropospheric O_3 mitigate the harm to public health caused by the independent environmental hazards known as global warming and stratospheric O_3 depletion. Nothing in the statute or its legislative history suggests that Congress intended EPA to set a less protective NAAQS because the pollutant of concern might mitigate the harmful health effects of a wholly independent, environmental hazard. Indeed, as discussed above, the 1977 amendments and their legislative history indicate, to the contrary, that Congress did not intend EPA to set less protective NAAQS even if CASAC advised that implementation of NAAQS might cause adverse public health effects. Further, Congress' directive to protect particularly sensitive populations such as asthmatics would be vitiated if EPA had to set a less protective NAAQS to account for the NAAQS pollutant's potential to mitigate a different type of harm caused by an independent environmental problem that may affect other members of the public.

Even if the law had been written in such a way as to permit consideration of these hypothesized disbenefits and if, as the commenter has not shown, the available science permitted some quantification of such effects, EPA believes that it would be bad public policy to place any weight on this issue in reaching a decision on the O_3 standards. EPA does not believe it is appropriate or, as noted above, consistent with the intent of the framers of the Clean Air Act to consider increasing, or leaving at arbitrarily high levels, air pollutants that have direct effects on public health in certain sensitive populations in order to mitigate the effects of another pollution-induced problem, in this case increased UV_b or global warming. This would mean balancing the risks of adverse effects of breathing O_3 in, for example, children that have asthma or other respiratory problems, with an attempt to intermittently reduce the risk of UV_b penetration that has been increased by CFC and other anthropogenic pollutants. Such a policy would ignore critical issues of equity and the distribution of relative risks.

The commenter's own citations provide little confidence in the calculations made to date with respect to this issue. The draft and final EPA documents commenters cited by the commenter were produced at a time when the criteria review process was in its early stages. EPA conducted an analysis and review of the extent to which the kinds of incremental O_3 reductions anticipated for a possible 8-hour standard might produce such an effect. The review of the draft estimates concluded "(1) the numbers resulting from these calculations are quite small and (2) the limitations of the accuracy and reliability of the input to the calculations produces numbers that cannot be defended, whether large or small." (Childs, 1994).

Furthermore, commenters have pointed to no convincing basis for concluding that any such effects as have been calculated would be significant, especially in comparison to the major risk reductions that will accompany the regulations of CFCs and other O_3 depleting substances. Commenters submitted a number of documents, including EPA assessments and one publication (Lutter et al., 1996) that all based estimated disbenefits on an average change in O_3 across the year of 10 ppb. Neither these documents nor commenters provide any support for the claim that the proposed or final O_3 standards would result in a long-term spatial and seasonal average change of this magnitude; by contrast, many commenters note the difficulty in achieving a 10 ppb O_3 reduction even for the 3rd highest maximum 8-hour concentration in a year, much less the long-term seasonal or annual average. The importance of the naturally occurring stratospheric O_3 layer in protecting against the effects of ultraviolet radiation (UV_b) is well documented. On average, about 95% of the "total column"O_3 protection comes from the stratosphere, leaving only about 5% for the sum of uncontrollable background and O_3 from U.S. anthropogenic sources. By contrast, even the 10 ppb reduction in average tropospheric O_3 that is erroneously assumed, in the documents cited by the commenter, to be the result of the proposed O_3 standards would account for a total column O_3 reduction of only 0.3 to 0.6 percent. Therefore, a small reduction in stratospheric O_3 (e.g., from chlorofluorocarbons) represents a much more significant issue than would a large change in tropospheric O_3. Accordingly, the primary remedy for this issue must necessarily be regulation of CFCs and other O_3 depleting substances, as provided for in both the Clean Air Act and the Montreal Protocol.

Moreover, there are a number of problems with the example estimates, particularly as they relate to implementation of the proposed 8-hour O_3 standard. While the focus of the proposed O_3 NAAQS is to reduce the distribution of episodic 8-hour peak values in areas that do not meet the standard, any relevant effects of O_3 on UV_b are not related to single 8 hour periods, but to population-wide exposures for all days of a summer or year. As noted above, both submissions by other commenters and EPA's air quality and modeling experience show that strategies to reduce peak periods will not be as effective in reducing O_3 on the far more numerous non-episode days. Although EPA has not relied on the Ozone Regulatory Impacts Analysis (RIA) in this standard decision, it is appropriate to note that based on the earlier RIA projections of long-term reductions that might occur with the proposed O_3 standard, the assumption of a reduction of average O_3 levels as large as 10 ppb appears to overstate what might be expected by more than a factor of 3.

Furthermore, the increase in skin cancer effects calculated by Lutter et al. represents the instantaneous steady state increase in annual incidence assuming that the affected populations in the U.S. are exposed to reduced O_3 levels (and thus higher UV levels) over their entire lifetime. As a result, these estimates do not incorporate any assumptions about delays between increased exposure to UV and the onset of skin cancer (i.e., the latency period). As a result, the already inflated disbenefits for the year 2010 calculated by Lutter et al. (1996) must be reduced even further, and by a substantial amount.[12]

For reasons detailed above, EPA rejects the recommendations of this commenter on legal, policy, and technical grounds. Most importantly EPA rejects the notion that air quality standards should be based on a principle of mitigating problems caused by anthropogenic emissions such as CFCs by increasing -- or leaving at arbitrarily high values -- the levels of air quality standards for other pollutants, whose presence in the air directly harms public health and welfare.

7. Miscellaneous Comments

This section addresses various comments not addressed above.

(1) *Comment*: EPA erred by not releasing guidance on control techniques simultaneously with the revised air quality criteria as required by § 108(b)(1) (AAMA, IV-D-2243; NMA, IV-D-2247; Exxon, IV-D-2596; NAIMA, IV-D-2151).

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[12]The results of recent high-dose animal toxicology studies suggest more research is needed into the direct effects of tropospheric O_3 on the skin before reaching any conclusions suggesting even very small disbenefits of reducing tropospheric O_3. Tests by Thiele et al. (1997) suggest that chronic O_3 can deplete Vitamin E in the skin, and this could make the skin more susceptible to the effects of UV_b. Therefore, reducing ground level O_3 exposure might serve to reduce skin problems. Even a very small O_3 effect in this regard could completely offset or counter the small UV_b blocking effect.

Response: Any such error would not affect the validity of the NAAQS themselves, which are to be based on air quality criteria containing the kinds of information specified in section 108(a)(2). In any event, section 108(b)(1) relates only to the initial issuance of criteria for a newly listed air pollutant. Where, as here, the Agency reissues such criteria for a NAAQS pollutant, the controlling provision is section 108(c). Section 108(c) states: "The Administrator shall from time to time review, and, *as appropriate*, modify, and reissue any criteria or information on control techniques issued pursuant to this section." 42 U.S.C. 7408(c) (emphasis added). As the statutory language makes clear, whether and when the modification or reissuance of a control techniques document is appropriate is left to the Administrator's discretion. In this instance, EPA has made control technology information available by publishing Control Technique Guidelines for Volatile Organic Compounds as well as issuing guidance on Reasonable Available Control Technology and Reasonable Available Control Measures. Periodically, as new technologies and related information becomes available, EPA updates this control technology information by either revising existing guidance or by issuing new guidance documents and makes them available through traditional mechanisms, such as National Technical Information Service, as well as through EPA's home page on the Internet. As a result, the States and others have more timely access to the latest information on control techniques than could be accomplished by compiling a single comprehensive control techniques document.

(2) *Comment*: EPA did not provide sufficient notice for the public hearings, and holding simultaneous hearings at four different locations and limiting the time for presentations to five minutes precluded effective participation. Some commenters sought additional hearings in the Southeast and the Southwest. (ATA, IV-D-2245; ARA, IV-D-7986; TTL, Inc., IV-D-7988; API, IV-D-2233).

Response: When announcing the proposed decisions on November 27, 1996, EPA made widely available copies of the proposal notice that clearly indicated that the date and location of the public hearing would be announced in a separate notice. Because of the strong public interest expressed, EPA decided to hold separate hearings at four locations to give interested parties more opportunity to participate. The EPA announced the dates, times, and locations of the hearings as soon as the necessary arrangements had been made - 3 weeks in advance. Because of the unusually large number of individuals who wanted to participate, it was necessary to limit oral presentations to five minutes. Under the circumstances, it was not feasible to hold public hearings in every region of the country and furthermore by holding four public hearings, EPA has more than satisfied the requirements of the Act to provide opportunity for oral comments. In addition to the public hearings, EPA also solicited comment by voice mail, e-mail, fax, and written comments.

(3) *Comment*: The EPA must explain the O_3 proposal's departure from prior decisions to reaffirm NAAQS for sulfur oxides and nitrogen dioxide, which were based on scientific evidence no

more solid than the highly uncertain evidence on which EPA proposes a revised O_3 standard (GM, IV-D-2694).

Response: The basis and rationale for EPA's decisions that revisions to sulfur oxides (SO_2) and nitrogen dioxide (NO_2) NAAQS were not appropriate were discussed in detail in the preambles to those rules (see 61 FR 25566, May 22, 1996; 61 FR 52852, October 8, 1996). Section II of the O_3 proposal notice (61 FR 65719, December 13, 1996) discusses in detail the basis and rationale for EPA's proposed decision to revise the O_3 standards. In EPA's periodic reviews of NAAQS, such factors as the nature and severity of the health effects involved, the size of sensitive population(s) at risk, the types of health information available, and the kind and degree of uncertainties that must be addressed vary from one pollutant to another. As a result, the decision whether and, if so, how the NAAQS for a given pollutant should be revised is necessarily specific to that pollutant and to the state of scientific knowledge available to the Administrator at the time of her decision. Thus, each standard review must be based on careful assessment of the available information in the air quality criteria for the pollutant in question. In the present case, EPA believes that the basis and rationale for the Administrator's decision to revise the O_3 NAAQS are fully explained in the preamble to the final rule and supporting documents, and that the decision is amply supported by the record.

(4) *Comment*. The EPA's treatment of O_3 background concentrations is unlawful because: 1) EPA failed to consider the impact of background concentrations on the attainability of alternative proposed standards, 2) EPA's proposal assumes, unreasonably, that Congress has delegated to the Agency final authority to decide whether to close down much of the economy or one or more industries of some, many, or all parts of the nation; and 3) EPA's proposal neglects to analyze the disparate regional impacts of moving from the existing 1-hr, 0.120 ppm standard to the proposed 8-hr, 0.08 ppm standard, and that this omission is especially egregious given that maintaining equitable burdens between regions is a highly relevant factor (GM, IV-D-2694).

Response: See responses in section II.A.3.f.ii above. Further, the costs and attainability of NAAQS are not to be considered in setting them. See section IV.A. of the preamble to the final rule.

(5) *Comment*: EPA cannot rely upon the non-quantitative plant data cited in the staff paper in considering to what extent the secondary standard should be precautionary in nature (UARG, IV-D-2253).

Response: While qualitative data alone cannot be used as the sole basis for setting a separate secondary standard, EPA disagrees with the contention that more qualitative data is to play no role in determining an appropriate level for a secondary standard. Under the Act, EPA is to consider all relevant information, both quantitative and qualitative, in the air quality criteria. In this instance, EPA concluded, based on its assessment of the air quality criteria, that the secondary standard should be set identical to the final primary standard.

(6) *Comment*: EPA may only set a secondary standard if it is "appropriate" to do so in light of the recommendations of its science advisors on the factors specified in section 109(d)(2)(c)(IV) (UARG, IV-D-2253).

Response: CASAC's responsibility to advise EPA on the factors specified in section 109(d)(2)(C)(iv) is separate from its responsibility to review and recommend revision of air quality criteria and NAAQS, and the advice pertains to the implementation of NAAQS rather than to setting them. See section IV.A of the preamble to the final rule.

C. Regulatory and Environmental Impact Analyses

1. Compliance with E.O. 12866

This section addresses comments that EPA failed to comply with the provisions of E.O. 12866.

(1) *Comment*: EPA erred by not complying with the requirement of E.O. 12866 to select among regulatory alternatives that are most cost-effective and maximize net benefits. Further, EPA has not examined alternative means to achieving its objectives that are more cost-effective as it did in the SO_2 NAAQS decision (API, IV-D-2233; State of N.C., IV-D-7003; NMA, IV-D-2247).

Response: For reasons discussed in section IV.A of the preamble to the final rule, the cited requirements of E.O. 12866 is not applicable to NAAQS decisions. Moreover, the SO_2 NAAQS decision is not analogous to this rulemaking. In SO_2, EPA determined, based on its assessment of relevant scientific and technical information, that revisions to the SO_2 NAAQS were not appropriate for the reasons discussed in the preamble to the final rule (61 FR 25566; May 22, 1996). As in this case, EPA did not consider cost-effectiveness or the results of the Regulatory Impact Analysis in reaching its decision on the SO_2 NAAQS.

2. Regulatory Flexibility Act

This section addresses comments that EPA's failure to prepare a regulatory flexibility analysis and to convene a Small Business Advocacy Review Panel violates the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act.

(1) *Comment*: EPA's certification that the proposed revision to the O_3 NAAQS would not have a significant economic impact on a substantial number of small entities and EPA's failure to prepare a regulatory flexibility analysis or convene a Small Business Advocacy Review Panel

violated the intent and plain language of the law (NAM, IV-D- 2274; ATA, IV-D-2245; NAHB,IV-D-2068).

Response: See section VII.B and section IV.A of the preamble to the final rule.

(2) *Comment*: It was also maintained: 1) that the NAAQS itself will have a significant impact on small business and that small business will bear a disproportionate impact; 2) that EPA's position that it cannot prepare a regulatory flexibility analysis is baseless (citing PM RIA); 3) that EPA's informal, ad hoc overtures to small business are inadequate to satisfy SBREFA; and 4) had EPA complied with statutory requirements, alternatives with less burdensome impacts on small business would have been identified (ATA, IV-D-2245; NAM, IV-D-2274; IV-D-2100; AAMA, IV-D-2243; API, IV-D-2233; UARG, IV-D-2253).

Response: See section VII.B and section IV.A of the preamble to the final rules. See also summary and response to comments for the small business meeting.

(3) *Comment*: A commenter argued that the only possible and appropriate time for EPA to comply with the RFA as amended by SBREFA is at the NAAQS revision stage since EPA acknowledges that it will not perform an RFA analysis at the SIP approval stage and if it were to do so, conducting 50 different RFAs would result in bureaucratic duplication and inefficiency. The commenter argued that EPA cannot "segment" its analysis in order to completely avoid RFA requirements (AAMA, IV-D-2243).

Response: See sections VII.B and IV.A of the preamble to the final rules. As noted therein, the Clean Air Act requires EPA to set a NAAQS and calls on States to develop and submit SIPs within a specified period of time after EPA issues the standard. Any "segmentation" that occurs thus results from the structure and requirements of the Clean Air Act and not from any EPA action or design. More importantly, the purpose of the RFA is to motivate federal regulators to design federal regulations in a way that fits the scale of the entities that will be subject to those regulations. That purpose cannot be served in the case of the NAAQS, since NAAQS simply define a level of air quality to be achieved everywhere in the country primarily through State regulation. Further, the RFA does not require or authorize EPA to disapprove a State's implementation plan because of the State's choice of sources to regulate. Fundamentally, the congressionally-designed mixture of Federal and State responsibilities for achieving clean air makes the RFA inapplicable to either setting or implementing the NAAQS, except to the extent EPA promulgates federal regulations establishing control requirements that will apply to small entities (e.g., reformulated gasoline standards).

(4) *Comment*: A number of commenters argued that EPA's claim that it cannot perform an RFA analysis is baseless and cited a variety of figures from EPA's RIA suggesting economic

disruption or differential impact on small businesses (NAM, IV-D-2274; API IV-D-2233; UARG, IV-D-2253; NMA, IV-D-2247).

Response: See sections VII.B and IV.A of the preamble to the final rules. As explained therein, EPA has attempted in the RIA to provide some insight into the potential impact on small entities of NAAQS implementation. In light of States' role in implementing the NAAQS, however, the RIA can assess only hypothetical State control strategies. As such, the RIA cannot and does not take the place of an RFA analysis, which is supposed to identify the types of small entities that will be subject to the federal rule being promulgated and ways of tailoring the rule to size of the small entities being regulated. The RIA's small entity analysis, by necessity, depends on hypothetical State control strategies that may not occur and that EPA is not in a position to control.

(5) *Comment:* Some commenters argued that EPA failed to identify less burdensome alternatives, including setting a less stringent standard for O_3, due to a lack of a "bright line" and staggering the timing of the O_3 and PM standards (ATA, IV-D-2245).

Response: See sections VII.B and IV.A of the preamble to the final rules. Section 606 of the RFA expressly provides that the requirements for initial and final regulatory flexibility analyses, including the requirement to identify and consider less burdensome alternatives, "do not alter in any manner standards otherwise applicable by law to agency action." As explained previously, the CAA provisions governing the NAAQS do not allow EPA to set a less stringent NAAQS than protection of public health with an adequate margin of safety requires. The fact that there is not a bright line in the health effects caused by O_3 does not mean that EPA may set the NAAQS so that small entities will less likely be affected by its implementation. In setting the NAAQS, the choice before EPA is still to be made based on considerations of public health protection alone. Moreover, that choice entails not only the stringency of the standard but its timing, since the standard cannot serve its purpose of beginning the process of achieving healthy air until it is promulgated. Thus, it is not a permissible alternative under the CAA or the RFA for EPA to stagger the timing of the O_3 and PM standards, in the face of scientific evidence indicating that a revision is appropriate in the judgment of the Administrator.

3. Unfunded Mandates Reform Act

This section addresses comments that EPA failed to comply with the requirements of the Unfunded Mandates Reform Act (UMRA).

(1) *Comment*: Commenters asserted that EPA erred because it failed to comply with the requirements of UMRA. EPA is obligated to prepare a section 202 written statement, to conduct outreach efforts with small governments pursuant to a small government plan under section 203, and to solicit and evaluate input from State, local, and tribal officials under section

204. Finally, EPA's present failure to comply with UMRA is inconsistent with the SO_2 and NO_2 NAAQS decisions in which EPA did not disclaim application of UMRA (NAM, IV-D-2274; ATA, IV-D-2245; AAMA, IV-D-2243; API, IV-D-2233; State of N.C., IV-D-7003).

Response: See section VII.D and section IV.A of the preamble to the final rule. See also the summary and response to key issues raised at outreach meetings with State and local officials .

IV. MISPLACED COMMENTS

A. Comments on implementation-related issues

1. **Attainability of standards** (e.g., transport issues, OTAG)

This section addresses comments included in section III.A and elsewhere in the Summary of Comments which raise issues concerning attainability of the ambient O_3 standard. These issues were raised by numerous industry associations and others.

(1) *Comment*: One commenter maintained a revised standard would not be requisite to protect public health if it could not be attained (UARG, IV-D-2253).

Response: As discussed in section IV.A of the preamble to the final rule, the costs and technological feasibility of attaining ambient standards are not to be considered in setting them.

(2) *Comment*: The issue of regional air pollution transport must be addressed if the proposed standard is to be attained (NESCAUM, IV-D-2169; GM, IV-D-2694).

Response: The issue of air pollution transport is an implementation issue that is being addressed as part of the process of developing new implementation programs and control strategies. See also response to (1) above.

(3) *Comment:* The proposed form of the standard will not respond to emissions reductions in the same manner that the present 1-hour standard does, more emissions reductions will be required to reduce ambient levels to the lower concentrations - that is non peak concentrations will make up the 8-hour average. EPA's Regulatory Impact Analysis (RIA) documents show that there are areas that could not find the emissions reductions necessary to achieve the proposed standard. The present control strategies "shave peaks," but will do little to reduce the lower values which are still above the standard. Using AIRS and NDDN data (1993-1995) for all sites in the U.S., Lefohn (private communication) identified 169 areas that would violate the 81CB3 standard. He found that 63% of violating areas experience design value sites where 4 or more of the 8 hours, making up the 3rd highest 8-hr. daily maximum exceedance of 81 ppb for a specific year, are less than 90 ppb. Attainment of an 80 ppb standard would require that

those values between 81-90 ppb be reduced, which may be difficult given that regional upwind O_3 levels are close to 80 ppb. The present approach to control strategy, focusing on 1-hr concentrations above 100 ppb, does not appear to have the same effect on these lower concentrations, and might not be better at reducing lower concentrations

Response: The preamble to the final rule presents the statutory requirements of the Clean Air Act for establishing ambient air quality standards and the Administrator's rationale for revising the O_3 NAAQS. Implementation issues are not a factor in establishing or revising the NAAQS. However, as discussed below, EPA believes the degree of the O_3 attainability problem is overstated in the comments.

The commenter notes ambient measurements suggesting that the 0.08 ppm level in the new NAAQS is not far above baseline concentrations in clean areas, which can be as high as .06 ppm. Results from a modeling study performed in the Chicago area are also cited to illustrate the difficulty in meeting a NAAQS with a specified O_3 concentration of 0.08 ppm. While we agree that .08 ppm is closer to natural background than .12 ppm, according to the most recent Criteria Document an average 7-hour background concentration of O_3 is in the range of 25-45 ppb (p.3-6). The document goes on to note that only a portion of this background O_3 is of natural origin. Thus, 8-hour O_3 concentrations as high as .06 ppm likely reflect some impact from regional transport of O_3 produced in part from anthropogenic sources. The Chicago analysis which is cited reflects only how difficult it would be to meet an 8-hour NAAQS of .08 ppm in the absence of control measures to reduce regional transport coming into the Chicago area. In addition, the study fails to consider the effect of having a NAAQS which allows as many as 4 exceedances of .08 ppm at each monitoring site. Thus, it is likely that the study overstates the difficulty in meeting the NAAQS.

The comment that 169 "areas" will fail to meet the proposed 8-hour standard was based on an assumption that designations would be made using the same geographic coverage as the 1991 designations for the 1-hour standard and was based on data from 1993-1995. Moreover, it was based on the assumption that no regional reductions in emissions would be achieved in order to reduce border conditions caused by upwind emissions. EPA has not yet determined how area boundaries should be drawn for purposes of the revised O_3 standard. In addition, designations will be based on data from 1996-1998 or 1997-1999. Since areas are implementing new controls with each passing year, it is logical to assume that data from 1993-1995 would likely indicate more areas not attaining the revised standard than would data from a later time period. Therefore, these conclusions are premature and speculative at best. More importantly, EPA believes that a regional NOX reduction strategy will be a critical component of any strategy to attain the revised standard.

2. Implementation Issues

A number of commenters submitted comments to Docket number A-95-58 regarding implementation issues that are not relevant to the O_3 NAAQS review. Therefore, they are not being responded to in this document.

B. Comments on Regulatory Impact Analyses

This section addresses comments concerning the adequacy of the Regulatory Impact Analysis (RIA).

(1) *Comment*: A number of commenters asserted that the draft RIA was inadequate because it assessed the cost of only partial attainment of the alternative standards analyzed. The RIA was also faulty because it failed to analyze the proposed primary and secondary O_3 standards. Further, the analysis was incomplete because it failed to analyze the full range of control measures likely to be imposed on the transport industry, did not assess indirect impacts (e.g., increased fuel costs), and did not assess the cost of administrative burdens (ATA, IV-D-2245; NLSG, IV-D-1503; AAMA, IV-D-2243).

Response: Because the costs of implementation cannot be considered in setting or revising ambient air quality standards (see section IV.A of the preamble to the final rule), the RIA was not considered in EPA's decision on the standards. For the same reason, comments on the RIA were not considered in the decision. Comments on the draft RIA were considered, as appropriate, in developing the final RIA.

REFERENCES

Adams, W.C.; Shaffrath, J.D.; Ollison, W. (1995) The relationship of pulmonary ventilation and heart rate in legwork alone, armwork alone, and in combined arm and legwork. Paper no. 95-WA84A.04, presented at the 88th Annual Meeting of the Air & Waste Management Association, Pittsburgh, PA.

Aneja, V. P.; Yoder, G. T.; Arya, S. P. (1992) Ozone in the urban southeastern United States. *Environ. Pollut.* 75: 39-44.

Avol, E. L.; Linn, W. S.; Venet, T. G.; Shamoo, D. A.; Hackney, J. D. (1984) Comparative respiratory effects of ozone and ambient oxidant pollution exposure during heavy exercise. *JAPCA* 34: 804-809.

Burnett, R. T., et al. (1992) The relationship between hospital admissions and ambient air pollution in Ontario, Canada: a preliminary report.

Burnett, R.T.; Dales, R.E.; Raizenne, M.E.; Krewski, D.; Summers, P.W.; Roberts, G.R.; Raad-Young, M.; Dann, T.; Brook, J. (1994) Effects of low ambient levels of ozone and sulfates on the frequency of respiratory admissions to Ontario hospitals. *Environ Res*. 65:172-194.

Christensen, E. R.; Nyholm, N. (1984) Ecotoxicological assays with algae: Weibull dose-response curves. *Environ. Sci. Techno*. 18: 713-718.

Cody, R. P.; Weisel, C. P.; Birnbaum, G.; Lioy, P. J. (1992) The effect of ozone associated with summertime photochemical smog on the frequency of asthma visits to hospital emergency departments. *Environ. Res*. 58: 184-194.

Contant, C.F.; Stock, T.H.; Buffler, P.A.; Holguin, A.H.; Gehan, B.M.; Kotchmar, D.J. (1987) The estimation of personal exposures to air pollutants for a community-based study of health effects in asthmatics - exposure model. *JAPCA* 37: 587-594.

Delfino RJ, Murphy-Moulton AM, Burnett RT, Brook JR, Becklake MR. (1997) Effects of air pollution on emergency room visits for respiratory illnesses in Montreal, Quebec. *Am J Respir Crit Care Med* 155:568-576.

Delfino RJ, Becklake MR, Hanley JA. (1994) The relationship of urgent hospital admissions for respiratory illnesses to photochemical air pollution levels in Montreal. *Environ Res*. 67:1-19.

Dockery, D.W.; Schwartz, J.; Spengler, J.D. (1992) Air pollution and daily mortality: associations with particulates and acid aerosols. *Environ. Res.* 59:362-373.

Gross, K. B.; White, H. J.; Sargent, N. E. (1991) The effect of ozone inhalation on metabolic functioning of vascular endothelium and on ventilatory function. *Toxicol. Appl. Pharmacol.* 109: 336-351.

Hain, F. P.; Arthur, F. H. (1985) The role of atmospheric deposition in the latitudinal variation of Fraser fir mortality caused by the balsam woolly adelgid, Adelges piceae (Ratz.) (Hemipt., Adelgidae): a hypothesis. Z. Angew. *Entomol*. 99: 145-152.

Heck, W.W.; Cowling, E.B. (1997) The need for a long term cumulative secondary ozone standard - an ecological perspective. *EM.* 23-32.

Heck, W.W.; Taylor, O. C.; Adams, R.; Bingham, G.; Miller, J.; Preston, E.; Weinstein, L. (1982) Assessment of crop loss from ozone. *JAPCA* 32: 353-361.

Higgins, I. T. T.; D'Arcy, J. B.; Gibbons, D. I.; Avol, E. L.; Gross, K. B. (1990) Effect of exposures to ambient ozone on ventilatory lung function in children. Am. Rev. Respir. Dis. 141: 1136-1146.

Hogsett, W. E.; Herstrom, A. A.; Laurence, J. A.; Lee, E. H.; Weber, J. E.; Tingey, D.T. (1995) Risk characterization of tropospheric ozone to forests. In Lee, S. D.; Schneider, T., eds. Comparative risk analysis and priority setting for air pollution issues: proceedings of the 4th U.S.-Dutch international symposium; June 1993; Keystone, CO. Pittsburg, PA: Air & Waste Management Association. AWMA publication no. VIP-43. 119-145.

Hornbeck, J. W.; Smith, R. B.; Federer, C. A. (1988) Growth trends in 10 species of trees in New England, 1950-1980. Can. J. For. Res. 18: 1337-1340.

Horst, R.; Duff, M. (1995) Concentration data transformation and the quadratic rollback methodology (round 2, revised). Unpublished memorandum to Rosalina Rodriguez, U.S. EPA, June 8.

Horst, R. (1995) Transmission of full set of data for RMF analysis. Unpublished memorandum to Rosalina Rodriguez, U.S. EPA, November 6.

Horstman, D.H.; Ball, B.A.; Folinsbee, L.J.; Brown, J.; Gerrity, T. (1995) Comparison of pulmonary responses of asthmatic and nonasthmatic subjects performing light exercise while exposed to a low level of ozone. *Toxicol. Ind. Health*:.

Horvath, S. M.; Bedi, J. F.; Drechsler-Parks, D. M.; Williams, R. E. (1991) Alterations in pulmonary function parameters during exposure to 80 ppb ozone for 6.6 hours in healthy middle aged individuals. In: Berglund, R. L.; Lawson, D. R.; McKee, D. J., eds. Tropospheric ozone and the environment: papers from an international conference; March 1990; Los Angeles, CA. Pittsburgh, PA: Air & Waste Management Association; pp. 59-70. (A&WMA transaction series no. TR-19).

Johnson, T.; McCoy, M.; Capel, J.; Wijnberg, L.; Ollison, W. (1993) A comparison of ten time/activity databases: effects of geographical location, temperature, demographic group, and diary recall method. *In: Tropospheric Ozone: Nonattainment and Design Value Issues - Proceedings of an International Specialty Conference*, Air & Waste Management Association; Pittsburgh, MA.

Johnson, T. (1995) Letter Report: Evaluation of air quality adjustment procedure for pNEM/O_3. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, August 4.

Johnson, T.; Weaver, M.; Mozier, J.; Wisbith, A.; Meiners, G.; Ollison, W. (1995) Ozone exposures within motor vehicles -- results of a field study in Cincinnati, Ohio. Paper no. 95-WA84A.02, presented at the 89th Annual Meeting of the Air & Waste Management Association, Air & Waste Management Association; Pittsburgh, PA.

Johnson, T; Capel, J.; Mozier, J.; McCoy, M. (1996a) Estimation of ozone exposures experienced by outdoor children in nine urban areas using a probabilistic version of NEM. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, April.

Johnson, T.; Capel, J.; McCoy, M.; Mozier, J. (1996b) Estimation of ozone exposures experienced by outdoor workers in nine urban areas using a probabilistic version of NEM. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, April.

Johnson, T.; Clark, K.; Anderson, K.; Geyh, A.; Ollison, W. (1996c) A pilot study of Los Angeles personal ozone exposures during scripted behaviors. In: *Measurement of Toxic and Related Air Pollutants*, VIP-64, Air & Waste Management Association; Pittsburgh, PA, pp. 358-365.

Johnson, T.; Capel, J.; McCoy, M. (1996d) Estimation of ozone exposures experienced by urban residents using a probabilistic version of NEM and 1990 population data. Prepared by IT/Air Quality Services for U.S. EPA, OAQPS; Research Triangle Park, NC, April.

Johnson, T. And M. Weaver (1996) Comparison of temporal and spatial patterns in ambient ozone concentrations estimated by pNEM/O3 and the regional oxidant model (ROM). Prepared by TRJ Environmental, Inc. and IT Air Quality Services, Inc. for the U.S. EPA, OAQPS; Research Triangle Park, NC, June 30.

Johnson, T.; Mozier, J.; and Capel, J. (1997) Supplement to "Estimation of ozone exposures experienced by outdoor children in nine urban areas using a probabilistic version of NEM." Prepared by TRJ Environmental, Inc. and IT Air Quality Services, Inc. for the U.S. EPA, OAQPS; Research Triangle Park, NC, January.

Johnson, T. (1997a) Sensitivity of exposure estimates to air quality adjustment procedure. Prepared by TRJ Environmental, Inc. and IT Air Quality Services, Inc. for the U.S. EPA, OAQPS; Research Triangle Park, NC, June.

Johnson, T. (1997b) Sensitivity testing of pNEM/O3 exposure estimates to changes in the model algorithms. Prepared by TRJ Environmental, Inc. for the American Petroleum Institute, API Publication Number FR2; Washington, D.C., March.

Kinney PI, Thurston GD, Raizenne M. (1996) The effects of ambient ozone on lung function in children: a reanalysis of six summer camp studies. *Environ Health Perspect*. 104:170-174.

Kinney, P. L., Ozkaynak, H. (1991) Associations of daily mortality and air pollution in Los Angeles County. *Environ. Res.* 54:99-120.

Kinney, P.L.; Ito, K.; Thurston, G.D. (1995) A sensitivity analysis of mortality/PM10 associations in Los Angeles. *Inhal Toxicol.* 7:59-69.

Kulle, T. J.; Sauder, L. R.; Hebel, J. R.; Chatham, M. D. (1985) Ozone response relationships in healthy nonsmokers. *Am. Rev. Respir. Dis*. 132: 36-41.

Lee, E. H.; Hogsett, W. E. (1996) Methodology for calculating inputs for ozone secondary standard benefits analysis: part II. Internal memorandum prepared for Eric Ginsburg and Rosalina

Rodriguez, OAQPS, U.S. EPA. March 18, 1996.

Lesser, V. M.; Rawlings, J. O.; Spruill, S. E.; Somerville, M. C. (1990) Ozone effects on agricultural crops: statistical methodologies and estimated dose-response relationships. *Crop Science* 30: 148-155.

Leston, A. and Ollison, W.M. (1993) Estimated accuracy of ozone design values: are they compromised by method interferences?. In *Tropospheric Ozone: Nonattainment and Design Value Issues*, TR-23, Air & Waste Management Association; Pittsburgh, PA, pp. 451-560.

Linn, W. S.; Avol, E. L.; Shamoo, D. A.; Spier, C. E.; Valencia, L. M.; Venet, T. G.; Fischer, D. A.; Hackney, J. D. (1986) A dose-response study of healthy, heavily exercising men exposed to ozone at concentrations near the ambient air quality standard. *Toxicol. Ind. Health* 2: 99-112.

Linn, W. S.; Shamoo, D. A.; Anderson, K. R.; Peng, R.-C.; Avol, E. L.; Hackney, J. D. (1994) Effects of prolonged, repeated exposure to ozone, sulfuric acid, and their combination in healthy and asthmatic volunteers. *Am. J. Respir. Crit. Care Med*. 150: 431-440.

Lipfert, F.W.; Hammerstrom, T. (1992) Temporal patterns in air pollution and hospital admissions. *Environ. Res.* 59: 374-399.

McCurdy, T. R. (1993) Testing pNEM/O3 runs to determine if a set of 10 Runs is "representative." EPA Memorandum; Research Triangle Park, NC, April 19.

McCurdy, T. R. (1994) Time spent by children in selected generalized micro environments. EPA Memorandum; Research Triangle Park, NC, June 15.

McCurdy, T. R. (1997) Response to comments on the ozone proposal related to exercise in children. EPA Memorandum; Research Triangle Park, NC, June.

McDonnell, W.F.; Horstman, D.H.; Hazucha, M.J.; Seal, E., Jr.; Haak, E.D.; Salaam, S.A.; House, D.E. (1983) Pulmonary effects of ozone exposure during exercise: dose-response characteristics. *J. Appl. Physiol.: Respir. Environ. Exercise Physiol.* 54: 1345-1352.

McDonnell, W.F. (1997) Ozone-exposure response relationships. Memorandum to Harvey Richmond, U.S. EPA, NHEERL; Research Triangle Park, NC, June 12.

McKittrick, T.; Adams, W. C. (1995) Pulmonary function response to equivalent doses of ozone consequent to intermittent and continuous exercise. *Arch. Environ. Health.* 50: 153-158.

Molfino, N. A.; Wright, S. C.; Katz, I.; Tarlo, S.; Silverman, F.; McClean, P. A.; Szalai, J. P.; Raizenne, M.; Slutsky, A. S.; Zamel, N. (1991) Effect of low concentrations of ozone on inhaled allergen responses in asthmatic subjects. *Lancet* 338(8761): 199-203.

Neufeld, H. S.; Renfro, J. R.; Hacker, W. D.; Silsbee, D. (1992) Ozone in Great Smoky Mountains National Park: dynamics and effects on plants. In: Tropos pheric ozone and the environment II - effects, modeling and control: papers from an international specialty conference; November; Atlanta, GA, Pittsburg, PA: Air & Waste Management Association; Air & Waste Management Association transactions series: TR-20:

594-617.

Ozkaynak H, Spengler JD, O'Neill M, Xue J, Zhou H, Gilbert K, Ramstrom S. (1996) Ambient ozone exposure and emergency hospital admissions and emergency room visits for respiratory problems in thirteen U.S. cities. Report to the American Lung Association. Excerpts submitted with comments on the ozone NAAQS proposal by Donald Croysdale, Private Citizen, Docket Number A-95-58, IV-D-8890 (February 15, 1997).

Pennypacker, S. P.; Knoble, H. D.; Antle, C. E.; Madden, L. V. (1980) A flexible model for studying plant disease progression. *Phytopathology* 70: 232-235.

Peterson, D. L.; Arbaugh, M. J. (1988) An evaluation of the effects of ozone injury on radial growth of ponderosa pine (*Pinus ponderosa*) in the southern Sierra Nevada. *JAPCA* 38: 921-927.

Peterson, D. L.; Arbaugh, M. J. (1992) Mixed conifer forests of the Sierra Nevada. In: Olson, R. K.; Binkley, D.; Bohm, M., eds. The response of western forest to air pollution. New York, NY: Springer-Verlag. 433-459. (Billings, W.D.; Golley, F.; Lange, O. L.; Olson, J. S.; Remmert, H., eds. Ecological studies: analysis and synthesis: v. 97).

Peterson, D.L.; Arbaugh, M. J.; Wakefield, V. A.; Miller, P. R. (1987) Evidence of growth reduction in ozone-injured Jeffrey pine (*Pinus jeffreyi* Grev. and Balf.) in Sequoia and Kings Canyon National Parks. *JAPCA* 37: 906-912.

Peterson, D.L.; Arbaugh, M. J.; Robinson, L. J. (1991) Regional growth changes in ozone-stressed ponderosa pine (*Pinus ponderosa*) in the Sierra Nevada, California, USA. Holocene 1: 50-61.

Pönkä, A. (1991) Asthma and low level air pollution in Helsinki. *Arch. Environ. Health* 46: 262-270.

Pye, J. M. (1988) Impact of ozone on the growth and yield of trees: a review. *J. Environ. Qual.* 17: 347-360.

Raizenne, M.; Stern, B.; Burnett, R.; Spengler, J. (1987) Acute respiratory function and transported air pollutants: observational studies. Presented at: 80th annual meeting of the Air Pollution Control Association; June; New York, NY. Pittsburgh, PA: Air Pollution Control Association; paper no. 87-32.6.

Rawlings, J.O.; Cure, W.W. (1985) The Weibull function as a dose-response model to describe ozone effects on crop yields. *Crop Science* 25: 807-814.

Rawlings, J. O.; Lesser, V.M.; Dassel, K. A. (1987) Statistical approaches to assessing crop losses in assessment of crop loss from air pollutants. In: W. W. Heck; Taylor, O. C.; Tingey, D. T., eds. Assessment of crop loss from atmospheric pollutants: procee dings of an international conference; October, 1987; Raleigh, NC. New York, NY: Elsevier Science. 389-416.

Richmond, H. (1997) Supplemental ozone exposure and health risk analyses. Memorandum to Karen Martin, U.S. EPA, OAQPS; Research Triangle Park, NC, February 11.

Rodecap, K.; Lee, H.; Herstrom, A.; Broich, S. (1995) Methodology for calculating inputs for ozone secondary standard benefits analysis. Internal memorandum to Bill Hogsett, U.S. EPA, NHEERL-WED. June 29, 1995. (See Lee, E.H.; Hogsett, W.E. (1996) which includes Rodecap, et al. (1995) as an attachment.)

Romieu I, Meneses F, Ruiz S, Sienra JJ, Huerta J, White MC, Etzel RA. (1996) Effects of air pollution on the respiratory health of asthmatic children living in Mexico City. *Am J Respir Crit Care Med*. 154:300-307

Schwartz, J. (1994a) Air pollution and hospital admissions for the elderly in Birmingham, Alabama. *Am. J. Epidemiol.* 139: 589-598.

Schwartz, J. (1994b) Air pollution and hospital admissions for the elderly in Detroit, MI. *Am. J. Respir. Crit. Care Med.* 150: 648-655.

Seal, E., Jr.; McDonnell, W. F.; House, D. E.; Salaam, S. A.; Dewitt, P. J.; Butler, S. O.; Green, J.; Raggio, L. (1993) The pulmonary response of white and black adults to six concentrations of ozone. *Am. Rev. Respir. Dis.* 147: 804-810.

Spektor, D. M.; Lippmann, M. (1991) Health effects of ambient ozone on healthy children at a summer camp. In: Berglund, R. L.; Lawson, D. R.; McKee, D. J., eds. Tropospheric ozone and the environment: papers from an international conference; March 1990; Los Angeles, CA. Pittsburgh, PA: Air & Waste Management Association; pp. 83-89. (A&WMA transaction series no. TR-19).

Spektor, D.M.; Thurston, G.D.; Bock, N.; Speizer, F.E.; Hayes, C. (1991) Effects of single and multi-day ozone exposure respiratory function in active, normal children. *Environ. Res*. 55:107-122.

Spektor, D. M.; Lippmann, M.; Lioy, P. J.; Thurston, G. D.; Citak, K.; James, D. J.; Bock, N.; Speizer, F. E.; Hayes, C. (1988a) Effects of ambient ozone on respiratory function in active, normal children. *Am. Rev. Respir. Dis.* 137: 313-320.

Spektor, D. M.; Lippmann, M.; Thurston, G. D.; Lioy, P. J.; Stecko, J.; O'Connor, G.; Garshick, E.; Speizer, F. E.; Hayes, C. (1988b) Effects of ambient ozone on respiratory function in healthy adults exercising outdoors. *Am. Rev. Respir. Dis.* 138: 821-828.

Stieb, D.M.; Burnett, R.T.; Beveridge, R.C.; Brook, J.R. (1996) Association between ozone and asthma emergency department visits in Saint John, New Brunswick, Canada. *Environ Health Perspect.* 104:1354-1360.

Thurston, G.D.; Ito, K.; Kinney, P.L.; Lippmann, M. (1992) A multi-year study of air pollution and respiratory hospital admissions in three New York State metropolitan areas: results for 1988 and 1989 summers. *J. Exposure Anal. Environ. Epidemiol.* 2:429-450.

Thurston, G.D.; Ito, K.; Hayes, C.G.; Bates, D.V.; Lippmann, M. (1994) Respiratory hospital admissions and summertime haze air pollution in Toronto, Ontario: consideration of the role of acid aerosols. *Environ. Res.* 65: 271-290.

Thurston GD, Lippmann M, Scott MB, Fine JM. (1997) Summertime haze air pollution and children with asthma. *Am J Respir Crit Care Med.* 155:654-660.

Trotter, S.M.; Pendergrass, W.R.; Davis, W.T.; Miller, T.L. (1996) Measurement of vertical distribution of ozone in eastern Tennessee. Paper no. 96-WA63.06, presented at the 89th Annual Meeting of the Air & Waste Management Association, Air & Waste Management Association; Pittsburgh, PA.

U.S. Environmental Protection Agency (1986) Air quality criteria for ozone and other photochemical oxidants. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; EPA report nos. EPA-600/8-84-020aF-eF. 5v. Available from: NTIS, Springfield, VA; PB87-142949.

U.S. Environmental Protection Agency (1996a) Air quality criteria for ozone and related photochemical oxidants. Research Triangle Park, NC: Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office; EPA report nos. EPA/600/AP-93/004a-c.

U.S. Environmental Protection Agency (1996b) Review of the national ambient air quality standards for ozone: assessment of scientific and technical information. OAQPS staff paper. Research Triangle Park, NC: Office of Air Quality Planning and Standards; EPA report no. EPA-452/R-96-007. Available from: NTIS, Springfield, VA; PB96-203435.

Weisel, C. P.; Cody, R. P.; Lioy, P. J. (1995) Relationship between summertime ambient ozone levels and emergency department visits for asthma in central New Jersey. *Environ. Health Perspect.* 103 (suppl. 2):97-102.

White, M. C.; Etzel, R. A.; Wilcox, W. D.; Lloyd, C. (1994) Exacerbations of childhood asthma and ozone pollution in Atlanta. *Environ. Res.* 65: 56-68.

Whitfield, R.G.; Biller, W.F.; Jusko, M.J.; Keisler, J.M. (1996) A probabilistic assessment of health risks associated with short-term exposure to tropospheric ozone. Report prepared for U.S. EPA, OAQPS. Argonne National Laboratory; Argonne, IL, June.

Whitfield, R. (1997a) A probabilistic assessment of health risks associated with short-term exposure to tropospheric ozone: a supplement. Letter Report prepared for U.S. EPA, OAQPS. Argonne National Laboratory; Argonne, IL, January .

Whitfield, R. (1997b) Sensitivity of risk estimates to air quality adjustment procedure. Letter Report prepared for U.S. EPA, OAQPS by Argonne National Laboratory. Argonne National Laboratory, Argonne, IL, June 30.

Wisbith, A.; Meiners, G.; Johnson, T.; Ollison, W. (1996) Effect of monitor probe height on measured ozone concentration. Paper no. 96RA111.02 presented at the 89th Annual Meeting of the Air & Waste Management Association, Nashville, TN, June.

Wolff, G. T. (1995a) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator. Dated November 28, 1995. EPA-SAB-CASAC-LTR-96-001.

Wolff, G. T. (1995b) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated November 30, 1995. EPA-SAB-CASAC-LTR-96-002.

Wolff, G. T. (1996) Letter from Chairman of Clean Air Scientific Advisory Committee to the EPA Administrator, dated April 4, 1996. EPA-SAB-CASAC-LTR-96-006.

Xu, X.; Gao, J.; Dockery, D.W.; Chen, Y. (1994) Air pollution and daily mortality in residential areas of Beijing, China. *Arch Environ Health.* 49:216-222.

APPENDICES