Compilation of Individual Panel Member Comments on EPA's completed *Risk and Exposure Assessment (REA) to Support the Review of the NO_2 Primary National Ambient Air Quality Standard*

This enclosure contains final written comments of individual members of the Clean Air Scientific Advisory Committee (CASAC) Oxides of Nitrogen Primary National Ambient Air Quality Standards (NAAQS) Review Panel. The comments are included here to provide both a full perspective and a range of individual views expressed by panel members during the review process. These comments do not represent the views of the CASAC or the CASAC Panel.

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Comments on Draft NO2 REA Document
(EPA-452/R-08-008a, November 2008)
Ed Avol

(Samet-proposed focus of CASAC Dec 5 teleconference)
Chapter 10 of the REA and the adequacy of the NOx ISA and NO2 REA for asking the question below:

What scientific evidence and/or scientific insights have been developed since the last NOx review to indicate if the current public-health based based NAAQS need to be revised or if alternative levels, indicators, statistical forms, or averaging times of these standards are needed to protect public health with an adequate margin of safety ?

Chapter 10 should be a NO2 document "grand unification" of sorts, in which the salient conclusions and judgments of the several hundred pages of thoughtful presentation, appendices, tables, and analyses are presented in an accessible and succinct presentation. In general, this has been achieved, and staff should be commended for the accomplishment. The chapter is carefully organized, framing the discussion in the context of indicator, averaging time, form, and level of the standard. Clarity and logic of argument is provided across most of the four main categories of discussion.

The scientific insights and research evidence that have become available since the 1996 NOx review have been substantial. Several informative epidemiologic, and controlled-human-exposure studies, as well as a wealth of ambient monitoring exposure information, has become available in the decade since the previous review. The staff has carefully reviewed this data and made a rational and substantive case for the Administrator to consider revision of the current standard to protect public health.

Chapter Section 10.4 ("Potential Alternative Standards") is generally well-constructed, logically described, and clearly presented. The explanation for the choice of "Indicator" is clear, logical, and compelling. The presentation of "Averaging Time" considerations is informative and convincing. The discussion of "Form" of the standard helpfully provides several examples using several metropolitan areas and seems justified.

The recommendations of the chapter section concerning "Level" of the standard (Section 10.4.4), however, seemed inconsistent with the presented evidence. The staff's conclusion that the upper end of the range of a one-hour daily maximum standard reasonably supported by the evidence is 0.2ppm seems inconsistent with the prior conclusions that "…the scientific evidence provides strong support for a standard at or below 0.1ppm (100ppb)…" Where is the adequate margin of safety? Where is the acknowledgement and adjustment for sensitive sub-populations (such as more severe

asthmatics) who were under-represented in the scientific studies? It appears that uncertainty concerns, with respect to measurement errors, health, and monitoring outcomes have been used to move the discussion in only one direction (towards a less-protective level). This is arguably the wrong direction, if the stated goal is to protect the public's health.

The final concluding section of the document (Section 10.4.4.3) appropriately lays out the range of NO2 exposure levels, which based on the current available evidence, would be protective, but this makes the conclusions of the evidence-based considerations section (10.4.4.1) seem out-of-step with the collective view of the chapter.

Comments from Dr. Dale Hattis

Premeeting Comments for Discussion of the Draft Final REA for NO2

Dale Hattis, Clark University

I am happy to report that there have been substantial efforts to address the issues I raised in my previous comments on the probabilistic methodology for APEX exposure modeling and the critical on road/off road concentration adjustment factor. In particular

- EPA staff in the revised Chapter 8 have done some sensitivity analysis for their distributional assumptions related to the indoor removal rate distributions. While I am not completely happy with the analysis, I think it reasonably suffices to reduce concerns that there is some large hidden uncertainty that could materially alter the results of the exposure analysis.

- EPA have now reasonably fully documented their database of empirical observations of Cv/Cb (or "m") that led to their assumption of the empirical distributions on-road/off-road sources of emissions for modeling of the NO2 concentrations on and near roadways (Section A-8.2 beginning on A-111 of Appendix A). Based on this documentation I have been able to critically evaluate EPA's conclusion that no parametric distribution can be found that reasonably describes the available data. Briefly, I think this is incorrect. However, using the documentation provided, I have developed a relatively simple alternative distributional suggestion that could at least be used for sensitivity analysis in the calculations for the eventual ANPR. This analysis is given briefly below:

The reason why it is desirable to avoid simple empirical distributions in the kind of exposure/risk analysis being done in the REA is that empirical distributions are necessarily limited to the range of values that have been directly observed in the available data. When there are only 41 available data points there is reason to suspect that this could effectively cut off the high tail of the distribution of actual concentrations; and this is unfortunate because the high end tail of the on road and near road concentrations determines the estimates of the frequency with which high end concentration benchmarks are exceeded. This concern is magnified in the current case because the 41 observations used for the analysis already reflect three exclusions of extreme values (see p. A-113)—two from the "not-summer" category and one from the "summer" category.

Figure 1 shows probability plots of the logarithms of the Cv/Cb ratios in the database that EPA has assembled and classified into its "summer" vs "not-summer" categories.[*] It can

[*] In this type of plot, the straight line represents a hypothesis that the data are lognormally distributed, and the correspondence of the points to the line is a quick qualitative indicator of the correspondence of the data to the theoretical distribution. The intercept and slope are estimates of the mean and standard deviations of the log-transformed values, respectively. Lognormal distributions are expected when there are many factors

be seen that the datapoints—particularly those from the "summer" distribution—are not perfectly described by the straight lines representing the lognormal hypothesis—but there is not a radical systematic departure either. Subdividing the "summer" points in to those that are listed as "downwind" measurements vs those classified as "both upwind and downwind" (Figure 2) locates the departure from lognormality mostly in the second category.

The two distributions shown in figure 1 have relatively similar slopes (standard deviations of the log-transformed values). Therefore there is reason to suspect that a simple regression analysis could capture both distributions by deriving a simple multiplicative factor to relate the distributions for the two seasonal categories. The regression I derived for this purpose is:

Response:	log(m)
Summary of Fit	
RSquare	0.152
RSquare Adj	0.130
Root Mean Square Error	0.227
Mean of Response	-0.091
Observations (or Sum Wgts)	41

Parameter Estimates

Term	Antilog(Est)	Estimate	Std Error	t Ratio	Prob>|t|
Intercept	0.643	-0.192	0.052	-3.69	0.0007
Season2--Summer	1.539	0.187	0.071	2.64	0.012

It can be seen that the "summer" parameter is statistically significant at well under P<.05. To check on whether the regression with its root mean square error of .227 (analogous to the standard deviation of the data points about the regression line) can be used to describe the dispersion of the observations, I did a probability plot of the residuals** from the regression (Figure 3). It can be seen that the regression residuals are in fact well described as lognormal--having a mean very close to zero and a standard deviation within rounding error of the expected 0.227. Therefore I recommend that in place of its empirical distribution, EPA should substitute lognormal distributions for their "m" values with the following parameters:

	Gmean	GSD
Not Summer	0.643	1.685
Summer	0.989	1.685

This should be done at least for sensitivity analysis for the calculations in the final analysis for the ANPR.

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that cause differences among individual observations, and those factors tend to act multiplicatively on the measured parameter.

** Each "residual" is the regression model predicted-value minus the observed value for an individual data point.

Figure 1

Lognormal Plot of On-Road/Off-Road Ratios
Sorted Into the EPA Summer/Not-Summer Categories

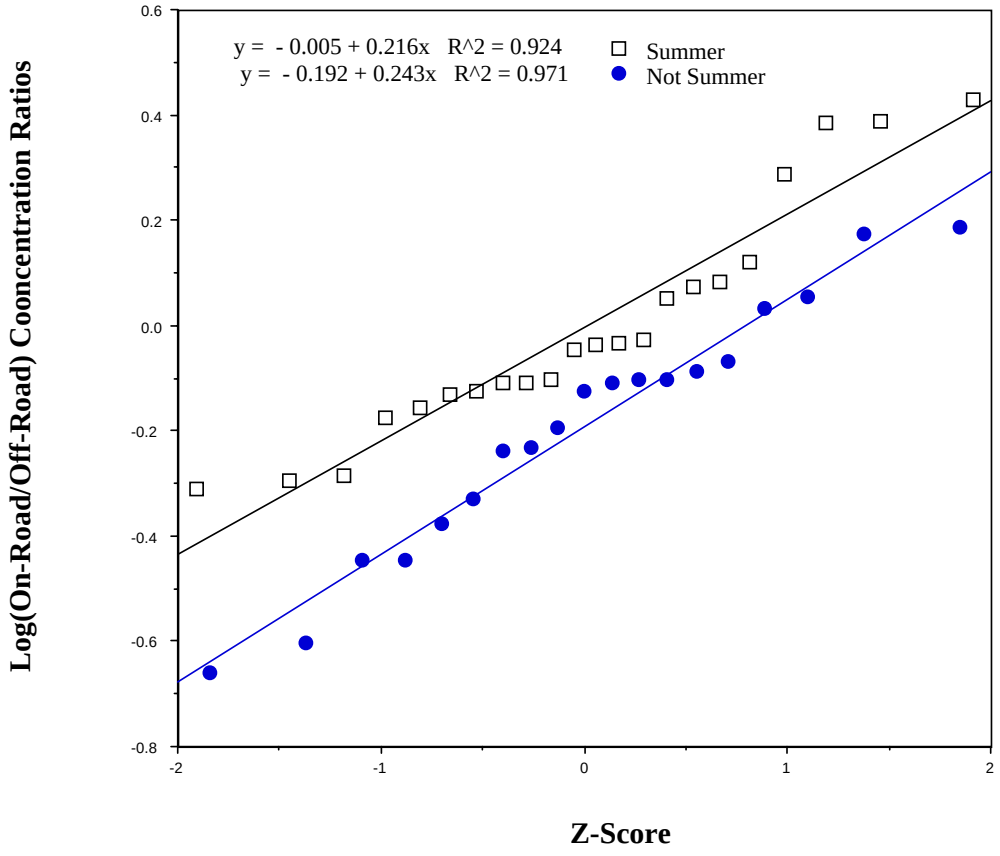
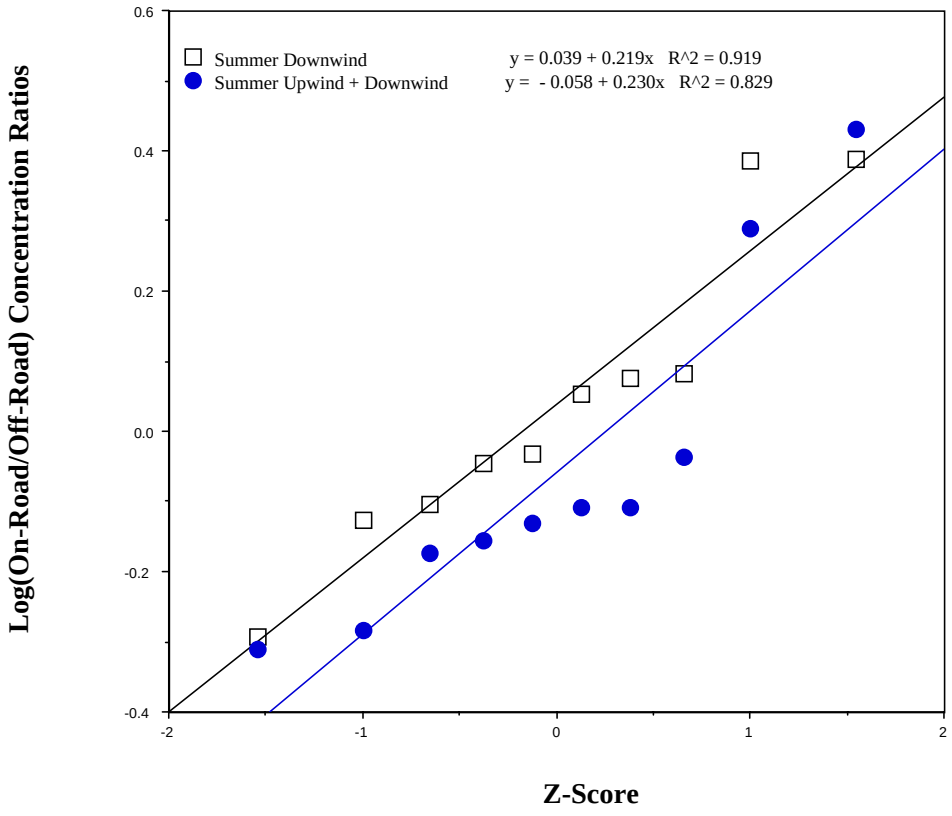
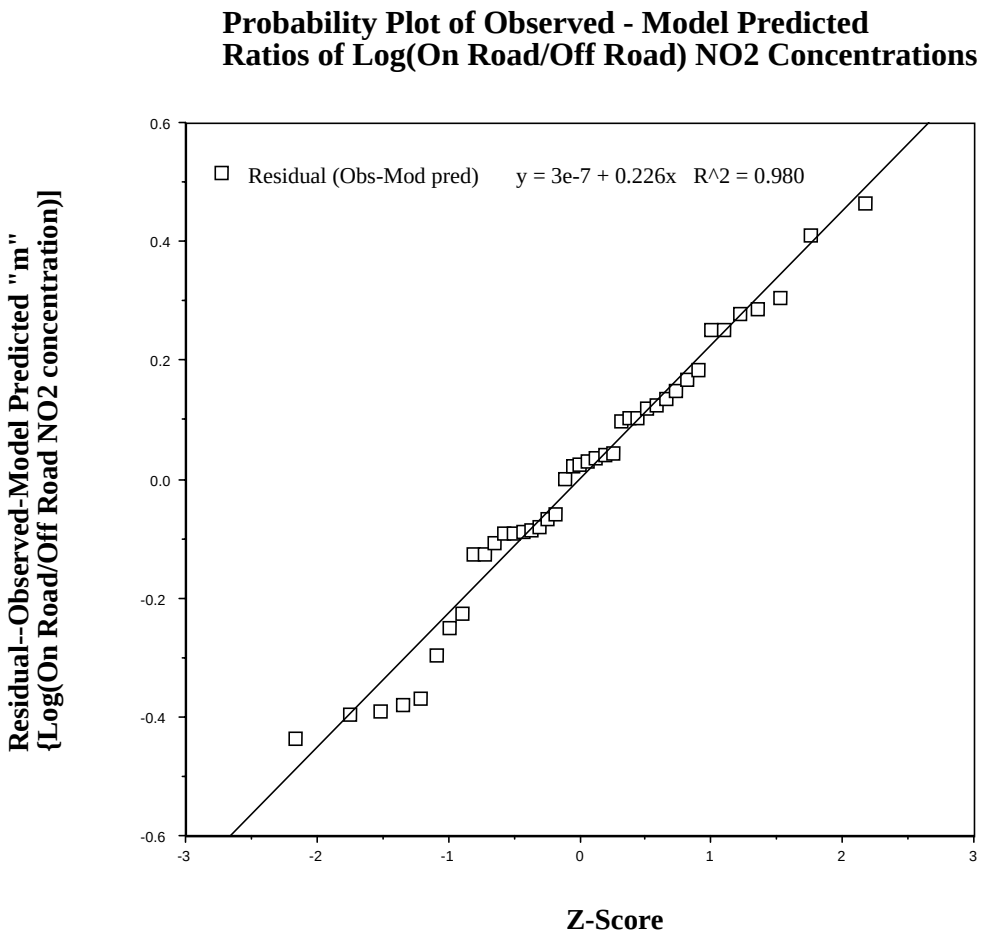


Figure 2

Distribution of Summer Log(On-Road/Off-Road) NO2 Concentration Ratios Subdivided by Those Classified as "Downwind" vs "Both Downwind and Upwind"




Probability Plot of Observed - Model Predicted
Ratios of Log(On Road/Off Road) NO2 Concentrations
Residual (Obs-Mod pred)
y = 3e-7 + 0.226x R^2 = 0.980
Residual--Observed-Model Predicted "m"
{Log(On Road/Off Road NO2 concentration)]
Z-Score
0.6
0.4
0.2
0.0
-0.2
-0.4
-0.6
-3
-2
-1
0
1
2
3

Comments from Dr. Rogene Henderson

Comments on final Risk and Exposure Assessment to Support the Review of the NO2 Primary National Ambient Air Quality Standard

I thought the document was well prepared and provided the information needed for rulemaking. I compliment the Agency on the clarity of their presentation.

My comments will focus on Chapter 10 and will be organized according to the indicator, form, averaging time and alternative levels for the standard and whether these elements of the current standard need to be changed to protect the public health with a margin of safety.

Indicator:

I agree with the reasoning given in Chapter 10 that the indicator should remain as NO_2.

Averaging time:

The current averaging time is based on earlier studies linking long-term exposure to low levels of NO2 to adverse respiratory effects. More recent studies indicate that there should be more concern for the short-term NO2 exposures. A review of the data in Table 10-3 indicates that a standard based on annual average NO2 concentrations would not likely be adequate to protect against the effects of short-term exposures. I agree with the analysis presented in Chapter 10 that indicates that the standard should be based on either a 24-hr or a 1-hr averaging time. Based on the data in Table 10-2, I agree that a 1-hr standard should protect against 24-hr NO2 concentrations and therefore agree with the staff conclusion to use a 1-hr averaging time for the standard.

Form:

I agree with the reasoning presented in Chapter 10 that a concentration-based form is better than a form based on expected exceedances. I agree that whether you use the 98th or the 99th percentile is dependent on the level one chooses.

Level:

I agree that the health endpoint of concern is increased airway responsiveness in asthmatics. I agree with the staff arguments given on page 303 that the lower end of the range should be 0.05 ppm. I do not agree with setting the upper end of the range at 0.2 ppm. I would prefer 0.1 ppm. My reasoning is based on the fact a meta-analysis of the controlled human exposure studies in mild asthmatics indicated a LOEL of 0.1 ppm NO2. No severe asthmatics were studied. The Clean Air Act stipulates that we should make our recommendations to protect public health with a margin of safety. Because the endpoint of interest is in asthmatics and because we need a margin of safety, I would not recommend an upper level of the range higher than 0.1 ppm.

Comments from Dr. Richard Schlesinger

Comments on REA, specifically Chapter 10:

Overall, this final draft presents in a clear manner the scientific bases for recommending the NOx standard.

The few specific comments are as follows:

P. 283. First bullet in second paragraph. The term "control" may not be the best word to use in this context. Perhaps the statement should read "negatively affect asthma treatment protocols."

P. 287. The last sentence in the first paragraph of section 10.3.2.2 notes that 1 hr levels above 0.2 pm are unlikely to occur in locations that meet the current annual standard. Levels at or above 0.2 ppm have been assocaited with adverse health outcomes. Thus, this line of thought seems to contradict the earlier statement in the last sentence on page 282 of section 10.3.2, which states that results of studies support a relationship between NO2 exposures and respiratory endpoints at ambient concentrations in areas that meet the current standard.

P. 309. Section 10.4.4.3 This section concludes that the standard level should be set between 50 and 100ppb. However, the prior discussion seems to indicate that if the current level of 53 ppb as annual average is maintained, that shorter term excursions would occur that may result in adverse health outcomes in some groups of the population. Furthermore, the last sentence implies that the REA is recommending a change from the current standard. Thus, this reviewer is somewhat confused as to what is being recommended here.

Comments from Dr. Frank Speizer

Pre-Conference Call Review Comments on Chapter 10 of REA- Primary NO2 document. Dated November 2008

Submitted by: Frank Speizer

Date December 2, 2008

I have focused my comments on Chapter 10 with specific considerations of the questions posed in the email dated Nov. 21, 2008.

General Comment:

Generally I found the Chapter one of the best I have read over many years. It follows a logical format, outlines the issues clearly and presents the Staff position well. (I will take issue with one conclusion, and have indicated that below).

Specific Comments:

Page275, para 2, line 6 and spilling over to the next page. There is a degree of emphasis here on "uncertainty" vs. "margin of safety". The issue is clarified on page 276, but starting as it does it suggests a bias that comes though later in the Chapter, where the issue of margin of safety is all but forgotten.

Page 284, 1st bullet, sentence beginning line 5: Not clear what is being assumed here. May require further spelling out.

Page 285, 1st bullet, sentence beginning line 4: Although I agree with the statement, it is conceivable that more severe asthmatics (because of treatment or chronic symptomatic state) might actually be less susceptible when actually measured.

Page 290, top discussion of two pollutant model and then effect of adding O3 or PM10: I t is not clear what makes up the two pollutant model to which O3 or PM10 is added. I would have thought that one or the other of these pollutants was added to NO2 to make up the 2 pollutant model. Please clarify.

Page 290, Section 10.3.3: Para 1, sentence beginning on line 7. I applaud the Staff's conclusion here, but believe it could be even more direct, rather than "called into question"

Potential Alternative Standards

Indicator: Summarized briefly and well. Agree that NO2 remain the indicator.

Averaging time: The argument summarized in Tables 10-1 and 10-2 is very convincing that moving to 1 hour is appropriate. I don't know if another table or some example of the text on the page 293 that uses the table to convert ratios to actual estimates would be useful. Alternatively table 10-1 could be expanded to show the hourly maximums.

Form: Clearly the discussion of the 99th and 98th percentiles is appropriate. However, Staff does not seem to reach a conclusion and it is at this point "uncertainty" seems to dominate the thinking rather than "margin of safety". I would agree that the form is partly related to the level, and thus move on to that discussion.

Level. Here I would disagree with the Staff. The argument is well presented that the effect level is seen at or below 0.1 ppm. Staff indicated "little evidence of any effect threshold"…"key studies …with a range of 98th/99th percentile 1-hr daily maximum levels from 0.05 ppm to 0.21 ppm". The several bullets on pages 303 and 304 clearly summarize that health relevant effects are noted, including the fact that the ISA does not draw distinctions between levels within the range of 0.1-0.3 ppm. The fact that there appears to be more uncertainty at the lower levels means to me that the margin of safety issue is important. Thus I take issue with including on page 304, that there is reasonable supported by evidence to go to 0.2 ppm. In fact as the series of bullets on pages 307 and 308 suggest at 0.2 there would be little improvement either in air quality or health effects from the level set in 1971 and little reason to change the standard. That would clearly be wrong, as Staff points out, and I would agree (as they conclude on page 309) that the range should be between 0.5-0.1 ppm.

Comments from Dr. George Thurston

Prof. George D. Thurston comments on final "Risk and Exposure Assessment to Support the Review of the NO2 Primary National Ambient Air Quality Standard"

My comments will also be organized according to the indicator, form, averaging time and alternative levels for the standard, and whether these elements of the current standard need to be changed to protect the public health with a margin of safety.

Indicator:

I agree that the indicator should remain as NO2.

Averaging time:

I agree that the annual standard is not sufficiently protective of health, and with the recommendation to use a 1-hr averaging time for the NO2 standard.

Form:

I agree that a concentration-based form is better than a form based on expected exceedances, and that the absolute level of the standard chosen will depend on whether

choose use the 98th or the 99th percentile. It will also depend on how many years are averaged to compare with the standard, if any multi-year averaging is done.

Level:

I concur with Dr. Henderson's argument that the upper level of the range should be no higher than 0.1 ppm.