Alliance of Automobile Manufacturers
Comments on the U. S. EPA's February 11, 2011 Proposed Rule on the National Ambient Air Quality Standards for Carbon Monoxide

Prepared by

George T. Wolff
Jon M. Heuss
Dennis F. Kahlbaum

Air Improvement Resource, Inc.
April 11, 2011

Introduction

The current national ambient air quality standards (NAAQS) for carbon monoxide (CO) are 9 parts per million (ppm), as an 8-hour average, and 35 ppm, as a 1-hour average, neither to be exceeded more than once per year. These primary standards were established to protect against the occurrence of carboxyhemoglobin (COHb) levels in human blood that were associated with health effects of concern. In the process of reviewing the carbon monoxide air quality standards, the US Environmental Protection Agency (EPA) prepared an Integrated Science Assessment (ISA),[1] a Risk and Exposure Assessment (REA),[2] and a Policy Assessment (PA).[3] The Alliance provided comments[4] on various drafts of these documents as they were being prepared.[5]

The final ISA, which was published in January 2010, evaluates the scientific evidence on the health effects of CO that is relevant to the Administrator's decision whether or not to revise the standards. It includes information on exposure, the physiological mechanisms by which CO might adversely impact human health, an evaluation of the clinical evidence for CO-related effects, and an evaluation of the epidemiological evidence for CO-related effects. The REA describes a quantitative assessment conducted by the Agency to support the review of the primary CO standards, and the PA focuses the information from the ISA and REA on the judgments the EPA Administrator must make in determining whether to revise the air quality standards, and if so, how to revise the standards.

[1] U.S. EPA, Integrated Science Assessment for Carbon Monoxide, National Center for Environmental Assessment, Research Triangle Park, NC, EPA/600/R-09/019F, January 2010.
[2] U. S. Environmental Protection Agency, Risk and Exposure Assessment to Support the Review of the Carbon Monoxide Primary National Ambient Air Quality Standards, EPA-452/R-10-009, as amended July 2010.
[3] U. S. Environmental Protection Agency, Policy Assessment for the Review of the Carbon Monoxide National Ambient Air Quality Standards, EPA-452/R-10-007, March 2010.
[4] J. M. Heuss, D. F. Kahlbaum, and G. T. Wolff, Review and Critique of the U. S. Environmental Protection Agency's Second External Review Draft of the "Integrated Science Assessment for Carbon Monoxide" and First External Review Draft of the "Risk and Exposure Assessment to Support the Review of the Carbon Monoxide Primary National Ambient Air Quality Standards," Air Improvement Resource, Inc. Report, Prepared for The Alliance of Automobile Manufacturers, November 13, 2009.
[5] J. M. Heuss and George T. Wolff, Alliance of Automobile Manufacturers Comments on the Second Draft Carbon Monoxide Risk and Exposure Assessment (REA) and the First Draft Carbon Monoxide Policy Assessment (PA), Air Improvement Resource, Inc. Report, April 1, 2010.

On February 11, 2011, the Administrator issued a Proposed Rule for the CO NAAQS.[6] The Administrator has proposed to retain the current suite of 1-hr and 8-hr CO standards but is soliciting comments on revisions to the form and level of the standards. The Administrator has also proposed changing the CO monitoring network by moving approximately 77 monitors to near-roadway sites to be co-located with the near-roadway NO_2 monitors required under the recent NO_2 NAAQS rule.

The Alliance reviewed the Proposed Rule focusing on the scientific basis for the judgments that the Administrator will make. The Alliance supports the Administrator's proposal to retain the current standards. In Section I below, the Alliance provides detailed technical comments showing that the current standards protect the public health with an adequate margin of safety.

However, the Alliance is concerned the proposed shift in monitoring is not necessary and will lead to a loss of CO monitors that can be used to determine trends and to determine population exposures. In Section II below, the Alliance demonstrates that neither the CO emissions trends estimates, nor the ambient CO concentration trends, nor the existing roadway and roadside measurements justify this redirection in ambient monitoring strategy. There are currently over 50 microscale CO monitoring sites that are located near roadways in locations where pedestrians and local residents are exposed. All these sites report CO concentrations that are well below the current NAAQS. The Alliance supports EPA's pilot study of near roadway exposures but requests that the decision to deploy additional roadside monitors be held in abeyance until the results of the pilot study are available and analyzed.

I. Comments on the Proposal to Retain the Current Standards

There are three major sources of information on CO health effects. The first is controlled studies of CO effects. The second is observational or epidemiological studies of the association of CO with various health endpoints. The third is studies of the mechanism of CO's action in the body. Each of these is discussed in turn followed by a summary section that integrates the information and leads to conclusions regarding the adequacy of the current standards.

A. Comments on the Controlled Human Exposure Studies

The Proposed Rule, following the ISA, REA, and PA, notes that the best-characterized health effect associated with CO is hypoxia (reduced oxygen availability) induced by increased COHb levels in blood.[7] CO elicits various health effects by binding with and altering the function of a number of heme-containing molecules, mainly hemoglobin (Hb). The formation of carboxyhemoglobin (COHb) reduces the O_2-carrying capacity of blood and impairs the release of O_2 from O_2Hb to the tissues. Human clinical studies of the impact of CO on angina patients along with an understanding of the well-established mechanism of tissue hypoxia were used to establish the current CO air quality standards.

The proposal relies on the REA estimates of CO exposures and resulting doses of COHb for the

[6] 76 Federal Register 8158, February 11, 2011.
[7] Ibid., at pages 8162 and 8174

population of adult residents with coronary heart disease in two urban study areas (Denver and Los Angeles). Prior reviews of the CO air quality standards in 1985, 1994, and 2000 included similar analyses of exposure to ambient CO and associated internal dose of COHb to characterize population risk.

The key paragraph in the proposal concerning the interpretation of human clinical studies of CO exposure and risk is the following:

> As at the time of the last review, the Administrator additionally considers the exposure and dose modeling results, taking note of key limitations and uncertainties associated with the exposure and dose assessment summarized in section II.C.2. above, and in light of judgments above regarding the health significance of findings from the controlled human exposure studies, placing less weight on the health significance of infrequent or rare occurrences of COHb levels at or just above 2% and more weight to the significance of repeated such occurrences, as well as occurrences of higher COHb levels. Under air quality conditions just meeting the current, controlling, 8-hour standard, the assessment estimates that, as was the case for the assessment conducted for the 1994 review, daily maximum COHb levels were below 2% COHb for more than 99.9% of person-days in the study areas evaluated. Further, under these conditions, greater than 99.9% of the at-risk populations in the study areas evaluated would not be expected to experience daily maximum COHb levels at or above 4% COHb, and more than 95% and 98.6% of those populations would be expected to avoid single or multiple occurrences, respectively, at or just above 2% COHb.[8]

As the Administrator indicates, the concern for CO effects on persons with heart disease begins at exposures of about 2 % COHb and increases with the number of occurrences and level of COHb. The Administrator also notes that the estimates of risk, for a given level of ambient CO, have not materially changed since the previous review of the CO standards. Since the Risk Assessment indicates that the current NAAQS keeps more than 99.9 % of the person-days below 2 % COHb, the current standards are highly protective for people with heart disease. In fact, the estimated risk in Los Angeles, as shown in Table 6-19 of the REA, of just meeting the current standard results in only 0.002 % of the person-days in the population of adults with coronary heart disease with COHb levels at or above 2 %. Actually less that 0.1 % of the person-days are above 1.5 %. This demonstrates that the current standard is highly protective. Since “as-is” CO concentrations are now below the standard, as documented in Tables 6-14 and 6-17, the risk from current ambient CO is even lower.

Thus, the Alliance concurs with the Administrator that the current standards provide a very high degree of protection for the COHb levels and associated health effects of concern.[9] The REA indicates that, when the current standards are met, more than 99.9 % of the person-days in Denver would be below 1.75 % COHb and more than 99.9 % of the person-days in Los Angeles would be below 1.5 % COHb. The overall distribution of person-days of COHb is an appropriate metric to evaluate the public health risk. In addition, this metric was used by the Administrator in past reviews to judge the public health risk and should be a major consideration in the current review.

---

[8] Ibid., at page 8184.
[9] Ibid., at page 8185.

In viewing the results of the REA, the Alliance also wants to bring attention to the following factors that result in the risk being overstated in the upper tail of the COHb distribution. The Alliance raised these issues in earlier public comments on the draft REA.[10]

1. The risk (as estimated from the distribution of COHb) is overstated for the upper tail of the distribution in Denver because of an overreliance on one microscale site.

The Alliance is concerned that the upper tail (extreme values) of the COHb distribution estimated for Denver in the REA is too high because one of the four sites is a micro-scale site located on a triangular-shaped traffic island at the intersection of major arterial roads. In the previous analysis, six monitoring sites were used to characterize the exposures. By reducing the number of sites, the importance of each remaining site is magnified. Since one of the remaining sites is a micro-scale site within a few meters of heavy traffic, the concentrations measured at that site will dominate the upper tail of the distribution of CO (and hence COHb) exposures. Although the analysis simulates CO in a number of microenvironments, the base exposures from which the micro-environmental exposures are calculated (or adjusted up or down from) are the monitoring data. Thus, the analysis assumes that the CO exposures for a substantial portion of the population of interest are determined from measurements at a site that is not representative of where anybody lives or works or spends very much time. This biases the distribution upward by overstating the number of people exposed to high CO concentrations and the fraction of time they are exposed to high concentrations.

2. The risk is overstated for the upper tail of the distribution in Denver and Los Angeles because the analysis overestimates in-vehicle and near-roadway CO concentrations.

There is a key assumption that causes the Agency to over-estimate the upper tail of the COHb distribution. Although it is well established that the in-vehicle or on-road exposures on busy highways are increased relative to up-wind monitors, the Alliance is concerned that the procedure EPA used in the REA to estimate the incremental increase due to in-vehicle exposures overestimates in-vehicle concentrations in heavy traffic and/or under adverse meteorology. In the 1st draft REA the Agency used a multiplicative factor of two to model the in-vehicle micro-environment. That factor was based primarily on the Shikiya et al. 1989 study in Los Angeles. CASAC was concerned that EPA was not taking the variability in the ratio of in-vehicle to monitor measurements into account. In the 2nd draft and final REA, a methodology similar to that used in the 2000 pNEM analysis was used, with a multiplicative factor with a geometric mean of 3.2 and 5th and 95th percentiles of 1.5 and 6. The ISA documents that the ratio between in-vehicle measurements and ambient monitors is highly variable. The change resulted in an increase in the maximum in-vehicle CO concentrations in the analysis. As indicated in Table 6-9 of the REA and in Figure 16 of the staff presentation on the draft REA at the March 22-23, 2010 CASAC meeting, in-vehicle 1-hour CO concentrations approaching 60 ppm are included in the analysis, and the elevated in-vehicle exposures are responsible for the upper tail of the CO and COHb distribution.

a. There is no data indicating that the in-vehicle concentrations in the U. S. approach the upper end of the ranges used in the model.

---

[10] Heuss and Wolff, 2010, supra note 5.

There is no data cited in the ISA or REA that demonstrates that in-vehicle 1-hour concentrations of anywhere near 60 ppm CO have been measured in the U. S. in locations that just attain the current CO air quality standards. In fact, there are numerous studies that report significantly lower concentrations. For example, the Rodes et al., 1998 study of in-vehicle exposures to CO and other pollutants reported in-vehicle CO concentrations between 3 and 5.4 ppm for two-hour measurements during “simulated commutes” on heavily-traveled freeways and major arterial roads in the Los Angeles Basin. The measurements were made in the Fall of 1997, a year when the ambient CO design value was 15 ppm as compared to the 9 ppm standard. Importantly, the CO concentrations on major arterial routes were similar to those on more-heavily travelled freeways.

The Shikiya et al., 1989 study of Los Angeles similarly reported in-vehicle commuting exposures in Los Angeles from data gathered in 1987. Both the Shikiya et al. and Rodes et al. studies were carried out for California air pollution control agencies. A comparison of the two studies conducted in 1987 and 1997 respectively shows that the in-vehicle CO concentrations were reduced by over a factor of two in the intervening decade. Although both the Shikiya et al. and Rodes et al. studies report peak CO concentrations of the order of 50 ppm, those measurements are peak 1-minute concentrations not peak 1-hour concentrations. The reduction in both ambient and in-vehicle CO concentrations has continued due to the nation’s motor vehicle control program. This is discussed in greater detail in Section II below.

The CO measurements (made in the year 2003) from the Westerdahl et al., 2005 study in the Los Angeles Basin are particularly informative. The authors measured CO and other pollutants in an instrumented electric vehicle driving on freeways in Los Angeles with a traffic density greater than 200,000 vehicles per day. The vehicle was driven on a freeway-dominated loop that took approximately two hours. Westerdahl et al. specifically report that roadway CO averaged from 2 to 4 ppm and was usually no more than twice the ambient concentration. This study, conducted on major freeways in the Los Angeles Basin, an area with both historic high CO concentrations, high traffic density, and adverse meteorology demonstrates the magnitude of on-roadway exposures in worst-case driving situations. When the three Los Angeles studies are compared, it is evident that in-vehicle CO concentrations have been dramatically reduced from 1987 to 2003. Importantly, even the peak 1-minute CO concentrations have been reduced substantially, with the peak 1-minute concentration measured during the Westerdahl et al. study being 14 ppm. Since the California and federal motor vehicle control programs are continuing to reduce vehicle CO emissions, current and future on-road exposures will be even lower. A recent Health Effects Institute Report documenting on-roadway concentrations of CO and other pollutants in the Los Angeles Basin during hourly commutes on major freeways and arterial roads in 2004 confirms the Westerdahl et al. findings. This is discussed in greater detail in Section II below.

The in-vehicle CO measurements reported in other studies referenced in the ISA and REA also provide no evidence of 1-hour CO exposures approaching the peak levels used in the REA modeling analysis.

b. Based on studies of the factors that determine in-vehicle exposures, the peak exposures assumed by EPA are biased high.

Since day-to-day emissions are relatively constant, the wide distribution in ambient CO concentrations arises due to differences in dispersion that are driven by variations in meteorology. Dispersion around a roadway is a function of wind speed, wind direction, and atmospheric stability. High ground-level concentrations result from low wind speeds and limited vertical dispersion due to the presence of inversions. However, as Chock and others have shown, the concentration fields around roadways are also influenced by the mechanical turbulence generated by the traffic that effectively limits the build-up of CO and other pollutants under adverse meteorological conditions.

Since a high ratio of on-road increment to background can occur in a situation where the actual on-road increment (in concentration units) is low but the background is very low, applying that high ratio to an urban situation with a high background can substantially over-estimate the on-road increment. Rather than use the ratio method, EPA should have analyzed the data in terms of the increment in concentration units and the traffic counts, since the magnitude of the on-road CO source is the major determinant of the on-road increment. Under conditions of adverse meteorology that lead to the highest ambient concentrations, low wind speeds and limited vertical dispersion, a high ratio is not likely. This is because the traffic that generates the CO also generates a great deal of mechanical mixing that acts to dilute the emissions.

In the mid-1970s when the catalytic convertor was introduced to reduce emissions, because of concerns that the sulfur in gasoline would be oxidized over the catalyst and cause excessive near roadway exposures to sulfate, General Motors and EPA carried out an experiment on a test track at the General Motors Proving Ground that simulated an expressway with a traffic density of 5462 cars per hour.[11] Experiments were conducted on the early morning of 17 days in October 1975, in order to collect data under the most adverse meteorological conditions available. Using the results from an array of chemical and meteorological measurements around the roadway, Chock demonstrated that the turbulence and heat generated by the traffic had a significant effect on the on-road and near-road wind and concentration fields.[12] For example, in the first 50 meters downwind of the road, mechanical mixing dominates the mixing due to stability considerations so that the vertical dispersion parameters in the first 50 meters approach neutral stability, regardless of the ambient stability. In addition, at very low wind speeds, the heat from the traffic lifts the exhaust above the Gaussian plume axis. These effects limit the concentrations that can build up on and near roadways under adverse ambient meteorology.

A review paper by EPA authors, Baldauf, et al. 2009, makes the same point, noting:[13]

> Regardless of roadway design, the activity of vehicles on the road induces turbulence at the point of pollutant emission, leading to enhanced pollutant mixing. In addition, the elevated temperature of exhaust emissions enhance thermal buoyancy in the plume, providing an initial mixing zone for vehicle-emitted pollutants that depends on the number, type, and speed of vehicles on the road. The more turbulence present, the more initial dilution of

[11] S. Cadle, D. Chock, P. Monson, and J. Heuss, "General Motors Sulfate Dispersion Experiment: Experimental Procedures and Results," J. Air Pollut. Control Assoc., **27**, 33-38 (1977).
[12] D. Chock, "General Motors Sulfate Dispersion Experiment: Assessment of the EPA HIWAY Model," J. Air Pollut. Control Assoc., 27, 39-45 (1977).
[13] R. Baldauf, N. Watkins, D. Heist, C. Bailey, P. Rowley, and R. Shores, Near-road air quality monitoring: Factors affecting network design and interpretation of data, Air Qual. Atmos. Health, **2,** 1–9 (2009).

pollutants will occur.

Thus, the mechanical mixing and turbulence generated by vehicles acts to limit the build-up of CO and other pollutants emitted on roadways under adverse ambient meteorology.

The three Los Angeles Basin studies noted above all found that the in-vehicle CO on major arterial roads is similar to that on major expressways. This arises because there is greater mechanical mixing and turbulence on expressways than on arterial roads due to the higher speeds on expressways, offsetting the difference in traffic count.

3. The cities chosen for the REA represent a "worst case" situation

During the March 22-23, 2010 CASAC meeting the panel discussed a need to put the results of the REA into a national perspective. The Alliance believes that the evidence supports the position that the cities chosen for the analysis are not average or typical, but represent more of a "worst case"situation. The upper extremes of the COHb distributions in the Denver and Los Angeles analyses are determined by the ambient measurements at the CAMP site in Denver and the Lynwood site in Los Angeles. It has been long recognized that these two monitors are particularly problematic due to unique meteorological and topographical conditions. The CO situations in Denver, in general, and at the CAMP and Lynwood sites, in particular, were intensively evaluated in a National Research Council (NRC) study a few years ago.[14] The unique meteorological and topographical factors that lead to higher CO concentrations at these sites are discussed in the NRC study in a section that includes references to earlier studies of the cause of higher CO at these sites. Thus, the upper extremes of the COHb distributions in the REA represent a national "worst case" situation.

In interpreting the results of the REA, the Administrator should consider that the cities chosen for the analysis are not average or typical, but represent more of a "worst case." In addition, the Administrator should consider that the nation's CO monitoring program has historically focused on sites that are expected to have maximum exposures at each of several monitoring scales, with the sites at each monitoring scale skewed to identify maximum exposures, not average exposures, at that monitoring scale. For example, in recent years there have been 57 microscale sites that are typically 2 to 10 meters from a roadway and sited to identify maximum exposures in the near-road or street canyon environment. There are another 71 monitors for which no scale is defined. Even in the case of neighborhood scale monitoring, the guidelines stress the need to put monitors in neighborhoods with the highest population density. Thus, the monitoring network is not designed to determine a national average CO exposure, but is skewed to measure higher than average exposures at each monitoring scale.

B. Comments on Epidemiological Studies

The PA, CASAC, and the Proposed Rule indicate that there is support in the evidence for either retaining the current standards or lowering the standard. Although the human clinical evidence has not changed substantially in recent years, the number of epidemiological studies in the literature

[14] National Research Council. (2003). Managing Carbon Monoxide Pollution in Meteorological and Topographical Problem Areas. The National Academies Press. Washington DC. pages 96 to 99.

reporting associations between CO and various health endpoints has increased dramatically. After discussing the epidemiological evidence, the Administrator indicates:

> Although CASAC expressed a preference for a lower standard, CASAC also indicated that the current evidence provides support for retaining the current suite of standards. CASAC's recommendations appear to recognize that their preference for a lower standard was contingent on a judgment as to the weight to be placed on the epidemiological evidence. For the reasons explained above, after full consideration of CASAC's advice and the epidemiological evidence, as well as its associated uncertainties and limitations, the Administrator judges those uncertainties and limitations to be too great for the epidemiological evidence to provide a basis for revising the current standards.[15]

Thus, the interpretation of the epidemiological evidence is a critical issue in the Administrator's choice. For both the reasons that the Administrator outlines and additional reasons discussed below, the Alliance believes that little weight should be given to the epidemiological studies of CO.

The November 2009 Alliance comments provided detailed reasons why the epidemiology summarized in the ISA should be given little weight. First, the pattern of acute associations reported for CO is remarkably similar to that of all the criteria pollutants. Second, multi-city studies report a biologically implausible wide range in individual-city associations from positive to negative for each pollutant. With 25 to 40 percent of the associations in various multi-city studies being negative, it is impossible to characterize the data as consistent. Third, with such stochastic variation, relying on any one individual study or a small cluster of studies is unreliable. Fourth, there is now greater appreciation that model selection uncertainty, publication bias, and issues of surrogacy or confounding limit the interpretation of the published associations as true effects.

1. A New Study of Model Selection Uncertainty Supports the Administrator's Proposal

A recent study focusing on the model selection issue suggests that the epidemiological evidence relied on by EPA in the ISA is scientifically unsound and should not be used as a reason to lower the present suite of CO NAAQS. The new study[16] underscores many of the issues raised in the preceding paragraph and adds additional insights as to the reasons why the real relationships between morbidity and air pollution at relevant exposures are small and insignificant. In this study, the authors conduct a comprehensive analysis on air pollution morbidity relationships for eleven Canadian cities over a long record from 1974 to 1994. As a result, they have a unique data set that allowed the examination of both spatial and temporal variations. In addition to including the five criteria pollutants, CO, PM, SO_2, NO_2, and O_3, they also controlled for socioeconomic factors, smoking and meteorology. Much shorter subsets of this data set have been without the socioeconomic and smoking variables by a number of research groups to demonstrate significant relationships with a number of health outcomes and individual pollutants. The long data set enables the present investigators to explore the impact of significantly lower air pollution concentrations at the end of the data set compared to the beginning. Koop et al. also employed the

[15] Proposed Rule, supra note 6, at page 8185.
[16] Koop, G., McKitrick, R. and Tole, L. (2010). Air pollution, economic activity and respiratory illness: Evidence from Canadian cities, 1974-1994. Environ. Model. Softw. Doi.10.1016/j.envsoft.2010.01.010 (in press).

two major methods used to formulate the statistical models in time-series studies: model selection by the use of some statistical criteria and Bayesian Model Averaging (BMA) to address the all important issue of model selection uncertainty.

As Koop et al. noted for air pollution/morbidity epidemiology results in general, and the Alliance noted in November, 2010 comments specifically for CO/morbidity studies, the results are conflicted. In other words, the results range from positive to negative and from significant to insignificant for all pollutants and for all health endpoints. Koop et al. state:

> One of the reasons for this profusion of apparently contradictory results is model uncertainty. With very few exceptions (e.g. Clyde, 2000;[17] Clyde and DeSimone-Sasinowska, 1997[18] and Koop and Tole, 2004,[19] 2006[20]), previous studies on air pollution-health effects have used model selection methods, i.e. choosing one or a few regression specifications and reporting point estimates and their associated variances conditional on that being the true model. However, the estimation exercise is inherently opportunistic. Many plausible covariates could be included, but the choice is not dictated by theory so much as by data availability. Hence there is not only uncertainty about regression slope coefficients conditional on the model selection, but about the model specification itself.[21]

Compounding the issue of selecting the true model is the large number of potential explanatory variables and possible forms that will influence the model results. As Koop et al. articulate it:

> However, the number of potential confounding variables implies that a huge number of models could be used to explain health effects. The number of potential models is on the order of 2^k where k is the number of potential explanatory variables, including lags. Since results can be sensitive to the particular regression specification, and since the number of potential models is so large, model uncertainty has been shown to be an important issue in this literature (Clyde, 2000; Koop and Tole, 2004).[22]

To address the model uncertainties, the authors use BMA. This method includes information from every potential model. The BMA results are weighted averages of the estimates from each model. The weights are proportional to the support the data give each model.

The results of the BMA analyses show that the health outcomes are explained by the smoking and the socioeconomic variables and that none of the air pollutants showed a statistically positive relationship with health. In fact most pollutant relationships were slightly negative, but not robust. With this particular data set the BMA results were largely similar (except NO_2 showed an effect in a single model) to the results obtained by selecting a single model. This is in contrast to their

---

[17] Clyde, M., 2000. Model uncertainty and health effect studies for particulate matter. Environmetrics 11, 745–764.
[18] Clyde, M., DeSimone-Sasinowska, H., 1997. Accounting for Model Uncertainty in Poisson Regression Models: Particulate Matter and Mortality in Birmingham, Alabama. Institute of Statistics and Decisions Sciences, Duke University Discussion Paper 97-06.
[19] Koop, Gary, Tole, Lise, 2004. Measuring the health effects of air pollution: to what extent can we really say that people are dying from bad air? J. Environ. Econ. Manage. 47, 30–54.
[20] Koop, Gary, Tole, Lise, 2006. An Investigation of thresholds in air pollution mortality effects. Environmental Modelling & Software. 21 (12), 1662–1673.
[21] Koop et. al., supra note 16 at 3.
[22] Ibid at 2.

earlier results (Koop and Tole, 2004[23]) for Toronto which found many relationships when a single model was used. In the earlier paper, a shorter data record was used and the smoking and socioeconomic variables were not included. This may explain the differences and underscores the importance of including these variables in a longer time-series in these types of studies.

In summary, this study demonstrates the importance of: 1) incorporating smoking and socioeconomic variable into the models, 2) using a longer time series that has significantly different pollutant concentrations at the beginning and end of the study, 3) using the BMA approach which minimizes model selection uncertainties and finds insignificant health impacts. This suggests that the epidemiological evidence relied on and summarized by EPA in the ISA is scientifically unsound and should not be used as a reason to lower the present suite of CO NAAQS.

2. Relying on specific single-city studies in light of the stochastic variation is unsound

The arguments in the PA for more stringent CO standards rely on cardiovascular hospital admissions associations reported in three Atlanta studies. In the one study that reports a statistically significant positive association with CO, the authors do not ascribe the positive association to an effect of CO, per se, but rather raise the same issues of CO acting as an indicator that are acknowledged in the ISA, the PA, and the Proposed Rule.

Relying on one or a small cluster of CO studies from the literature, when there is so much stochastic variation, is akin to choosing one point from a scatter plot of all results. The wide variation in individual-community results in single-pollutant models and the highly variable changes in multi-pollutant models (with some CO associations increasing, some decreasing, and others relatively unchanged) are demonstrated in the following figure, taken from the supplemental material for the Bell et al., 2009 study of emergency hospital admissions for cardiovascular disease.

As documented in detail in the Alliance November 13, 2009 comments, the pattern of associations reported by Bell et al. is not consistent with a causal relationship. In addition to the stochastic variation shown below and in other figures in the Bell et al. supplementary material for the lag 0 individual-community associations, the combined association on lag1 was negative, even though one would expect a positive association from the evening peak in the CO on day 0 if CO were actually causing cardiovascular hospital admissions.

[23] Koop and Tole supra note 19.

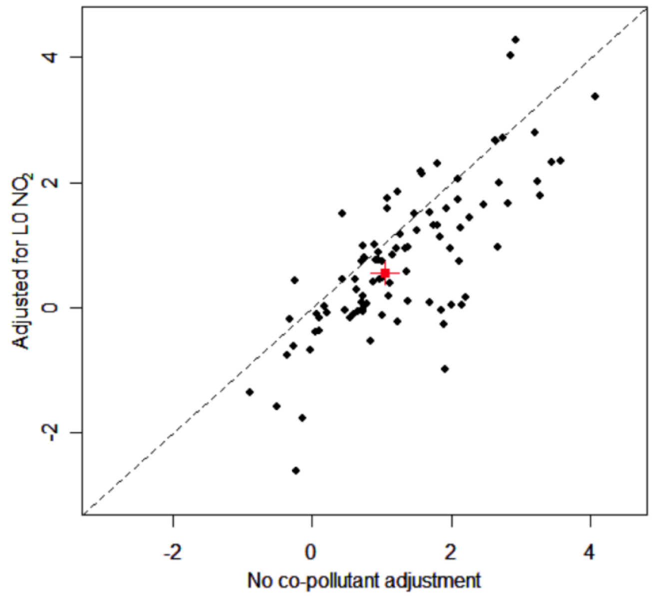

Fig. IIa. With and without adjustment by same day NO_2

C. Comments on the Mechanism of Action of CO.

New information on potentially beneficial mechanisms of CO action needs to be considered by the Administrator. The basic understanding of the hypoxic mechanism of CO action, formation of COHb and reduction of oxygen-carrying capacity of the blood, has not changed substantially since the 2000 Criteria Document. The ISA notes, however, that current literature primarily focuses on endogenous CO produced by the metabolic degradation of heme by heme oxygenase (HO) and its role as a gaseous messenger. While the endogenous production of CO has been known for a long time, the role of the CO produced as an active participant in cellular processes rather than as a waste product is of more recent vintage.

There is now a large and growing body of literature indicating that non-toxic exposures to CO may have substantial beneficial potential. This new information is also relevant to the interpretation of the epidemiological results and should be fully discussed by the Administrator. The ISA acknowledges that work from numerous laboratories has demonstrated the potential for CO to be used as a therapeutic gas with numerous possible clinical applications, since it can produce anti-inflammatory, anti-apoptotic, and anti-proliferative effects, referencing Ryter et al., 2006 and Durante et al., 2006. Ryter et al. in their extensive review note that inhalation CO has been effective in animal models of inflammation, hypertension, organ transplantation, vascular injury, and ventilation-induced lung injury. The implications of the growing body of controlled studies demonstrating beneficial anti-inflammatory, anti-proliferative, and cytoprotective effects of CO under certain circumstances needs to be considered in the final rule.

D. Integrating the Information from Clinical, Epidemiological and Mechanistic Studies

Integrating the information from the three areas of study leads to the conclusion that the current standards are adequately protective of public health.

1. Human Clinical Studies

In judging the public health implications of attaining the current CO standards, it is useful to consider the judgments that were made by CASAC and the Administrator in the 1994 review concerning the clinical studies. As summarized in section 2.2.1 of the PA, EPA and CASAC recognized the existence of a range of views among health professionals on the clinical significance of the responses observed in the clinical studies, but the dominant view was that they should be considered "adverse or harbinger of adverse effect." Despite the uncertainty associated with the clinical importance of the cardiovascular effects that resulted from COHb levels of 2 to 3 percent, EPA and CASAC agreed to minimize such exposures. Although EPA and CASAC recognized the possibility that there is no threshold for these effects even at lower COHb levels, the health significance of the small changes in ST-segment depression observed was considered somewhat minor. Furthermore, the first effects identified in healthy adults, findings of short-term reduction in maximal work capacity measured in trained athletes exposed to CO, occurred at higher levels of COHb, resulting in COHb levels of 3 to 7 percent. The ISA notes that the decreases in exercise duration were relatively small and only likely to be noticed by competing athletes. Studies with healthy adults also found no cardiovascular effects on ST-segment depression or cardiac rhythm with exercising adults who had COHb levels up to 20 percent.

The information on health effects related to various COHb levels from the clinical studies has not changed from the 1994 review or the 2000 CD. As noted above, the information on the COHb exposures expected from a given CO exposure has not changed. Therefore, there is no reason from the clinical studies to change the conclusion that the current CO standards protect the public health with an adequate margin of safety.

2. Epidemiology

Although there is a substantial increase in the number of studies that report weak associations of CO with various health endpoints since the 2000 CD, the issues with interpreting that data as an independent effect of CO that were voiced in the 2000 CD have not changed. Although the controlled human studies do demonstrate effects on the cardiovascular system at 2 % COHb and above, interpreting the epidemiological evidence as causal below the level of the current standards is even more difficult than it was in 2000 because 1) ambient levels of CO are now extremely low compared to levels that cause effects in controlled animal or human studies, 2) there is now evidence that both endogenous and exogenous CO have anti-inflammatory and cytoprotective properties through non-hypoxic mechanisms.

As EPA has reviewed the air quality standards for each of the criteria pollutants, the pattern of epidemiological evidence and the discussion of that evidence are remarkably similar. Each CD or ISA focuses on the single-pollutant associations for the pollutant under consideration. The primary display of the evidence is in figures where only the combined association for multi-city studies is plotted, thereby obscuring the full range of associations from positive to negative. The text discusses the data without regard to whether the authors of the study implicated the pollutant under consideration or air pollution in general or another pollutant. The document considers multi-pollutant models to some degree and concludes that at least for some endpoints, the results are generally robust to other pollutants. The summary discussion refers to the data in terms that range from mixed and inconsistent to generally consistent. In no place is the wide range of associations in systematic analyses or multi-city studies addressed. Although publication bias and model selection uncertainty may be mentioned somewhere in the document, their implications for the final conclusions are not fully considered. Based on the qualitative discussion in the text, the document applies the causality framework EPA has developed from other, similar frameworks. For the most part, the evidence for effects in various health endpoint categories is categorized as likely causal or suggestive of causality. There is also discussion with respect to how the observational studies compare to the controlled studies of the pollutant under consideration. If there are known respiratory or cardiovascular effects from the pollutant, the epidemiology in that category is bumped up one causality category because of perceived coherence with the clinical studies. There is also the obligatory discussion that the pollutant may have an independent effect or be considered an indicator of some other pollutant.

When one looks at the epidemiological evidence, whether in systematic analyses or in the figures in EPA's recent ISAs and CDs, the pattern looks remarkably similar. The remarkably similar pattern for each pollutant, together with the evidence of stochastic variability, model selection uncertainty, and publication bias, raises the concern that it is beyond the capability of current methods to identify which positive associations may be real health effects and which are not. Time-series epidemiology of air pollution associations is only capable of very blunt analysis. CASAC raised this issue in a June 2006 letter to the Administrator, noting that "because results of time-series studies implicate all of the criteria pollutants, findings of mortality time-series studies do not seem to allow us to confidently attribute observed effects specifically to individual pollutants."[24]

Despite this concern, as the Administrator and the various CASAC panels consider the epidemiological information, the conclusion is drawn that the pollutant under consideration probably has an independent effect and that is used as a reason to tighten the existing air quality standard. This has occurred recently in the NO_2, SO_2, and ozone proposals to revise those standards and is also included in the PA for particulate matter that is undergoing CASAC and public review. This leads to double, triple, or quadruple counting of health effects.

The comprehensive new study of 20 years of Canadian data in 11 major cities by Koop, McKitrick and Tole discussed above confirms the prior Alliance concerns with air pollution epidemiology. The authors conclude:

> We also illustrated the danger that incomplete modeling efforts could yield apparent

[24] Henderson R. (2006). CASAC letter. EPA-CASAC-06-07. June 5, 2006. at page 3.

> pollution-health correlations that are not robust to reasonable variations in estimation methods. Model selection methods applied to a subset of the data, or without use of the appropriate socioeconomic controls, can (for example) yield an apparently significant health effect from increased carbon monoxide levels, but such effects change sign and/or become insignificant upon application of more complete empirical methods.

In discussing the example of a limited data set in which there is a positive CO association with respiratory hospital admissions, they note:

> Consequently, this finding mainly serves as an example of how a positive and significant relationship between pollution and illness can be found in a data set with some digging, but may not be robust to a change in modeling technique nor an extension of the data back in time.

Given the limitations on the use of time series and other epidemiological studies to set ambient standards that the Alliance and others have identified, EPA should not rely on one or a few studies that report positive CO associations in single pollutant models to determine the appropriate range for the level of the CO standards.

3. Mechanisms of Action

The hypoxic mechanism for CO action is well established. The clinical significance of the first known changes, which occur at or above 2 % COHb in exercising adults with coronary heart disease, is not entirely clear. The previous judgment was that the effects should be considered as adverse or a harbinger of adverse effects. There is no reason to change that conclusion.

While there is now a great deal of interest in non-hypoxic mechanisms, there is now growing evidence that both endogenous and exogenous CO have anti-inflammatory and cytoprotective properties through non-hypoxic mechanisms.

4. Conclusion Regarding the CO NAAQS

The Alliance believes that great weight should be placed on the controlled studies for which the interpretation of risk is unchanged from previous reviews. The Proposed Rule also indicates that particular weight should be placed on the controlled studies. The first effects of CO involve exercise-induced aggravation of angina in controlled exposures of patients with diagnosed ischemic heart disease (IHD) to elevated CO concentrations. These effects have been documented in a series of clinical studies carried out by various investigators between 1973 and 1991.

The current CO standards were established in 1971 and have been retained in several reviews. Although EPA initiated a review in 1997 and completed both a new Criteria Document and exposure analysis in 2000, a rulemaking was not initiated at that time. Thus, the last full review was completed in 1994. As discussed above, the estimated COHb exposures due to ambient CO, for a given ambient CO level, have not changed substantially from that estimated in prior reviews. In addition, due to the issues raised concerning a bias to overestimate in-vehicle exposures, the

REA analysis is conservative in that it overestimates the upper percentiles of the COHb exposures and hence overestimates the risk.

Based on these considerations, and the estimates of COHb exposures in the REA, the current 8-hour and 1-hour standards are protective of public health. It should be borne in mind that (1) the EPA estimates of risk have not changed materially since the prior review, (2) the REA estimates that just meeting the current standard results in only 0.002 % of the person-days in the population of adults in Los Angeles with coronary heart disease with COHb levels at or above 2 %, and (3) there is substantial evidence that these EPA estimates are biased high.

II. Comments on Proposed New Monitoring Strategy

A. Proposed CO Monitoring Requirements

EPA is proposing a significant change in the nation's ambient CO monitoring strategy. The past emphasis was on assessing peak concentrations in areas around major traffic arteries and near heavily traveled streets in downtown areas along with monitors intended to represent a wider geographic area, particularly at neighborhood scales where concentration exposures were significant. The proposal is to replace this strategy with a strategy to locate monitors in expected "hot spots" near the most heavily trafficked roadways along with monitoring at the NCore multipollutant monitoring sites. The proposed strategy would also allow states to remove CO monitors at other sites with the approval of the EPA Regional Administrator. Consequently, the Administrator is proposing to require collocating CO monitors at a subset of NO_2 roadside monitoring sites that are located within 50 meters of the most heavily traveled roadways. The proposal is to require these sites in CBSAs[25] of 1 million or more persons but the Administrator invites comments on this threshold and even "on the merits of having any minimum near-road requirements." EPA is also proposing that the microscale CO siting criteria for probe height and horizontal spacing be changed to match those of near-road NO2 sites. As noted above, the near-road monitors would be in addition to CO monitors that are coming on line at the National Core Monitoring sites (NCore).[26]

In the following sections, the Alliance demonstrates that neither the CO emissions trends estimates, nor the ambient CO concentration trends, nor the existing roadway and roadside measurements justify this redirection in ambient monitoring strategy. This is followed by specific Alliance comments on the proposed new monitoring strategy. The Alliance believes that EPA regulations and the resulting technological fixes that the motor vehicle industry has developed have eliminated motor vehicle CO emissions as an air quality problem. Thus, the proposed changes are not necessary.

B. Trends in CO Emissions and Concentrations

According to EPA's latest emissions estimates[27] for 2008, the U.S. emitted 77.7 million short tons of CO from man-made sources. Of that total, 39.9 tons or 50.1% came from highway vehicles. The trends in these emissions are shown in Figure 1. As demonstrated in Figure 1, total emissions of CO have been dramatically reduced by 61.9% since 1970 and that reduction is due to the reductions from highway vehicles which declined by 76.2%. Non-highway emissions of CO have been essentially flat since 1970.

Nationwide trends in ambient air concentrations[28] are also plotted in Figure 1. It should be noted that there are two NAAQS for CO: an 8-hour standard of 9 ppm which cannot be exceeded more

---

[25] A Core Based Statistical Area (CBSA) is an area defined by the Office of Management and Budget (OMB) based around an urban center of at least 10,000 people and adjacent areas that are socio-economically tied to the urban center by commuting.

[26] http://www.epa.gov/ttnamti1/ncore/index.html.

[27] http://www.epa.gov/ttn/chief/trends/index.html.

[28] http://www.epa.gov/airtrends/carbon.html

than once per year and a 1-hour standard of 35 ppm which likewise cannot be exceeded more than once per year. Generally the 8-hour NAAQS is the controlling standard (i.e., more likely to

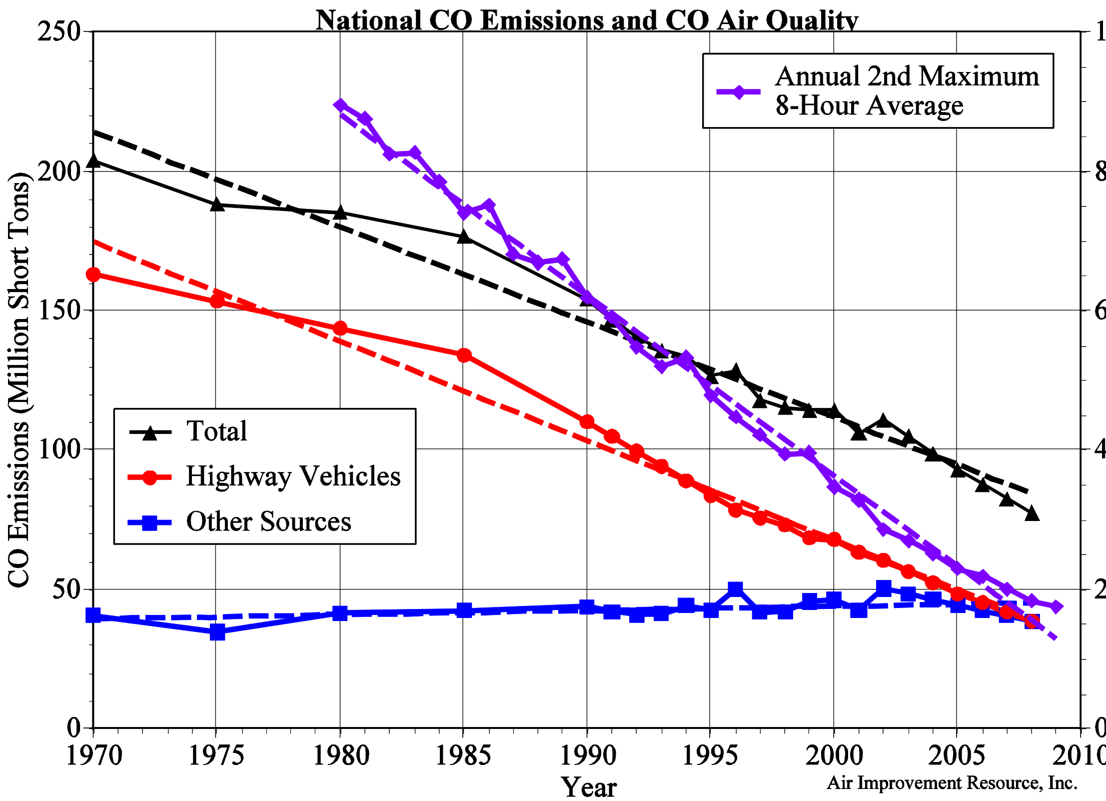

Figure 1: Trends in total, highway vehicle and other anthropogenic CO emissions from 1970 to 2008 and the trends in the annual 2nd maximum 8-hour average ambient CO concentrations for the U.S.[27,28]

experience an exceedance). Originally there were 41 metropolitan areas in the U.S. that were designated as nonattainment areas. In the early 2000s, all 41 were redesignated to attainment. In 1980, the U.S. annual mean of the second highest 8-hour concentration was about 9 ppm as illustrated in Figure 1. By 2008, it was a mere fraction of that value (< 2 ppm). Although the air quality concentrations track the vehicle emission trends quite closely, they have declined at a faster rate than the emissions estimates. This is likely due to urban sprawl, the growth in the spatial extent of urban areas that spreads the emissions over a larger area. However, as discussed below, newer emissions modeling results using MOVES (Mobile Vehicle Emissions Simulator) indicate that the highway vehicle emissions estimates in recent years are likely overestimated. Since 1980, the mean trend in the 2nd highest 8-hour maxima has declined by 80.3%. Figure 2 shows the close relationship between estimated highway vehicle CO emissions and the measured ambient CO concentrations. The linear correlation (r^2) for the two data sets is 0.99. Since the relationship is almost perfect, it is reasonable to project future ambient CO concentrations based on future emission estimates for highway vehicles derived from EPA's MOVES emission model.

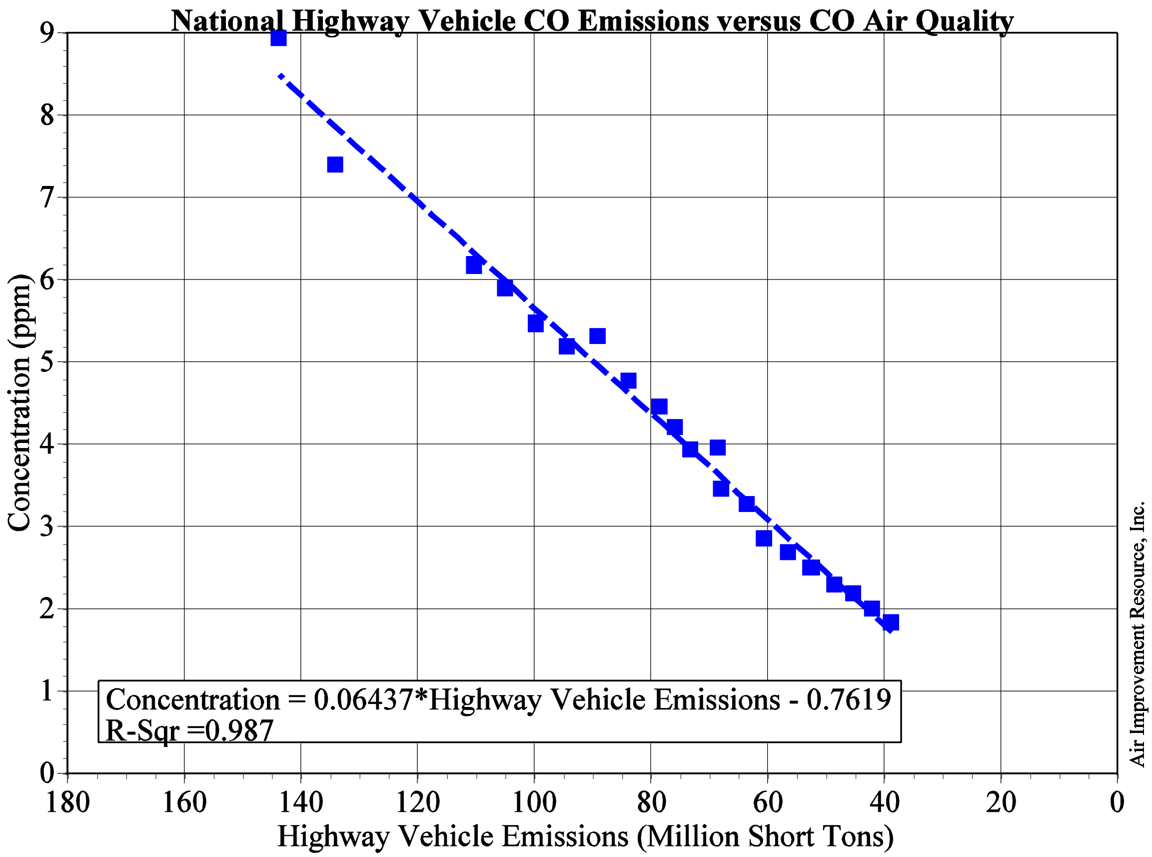

Figure 2: Relationship between the annual 2nd maximum 8-hour average ambient CO concentrations for the U.S. and the CO emissions estimates from highway vehicles from 1980 to 2008.[27,28]

The national CO projections for 2008 to 2020 shown in Figure 3 were generated via the latest version of the EPA's MOVES model (MOVES2010a, released 23 August 2010).[29] The model was run using all of the default parameters for vehicle population, vehicle miles traveled (VMT), fuel composition, and ambient conditions (temperature, pressure, and humidity). All fuel types, vehicle classes, and road types were included. The emissions are the total from both start and running modes. Figure 4 shows a comparison of the MOVES estimates and the EPA highway vehicle emissions estimates from Figure 1 (which EPA derived from MOBILE6, a previous EPA vehicle emissions model) for the period from 2000 to 2010. It is very obvious from Figure 4 that the MOVES emissions estimates are lower than those from MOBILE6. The lower estimates from MOVES are thought to be more realistic and are more consistent with the trends in the ambient air concentrations. Figure 5 shows a scatter plot of the estimates from 2000 to 2008 with the best fit linear least squares regression line which shows a near perfect fit.

---

[29] http://www.epa.gov/otaq/models/moves/index.htm.

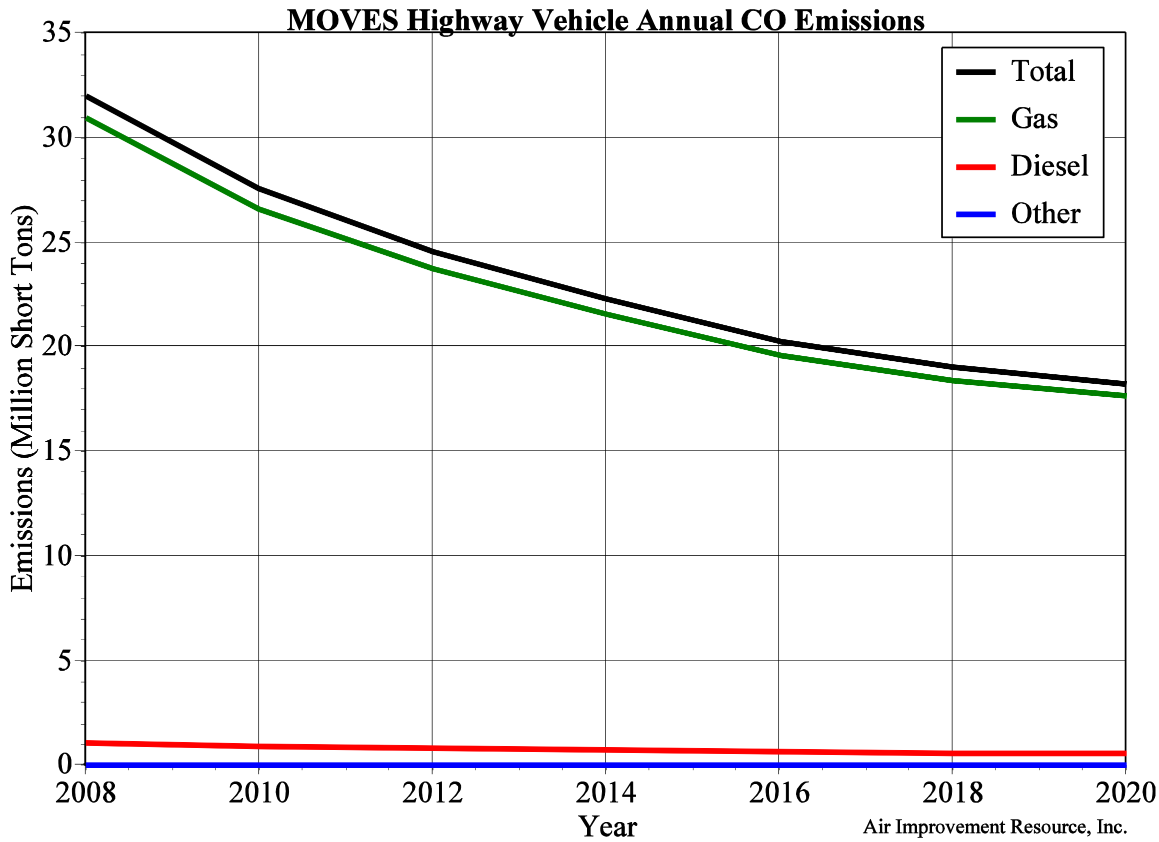

Figure 3: Projected U.S. CO emissions from highway vehicles for 2008 to 2020 using EPA's MOVES model.[29]

Since the MOVES emission estimates are considered to be the more realistic of the two estimates, they were used to obtain the future concentration estimates. Using the calculated MOVES emission estimates and the mean annual 2nd highest 8-hour ambient concentrations plotted in Figure 1 for the years 2000 to 2008, a least squares regression line of CO concentration = 0.0957(CO emissions) -1.47 with an r^2 of 0.99 was obtained. The estimated mean 2nd highest 8-hour ambient CO concentrations for 2010, 2014 and 2020 are then 1.17, 0.66 and 0.28 ppm, respectively. Compared to a base year of 2008 (the last year for which EPA reported the mean annual 2nd highest 8-hour ambient concentrations) that had a mean annual 2nd highest 8-hour concentration of 1.53, the future estimates represent further ambient concentration reductions of 24% by 2010, 57% by 2014 and 82% by 2020.

In summary, the emissions estimates and the ambient air quality data show vastly improved CO air quality throughout the nation. Observed concentrations of CO in 2008 are only a fraction of what they were in 1980 and everywhere in the U.S. is in attainment. In addition, emission projections into the future indicate that the concentrations in 2014 and 2020 will be a fraction of what they were in 2008. In other words, EPA has eliminated CO as an air quality problem, and their proposal to locate more near roadway monitors appears to be an attempt to find problems where none are likely to exist. The roadway measurements discussed below will provide additional evidence of a non-problem.

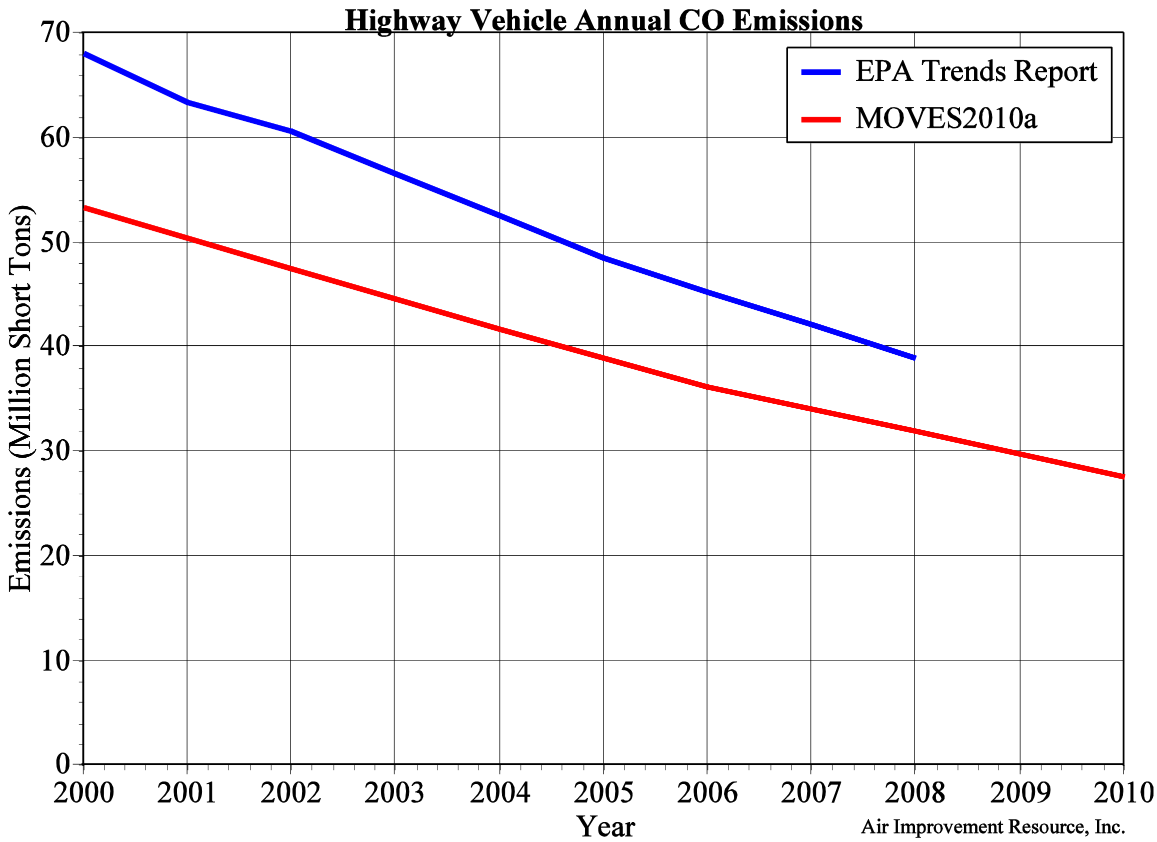

Figure 4: A comparison of EPA's highway vehicle CO emissions trends which are based on MOBILE6 with the estimates from MOVES.

C. Roadway Measurements

1. Existing Roadway Monitoring Sites

In 2007, there were 376 CO monitoring sites nationwide reporting values to the EPA Air Quality System (AQS) database. EPA classified these monitors into 6 categories: microscale, middle scale, neighborhood scale, urban scale, regional scale, and other. Of these, 57 were classified a microscale which EPA defines as being sited 2 - 10 m from a roadway. These monitors were intended to represent exposures in the near-road or street canyon environment that is limited to an area within a radius of 100 m from the monitor. Thus, these sites would fit the distance criteria for being a "near-road" CO monitor as described in the proposed CO rulemaking. The national distribution of all hourly observations, 1-hour daily maxima, 1-hour daily averages and 8-hour daily maxima for the years 2005 - 2007 are presented in Table 1[30] based on EPA's monitor scale classification. Since the existing microscale monitors are intended to represent near-road environments, it would be expected that they would measure significantly higher concentrations than the other monitors whose measurement are representative of larger scales. However, while the microscale sites generally do report higher concentrations and the

[30] U.S. EPA (2010), *Integrated Science Assessment for Carbon Monoxide*, EPA/600R-09/019F, January 2010, Table 3-12.

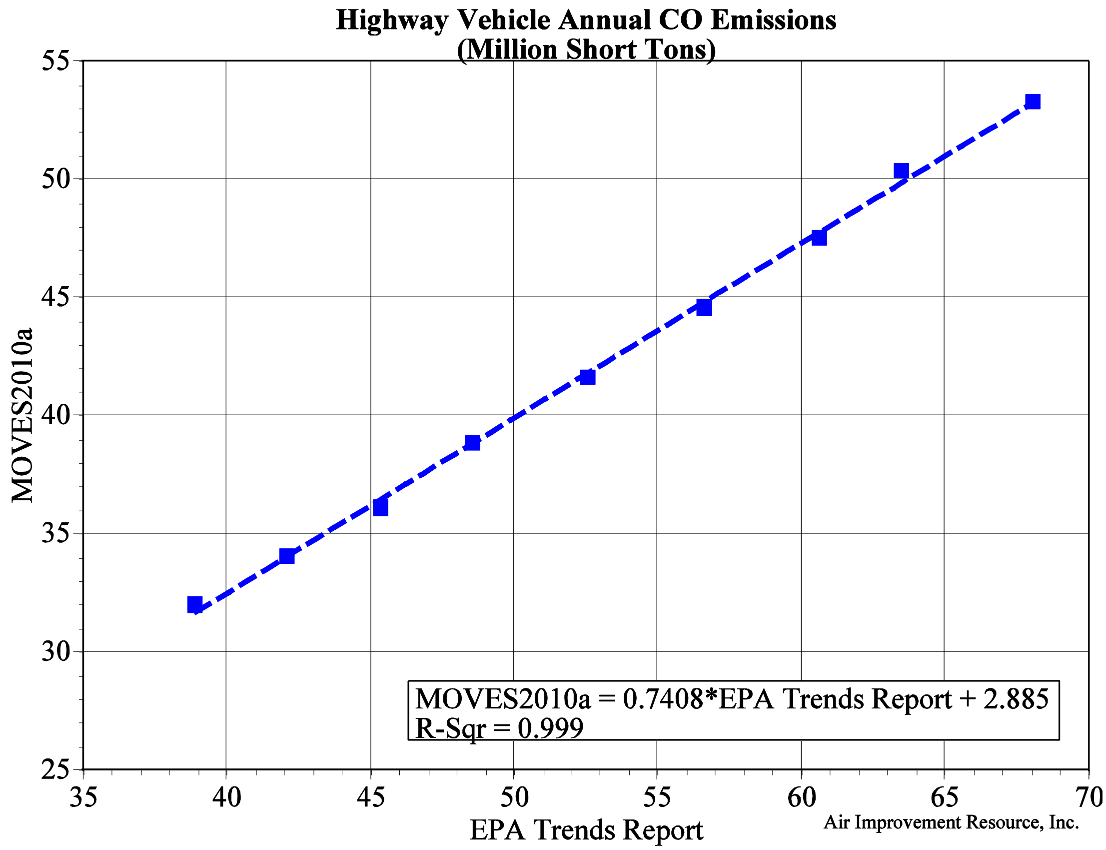

Figure 5: Relationship between nationwide highway vehicle CO emissions estimates from MOVES and MOBILE6 from 2000 to 2008.

differences are probably significant, they are not that much higher than the other sites. In addition, the disparity between the microscale monitors and the other monitors diminishes at the higher concentrations, especially at the extreme values of the distribution. Since the 8-hour CO design value is an extreme value statistic, this suggests that the deployment of new roadside monitors may not have a substantial impact on the design values.

Thus the data from the existing roadside monitors do not provide any evidence of the existence of CO "hot spots" that are not currently being monitored and suggest that the concentration distributions are not significantly different than those from non-roadside monitors. In addition, since the projected future concentrations (based on the current motor vehicle emission control program) are expected to be a fraction of those measured in 2005 - 2007, EPA's proposed monitoring strategy appears to be a waste of resources.

2. Roadway Monitoring Studies

In the final ISA, EPA presents a graph from Zhu et al. (2002)[31] showing the distribution of CO and black carbon PM at various upwind and downwind distances from I-710 in Los Angeles.

[31] Zhu, Y., Hinds, W.C., Kim, S., Shen, S. and Sioutas, C., (2002), "Study of ultrafine particles near a major highway with heavy-duty diesel traffic," *Atmos. Environ.*, 36: 4323-4335.

				PERCENTILES									
Time Scale	n	Mean	Min	1	5	10	25	50	75	90	95	99	Max
ALL HOURLY													
Microscale	1,428,745	0.6	0.0	0.0	0.1	0.2	0.3	0.5	0.8	1.1	1.4	2.2	19.6
Middle Scale	771,941	0.5	0.0	0.0	0.0	0.1	0.2	0.4	0.6	1.0	1.3	2.3	18.9
Neighborhood Scale	2,878,993	0.4	0.0	0.0	0.0	0.0	0.2	0.3	0.5	0.8	1.1	2.1	35.3
Urban Scale	279,311	0.3	0.0	0.0	0.0	0.0	0.1	0.3	0.5	0.7	0.9	1.6	10.8
1-H DAILY MAX													
Microscale	59,905	1.2	0.0	0.2	0.3	0.4	0.7	1.0	1.5	2.1	2.5	3.9	19.6
Middle Scale	32,659	1.0	0.0	0.1	0.2	0.3	0.5	0.8	1.2	2.0	2.5	4.0	18.9
Neighborhood Scale	121,328	0.9	0.0	0.0	0.1	0.2	0.4	0.6	1.1	1.8	2.4	4.0	35.3
Urban Scale	11,784	0.7	0.0	0.0	0.0	0.1	0.3	0.5	0.9	1.3	1.8	3.1	10.8
1-H DAILY AVERAGE													
Microscale	59,905	0.6	0.0	0.0	0.1	0.2	0.4	0.5	0.8	1.0	1.2	1.7	4.0
Middle Scale	32,659	0.5	0.0	0.0	0.1	0.1	0.3	0.4	0.6	0.9	1.2	1.9	5.5
Neighborhood Scale	121,328	0.4	0.0	0.0	0.0	0.1	0.2	0.3	0.5	0.8	1.0	1.6	7.0
Urban Scale	11,784	0.3	0.0	0.0	0.0	0.0	0.2	0.3	0.5	0.7	0.8	1.2	2.5
8-H DAILY MAX													
Microscale	59,905	0.8	0.3	0.3	0.3	0.3	0.5	0.7	1.1	1.5	1.8	2.6	5.8
Middle Scale	32,659	0.7	0.1	0.3	0.3	0.3	0.3	0.6	0.9	1.4	1.9	2.8	6.2
Neighborhood Scale	121,328	0.6	0.0	0.3	0.3	0.3	0.3	0.4	0.8	1.2	1.6	2.7	10.9
Urban Scale	11,784	0.5	0.0	0.2	0.3	0.3	0.3	0.4	0.7	1.0	1.3	2.1	4.0

Table 1: National distribution of all hourly observations, 1-h daily max, 1-h daily average, and 8-h daily max concentration (ppm) derived from AQS data, based on monitor scale designations, 2005-2007.[30]

This graph is reproduced in Figure 6.[32] The figure shows that the CO concentration decreases rapidly with distance downwind from the roadway. By 50 m the concentration has decreased by approximately 50% and 80% by 100 m.

A comprehensive review of real-world roadside measurements was published since the completion of the final ISA. The authors, Karner et al. (2010)[33] synthesized the results of 41 roadside monitoring studies. Figure 7 is copied from Karner et al. and summarizes all of the data included in their analysis. Like Figure 6, Figure 7 plots the relative pollutant concentrations as a function of the downwind distance from the edge of the roadway. As in Zhu et al., CO decreases to about 50% and 20% of its roadside concentration by 50 and 100 m, respectively.

In February 2011, the Health Effects Institute (HEI) published the results of a study designed to find motor vehicle emissions "hot spots."[34] Although the study's main focus was on air toxics

[32] U.S. EPA (2010), *Integrated Science Assessment for Carbon Monoxide,* EPA/600R-09/019F, January 2010, Figure 3-29.
[33] Karner, A. A., Eisinger, D.S. and Niemeier, D.A. (2010). "Near-roadway air quality: synthesizing the findings from real-world data, *Eviron. Sci. Technol.*, 44: 5334-5344.
[34] Fujita, E. M., Campbell, D.E., Zielinska, B., Arnott , W.P. and Chow, J.C. (2011), *Concentrations of Air Toxics in Motor Vehicle-Dominated Environments,* Research Report 156, February 2011.

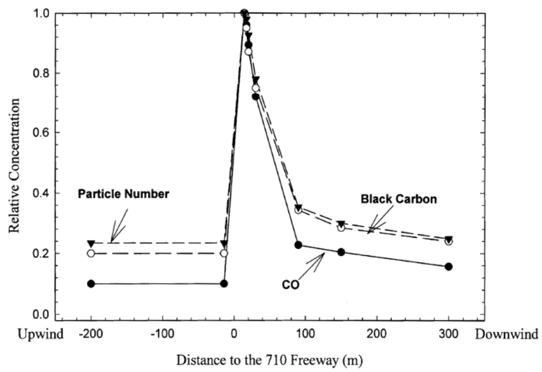

Figure 6: Relative concentrations of CO and co-pollutants at various distances from the I-710 freeway in Los Angeles.[32]

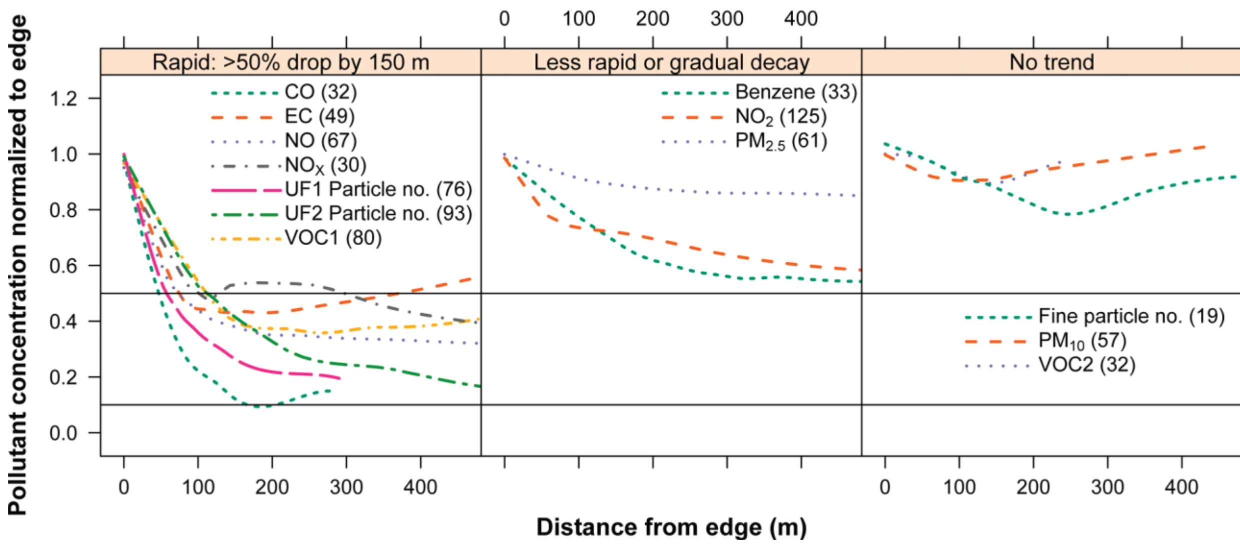

Figure 7: Local regression of road edge normalized concentrations on distance. The horizontal black lines show a reduction from the edge-of-road concentration of 90% (at 0.1) and 50% (at 0.5). A loess smoother (alpha) 0.70, degree) 1) was fitted to pollutant data which was placed in one of three groups. The regression sample size, n, is given in parentheses after each pollutant. The n includes an estimated (not in the literature) edge-of-road value to facilitate normalization.[33]

and $PM_{2.5}$, CO measurements were included in all sampling venues. Here is a description of the extensive measurements that were made:

> The study was conducted in the southern portion of Los Angeles County for several weeks during the summer and fall of 2004. A combination of time-integrated and continuous measurements were made in the following location classes: (1) on roads; (2) at sites at various distances from the roads (referred to as spatial surveys); and (3) at three near-road sites with varying proportions of gasoline- and diesel-powered vehicles. For the on-road sampling, a van equipped with monitoring instruments and operating with windows and vents fully opened and a circulating fan turned on was driven

> for 1 hour on three commuting routes at peak commuting times and on one freeway loop with a higher fraction of diesel-truck traffic (referred to as the truck route). Spatial surveys were conducted immediately after the morning on-road sampling and immediately before the afternoon on-road sampling by stopping the van for a few minutes at locations at various distances from these routes. The three near-road sites, Long Beach, Lynwood, and Diamond Bar, were located in the same general geographic area as the routes for the on-road measurements and were sampled for 24 hours.

The commuting routes in the Fujita et al. study included long sections of driving on major multi-lane Los Angeles freeways. The report contains many tables with hundreds of on-roadway[35] and roadside CO measurements, none of which come close to approaching either the 8-hour or 1-hour NAAQS for CO. For example, the mean on-roadway CO concentrations during the various 1-hour commuting routes ranged from 2 to 7.8 ppm depending on the route and whether the measurements were made in the summer or fall or during the morning or evening commute. Even the peak 1-minute on-roadway concentrations during the study did not approach the current 1-hour NAAQS. The near-roadway measurements were, as expected, lower than the on-roadway measurements. It also needs to be emphasized that these measurements were made on heavily travelled and congested routes in Los Angeles in 2004. Since 2004, the roadway CO emissions and hence the CO concentrations should have decreased another 50% by 2011. Finally, it is relevant that Fujita et al. report that the higher on-roadway CO exposures typically occurred during congested commuter traffic, at intersections, or when the mobile sampling van was following gasoline vehicles that were high emitters. This indicates that the existing microscale sites do capture peak CO concentrations.

Another relevant study was reported by Zhu et al., 2006.[36] Zhu et al. measured CO 30 meters from both sides of the I-405 freeway in Los Angeles as part of a study of ultrafine particulate matter dispersion from a freeway. The study was conducted during several overnight sampling periods in early February, 2005 at a site on the I-405 freeway (between the Los Angeles National Cemetery and a Veteran's Administration facility) that is isolated from other local sources. The meteorology during the study can be considered worst case. As shown in Figure 1 of Zhu et al., the wind speeds were very low, predominately below 1 m/s and often below the detection limit of the instrument. The wind direction was within about 20 degrees of parallel to the road which would maximize the build-up of pollutants on the down wind side of the roadway. Under these nighttime conditions of a stable atmosphere and a weak offshore sea breeze, Zhu et al. report that the CO concentration 30 meters downwind of the road was 0.5 ppm. The authors also report that the traffic volume overnight was about 25 % of the daytime volume and that the CO concentration they measured in an earlier daytime study at the same site was 2 ppm. Thus, even under worst-case ambient meteorological conditions, the turbulence generated by the moving vehicles provides sufficient

---

[35] The Fujita et al. measurements are referred to as on-roadway measurements since the design of the in-vehicle sampling did not reflect the ventilation conditions in the vehicles of most commuters. Thus, peak in-vehicle exposures could be less than the on-roadway exposures reported by Fujita et al.

[36] Y. Zhu, T. Kuhn, P. Mayo, and W. C. Hinds, "Comparison of Daytime and Nighttime Concentration Profiles and Size Distributions of Ultrafine Particles near a Major Highway, *Environ. Sci. Technol*. 2006, 40, 2531-2536.

dispersion to limit the build-up of CO concentrations near a heavily traveled expressway. Since the observed CO would scale linearly with emission rate or traffic volume, the near-roadway CO concentrations from higher traffic volumes would still be way below the current CO NAAQS under worst-case meteorological conditions. Although the Zhu et al. 2006 study is not referenced in the CO ISA, the earlier Zhu et al. 2002 study is fully discussed. The Agency should be aware of the results of the Zhu et al. 2006 study since it was sponsored in part under U. S. EPA grant R82735201.

There are two additional relevant studies that include CO measurements near major expressways. Nztiachristos et al., 2007 measured CO for over 100 hours at a site ten meters from the shoulder of the I-710 freeway in Los Angeles during February through April 2006.[37] The I-710 is an eight-lane freeway with traffic counts of between 150,000 and 200,000 vehicles per day. The authors report an average CO concentration of 0.23 ppm over the seven-week sampling period with a range in the continuous data of from 0.1 to 3.6 ppm. Zhu et al., 2005 measured CO inside four two-bedroom apartments within 60 meters from the center of the 10-lane I-405 Freeway in Los Angeles during the Fall/Winter of 2003.[38] The indoor CO concentrations averaged between 0.4 and 1.1 ppm during a series of daytime and nighttime measurements in the apartments. The CO concentrations outside the apartments ranged between 0.4 and 1.2 ppm during the indoor sampling periods.

Neither the CO data discussed in Section 3.5.1.3 of the ISA, nor the additional roadway CO data referenced in earlier Alliance comments on the CO draft REA and draft PA, nor the CO data discussed above provide any evidence for the EPA assumption that the most heavily travelled roadways have elevated concentrations that approach the CO NAAQS and are going unmonitored.

Collectively, the roadway monitoring studies provide no evidence that CO hot spots, with concentrations beyond those already monitored at the current microscale sites, exist and question why resources should be redirected to nationwide roadside CO monitoring.

D. Comments on EPA Proposed Monitoring Changes

The EPA proposal seems to be based on two pillars. The first is the CASAC CO Panel's recommendation that "More extensive coverage may be warranted for areas where concentrations may be more elevated, such as near roadway locations." The second is the statement on page 3-58 of the ISA that "…with little microscale data at roads with AADT of more than 100,000 vehicles per day, there is still much uncertainty regarding the magnitude of concentrations in the near-road environment."

With regard to the CASAC recommendation, CASAC appears to have been influenced more by the model-estimated in-vehicle concentrations used in the REA than the actual observations of in-vehicle or near-roadway CO concentrations in the literature, particularly in the more recent

---

[37] L. Ntziachristos, Z. Ning, M. Geller, and C. Sioutas, "Particle Concentration and Characteristics near a Major Freeway with Heavy-Duty Diesel Traffic," Environ. Sci. Technol., 41, 2223-2230, 2007.
[38] Y. Zhu, W. Hinds, M. Krudysz, T. Kuhn, J. Froines, and C. Sioutas, "Penetration of freeway ultrafine particles into indoor environments," Aerosol Science, 36, 303-322, 2005.

literature. As shown above in the discussion of the REA results, the peak in-vehicle concentrations estimated in the REA are gross overestimates, an artifact of the multiplicative statistical form of the relationship assumed by the Agency.

With regard to the limited number of microscale monitoring sites with AADT greater than 100,000 (which is currently 2), the Agency has not fully considered the data from specialized studies such as Fujita et al., 2011, several Zhu et al. studies, and Westerdahl et al., 2005 that provide relevant data. Westerdahl et al. measured CO and other pollutants in 2003 in an instrumented electric vehicle driving on freeways in Los Angeles with a traffic density greater than 200,000 vehicles per day. The vehicle was driven on a freeway-dominated loop that took approximately two hours. Westerdahl et al. specifically report that roadway CO averaged from 2 to 4 ppm and was usually no more than twice the ambient concentration. This study, conducted on major freeways in the Los Angeles Basin, an area with historic high CO concentrations, high traffic density, and adverse meteorology demonstrates the magnitude of on-roadway exposures in worst-case driving situations. The Westerdahl et al. and Fujita et al. results are similar for both mean and peak 1-minute in-vehicle CO concentrations.

While EPA justifies the proposed changes based on the CASAC CO Panel's general recommendation that extended coverage of roadways may be warranted, the Agency appears to be ignoring specific advice from another CASAC Panel that was asked to review the Agency's near-road monitoring plan.[39] The Monitoring Panel (with the title U.S. Environmental Protection Agency Clean Air Scientific Advisory Committee Ambient Air Monitoring and Methods Subcommittee for the Review of Near-Road Monitoring to Support Measurement of Multiple National Ambient Air Quality Standard (NAAQS) Pollutants) consisted of experts well-versed in the technical fields needed to give the Agency sound advice on its near-roadway monitoring plans.

Specifically, the Monitoring Panel was concerned that EPA was putting too much emphasis on annual average daily traffic counts in making site selections, was deeply concerned about the timing proposed for the network deployment, and was concerned that there would be a decrease in the number of population-oriented monitors. In addition, the Panel recommended a staged approach to the deployment of the near-road monitoring network and a tiered approach to the design of the near-road monitoring sites. The Alliance concurs with these concerns.

With regard to timing, the Panel indicated "…CASAC is deeply concerned about the timing proposed for the current network deployment, as well as for the Pilot Study."[40] While the Panel was responding to EPA's plan for deploying NO2 monitors, the CO proposal has the same deadline for deployment of co-located CO monitors, January 1, 2013. CASAC went on to note "This ambitious schedule may make it difficult to absorb lessons learned from EPA's Pilot Study to evaluate and improve the siting and monitoring process." CASAC recommended that EPA deploy the network in stages over time. The Panel indicated "In this way, the network can evolve based on lessons learned from the Pilot Study as well as from the operation of the initial sites."

[39] Russell T. and Samet J. (2010) Letter to Administrator Johnson from Drs. Russell and Samet, Clean Air Scientific Advisory Committee. Subject: Review of the "Near-road Guidance Document - Outline" and "Near-road Monitoring Pilot Study Objectives and Approach" EPA-CASAC-11-001. November 24, 2010.
[40] Ibid., at page iii.

If the Administrator chooses to add near-roadway CO monitors, the Alliance highly recommends that it be done in stages after a pilot study, with decisions for deployment of the first stage and future expansion of the network contingent upon the findings from the pilot study. In this way, if near-roadway CO turns out to be a non-problem as the Alliance predicts, the States can save precious resources. Since EPA is already conducting a pilot study, no new Agency resources would be required.

With regard to the provision that allows States to remove monitors that are not at NCore sites or in the new near-roadway network, the Alliance is very concerned that data that can be used to estimate the distribution of population exposures will be lost. In addition, the Alliance is also concerned that by removing many monitors, the ability to track CO air quality trends will be lost.

The Monitoring Panel, which was asked a series of questions concerning monitoring for NO_2, for CO, and for multiple pollutants near roadways, recognized the importance of considering the exposure of human populations in the design of the network. In discussing the intended focus on NAAQS compliance, CASAC stressed the importance of exposure in the overall balance of siting considerations.[41] In providing advice about a possible national CO proposal, CASAC was concerned about situations that will result in high exposures involving commuters, pedestrians and local residents. The Panel indicated that decisions to monitor at such locations must consider these exposures relative to other near-road exposure environments associated with high density population regions. The Alliance also stresses that the exposure of human populations must be included in the siting and network design requirements. The current proposal does not include a requirement that the near-roadway monitors be sited in locations where there is actual human exposure to the ambient air for time periods corresponding to the 1-hour or 8-hour CO NAAQS. This is a major flaw in the proposal.

In addition to the recommendations of the full Panel, a number of the individual panelists provided cogent recommendations for the Administrator. For example, a number of panelists were skeptical of the Agency's plan. One indicated:

> I am not convinced that a substantial near-road monitoring program for NO_2 and other traffic-related species is a good use of Agency resources. I think it will be hard to implement in a meaningful way, and I don't see great potential value in the data it will produce.[42]

Another noted "It's not clear what EPA is trying to accomplish with its proposed near road monitoring program."[43] A panelist queried "…I would like to ask if monitoring these pollutants with extremely high spatial variability in a micro-scale is a good idea."[44] A panelist indicated "CO monitoring for a health based NAAQS near roadways may not be warranted."[45] One panelist noted in response to CO-specific questions:

[41] Ibid., at page xiv.
[42] Russell and Samet, 2010, supra note 37, at page 89.
[43] Ibid., at page 29.
[44] Ibid., at page 92.
[45] Ibid., at page 53.

> The 3 questions (9,10 and 11) assume that there are high enough CO concentrations at typical near-road locations to justify including health related NAAQS CO monitors at these sites. The EPA must determine if this is the case before establishing a new, expensive and potentially un-necessary monitoring requirement.[46]

Another Panelist indicated "The timeframe for establishing a national network (by January 1, 2013) seems much too rushed to allow for full availability and analysis of results from the near road monitoring pilot study."[47] These CASAC comments support the Alliance position that EPA should carry out a pilot study and evaluate the results before promulgating a new CO monitoring program.

A number of CASAC panelists stressed the importance of monitoring at locations that were relevant to people's exposures. One panelist indicated "Ambient monitoring is concerned with the current exposure to the population from sources of pollutants."[48] Another indicated "The purpose of near-road monitoring is to protect the health of residents living near roadways."[49] This panelist recommended that the monitoring take place in communities where there are residents living within the 50-m corridor and "In a particular CBSA, if there are no residents living within the 50-m corridor, near-road monitoring should be exempted." One panelist asked the question "Shouldn't proximity to where people live be a more important consideration" than the factors listed by the Agency.[50] Another indicated that high concentration locations may be the preferred locations for some CBSAs particularly if they are also significant for population exposure.[51] Referring to the plans for NO_2 and CO monitoring, a panelist indicated "For both pollutants, I think the objective should be to characterize near-road population exposures to mix of traffic-related emissions, and not just to witch-hunt for the worst-case locations of maximum single-pollutant concentrations."[52] Finally, a panelist pointed out "…that large fractions of the population spend time within a 5 or so meters of congested urban streets, but population proximity to the edges of high-speed interstates with maximum AADTs is typically more distant.[53]

The locations of the near-road monitors are proposed to be very close to the edge of the most heavily travelled segments of the most heavily travelled expressways. As such, this approaches peak source monitoring rather than monitoring locations that represent population exposures. Based on the Alliance's evaluation of the Agency proposal together with these CASAC Panelist's comments, any near-road monitoring must be made at locations where people are exposed for time periods that match the time period in the definition/form of the respective NAAQS. Since there is a difference in the access to locations near the road between urban and arterial roads that have sidewalks and limited access freeways that have a restricted right-of-way, there should be two separate criteria for siting microscale CO monitors. The earlier height and distance guidelines are still appropriate for downtown areas and arterial highways with sidewalks, but a separate set of guidelines should be established for limited access, heavily-travelled expressways.

---

[46] Ibid., at page 58.
[47] Ibid., at page 29.
[48] Ibid., at page 54.
[49] Ibid., at page 90.
[50] Ibid., at page 31.
[51] Ibid., at page 55.
[52] Ibid., at page 76.
[53] Ibid., at page 73.

The data from over 50 existing microscale sites establishes that CO exposures even close to heavy and congested traffic are now well below the current CO NAAQS. CASAC panelists recognized that the major factors in the location of peak CO levels are high light-duty vehicle volumes, stagnant meteorology, and containment by nearby buildings (e.g., urban street canyons).[54] However, the build-up of CO under either stagnant meteorology or under light and variable winds is limited because vehicle-induced turbulence dominates over the prevailing air flow.[55] As Solazzo et al. 2007 point out,

> Low wind scenarios are associated with the worst air pollution episodes in urban street canyons. Under these conditions, operational dispersion models often over-predict the pollutant concentration. Traffic-producing turbulence (TPT) becomes dominant in mixing and diluting traffic-related pollutants under low wind speed conditions.[56]As documented in these comments, the monitoring data from the existing microscale sites along with the research data from on- and near-roadway research studies of high volume expressways in California and elsewhere show that the proposed expansion of near-roadway CO monitoring is not necessary.

E. Unaddressed Attainment/Nonattainment Issues

The combination of continual declines in the CO ambient air concentrations that are projected to continue for the near future and the steep drop off in CO concentrations downwind of roadways makes it unlikely that EPA will be successful in finding worst-worst case situations that persist long enough to cause a violation of the CO NAAQS. However, the remote possibility still exists. Unfortunately, EPA has not given any guidance as to what they or the States would do if they did find a "hot spot." As the spatial scale of the peak measurement gets smaller, important issues related to the size of any non-attainment area that would be established and what a State Implementation Plan would entail are raised.

Would it qualify as an unusual event if it was caused by unusual worst-worst case meteorological conditions or some massive traffic jam due to an accident or some other unusual event? If not, how big a geographic area would EPA declare as the nonattainment area? Since the microscale monitors, by design, are limited to representing the ambient air quality only for an area within a 100 m radius of the monitor, would that be the extent of the nonattainment area? What if no one lives or works within the circle? Since highway vehicle emissions are regulated by Federal Regulations, what kinds of control measures would the States be required to put in their State Implementation Plans (SIPs)?

A member of the CASAC Monitoring Panel also asked "For example, how will nonattainment

---

[54] Ibid., at pages 34 and 91.
[55] Ibid., at page 81.
[56] Solazzo, E.; Vardoulakis, S.; Cai, X.M. (2007). Evaluation of traffic-producing turbulence schemes within operational street pollution models using roadside measurements. *Atmos. Environ.*, **41**(26): 5357-5370.

boundaries be established for these microscale environments?"[57] Another member of the Panel raised the same issue with regard to NO_2 but it also applies to CO:

> The end-point of near-road monitoring: Normally when an ambient monitor shows exceedance of NAAQS, state/local authorities are required to develop a State Implementation Plan (SIP) to bring the area into attainment with NAAQS. The State Implementation Plan will include some control measures to achieve attainment. If a near-road NO2 monitor shows exceedance of NAAQS, how will a non-attainment area be delineated and what does EPA expect the state/local authority to do? Due to the nature of significant concentration gradient along the roadways, the area with high NO2 concentrations could be extremely small. What will be the basis for designating an area as non-attainment area? The non-attainment is basically caused by mobile sources. In some areas, it is largely attributable to vehicles passing through the area on the interstate highways. What can the state/local authority do to achieve attainment? If the state/local authority cannot do anything, what is the point of requiring this type of near-road monitoring? EPA could conduct some studies and achieve attainment through regulations on vehicle emission standards.[58]

These are questions that need to be addressed before EPA makes the final rulemaking.

F. Comments on Other Benefits

The proposal lists several benefits from the proposed changes to the monitoring network. One benefit noted is that the overall network would be smaller. The Alliance is concerned, however, that the proposed changes on top of the movement of sites to the new NCore monitoring network will cause the nation to lose many sites that can be used to determine nationwide trends or be used for health studies. Maintaining a consistent set of sites to determine long-term trends should be a priority for the Agency.

Another benefit listed is that the sites will provide data that can support health studies. However, fixed microscale sites that are located to be close to the very highest traffic density in a city will not be particularly useful for health studies. The Alliance believes that personal exposure monitoring of populations that live close to roadways would provide much better information on the distribution of their CO exposures. A member of the CASAC Monitoring Panel also raised questions concerning this issue:

> How are concentrations from microscale locations to be linked to available public health statistics for epidemiologic analyses? Data from neighborhood- or urban-scale monitors have demonstrated utility for epidemiology because they are indicative of typical exposures for identifiable populations large enough to generate routine public health statistics. The numbers of residences near microscale monitors will be small, and the vehicle occupants driving by them will be anonymous. Will site-specific panel studies be required to connect the near-road data to health effects? [59]

[57] Russell and Samet, 2010, supra note 37, at page 29.
[58] Ibid., at page 90.
[59] Ibid., at page 114.

Another benefit listed is providing data that can be used in verification of modeling results. However, the data necessary to validate a model in the near roadway context is much more extensive than the proposal would supply.

The final other benefit discussed in the proposal is supporting the implementation of the Agency's multi-pollutant monitoring objectives. With regard to multipollutant monitoring, CASAC Monitoring Panel indicated:

> Just as we recommended a staged approach to the deployment of the near-road monitoring network, CASAC also recommends a tiered approach to the design of the near-road monitoring sites. A few sites should be comprehensively equipped such that they can provide comprehensive information about the composition of mobile source emissions and how pollutant concentrations and mixtures change over time with changes in sources and control measures.[60]

The Alliance agrees that there is a need for multipollutant monitoring in the vicinity of roadways to document the human exposures in such locations. However, the design of such a measurement program should be focused on estimating exposures of real populations to the full range of atmospheric constituents, not just the concentrations of CO and NO_2 at a fixed site next to a roadway. As such, this is a research endeavor and the data from the comprehensive sites should not be gathered for NAAQS compliance. As one of the individual CASAC panelists noted, this program is an initial step towards better understanding the exposure issues behind the observed near-road health effects, and the measurements of NAAQS and non-NAAQS pollutants are critical for characterization of near-road zones of influence.[61] Another panelist noted that if the purpose is to conduct multi-pollutant monitoring to help inform exposure and health studies, then linkages with these types of research studies appears to be missing from the plan.[62]

In summary, the other benefits noted in the proposal do not provide a justification for the proposal and, in fact, the loss of continuity for determining CO population exposures and CO air quality trends would be a major disbenefit from the proposed changes.

[60] Ibid., at page iii.
[61] Ibid., at page 2.
[62] Ibid., at page 29.