Alliance of Automobile Manufacturers Comments on EPA's Proposal to Revise the National Ambient Air Quality Standards for Particulate Matter
77 Fed. Reg. 38890 (June 29, 2012)

August 28, 2012

EXECUTIVE SUMMARY

Since 1990, PM concentrations have declined dramatically across the U.S. and will continue to do so as a result of emission control programs in place. These various emission control programs will help to reduce all criteria pollutant concentrations across the country, while improvements to air quality and fuel economy will continue to occur. These reductions will occur *regardless* of whether the existing PM annual standard is revised.

The Alliance has carefully examined the evidence in the PM Integrated Science Assessment (ISA), the Risk and Exposure Assessment (REA), the Urban-Focused Visibility Assessment, the Policy Assessment (PA), and in the proposed rule. The current PM standards are protective of public health with an adequate margin of safety and protective of public welfare in accordance with Section 109 of the Clean Air Act. There is no basis for EPA to revise the standards at this time.

Primary Standard

- The Alliance does not support the proposal to lower the level of the annual $PM_{2.5}$ standard to within a range of 12.0 to 13.0 micrograms per cubic meter ($\mu g/m^3$).

- The Alliance supports retaining the current annual standard along with the other PM NAAQS.

- The Alliance takes these positions because the Proposed Rule overstates the case for $PM_{2.5}$ health effects.

  - Despite the publication of many new studies of cardiovascular and respiratory endpoints, the estimate of the magnitude of association of acute effects with $PM_{2.5}$ is smaller and less consistent than thought in the previous review.

  - The individual-city results in multi-city acute PM studies demonstrate a biologically implausibly wide range of associations from positive to negative; such a range is not consistent with causality.

  - In large multi-city studies, there are spatial and temporal patterns in combined associations that are not consistent with causality.

  - The evidence from new long-term exposure studies is not as consistent as portrayed in the NPRM.

- There are spatial differences and inconsistencies in the chronic mortality studies; for example, there is no cardiovascular mortality signal in a large study in the Netherlands and there is no chronic mortality signal in several studies in the Western U. S. This leads to the conclusion that, to the extent there are positive $PM_{2.5}$ chronic-mortality associations, they are caused either by unidentified covariates that may or may not be pollution-related, by components of PM not PM mass, or by historic high exposures and sources unique to the Eastern U. S.

- The proposed revision is based on selected epidemiologic associations, ignores many studies in the literature, and is not supported by evidence from controlled human exposures or animal toxicology.

- The cardiovascular health risk assumed by EPA is not consistent or coherent with fine PM risks from other PM exposure situations including indoor pollution in developed countries, indoor pollution in underdeveloped countries, smoking, and occupational exposures.

- The PM Risk Assessment in the proposal is based on assumptions that are known to be wrong (all fine PM is equally toxic) or unverifiable (the dose-response is linear with no threshold). Based on these issues, little or no weight should be afforded to the results of the risk assessment.

- Given the many limitations and uncertainties of interpreting the acute and chronic epidemiological data, retaining the current annual standard would be a prudent, health-protective decision.

Secondary Standard

- The Alliance does not support the proposal to create a new 24-hour secondary standard within the range of 28 to 30 deciviews which would be the controlling standard in many urban areas.

- The Alliance supports retaining the current secondary standards which are identical to the current primary standards.

- The Alliance takes these positions because EPA has not made a case that the proposed secondary NAAQS is needed to improve urban visibility.

  - EPA has not used sound science to provide a basis for the proposed secondary NAAQS.

  - EPA has not demonstrated that the visibility level that is acceptable in any one place, is appropriate for the entire U.S.

  - The way in which the proposed NAAQS is formulated is unnecessarily stringent.

Spatial Averaging

The Alliance supports the proposal to eliminate spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations. However, the Alliance is concerned that revoking the population-oriented requirement may result in monitoring at locations that are not appropriate for comparison with either the annual standard or the 24-hour standard. The Alliance is also concerned that the proposed change may result in inappropriate use of modeling results in the implementation of revised standards. Since computer modeling is used for PSD permitting, transportation conformity, and attainment demonstrations of the NAAQS standards, the Alliance is concerned that, by removing the population-oriented concept, the Agency may require computer simulations to show compliance with the $PM_{2.5}$ standards at receptor locations where the public only has access in a theoretical sense or has access but is not exposed for relevant time periods. Since this would result in added stringency for the standard without any commensurate public health protection, it would be inappropriate.

Near-Road Monitoring

The EPA proposes that some $PM_{2.5}$ monitors be collocated with measurements of other pollutants (e.g., nitrogen dioxide, carbon monoxide) in the near-road environment. The Alliance has no problem with monitoring anywhere in the near-road environment for research purposes, but the Alliance is concerned that any $PM_{2.5}$ monitoring that is to be used to compare with the annual standard for attainment purposes must be population-oriented. The Alliance is concerned that the elimination of spatial averaging and the definition of population-oriented when combined with the requirement to co-locate $PM_{2.5}$ monitors with near-road NO_2 and CO monitors will result in collection of data in locations that are representative of no one's annual average or 24-hour average $PM_{2.5}$ exposure. This could result in a major tightening of the standard, with significant unintended consequences for industry and economic development. Entire metropolitan areas could be placed in non-attainment based on measurements made where no one is actually exposed.

Alliance of Automobile Manufacturers Comments on EPA's Proposal to Revise the National Ambient Air Quality Standards for Particulate Matter
77 Fed. Reg. 38890 (June 29, 2012)

Introduction

These comments are being submitted by the Alliance of Automobile Manufacturers (Alliance) on behalf of its member companies in response to the U.S. Environmental Protection Agency's (EPA or the Agency) Proposed Rulemaking for National Ambient Air Quality Standards for Particulate Matter (Proposed Rule).[1] The Alliance of Automobile Manufacturers is a trade association of 12 car and light truck manufacturers including BMW Group, Chrysler Group LLC, Ford Motor Company, General Motors Company, Jaguar Land Rover, Mazda, Mercedes-Benz USA, Mitsubishi Motors, Porsche, Toyota, Volkswagen Group of America and Volvo. One out of every ten jobs in the United States is dependent on the automotive industry.

The Alliance members share the concerns of our customers and the American public about this nation's air quality and recognize the importance of assuring clean air that protects public health. Our air is cleaner today than it was a generation ago, and air quality is continuing to improve. Our nation's air is getting cleaner even as our economy grows and vehicles travel more and more miles.

According to EPA's most recent air trends analysis[2], between 1990 and 2010, when the economy grew by 65 %, vehicle miles traveled increased 40 %, population grew by 24 % and energy use grew by 15 %, nationwide air quality has improved significantly for the six common air pollutants. The decreases range from 17 % for 8-hour ozone to 83 % for 3-month average lead.

With regard to PM, nationally between 1990 and 2010, PM_{10} has declined by 38 %. In addition, annual $PM_{2.5}$ concentrations were 24 % lower and 24-hour $PM_{2.5}$ concentrations were 28 % lower in 2010 compared to 2001. Investments and improvements in vehicle technology and manufacturing processes are a major part of this success story. Today's vehicles are 99% cleaner than vehicles of the 1970s, thanks to dramatic reductions in smog-forming emissions. On-road primary $PM_{2.5}$ emissions are now only 2 % of the nation's $PM_{2.5}$ primary emissions inventory.[3] In addition, the reductions in gaseous emissions from vehicles will continue to reduce the contribution of vehicles to secondary PM. For example, according to EPA's own statistics, nitrogen oxide (NOx) emissions from light duty vehicles will be reduced by over 70 percent by 2030 as the result of the Tier II Vehicle and Gasoline Sulfur Program.[4] Further, California has recently established new PM and NOx emission standards for passenger cars and trucks and EPA

[1] 77 Fed. Reg. 38890, June 29, 2012.
[2] EPA, *Our Nation's Air – Status and Trends Through 2010*, EPA 454/R-12-001, February 2012 available at http://www.epa.gov/airtrends/2011/report
[3] U.S. EPA, *Integrated Science Assessment for Particulate Matter.* EPA/600/R-08/139F, 2009, Research Triangle Park, NC, Figure 3-3 at page 3-9.
[4] http://www.epa.gov/tier2/faqs.htm.

is evaluating similar standards. These various emission standards will help to reduce criteria pollutant concentrations across the country, while improvements to air quality and fuel economy will continue to occur. These reductions will occur *regardless* of whether the existing PM annual standard is revised.

The Alliance has carefully examined the evidence in the PM Integrated Science Assessment (ISA), the Risk and Exposure Assessment (REA),[5] the Urban-Focused Visibility Assessment,[6] the Policy Assessment (PA),[7] and in the proposed rule. The current PM standards are protective of public health with an adequate margin of safety and protective of public welfare in accordance with Section 109 of the Clean Air Act. There is no basis for EPA to revise the standards at this time.

These comments focus on the reasons why EPA's scientific justification for lowering the existing annual $PM_{2.5}$ standard and proposing a new secondary standard are unfounded and not supported by the relevant scientific body of literature and evidence produced since the Agency's 1997 Review. In addition, the Alliance has comments on EPA's proposal to eliminate spatial averaging, and to require monitoring in the near-road environment.

A non-attainment designation for $PM_{2.5}$ under the Clean Air Act has serious and immediate consequences to the designated geographic area and directly impacts major sources in and near the area. These include restrictive permitting requirements for new projects or modifications to existing facilities that do not apply to similar facilities in attainment areas. In addition, existing facilities may be required to install more restrictive control technology than is required for similar facilities in attainment areas. There are also emission offset requirements and potential restrictions on highway and transit projects that come into play. The Alliance is concerned that these requirements will increase the cost of goods and services, hamper economic development, and may put federal highway funding at risk. In this way, overzealous regulation can inadvertently harm individuals and families as swell as the nation's overall economic vitality. Therefore, it is important to establish air quality standards that are "neither more nor less stringent than necessary" to protect public health.[8]

I. Comments on revising the annual $PM_{2.5}$ standard

- **The Alliance does not support the proposal to lower the level of the annual $PM_{2.5}$ standard to within a range of 12.0 to 13.0 micrograms per cubic meter ($\mu g/m^3$).**

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[5] U.S. EPA, *Quantitative Risk Assessment for Particulate Matter*. EPA-452/R-10-005, 2010, Research Triangle Park, NC.

[6] U.S. EPA, *Particulate Matter Urban-Focused Visibility Assessment Final Document*, EPA 452/R-10-004, July 2010.

[7] U.S. EPA, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards*. EPA-452\R-11-003, 2011, Research Triangle Park, NC.

[8] *Whitman v. American Trucking Ass'ns, Inc.*, 531 U.S. 457, 473 (2001) (citation omitted).

- **The Alliance supports retaining the current annual standard along with the other PM NAAQS.**

- **The Alliance takes these positions because the Proposed Rule overstates the case for $PM_{2.5}$ health effects.**

  - **Despite the publication of many new studies of cardiovascular and respiratory endpoints, the estimate of the magnitude of association of acute effects with $PM_{2.5}$ is smaller and less consistent than thought in the previous review.**

An important study that demonstrates this point is the Health Effects Institute (HEI) sponsored *Air Pollution and Health: A European and North American Approach (APHENA)* study (Katsouyanni and Samet, 2009).[9] The APHENA project was designed to take advantage of the largest databases available. These had been developed by the three groups of investigators for earlier studies: 1) the *Air Pollution and Health: A European Approach* Phase 2 (APHEA2) study involving 32 European cities; 2) the National Morbidity, Mortality, and Air Pollution Study (NMMAPS), conducted in the 90 largest U. S. cities; and 3) multicity research on the health effects of air pollution in 12 Canadian cities. Each database included air pollution monitoring data for particulate matter and ozone, health outcome data in the form of daily mortality for all ages, for persons younger than 75 years, and for persons 75 years or older (from all nonaccidental causes [all cause]), cardiovascular disease, or respiratory disease) and daily hospital admissions for persons 65 years or older (for cardiovascular and respiratory disease). Other database variables used for APHENA included weather data and a number of socioeconomic and other variables known or suspected to influence mortality or hospital admissions.

In the original studies, each of the three groups used different modeling methodologies and entered different variables into their models. Although each group found positive and significant relationships between PM_{10}/O_3 and mortality and some morbidity endpoints, the magnitude of the relationships differed by geographic region. One goal of APHENA was to use common methodologies and variables and reanalyze their data sets. They intended to create a central repository for all three of the time-series databases and use a common quality assurance approach. In addition, they would conduct analyses on a combined, pooled dataset to study a variety of sensitivity issues including effect modification. They would then investigate the sensitivity of the estimates to a variety of smoothing methods and to the number of degrees of freedom. They also intended to explore reasons for the geographical heterogeneity of the effect estimates seen in their original studies. Another important goal of the program was to understand the extent of coherence between mortality and hospitalizations using data from cities in North America and Europe.

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[9] K. Katsouyanni and J. Samet, *Air Pollution and Health: A European and North American Approach (APHENA)*, Health Effects Institute Report 142, Cambridge, MA, 2009.

In the original analyses, all three groups used a two-stage approach. In the first stage, risks were estimated for the individual cities, and in the second stage, evidence across the cities was combined. Each group used different methods to perform both stages in the original analyses. In APHENA, the investigators wanted to identify a preferred way to do both stages and apply common methodologies to the three data sets. For the first stage, they identified two smoothing techniques, natural splines (NS) and penalized splines (PS), and decided to use a number of degrees of freedom choices. They chose to use 3, 8 and 12 degrees of freedom and also the number of degrees of freedom chosen by minimizing the partial autocorrelation function (PACF).

For the second stage analyses, the two approaches used in original NMMAPs and the European studies represented the two major approaches used at the time to pool estimates. NMMAPS used Bayesian hierarchical regressions models while the Europeans used metaregression models. However, they could not determine which method was best, so they decided to use the models interchangeably. Using the two smoothing techniques together with the four choices for the degrees of freedom and three choices of lags (0-1 day, 1 day and distributive lags which provided the cumulative effects of days 0 through 2) for each health outcome, the investigators ran a total of 24 different models for PM_{10}. In addition, subsets of these choices were also used to examine the effects of controlling for ozone.

The overall PM modeling results for the mortality models and the morbidity models are summarized in Tables 1 and 2, respectively. The denominator in the tables is the total number of different models that were run for each health effect outcome examined and the numerator is the number of models that resulted in a positive and statistically significant relationship between PM_{10} and the health effect outcome. The way to interpret these tables is as follows. High ratios are suggestive of a robust and consistent relationship while low ratios are suggestive of no significant relationship. Intermediate values of the ratio ($\approx 1/2$) suggest inconsistent and non-robust relationships that are dependent upon the model selected. Since there is no a priori way to determine the "correct" model, it is not possible to determine whether a significant and positive relationship represents real causal relationship or if they are false positives that can occur by chance or by confounding.

For mortality, the strongest and most consistent significant relationships are observed for all cause and cardiovascular mortality, but only for the ≥ 75 years age group in Canada and Europe. Importantly, the signal is inconsistent in the U. S. as it is model dependent. For the younger age group, few models are significant except in Europe for all cause but not cardiovascular or respiratory. None of the three geographic areas show consistent significant positive model results for respiratory mortality. Further, none of the models in Canada produce significant results for respiratory mortality.

The models also show mixed results for the hospital admissions. The most consistent significant positive signal is seen for cardiovascular admissions in the U. S. and to a slightly less degree in Europe. However, none of the model formulations produce significant results in Canada. No consistent results are seen for respiratory admissions anywhere. They are strongly model dependent.

The above results from the APHENA study demonstrate the importance of model selection. However, APHENA did not undertake an exhaustive, comprehensive analysis of model selection as they include a limited number of model choices and only considered two pollutants, PM_{10} and ozone.

While there are positive and significant combined associations for some models and for some endpoints and for some geographic areas, the overall pattern of associations in the large APHENA study is mixed and inconsistent. The overall pattern is not what one would expect if PM health effect associations have a real physiological basis. For example, it is not logical that PM would be causing cardiovascular hospital admissions in the U. S. but not in Canada. It is not logical that PM would have a strong cardiovascular mortality signal in Canada but not in the U.S.

It is interesting to note that APHENA conducted the identical analyses with ozone data and the results showed a similar pattern of mixed and inconsistent results.

Cause of Death	Canada	Europe	United States
All Cause – all ages	8/8	18/24	15/24
≥ 75 yrs	8/8	21/24	15/24
< 75 yrs	4/8	16/24	8/24
All Cause ozone controlled – all ages	8/8	16/16	9/16
≥ 75 yrs	8/8	13/16	10/16
< 75 yrs	0/8	13/16	4/16
Cardiovascular – ≥ 75 yrs	8/8	19/24	16/24
< 75 yrs	0/8	8/24	2/24
Cardiovascular –ozone controlled ≥ 75yrs	7/8	16/16	10/16
< 75 yrs	0/8	6/16	2/16
Respiratory – all ages	0/8	11/24	7/24
≥ 75 yrs	0/8	11/24	4/24
Respiratory – ozone controlled – all ages	0/8	7/16	3/16
≥ 75 yrs	0/8	7/16	3/16

Table 1: APHENA modeling results for mortality. The numerators represent the number of models that showed a positive and statistically significant relationship between PM_{10} and mortality while the denominator is the total number of models run.

Type of Admission	Canada	Europe	United States
Respiratory	2/8	16/24	9/24
Respiratory – ozone controlled	0/8	10/16	10/16
Cardiovascular	0/8	20/24	24/24
Cardiovascular – ozone controlled	0/8	12/16	16/16

Table 2: APHENA modeling results for hospital admission for patients 65 years and older. The numerators represent the number of models that showed a positive and statistically significant relationship between PM_{10} and admissions while the denominator is the total number of models run.

- **The individual-city results in multi-city acute PM studies demonstrate a biologically implausibly wide range of associations from positive to negative; such a range is not consistent with causality.**

The study that best demonstrates this is the National Morbidity, Mortality, and Air Pollution Study (NMMAPS)[10] because it is one of the few multi-city studies that provided the individual city results for 90 U.S. cities for not only PM, but for the other criteria pollutants as well. The results show two important features found in the results of all the multi-city studies. First, the results exhibit significant heterogeneity (i.e., they were inconsistent) both across the country and within each geographical region. For PM_{10}, the ranges of risks are implausible and inconsistent with a causal PM_{10}/mortality relationship. The risks range from -3.4 to +3.0 with 63% of the cities displaying a positive statistical relationship between mortality and $PM_{10.}$ Only 2 cities (New York and Oakland) have a statistically significant positive effect. On the other hand, 37% of the cities have a zero or negative relationship. Taken at face value, a negative effect would imply a biologically implausible protective effect (i.e. PM_{10} provides protection from mortality).

It should also be noted that the distribution of risks across all the cities is nearly the same for all the pollutants - more than half exhibit a positive risk and a quarter to nearly half show a zero or negative risk. It seems irrational to single out PM_{10} as the causal agent when the results for the other criteria pollutants are nearly identical.

- **In large multi-city studies, there are spatial and temporal patterns in combined associations that are not consistent with causality.**

EPA's 2009 PM ISA correctly notes new multi-city studies that report major differences in PM associations as a function of geography and season. For example, all of the studies identified in the current PM ISA that have examined the PM-mortality relationship, in regards to geographic location within the U.S., have concluded that the effects are greater in the East compared to the West.

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[10] F. Dominici, A. McDermott, M. Daniels, S.L. Zeger and J.M. Samet, "Revised analysis of the National Morbidity, Mortality, and Air Pollution Study, Part II," In: *Revised Analyses of Time-Series Studies of Air Pollution and Health,* HEI Special Report, pp. 5-24, 2003.

The NMMAPS analysis by season and region by Peng et al. (2005)[11] which used updated mortality data from 1987-2000 in 100 cities, reported that summer was the only season for which the combined effect was statistically significant. An analysis by geographical regions showed a strong seasonal pattern in the Northeast with a peak in the summer and little seasonal variation in the southern regions of the country. The authors acknowledge that there are several possible explanations for their results. One obvious hypothesis is that the most toxic particles have a spring/summer maximum and are more prevalent in the Northeast. Another hypothesis mentioned by the authors is that there could be a seasonally varying bias from an, as yet, unidentified source.

The largest hospital admissions study also clearly shows differences in cardiovascular hospital admissions between East and West. The Dominici et al. (2006)[12] study evaluated fine PM hospital admissions associations for 204 U. S. urban counties with a population greater than 200,000 using 1999-2002 Medicare hospital admission data. The results are presented for a two-stage Bayesian analysis for various types of admissions and by region. Combined associations on the order of a 1 % increase in various cardiovascular or respiratory outcomes per 10 $\mu g/m^3$ increase in $PM_{2.5}$ are reported. However, there are issues that call into question the interpretation of this as an effect from generic fine PM.

The authors present results from seven separate regions as well as a comparison of the three western regions with the four eastern regions. There is a clear difference in the combined associations among the regions and particularly between the eastern and western regions. The combined association is positive for cardiovascular outcomes in the east, but negative in the west except for heart failure that is positive in both areas. This is not consistent with an effect of generic $PM_{2.5}$ on cardiovascular hospital admissions and, indeed, the authors point out the need to shift the focus of research to identifying those characteristics of particles that determine their toxicity.

Other multi-city studies that demonstrate spatial and temporal differences include Dominici et al. 2007b for acute PM_{10} mortality and Franklin et al. 2007 for acute $PM_{2.5}$ mortality.

A similar spatial pattern exists in the chronic studies. The HEI-sponsored re-analysis of the Six-City and ACS studies (Krewski et al., 2000)[13] showed that the increased risk was cardiovascular not respiratory, and there was significant spatial heterogeneity in the

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[11] R.D. Peng, F.Dominici, R. Pastor-Barriuso, S.L. Zeger and J.M. Samet, "Seasonal analyses of air pollution and mortality in 100 U. S. Cities," *Am. J. Epidemiol.*, 161:585-594, 2005.
[12] F.D. Dominici, D. Peng, M. Bell, A. Pham, A. McDermott, S.L. Zeger and J.M. Samet, "Particles, air pollution and hospital admissions for cardiovascular and respiratory diseases." *J. American Medical Association*, 295:1127-1134, 2006.
[13] D. Krewski, R.T. Burnett, M.S. Goldberg, K. Hoover, J. Siemiatycki, M. Jerrett, M. Ambramowicz, and W. H. White, *Reanalysis of the Harvard Six Cities Study and the American Cancer Study of Particulate Air Pollution and Mortality*, Health Effects Institute Special Report, Cambridge, MA, 2000.

association, with no effect seen in western U. S. cities. In fact, a negative estimate of excess $PM_{2.5}$ mortality risk was found in the West. Krewski et al. also identified other patterns in the data including: SO_2 had a strong association with mortality, the PM all-cause mortality association was significantly reduced and became non-significant when SO_2 was added in a two pollutant model, and the increased mortality only occurred in the participants that had a high school education or less.

A recent analysis by Zeger et al. (2008)[14] confirms the large spatial difference in chronic mortality association in a cohort of 13 million Medicare enrollees. Zeger et al. reported statistically significant results for the eastern and central United States that are in general agreement with previous publications, but Zeger et al. found no significant effect of $PM_{2.5}$ on mortality in the western United States. A caution in interpreting the Zeger study is that effect estimates for the Medicare cohort may be biased upward due to lack of adjustment for individual level risk factors.

The Proposed Rule acknowledges that there is heterogeneity of response that indicates uncertainty and may influence the conclusions on alternative standard levels that are appropriate to consider, indicating:[15]

> Most notably, these uncertainties relate to our currently limited understanding of the heterogeneity of relative risk estimates in areas across the country. This heterogeneity may be attributed, in part, to the potential for different components within the mix of ambient fine particles to differentially contribute to health effects observed in the studies and to exposure-related factors.

Uncertainty due to the acknowledged heterogeneity is used in the Proposed Rule to support the upper end of the range for the annual standard.[16]

There are seasonal and regional analyses since the last review that show positive associations in some seasons and regions but null associations in other seasons and regions. Two studies in particular (Bell et al., 2008 and Zanobetti and Schwartz, 2009) are important because they are the two acute studies among four studies relied upon by the Administrator in choosing the range to propose for the annual standard. For example, the Proposed Rule indicates “the Administrator recognizes that these four studies represent some of the strongest evidence available within the overall body of scientific evidence.”[17] The Bell et al., 2008 study entitled “Seasonal and Regional Short-term Effects of Fine Particles on Hospital Admissions in 202 US Counties, 1999–2005” reports statistically significant heterogeneity in $PM_{2.5}$ associations. They report that cardiovascular hospital admissions are strongest and statistically significant in winter but lower and not significant in summer. In fact, the associations are actually negative in

[14] S. Zeger, F. Dominici, A. McDermott and J. Samet, "Mortality in the Medicare population and chronic exposure to fine particulate air pollution in urban centers (2000-2005)", *Environ. Health Perspect.*, 116:1614-1619, 2008.
[15] Proposed Rule, supra note 1, at pp. 38905.
[16] Ibid., at 38935.
[17] Ibid., at 38940.

three of the four regions of the country in summer. For respiratory admissions, the associations are only significant in winter. In contrast, the Zanobetti and Schwartz, 2009 study of mortality associations in 112 cities by season and region reported statistically significant positive associations in spring but dramatically lower associations for all-cause mortality in summer with cardiovascular mortality in summer actually slightly negative. Zanobetti and Schwartz evaluated seven regions of the country and reported that one (California, Oregon, and Washington) had substantially lower associations even though the study indicates that the highest $PM_{2.5}$ ambient concentrations are found in California.

Importantly, the studies that report heterogeneity report findings that are not consistent and coherent, except for the consistent difference between the East and West. The overall pattern is not consistent with generic $PM_{2.5}$ causing mortality and morbidity. The heterogeneity in associations is much too great to be explained away by different mixes of pollutants or exposure factors. For example, Domimici, et al., 2007b report positive associations of PM_{10} that peak in the summer as shown in Figure 6-16 of the ISA. It is not coherent that PM would be causing mortality in the summer in one study but not cardiovascular or respiratory hospital admissions in the summer in another.

In addition, the ISA notes that no U.S.-based multicity studies analyzed potential confounding of PM risk estimates by gaseous pollutants and no studies have evaluated potential confounding by gaseous pollutants of cardiovascular mortality risk.[18] Thus, the single-pollutant results demonstrate spatial and temporal variations that are not consistent with generic $PM_{2.5}$ causality and potential confounding by other pollutants has not been adequately evaluated.

- **The evidence from new long-term exposure studies is not as consistent as portrayed in the NPRM.**

The Administrator calls out the Krewski et al., 2009 and Miller et al., 2007 studies as the two long-term studies that are among the strongest evidence and that were relied upon to develop the proposed range for the annual standard. The Proposed Rule also indicates, in discussing the long term studies, that:[19]

> Collectively, these new studies, along with evidence available in the last review, provide consistent and stronger evidence of associations between long-term exposure to $PM_{2.5}$ and mortality.

Even though the Proposed Rule claims consistency, there is substantial evidence for important spatial differences, inconsistencies, and issues with the body of long-term mortality studies that has been provided to the Agency during the current review. For the most part, the Proposed Rule does not address or weigh these issues in evaluating the strength of evidence.

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[18] ISA, supra note 3, at pp. 6-78.
[19] Proposed Rule, supra note 1, at pp. 38907.

During the review, substantive scientific comments were provided by AIR, Inc. on behalf of the Alliance of Automobile Manufacturers,[20] by Anne Smith of Charles River Associates,[21] and by Julie Goodman and Sonja Sax of Gradient Corporation.[22] The combination of these public submissions raised numerous substantive issues that are relevant to the final rule yet the Proposed Rule, for the most part, does not acknowledge the concerns. A summary of these issues is presented in the following section.

- **There are spatial differences and inconsistencies in the chronic mortality studies; for example, there is no cardiovascular mortality signal in a large study in the Netherlands and there is no chronic mortality signal in several studies in the Western U. S. This leads to the conclusion that, to the extent there are positive $PM_{2.5}$ chronic-mortality associations, they are caused either by unidentified covariates that may or may not be pollution-related, by components of PM not PM mass, or by historic high exposures and sources unique to the Eastern U. S.**

Both Gradient and AIR comments focused on the Zeger et al., 2008 study that reported positive $PM_{2.5}$ associations with mortality in the Eastern and Central U. S. but no association in the Western U. S. despite all three regions having similar recent $PM_{2.5}$ ambient levels. For example, Zeger et al. report "substantial and unexplained geographic heterogeneity in the effect of $PM_{2.5}$ across the United States." There are a number of additional chronic studies that report little or no $PM_{2.5}$ association with total mortality in California. In Enstrom, 2005 and in various analyses of the California subjects within the American Cancer Society cohort evaluated in Krewski et al., 2009 there is little association.[23] There are also other cohort studies in California in which there is little or no association of $PM_{2.5}$ with total mortality, although these studies report positive associations for some genders and sub-categories.[24]

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[20] J. M. Heuss and G. T. Wolff, AIR, Inc. Comments on the U. S. EPA's First External Review Draft of the Policy Assessment for Particulate Matter, Air Improvement Resource, Inc. report prepared for the Alliance of Automobile Manufacturers, April 23, 2010; Docket No. EPA-HQ-OAR-2007-0492-0095.1.

[21] Docket No. EPA-HQ-OAR-2007-0492-0092.1

[22] Docket No. EPA-HQ-OAR-2007-0492-0096.1

[23] See August 31, 2010 letter from D. Krewski to HEI President D. Greenbaum that includes special analyses of the California subjects in HEI Research Report 140; See also M. Jerrett, R.T. Burnett, A. Pope III, D. Krewski, G.Thurston, G. Christakos, E. Hughes, Z. Ross, Y. Shi, M. Thun, B. Beckerman, M. C. Turner, J. Su, and S.-J. Lee, "Spatiotemporal Analysis of Air Pollution and Mortality in California Based on the American Cancer Society Cohort: Final Report" Final Report for California Air Resources Board Contract No. 06-332, October 2011 in which there is a null association in eight of nine separate exposure models.

[24] McDonnell et al., 2000; Chen et al., 2005; M. Lipsett, B. Ostro, P. Reynolds, D. Goldberg, M. Jerrett, and D. Smith, Extended Analysis of Air Pollution and Cardiovascular Disease in the California Teachers Study Cohort, Final Report, California Air Resources Board Contract #06-336, October 2011.

In discussing the overall contribution of new acute and chronic studies, Gradient concludes that much of the new evidence points to large unexplained differences in effects across regions, cities, and seasons. This is the evidence discussed above for acute studies. The Proposed Rule acknowledges the lack of association in the West in the Zeger et al., 2008 study but does not follow up to discuss the implications of the geographic heterogeneity. One possible implication is that there is a high probability that the reported associations of risk of cardiovascular death in the Central and Eastern U. S. with $PM_{2.5}$ are unique to that area. Additional evidence in support of this interpretation comes from a new European study, Beleen et al., 2008, a large cohort study from the Netherlands. In Beelen et al., 2008, none of the $PM_{2.5}$ associations in the full cohort of over 120,000 participants were statistically significant although the strongest association was with respiratory mortality. Thus, Beelen et al. observed, if anything, a small respiratory signal as compared to the cardiovascular signal in portions of the ACS and Medicare cohorts that EPA relies on in the Proposed Rule. While the Beelen et al. study is included in the ISA, the $PM_{2.5}$ associations are not presented in the text, although they are included in a table in an Appendix. The Beelen et al. study is not discussed in the Proposed Rule. If generic $PM_{2.5}$ is causing cardiovascular mortality, it should cause it the Western U. S. and in Europe as well.

The spatial differences and inconsistencies in the chronic mortality studies lend additional credence to the conclusion that, to the extent there are positive $PM_{2.5}$ associations, they are caused either by unidentified covariates, by components of PM not PM mass, or by historic high exposures and sources unique to the Eastern U. S. These possibilities are not discussed in the Proposed Rule. The Health Effects Institute's Health Research Committee Commentary on the Krewski et al., 2009 study concludes "with the emergence of new cohort evidence from the United States and Europe — the similarities and differences among the results of the various studies need to be examined closely."[25] Thus, the new studies do not report consistent effects as posited in the Proposed Rule. The Commentary also concludes that residual confounding (by climate and possibly other unmeasured determinants of large-scale spatial variation) cannot be excluded, particularly in the Nationwide Analysis from Krewski et al., 2009 which EPA relies on in the Proposed Rule.

Even if the various other explanations for positive associations in the cohort studies EPA relies on are dismissed, Charles River and Gradient raised a concern related to the lack of knowledge of the appropriate exposure period for attributing effects in the cohort studies that may cause recent associations. This issue that is not acknowledged in the Proposed Rule needs to be fully vetted in the Final Rule.

Charles River points out that there are several possible explanations for the continued evidence of relative risks reported in the newer studies. First, recent mortality may be the result of cumulative exposure to $PM_{2.5}$ over an entire lifetime. Second, recent mortality may be the result of chronic conditions that developed due to earlier, higher $PM_{2.5}$ concentrations to which all members of the cohorts have been exposed during their

[25] Health Effects Institute Research Report 140, Health Effects Institute, Boston, Massachusetts, at page 134.

lifetimes. In addition, it may be that there is no causal relationship between $PM_{2.5}$ exposure and death --the mortality observed in long-term epidemiologic research may be caused by some other factor for which PM is a proxy. There is no way to determine which of these or other possible explanations accounts for the results of recent $PM_{2.5}$ chronic exposure studies. Thus, the results of the "new" studies do not support tightening the annual standard. This is a particularly important issue because the Proposed Rule implicitly assumes that the associations reported in the cohort studies noted above are caused by the recent exposures.

The AIR, Gradient, and Charles River comments raised additional specific concerns with the cohort studies the Agency relies on. For example, none of the studies evaluated co-pollutant effects in spite of the fact that the 2000 HEI re-analysis of the original ACS study showed that one gaseous pollutant, SO_2, had a strong association with mortality, and that when SO_2 was included in the model the PM all-cause mortality association was materially reduced and became non-significant. The 2000 HEI re-analysis also reported that there was a significant spatial heterogeneity in the association, with no sulfate association seen in western U. S. cities. Thus, the recent cohort studies that EPA relies on did not follow-up on important extenuating factors that might materially change the interpretation of the results as a universally applicable chronic PM health effect caused by generic $PM_{2.5}$.

The Proposed Rule includes a discussion of the Miller et al. 2007 Women's Health Initiative Study that reported higher cardiovascular risk estimates than the other studies. However, the within-city risk (the risk associated with differences in fine PM levels within cities) for a 10 $\mu g/m^3$ increase in $PM_{2.5}$ is greater than the risk associated with smoking 40 cigarettes a day, findings that defy plausibility, casting doubt on the results of the study.

Lacking any empirical evidence on the timing of the exposures that best explain the observed relative risks, one is left with no further evidence on long-term exposure risks than was available at the time of previous standard settings. Most importantly, the public submissions point out the fact that relative risks continue to be elevated in the face of longer cohort follow up periods cannot be viewed as evidence that the health-risk associations are *attributable* to the lower $PM_{2.5}$ exposures of the more recent past. The relative risks observed in the aging cohort now that $PM_{2.5}$ concentrations are in the range of 14 $\mu g/m^3$ were also present long before $PM_{2.5}$ had been reduced to those lower levels. Thus, the evidence of a relative risk association that was used to justify setting the standard at 15 $\mu g/m^3$ back in 1997, and again in 2006, has not fundamentally changed. Thus, there is substantial evidence in support of retaining the current annual $PM_{2.5}$ standard that is not being considered in the Proposed Rule.

- **The proposed revision is based on selected epidemiologic associations, ignores many studies in the literature, and is not supported by evidence from controlled human exposures or animal toxicology.**

Toxicology is known as the science of poisons, where a poison may be any substance which when acting directly through its inherent chemical properties is capable of destroying or seriously endangering life. Any substance, even food and water, may be harmful if absorbed or ingested in excessive amounts. The dose determines whether or not injury will occur, requiring the toxicologist to pay careful attention to the quantitative measurement of both dosage and effect, before the delivered dose is declared as "harmful." One of the major uncertainties EPA acknowledged during the 1996 review of PM NAAQS was the lack of demonstrated mechanisms that would explain the mortality and morbidity effects implied by the epidemiological associations. A review of the toxicology material EPA used for the 2009 review reveals that, despite over a decade of expanded and focused research, there are still no data from controlled studies that indicate how anthropogenic PM at current ambient levels is causing the mortality and morbidity effects implied by the epidemiological associations that EPA relies on.

A study by Valberg (2004)[26] illustrates the disconnect between the epidemiological and toxicological results. Valberg used the chemical-specific, dose-response data typically used in U.S. EPA human health risk-assessments to evaluate the risk associated with a mixture of 27 separate chemical constituents typical of ambient PM with a total $PM_{2.5}$ concentration of 15 $\mu g/m^3$. The assessments rely on established, no-effect thresholds for noncancer health endpoints. Valberg found that the chemicals identified as constituents of ambient PM are present at concentrations considerably below the regulatory thresholds (for which no adverse health effects are anticipated for a lifetime exposure) used in risk assessment. From the perspective of risk assessment, Valberg concluded that exposure to the concentrations of chemicals in ambient PM (e.g., sulfate, nitrate, and 25 other constituents) cannot be expected to cause death. Hence, he noted that the health effects attributed to ambient PM in the NAAQS review appear to be at odds with what would be predicted from a standard U.S. EPA health-risk assessment for PM chemicals. Valberg discusses four possible explanations for this paradox: 1) the toxicity of ambient PM is unrelated to its chemical constituents, 2) PM mass concentration is not the causal factor in the reported associations, 3) the mixtures of chemicals in ambient PM are vastly more toxic than the sum of individual components, or 4) a small portion of the general population are vastly more sensitive to certain PM chemicals than reflected in the EPA toxicity factors. A more likely explanation of this paradox, however, is model selection bias, confounding and exposure uncertainty. The EPA rulemaking materials (ISA, PA, NPRM) are silent on the existence of this paradox, much less on the possible explanations.

- **The cardiovascular health risk assumed by EPA is not consistent or coherent with fine PM risks from other PM exposure situations including indoor pollution in developed countries, indoor pollution in underdeveloped countries, smoking, and occupational exposures.**

If low doses of generic ambient $PM_{2.5}$ are causing the serious health effects implied by the statistical associations EPA relies on, then low doses of particles should be causing similar effects in other exposure situations. As documented in the ISA, the

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[26] P. A. Valberg, "Is PM More Toxic Than the Sum of Its Parts? Risk-Assessment Toxicity Factors vs. PM-Mortality 'Effect Functions,'" *Inhalation Toxicology*, 16(suppl. 1):19–29, 2004.

exposure to nonambient particles is as high or higher than the exposure to ambient particles. Therefore, there should be a health signal for generic particles as measured by mass in the indoor pollution literature. Although there are well-established indoor health risks from environmental tobacco smoke and from particles of biological origin such as house dust-mite, cockroach, and animal allergens, no substantial or consistent health signal from generic PM has been documented. A review of the scientific literature focusing on non-industrial indoor environments looked for evidence of particle health effects.[27] An interdisciplinary group of European researchers surveyed over 10,000 articles by title, chose 1725 abstracts to screen, and chose 70 articles for full review. They concluded that "there is inadequate scientific evidence that airborne, indoor particulate mass or number concentrations can be used as generally applicable risk indicators of health effects in non-industrial buildings." The lack of a health signal from generic indoor PM is not coherent with the assumed presence of a strong outdoor generic ambient PM health signal.

Gamble and Nicolich[28] compared the risks from smoking and occupational exposures with the risks implied by several of the cohort studies that EPA relies on and concluded that the toxicity per unit mass of ambient PM would have to be 2 to 4 orders of magnitude higher than that from smoking to explain the reported ambient risks. The finding led them to conclude that the risks from the cohort studies were not coherent with the risks derived from smoking or occupational studies.

The findings from massive indoor pollutant exposures in developing nations are also relevant. Approximately half the world's population relies on unprocessed biomass fuels (wood, coal, crop residues, or animal dung) for cooking and space heating. These fuels are typically burned indoors in simple unvented cookstoves. The exposures to both gases and particles are many times higher than the indoor exposures in developed countries. For example, a detailed exposure study[29] of 55 households in rural Kenya reports PM_{10} exposures of adult women (who normally cook and tend the fire) were the order of 5 mg/m^3 while adult male exposures were the order of 1 mg/m^3. These levels are 40 to 200 times higher than the current average U. S. outdoor PM_{10} levels of 25 μg/m^3. A 2002 World Health Organization report[30] of the health effects of indoor pollution exposures in developing countries reviews the evidence for health effects from these exposures. While there is strong evidence of important effects on acute and chronic

[27] T. Schneider, J. Sundell, W.Bischof, M. Bohgard, J. W. Cherrie, P. A. Clausen, S. Dreborg, J. Kildeso, S. K. Kjaergaard, M. Lovik, P. Pasanen, and K. Skyberg, EUROPART. Airborne Particles in the Indoor Environment. A European Interdisciplinary Review of Scientific Evidence on Associations between Exposure to Particles in Buildings and Health Effects, *Indoor Air*, 13:38-48, 2003.

[28] J. F. Gamble and M. J. Nicolich, Comparison of Ambient PM Risk with Risks Estimated from PM Components of Smoking and Occupational Exposures, *J. Air & Waste Manage. Assoc*., 2000, *50*, 1514-1531.

[29] M. Ezzati, H. Saleh, and D. M. Kammen, The Contributions of Emissions and Spatial Microenvironments to Exposure to Indoor Air Pollution from Biomass Combustion in Kenya, *Environmental Health Perspectives*, 2000, 108, 833-839.

[30] N. Bruce, R. Perez-Padilla, and R. Albalak, The health effects of indoor air pollution exposure in developing countries, World Health Organization Report WHO/SDE/OEH/02.05, 2002.

respiratory disease in many countries and effects on lung cancer from coal use in China, there is little evidence to date of a strong cardiovascular signal from these massive exposures.

Yusuf et al., 2001[31] discuss the global burden of cardiovascular disease in detail. A comparison of the overall cardiovascular heart disease rates in various areas of the world together with urban/rural and male/female differences in countries like China and India that have large populations and massive biomass fuel exposures reveals little support for fine PM being a significant cardiovascular risk factor. This also does not appear to be coherent with the assumption of a strong cardiovascular signal from low doses of generic ambient $PM_{2.5}$.

EPA should not tighten the current $PM_{2.5}$ standards based on questionable assumptions without addressing the coherence of the PM risks they posit with the risks observed or not observed in other PM exposure situations.

- **The PM Risk Assessment in the proposal is based on assumptions that are known to be wrong (all fine PM is equally toxic) or unverifiable (the dose-response is linear with no threshold). Based on theses issues, little or no weight should be afforded to the results of the risk assessment.**

In the last review, the Administrator placed little weight on the quantitative risk assessment because it was not clear that controls that would reduce fine PM would also reduce the toxic components. That concern is still relevant. In addition, since there are acute and chronic fine PM associations in cities and regions that are negative or zero, the final rule should acknowledge that the lower limit of the risk from attainment of the current standards is zero.

Although the Proposed Rule gives substantial weight to the risk assessment, the fact that it is based on flawed (equal toxicity per unit mass) and unverifiable (linear, no threshold concentration-response) assumptions needs to be explicitly acknowledged in the final rule. Based on theses issues, little or no weight should be afforded to the results of the risk assessment. If little weight is given to the risk assessment, and greater weight is given to the issues raised above concerning both the acute and chronic epidemiological studies, retention of the current $PM_{2.5}$ standards becomes a prudent public policy choice.

PM air pollution is a complex mixture of solid and liquid particles that vary in number, size, shape, surface area, chemical composition, solubility, and origin. The 2004 PM

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[31] S. Yusuf, S. Reddy, S. Ôunpuu and S. Anand, Global Burden of Cardiovascular Diseases: Part I: General Considerations, the Epidemiologic Transition, Risk Factors, and Impact of Urbanization, Circulation, 2001;104;2746-2753 DOI: 10.1161/hc4601.099487; S. Yusuf, S. Reddy, S. Ôunpuu and S. Anand, Global Burden of Cardiovascular Diseases: Part II: Variations in Cardiovascular Disease by Specific Ethnic Groups and Geographic Regions and Prevention Strategies, Circulation, 2001;104;2855-2864 DOI: 10.1161/hc4701.099488.

CD[32] indicated that different PM materials also vary extensively in toxicity based on over 30 years of toxicological study. The CD concluded that the historical toxicological data provide little basis for concluding that specific PM constituents have substantial respiratory effects at current ambient levels. This substantial body of information is routinely used to establish chemical-specific standards that are used in occupational and other settings and demonstrates that the relative toxicity of different $PM_{2.5}$ species per unit mass varies by over three orders of magnitude.[33]

In the high dose studies reviewed in the 2004 CD and the 2009 ISA, there are many examples that show that biological response varies dramatically depending on the chemical composition of the PM used. The 2004 CD summarized this material noting "overall, the new studies suggest that some particles are more toxic than others." The CASAC specifically commented on this issue indicating "The chapter must make it clear that there is a large data base that indicates that PM is markedly variable in its toxic potency."[34] Thus, the assumption that all PM is equally toxic cannot be supported and the current practice of measuring and regulating all $PM_{2.5}$ as if it were equally toxic is a gross simplification that leads to substantial uncertainty.

CASAC's May 17, 2010 letter to EPA Administrator Jackson indicates:

> $PM_{2.5}$ has been a useful surrogate index since it was adopted in the 1997 PM NAAQS promulgation, but may become an increasingly inadequate index of health risk as the mass concentration limits are reduced to the levels being contemplated in the current *Policy Assessment*.[35]

The CASAC also encouraged the Agency to move aggressively forward toward developing the next generation of indicators for primary PM standards. CASAC would not of made these statements unless the Panel had understood that (1) $PM_{2.5}$ mass is a surrogate for the mix of PM components (alone or with gaseous pollutants) that may be causing heath effects, and (2) the assumption of equal toxicity by mass used in the risk assessment is weak, if not scientifically unsound.

Despite whatever opinions various experts might hold, the shape of the concentration-response function is not known. The question of the shape of the concentration-response function was a major consideration during the review of the 2004 PM Criteria Document

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[7] U.S. EPA, *Air Quality Criteria for Particulate Matter*; EPA/600/P99/002aF and bF; U.S. Environmental Protection Agency, Washington, DC, 2004CD at page 7-85.

[8] 2006 Threshold Limit Values and Biological Exposure Indices, American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio.

[9] P. Hopke, Clean Air Scientific Advisory Committee (CASAC) Particulate Matter (PM) Review Panel's Ongoing Peer Review of the Agency's *Fourth External Review Draft of Air Quality Criteria for Particulate Matter*, EPA-SAB-CASAC-04-005, U.S. EPA, Washington, DC, March 1, 2004.

[35] CASAC Review of Policy Assessment for the Review of the PM NAAQS - First External Review Draft (March 2010), CASAC letter to Administrator Jackson, EPA-CASAC-10-011, May 17, 2010.

and the development of the risk assessment included in the PM Staff Paper. Although early drafts of the CD indicated that the PM studies generally show linear concentration-response associations, responding to specific input in CASAC's October 4, 2004 letter, the final CD conclude that "In summary, the available evidence does not either support or refute the existence of thresholds for the effects of PM on mortality across the range of concentrations in the studies."[36] The final Chapter 8 also noted "the available information does not allow for a clear choice of "threshold" or "no threshold" over the other."[37] This view is consistent with points made by the Special Panel of the HEI Review Committee that raised several cautions in interpreting the NMMAPS concentration-response results. They point out[38] that measurement error could obscure any threshold that might exist, that city-specific concentration-response curves exhibited a variety of shapes, and that the use of Akaike Information Criterion may not be an appropriate criterion for choosing between models. The HEI Panel cautioned that lack of evidence against a linear model should not be confused with evidence in favor of it. In addition, Rhomberg et al. (2011)[39] have recently shown, as others have previously shown, that measurement error can give a false linear result. Thus, the epidemiological studies cannot inform us as to whether there is or is not a biologic gradient for ambient PM at low concentrations or whether there is or is not a threshold.

The toxicological studies of PM components that have been used to set chemical–specific standards demonstrate both threshold behavior and the presence of effects that not only become less common with progressively lower doses, but they also become less severe. The existence of a substantial threshold for the first physiological effects in controlled studies is not consistent with the assumption that the more severe effects suggested by some epidemiological studies have no threshold. Such assumptions are not consistent with either the general principals of toxicology or the specific findings of PM toxicological studies. Rhomberg et al. (2011)[40] discusses these issues in detail. Rhomberg et al. argue:

> The no-threshold proposal for noncancer toxicity is at variance with decades of experience in observing exposure-response relationships in pharmacology and toxicology, both within and below the usual experimental range for environmental chemicals.

They note:

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[36] 2004 CD, supra note x, at pp. 9-44.
[37] Ibid., at pp. 8-320.
[13] Health Effects Institute; Commentary on the National Morbidity, Mortality and Air Pollution Study Part III: PM_{10} Concentration-Response Curves and Thresholds for the 20 Largest U.S. Cities, HEI Research Report Number 94, Part III, May 2004.
[39] L. R. Rhomberg, J. K. Chandalia, C. M. Long, and J. E. Goodman, "Measurement error in environmental epidemiology and the shape of exposure-response curves," *Critical Reviews in Toxicology*, Sept. 2011, Vol. 41, No. 8; pp. 651-671. (doi: 10.3109/10408444.2011.563420).
[40] L. Rhomberg, J. Goodman, L.Haber, M. Dourson, M. Andersen, J. Klaunig, B. Meek, P. Price,R. McClellan, and S. Cohen. "Linear low-dose extrapolation for noncancer health effects is the exception, not the rule." *Crit. Rev. Toxicol*. 41:1-19 (2011).

> The no-threshold idea is also belied by our experience with medicines, poisons, foodstuffs, and many other kinds of exposure to agents that can have toxic effects if experienced in excess. With the possible exception of allergic reactions, within the range of low exposures, we do not observe slightly increased exposures to such agents somewhat increasing the probability that we will suffer the full effect of a toxic dose. In therapeutics, a small fraction of the therapeutic dose will not necessarily produce a moderate or full response in a diminished fraction of the treated population. It is only when the critical concentration is sustained at the site of action for the necessary period of time that an effect will be elicited. The experience of exposure thresholds for biological effects, including adverse effects, pervades daily life.

They also argue that the no-threshold proposal is at variance with basic tenets of homeostasis—the robust nature of living systems.

Given that the shape of the C-R is unknown, the assumption of no-threshold is not consistent with the general principals of toxicology, and the assumption of equal toxicity is known to be wrong, the Administrator should not place any weight in the final decisions on the risk assessment.

- **Given the many limitations and uncertainties of interpreting the acute and chronic epidemiological data, retaining the current annual standard would be a prudent, health-protective decision.**

II. Comments on eliminating spatial averaging

The Alliance supports the proposal to eliminate spatial averaging provisions as part of the form of the annual standard to avoid potential disproportionate impacts on at-risk populations with one important qualification. The key is that monitor siting should represent community-wide exposure as currently required. The current regulations allow micro or middle-scale $PM_{2.5}$ sites that are population-oriented when they represent many such locations throughout a metropolitan area. The EPA's definition of ''population-oriented'' is provided in 40 CFR 58.1—''Population-oriented monitoring (or sites) means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day.'' As long as these requirements are retained, the Alliance supports eliminating spatial averaging.

The proposed rule indicates that, with the spatial averaging provisions eliminated, "the level of the annual $PM_{2.5}$ standard would be compared to measurements made at the monitoring site that represents area-wide air quality recording the highest PM concentrations."[41] However, the EPA also proposes to revoke the requirement that $PM_{2.5}$ monitoring sites be ''population-oriented'' for comparison to the NAAQS. The reason given for revoking the population-oriented definition is that it is inconsistent with EPA's

[41] Proposed Rule, supra note 1, at 38925.

definition of ambient air. The proposed rule also indicates:[42]

> EPA's proposal to revoke this term in no way changes the requirements in the $PM_{2.5}$ network design criteria, which will continue to focus on sites representing ''area-wide'' locations; thus continuing to represent locations with population exposure.

The Alliance is concerned that revoking the population-oriented requirement may result in monitoring in locations that are not appropriate for comparison with either the annual standard or the 24-hour standard. The Alliance is also concerned that the proposed change may result in inappropriate use of modeling results in the implementation of revised standards. Each of these concerns will be discussed in turn.

Monitoring Concerns

EPA's definition of ambient air is specified in 40 CFR 50.1—''Ambient air means that portion of the atmosphere, external to buildings, to which the general public has access.'' While this is an appropriate definition of ambient air, monitoring for compliance with any given air quality standard should be carried out at locations where there are people actually exposed for time periods that correspond approximately to the averaging time of that NAAQS. Thus, for comparison with the annual $PM_{2.5}$ standard, the population-oriented definition is appropriate since it involves locations where a substantial number of people spend a significant fraction of the day.

The concern that the Alliance has is that without a requirement to site monitors in this manner, monitoring from locations that have little or no population exposure could be used for comparison with the $PM_{2.5}$ NAAQS. For example, the Agency indicates:[43]

> Area-wide means all monitors sited at neighborhood, urban, and regional scales, as well as those monitors sited at either micro- or middle-scale that are representative of many such locations in the same CBSA.

The key issue with this approach is that there may be many similar micro-scale locations in a metropolitan area but none of them may have actual human exposures relevant to the averaging time of the NAAQS.

The proposed rule indicates:[44]

> In reviewing the impact that this proposed change might have on the nation's $PM_{2.5}$ monitoring network, the EPA notes that there are no remaining sites operating affirmatively as ''non-population-oriented.''

While this may be true, the proposed rule also requires the addition of a substantial

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[42] Ibid., at 39008.
[43] Ibid., at 39048.
[44] Ibid., at 39008.

number of near-road monitoring sites the location of which is still to be decided. The Alliance concerns with the near-road monitoring requirements are discussed below. In addition, the Agency provides no examples of cases where the current definitions have resulted in any ambiguity with regard to monitoring locations. Therefore, the Alliance does not support the EPA proposal to revoke the requirement that $PM_{2.5}$ monitoring sites be ''population-oriented'' for comparison to the NAAQS.

Modeling Concerns

The proposed rule indicates:[45]

> …this requirement in the monitoring rules creates substantial ambiguity in how to treat potential locations of exposure such as in applying modeling across an area. By reverting to the long-standing definition of ambient air, the EPA will be able to more clearly define how to treat potential exposure receptors, regardless of whether monitoring exists or not.

Since computer modeling is used for PSD permitting, transportation conformity, and attainment demonstrations of the NAAQS standards, the Alliance is concerned that, by removing the population-oriented concept, the Agency may require computer simulations to show compliance with the $PM_{2.5}$ standards at receptor locations where the public only has access in a theoretical sense or has access but is not exposed for relevant time periods. Since this would result in added stringency for the standard without any commensurate public health protection, it would be inappropriate. In addition, since such modeling is already in place, the Agency should be able to give specific examples of the ambiguity it claims to want to remove. None are provided in the proposed rule. Therefore, the Alliance does not support the removal of the definition of "population-oriented" with regard to the choice of receptors in computer modeling for $PM_{2.5}$.

III. Comments on requiring monitoring in the near-road environment

The EPA proposes that some $PM_{2.5}$ monitors be collocated with measurements of other pollutants (e.g., nitrogen dioxide, carbon monoxide) in the near-road environment. The Alliance has no problem with monitoring anywhere in the near-road environment for research purposes, but the Alliance is concerned that any $PM_{2.5}$ monitoring that is to be used to compare with the annual standard for attainment purposes must be population-oriented.[46]

The proposed rule indicates the rationale for the near-road monitoring as follows:[47]

[45] Ibid.

[46] Population-oriented monitoring (or sites) means residential areas, commercial areas, recreational areas, industrial areas where workers from more than one company are located, and other areas where a substantial number of people may spend a significant fraction of their day (40 CFR 58.1).

[47] Proposed Rule, supra note 1, at 39009.

> The EPA believes that there are gradients in near-roadway $PM_{2.5}$ that are most likely to be associated with heavily travelled roads, particularly those with significant heavy-duty diesel activity, with the largest numbers of impacted populations in the largest CBSAs in the country (Ntziachristos et al., 2007; Ross et al., 2007; Yanosky et al., 2008; Zwack et al., 2011). To better understand the potential health impacts of these exposures, the EPA proposes to add a near-road component to the compliance network design for $PM_{2.5}$ monitoring.

The specific requirement is to monitor near-road $PM_{2.5}$ at one location in each CSBA[48] with a population of one million or more. EPA proposes that the PM monitor be co-locate with other near-road monitors for NO_2. In addition, EPA is making two additional changes. First:[49]

> The EPA is clarifying language to explicitly state that measuring $PM_{2.5}$ in micro- and middle-scale environments near emissions of mobile sources, such as a highway, does not constitute being impacted by a ''unique'' source. Mobile sources are rather ubiquitous and, as such, there are many locations throughout an urban area where elevated exposures could occur. Therefore, any potential location for a $PM_{2.5}$ monitoring site, even micro- and middle-scale sites near roadways would be eligible for comparison to the annual NAAQS.

Second:[50]

> EPA proposes that $PM_{2.5}$ monitoring sites at micro- and middle-scale locations be comparable to the annual standard unless the monitoring site has been approved by the Regional Administrator as a ''relatively unique micro-scale, or localized hot-spot, or unique middle-scale site.''

The Alliance has several issues with the way EPA proposes to implement the near-road requirement. The Alliance is concerned that the elimination of spatial averaging and the definition of population-oriented when combined with the requirement to co-locate $PM_{2.5}$ monitors with near-road NO_2 and CO monitors will result in collection of data in locations that are representative of no-one's annual average or 24-hour average $PM_{2.5}$ exposure. This could result in a major tightening of the standard, with significant unintended consequences for industry and economic development. Entire metropolitan areas could be placed in non-attainment based on measurements made where no-one is actually exposed.

The Alliance is concerned that the decision to co-locate with NO_2 monitors was based on convenience and the intent of the NO_2 near-road monitoring is to find the highest micro-scale concentrations within a few meters of the most heavily travelled segments of the most heavily travelled expressways, a unique situation.

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[48] CSBA stands for Core Based Statistical Area, a term synonymous with Metropolitan Statistical Area for the purposes of the proposed rule.
[49] Proposed Rule, supra note 1, at 39008.
[50] Ibid., at 38925.

The proposed rule defends the decision to piggy-back the PM monitoring with the planned NO_2 monitoring because considerable thought and review has gone into that network design. However, the final guidelines for monitor placement do not require population exposure at the monitoring site. The final Technical Assistance Document notes "It is important to recall that the objective is to monitor in locations that are as near as practicable to roads where peak, ground-level NO_2 concentrations are expected to occur."[51] Once candidate sites are identified based on traffic counts and other factors, the potential for population exposure can be considered as noted in the TAD. However, the discussion of population exposure suggests that it is near-by population rather than actual population exposure at the monitoring site that is the relevant consideration. Once a site has been selected and approved, the TAD indicates that the information for the site in EPA's Air Quality System identify the site as "source-oriented" and include the horizontal distance from the probe to the nearest edge of the target road.[52] The TAD also discusses the fact that the probe may be located in the right-of-way (ROW) of a limited access expressway.[53] Thus, the location of NO_2 and any co-located $PM_{2.5}$ monitors will be source-oriented and not population-oriented. This would be a major change from prior practice and is not justified. Near-road monitor results should not be used to compare to the annual or 24-hour $PM_{2.5}$ standard unless it can be shown that it is from a population-oriented site consistent with the definition in 40 CFR 58.1. Although EPA proposes to allow the Regional Administrator to give a waiver for "unique" micro-scale sites, the Agency should not allow consideration of source-oriented sites in the first place.

The Alliance is also concerned that EPA is overestimating the gradients in $PM_{2.5}$ near the road. The four references provided in the proposed rule do not make a sufficient case to add near-road $PM_{2.5}$ monitoring. The Zwack et al., 2011[54] study involves the impact in street canyons in mid-town Manhattan and concludes that $PM_{2,5}$ is elevated by from 5 to 8 % over background. Although the Zwack et al. study is useful, it does not apply to the multi-lane expressway case that is at issue in the proposed rule. The Ross et al., 2007[55] and Yanosky et al., 2008[56] references are to studies that used land-use regression to estimate $PM_{2.5}$ exposures and do not include any data on actual roadway impacts. The Ntziachristos et al., 2007[57] study evaluated the composition near the road with a site 1

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[51] U. S. EPA, *Near-road NO2 Monitoring Technical Assistance Document*, EPA-454/B-12-002, June 2012, at page 71.

[52] Ibid., at page 78.

[53] Ibid., at pages 62 and 78.

[54] L.M. Zwack, C.J. Paciorek, J.D. Spengler and J.I. Levy, "Characterizing local traffic contributions to particulate air pollution in street canyons using mobile monitoring techniques," *Atomspheric Environment,* 45:2507–2514, 2011.

[55] Z. Ross, M. Jerrertt, K. Ito, B. Tempalski and G. Thurston GD, "A land use regression for predicting fine particulate matter concentrations in the New York City region," *Atmospheric Environment,* 41:2255–2269, 2007.

[56] J.D. Yanosky, C.J. Paciorek and H.H. Suh, "Predicting chronic fine and coarse particulate exposures using spatiotemporal models for the Northeastern and Midwestern United States." *EHP*, 117:522–529, 2009.

[57] L. Ntziachristos, Z. Ning, M.D. Geller, R.J.Sheesley, J.J. Schauer and C. Sioutas, "Fine,

mile downwind and did not evaluate the gradient near the roadway. In contrast to these studies, Karner et al., 2010[58] synthesized the results of 41 studies evaluating the shape and rate of decay curves of pollutants near roadways. The review included 16 studies with $PM_{2.5}$ measured at various distances from the roadway. Karner et al. report, in contrast with other pollutants, $PM_{2.5}$ shows little or no gradient with distance from the road. Since the Karner et al. review analyzed real-world data from a variety of roadway situations, the Alliance urges the Agency to re-visit its concern over $PM_{2.5}$ gradients near roadways and the need for near-road monitoring. Karner et al. show that near-road exposures to $PM_{2.5}$ are not substantially elevated compared to community-wide exposures.

Along with the small gradient near roadways, there is also evidence that drivers and passengers in vehicles experience lower $PM_{2.5}$ exposures due to deposition losses in the vehicle air handling system. For example, Riedeker et al., 2003[59] report in-vehicle $PM_{2.5}$ was 24% lower than ambient and roadside levels, in a study of the occupational exposure of North Carolina State troopers during their normal work shifts, probably due to deposition associated with the recirculating air. Similarly, Rodes et al., 1998[60] in a study of thirty-two, 2-hour commuting trips in Los Angeles and Sacramento, CA in the fall of 1997 reported that particle concentrations were significantly higher outside the vehicles than inside, with inside levels often less than roadside levels, presumably due to losses in the vehicles ventilation system. Thus, there is also evidence that in-vehicle exposures to $PM_{2.5}$ are not elevated compared to community-wide exposures.

IV. Comments on the proposed secondary standard to protect visibility

EPA is proposing to set a new, secondary, 24-hour $PM_{2.5}$ NAAQS to address visibility impairment in urban areas. The proposed range of the level of the standard is a visibility index of 28 to 30 deciviews (dv). The form of the standard is the 90th percentile averaged over 3 years. The visibility index is calculated from an equation whose inputs depend upon the measured 24-hour chemical composition of $PM_{2.5}$ and the climatologically-averaged monthly relative humidity. The mass of the following chemical species are included in the calculation: sulfate, nitrate, organic carbon, elemental carbon and the principal crustal species (Al, Si, Ca, Fe and Ti).

Based on the very limited information that EPA has provided on the current existing levels of the visibility index in deciviews across the U.S., AIR has concluded that it will be the controlling $PM_{2.5}$ NAAQS in most areas of the country. Only in those areas of the

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ultrafine and nanoparticle trace element compositions near a major freeway with a heavy-duty diesel fraction," *Atmospheric Environment*, 41:5684–5696, 2007.

[58] A. Karner, D. Eisinger, and D. Niemier, “Near-Roadway Air Quality: Synthesizing the Findings from Real-World Data,” *Environ. Sci. Technol*., 44, 5334–5344, 2010.

[59] M. Riediker, R. Williams, R. Devlin, T. Griggs, and P. Bromberg, “Exposure to Particulate Matter, Volatile Organic Compounds, and Other Air Pollutants Inside Patrol Cars,” *Environ. Sci. Technol*., 37, 2084-2093, 2003.

[60] C. Rodes et al., “Measuring Concentrations of Selected Air Pollutants Inside California Vehicles, Final Report, Contract 95-339, California Air Resources Board, December 1998.

country where the $PM_{2.5}$ is dominated by crustal species will a primary NAAQS be the controlling NAAQS. In the eastern half of the U.S. and in southern California, where sulfate and/or nitrate comprise a significant part of the $PM_{2.5}$ mass, the proposed secondary NAAQS will likely be the limiting NAAQS. The reason for this is that these species are hydroscopic (adsorb water vapor) and at humidities above 40%, the coefficients for these terms increase exponentially with increasing relative humidity.

Legal Action Drives Secondary NAAQS

When EPA first promulgated a $PM_{2.5}$ NAAQS in 1997, they saw no need for an additional secondary NAAQS to address urban visibility. The NPRM states:

> The agency concluded that the spatially averaged form of the annual $PM_{2.5}$ standard was well suited to the protection of visibility, which involves effects of $PM_{2.5}$ throughout an extended viewing distance across an urban area. Based on air quality data available at that time, many urban areas in the Northeast, Midwest, and Southeast, as well as Los Angeles, were expected to see perceptible improvement in visibility if the annual $PM_{2.5}$ primary standard were attained.[61]

However, they did recognize that in certain urban areas may have unique scenic resources that may not be addressed by a $PM_{2.5}$ NAAQS and that additional local controls may be warranted:

> The EPA concluded that in such cases, state or local regulatory approaches, such as past action in Colorado to establish a local visibility standard for the City of Denver, would be more appropriate and effective in addressing these special situations because of the localized and unique characteristics of the problems involved.[62]

In 1999, EPA promulgated the Regional Haze Program which established goals for improving visibility in Federal Class I areas and required the formulation of control strategies to achieve these goals. In 2006, EPA reaffirmed the 1997 annual $PM_{2.5}$ NAAQS but lowered the 24-hour primary and secondary NAAQS from 65 to 35 $\mu g/m^3$. The EPA Administrator concluded at that time that this was adequate to protect against visibility impairment in urban areas.

During the 2006 review, however, there was considerable discussion of establishing a distinct sub-daily secondary standard for visibility protection which CASAC and EPA's staff favored. Although the Administrator did not agree with CASAC, CASAC's arguments were the basis for subsequent legal petitions. Several parties files petitions for review in 2006 and they challenged several aspects of the final rule. On the first aspect:

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[61] Proposed Rule, supra note 1, at 38966.
[62] Ibid., at 38967.

> First, they asserted that EPA never determined what level of visibility was "requisite to protect the public welfare." They argued that EPA unreasonably rejected the target level of protection recommended by its staff, while failing to provide a target level of its own. The court agreed, stating that "the EPA's failure to identify such a level when deciding where to set the level of air quality required by the revised secondary fine PM NAAQS is contrary to the statute and therefore unlawful. Furthermore, the failure to set any target level of visibility protection deprived the EPA's decision-making of a reasoned basis."[63]

On the second aspect:

> Second, the petitioners challenged EPA's method of comparing the protection expected from potential standards. They contended that the EPA relied on a meaningless numerical comparison, ignored the effect of humidity on the usefulness of a standard using a daily averaging time, and unreasonably concluded that the primary standards would achieve a level of visibility roughly equivalent to the level the EPA staff and CASAC deemed "requisite to protect the public welfare." Again, the court found that EPA's equivalency analysis based on the percentages of counties exceeding alternative standards "failed on its own terms". The same table showing the percentages of counties exceeding alternative secondary standards, used for comparison to the percentages of counties exceeding alternative primary standards to show equivalency, also included six other alternative secondary standards within the recommended CASAC range that would be more "protective" under EPA's definition than the adopted primary standards. Two-thirds of the potential secondary standards within the CASAC's recommended range would be substantially more protective than the adopted primary standards. The court found that EPA failed to explain why it looked only at one of the few potential secondary standards that would be less protective and only slightly less so than the primary standards. More fundamentally, however, the court found that PA's equivalency analysis based on percentages of counties demonstrated nothing about the relative protection offered by the different standards, and that the tables offered no valid information about the relative visibility protection provided by the standards.[64]

The third aspect:

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[63] U.S. EPA, supra note 7, at 4-8.
[64] Ibid., at 4-8.

> Finally, the Staff Paper had made clear that a visibility standard using $PM_{2.5}$ mass as the indicator in conjunction with a daily averaging time would be confounded by regional differences in humidity. The court noted that EPA acknowledged this problem, yet did not address this issue in concluding that the primary standards would be sufficiently protective of visibility.[65]

In 2009, the U.S. Court of Appeals in DC remanded the secondary NAAQS to EPA. EPA is using the present $PM_{2.5}$ NAAQS to respond to the court's remand. EPA's proposed new secondary NAAQS is EPA's response to the Court.

The Indicator Used For The Proposed Secondary NAAQS

EPA is proposing the use of a visibility index as the form of the NAAQS. The index is based on an empirical relationship that relates the chemical composition of the $PM_{2.5}$ and the relative humidity to the visibility index which is measured in deciviews. The use of empirically derived equations relating the chemical composition of PM to visibility has been recognized for some time.[66] Based on refinements from their IMPROVE program, EPA proposes that the following relationship be used to estimate total light extinction (b_{ext}):[67]

$$b_{ext} = 3f(RH)(SO_4+NO_3) + 4OC + 10EC + Crustal, \qquad (1)$$

Where f(RH) is a function of the relative humidity, SO_4 and NO_3 are the concentrations of fine ammonium sulfate and ammonium nitrate, OC and EC are the masses of fine organics and elemental carbon and Crustal is the mass of fine crustal material. The f(RH) term is 1 for relative humidities $\leq$ 40% and it increases exponentially to 6 at a relative humidity of approximately 95%. EPA proposes to use values of f(RH) obtained from historical climatological data that were developed for the IMPROVE program rather than those calculated from measured relative humidities. Crustal is calculated from the fine elemental mass of the crustal components using the equation:

$$Crustal = 2.2Al + 2.49Si +1.63Ca +2.42Fe + 1.94Ti. \qquad (2)$$

The visibility index in deciviews is computed from:

$$VI = 10 \ln[(b_{ext} + 10)/)10]. \qquad (3)$$

The levels of the proposed standard in deciviews can be put in perspective if it is assumed that the composition of the $PM_{2.5}$ is that of the national average $PM_{2.5}$ composition. In that case, 28 dv corresponds to a concentration of approximately 20 µg/m^3 and 30 dv corresponds to approximately 25 µg/m^3.

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[65] Ibid., at 4-9.

[66] P.J. Groblicki, G.T. Wolff and R.J. Countess, "Visibility-reducing species in the Denver "Brown Cloud" - I. Relationships between extinction and chemical composition, " *Atmos. Environ.*, 15:2473-2484, 1981.

[67] Final Rule, supra note 1, at 39003.

Rationale for the Proposed Range of 28 - 30 dv

The basis for the proposed range are urban visibility preference studies conducted in four urban areas: Denver, CO, Vancouver, BC, Phoenix, AZ and Washington, DC. In these studies, the participants were shows photographs of a local scene under different visibility conditions ranging over the four studies from less than 10 dv to over 40 dv during full sunshine conditions. The participants rated each view as acceptable or unacceptable. The results of all the studies are summarized in Figure 5 of the NPRM,[68] which shows the percentage of the participants that rated each scene, ranked in deciviews, as "acceptable." Also shown are the best-fit logistical regression lines (response curves) for each city. In general, the scenes in Denver needed the lowest pollution levels to be ranked acceptable while more pollution was tolerated in Washington, DC. Phoenix was about midway between the two, and Vancouver was between Denver and Phoenix.

EPA gives weight to the "50% acceptability" criteria. The 50% acceptable criteria identifies the deciview level where 50% of the study participants found the visual air quality level to be acceptable. For each of the cities the approximate 50% points are: Denver, 20 dv, Vancouver 22.5 dv, Phoenix, 24 dv and Washington, 29 dv. The NPRM also identifies a range 20 - 30 dv that brackets the 50% acceptance criteria across all four urban areas. The PA concluded that it is appropriate to give consideration for a standard towards the upper end of this range. Hence the range of 28 - 30 dv was chosen but comments are solicited on a range down to 25.

Averaging Time of the Proposed NAAQS

As noted above, in the previous review CASAC recommended a sub-daily NAAQS for visibility. When EPA began this review, that is what the Agency was considering. In the first draft of the PA, EPA concluded that "consideration should be given to a one-hour averaging time based on the maximum hour in the daylight period or on all daylight hours."[69] In the second draft PA, this was somewhat refined: "consideration should be given to a 1-hour averaging time, considering only daylight hours with relative humidity no higher than 90 %, and a level, defined in terms of $PM_{2.5}$ light extinction, in the range of 191 to 64 Mm^{-1} to target protection against visibility impairment related to fine particles."[70]

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[68] Ibid., 38975.

[69] U.S. EPA, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards First External Review Draft,* EPA-452\P-10-003, March 2010, Research Triangle Park, NC, pp. 4-44.

[70] U.S. EPA, *Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards Second External Review Draft,* EPA-452\P-10-007, June 2010, Research Triangle Park, NC, pp. ES-2.

It then was a surprise that in the final PA and in the NPRM, EPA switched to a 24-hour averaging time with no opportunity for CASAC to respond. In the final PA, after making a shift to a 24-hour averaging time, EPA states:

> Staff concludes that it would also be appropriate to consider a multi-hour, sub-daily averaging period (e.g., 4 hours) to the extent that data quality issues that have recently been raised about data from continuous $PM_{2.5}$ monitors classified as Federal Equivalent Methods (FEMs) can be appropriately addressed.[71]

If EPA adopted a 1-hour or a 4-hour NAAQS, they would need 1- or 4-hour speciation data. Given the sampling and monitoring technology that is currently in use today, that is not feasible. Consequently, the 24-hour averaging time is a compromise.

Secondary NAAQS Will Be the Controlling Standard in Many Areas

Based on the observed relationships between $PM_{2.5}$ mass and light extinction, the $PM_{2.5}$ mass that corresponds to a 90th percentile visibility index in deciviews can be estimated. The relationship between b_{ext} and $PM_{2.5}$ is presented in Figure 3-2 of the Visibility Assessment.[72] Using the regression equation derived for the entire US, the following approximations can be made: 30 dv ≈ 25 $\mu g/m^3$, 28 dv ≈ 20 $\mu g/m^3$, and 25 dv ≈ 15 $\mu g/m^3$. Since these are 90th percentile values, it is not straightforward to compare these levels with the current 24-hour primary $PM_{2.5}$ NAAQS of 35$\mu g/m^3$ which is a 98th percentile averaged over three years. However, it seems reasonable to assume that an area having difficulty meeting the primary NAAQS would have difficulty meeting a secondary of 30 dv and would not likely meet a 25 or 28 dv NAAQS.

These conclusions are consistent with an EPA analysis that is presented in Table H-2 of the final PA[73] and is reproduced as Table 3 below. This Table indicates that while only 11% of US counties do not meet the primary 24-hour NAAQS, 24% would not meet a secondary NAAQS of 28 dv and 65% would not meet 25 dv. For the Northeast and Industrial Midwest, the numbers are even worse. In the Northeast and Midwest, 0% and 6% do not meet the primary NAAQS, while 18% and 51% would not meet a 28 dv NAAQS and 79% and 92% would not meet a 25 dv NAAQS. Somewhat surprisingly, a new secondary NAAQS appears easier to attain than the primary NAAQS in the Northwest. The reason for this is the differences in chemical composition. From equation 2, it is obvious that the $PM_{2.5}$ in areas with higher percentages of nitrates and sulfates, whose effect is enhanced significantly by humidity, will have more of an impact on visibility than $PM_{2.5}$ in areas with lower relative amounts of the hydroscopic compounds. Figure 3-17 in the ISA shows that nitrates and sulfates comprise about 60% of the $PM_{2.5}$ mass in the Midwest and Northeast, but only about 25% in the Northwest.

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[71] U.S. EPA, supra note 7, at ES-3.
[72] U.S. EPA, *Particulate Matter Urban-Focused Visibility Assessment Final Document*, EPA 452/R-10-004, July 2010.
[73] U.S. EPA, supra note 7, at H-2.

Consequently, based on the very limited analyses available, it appears that a proposed secondary NAAQS in the range of 25 - 30 dv will be the controlling standard for $PM_{2.5}$ in most places.

Alliance Position on a Proposed Secondary NAAQS for Urban Visibility

- **The Alliance does not support the proposal to create a new 24-hour secondary NAAQS for urban visibility.**

- **The Alliance supports retaining the existing secondary $PM_{2.5}$ NAAQS which are identical to the current primary NAAQS.**

- **EPA has not made a case that the proposed secondary NAAQS is needed to improve urban visibility.**

Based on the recent $PM_{2.5}$ trends, most urban areas of the U.S. are approaching, have attained or gone below the current suite of $PM_{2.5}$ NAAQS. Because of State Implementation Plans (SIPs) that are being implemented for the current annual NAAQS and those that will be implemented for the 24-hour NAAQS, these downward trends will continue for the foreseeable future. In addition, the current regulations in place for light- and heavy-duty vehicles, the new regulations on EGUs and the Regional Haze Rule will further insure that $PM_{2.5}$ will continue to decrease and urban visibilities will continue to improve.

- **EPA has not used sound science to provide a basis for the proposed secondary NAAQS.**

The selection of a NAAQS based on the subjective preferences of randomly chosen individuals is not sound science. In addition, EPA has not demonstrated that the "50% acceptability" criterion is a valid benchmark for setting a NAAQS. Further, there is a wide range of what the study participants determined to be "acceptable." It appears to be location specific. If so, it has not been demonstrated that different views in different urban areas would produce the same results. Much additional work is needed to demonstrate the appropriateness of this approach.

- **EPA has not demonstrated that the visibility level that is acceptable in any one place, is appropriate for the entire U.S.**

EPA acknowledges that some urban areas value their visual air quality more than others and understands that these areas may want to impose additional local controls to achieve their desired visibility targets. What they do not consider is that there may be other urban areas where it does not make economic sense to improve their visibility because an EPA-mandated, one-size-fits-all level of visibility is not necessary for the enjoyment of their vistas.

Setting a national secondary air quality standard to protect visibility is a formidable task. Unlike the situation with public health, where the inhaled dose of PM is the proximate cause of any health effects, the enjoyment of scenic vistas depends on the presence of such vistas, which varies from place to place primarily based on the local topography. For example, three of the preference studies were carried out in locations where there were mountains in the distant background. Furthermore, the Proposed Rule acknowledges that humidity plays a major role in light extinction from PM constituents. Thus, the topography and humidity that nature provides play an important role in establishing what is protective of public welfare. These factors vary from place to place making the use of a national standard to protect visibility problematic.

In addition, the concentrations of PM constituents at the observer are not the concentrations that cause a visual scene to be acceptable or not. The Proposed Rule indicates that what people see "is determined by the extinction of light along the paths between observers and the various objects they view."[74] Since the concern is primarily for the viewing of distant objects or scenes, it is the concentrations of PM constituents over the entire path that determines the extinction. Due to the presence of substantial spatial gradients, measurements of the localized extinction at any single point will not determine whether the viewing of a distant object or scene is adversely affected. Thus, the traditional monitoring of pollution at one or more stationary sites in a city is not well-suited for the protection of visibility. This is particularly true for the viewing of distant objects or scenes that are outside the urban area.

- **The way in which the proposed NAAQS is formulated, it is unnecessarily stringent.**

The visibility preference studies that EPA relied on to determine "acceptable" visual air quality utilized photographs of daytime views under conditions of full sun and cloudless skies. As shown in Figures A-157 to A-163 in Appendix A of the ISA, the diurnal $PM_{2.5}$ patterns for all the urban areas exhibit a $PM_{2.5}$ minimum in the late afternoon and all show a broad period of higher concentrations at night when dispersion conditions are poorer. Consequently, a 24-hour average concentration would be an overestimate of the $PM_{2.5}$ concentrations that occur during daytime viewing condition. More importantly, relative humidity also exhibits a significant diurnal pattern with the maximum occurring around dawn and the minimum occurring in the late afternoon. Since the relative humidity function [f(RH)] varies exponentially with relative humidity, the light extinction will be significant during the early morning hours. Consequently, a 24-hour average of the relative humidity will be an overestimate of the relative humidity during daylight viewing periods.

EPA proposes the use of monthly average relative humidities based on a long-term climatological database instead of the actual relative humidity measured concurrently with the $PM_{2.5}$. To calculate the monthly averages, EPA takes the average of all the hourly data in a month. In an attempt to screen out periods of precipitation and fog, EPA sets all hours with relative humidities above 95% to 95% before calculating the means.

[74] Proposed Rule, supra note 1, at pp. 38973.

The resulting means calculated in this manner, however, are going to be higher than the actual relative humidity that occurs during daytime viewing conditions on sunny days and thus introduces another positive bias in the calculated extinction coefficient. EPA should use actual measured daytime relative humidities.

As noted above, extinction over the path between the observer and the objects or scenes they view is the relevant cause of visibility impairment. The proposed standard relates to measurements at fixed sites. It would be preferable to develop and use long-path measurements of PM constituents to implement a secondary standard to protect visibility. At a minimum, there should be spatial averaging for any secondary standard to protect visibility. The need for spatial averaging was acknowledged in the 1997 final rule as it relates to protecting visibility. Without spatial averaging, the maximum local extinction at a site would over-estimate the extinction over long viewing paths.

The Proposed Rule acknowledges that there are issues with the assumptions concerning nitrate measurements in the IMPROVE formulation.[75] However, there is another major issue with the nitrate component. As acknowledged in the PM ISA, there is a temperature-driven partition and volatilization of nitrate.[76] Thus, nitrate during many of the daylight hours in the warmer part of the year is no longer present as a particulate species. Without correction for volatilization of nitrate, the standard will over-estimate extinction. In addition, the formulation will over-estimate the contribution of nitrate to visibility reduction and, in the implementation phase, improperly focus control strategies.

The proposed secondary NAAQS relies on 24-hour average measurements even though CASAC advised the Administrator:[77]

> …the sub-daily standard more clearly matches the nature of visibility impairment, whose adverse effects are most evident during the daylight hours; using a 24-hour $PM_{2.5}$ standard as a proxy introduces error and uncertainty in protecting visibility...

The Administrator proposed using the 24-hour measurements because of errors and uncertainty in the sub-daily measurements. Given the additional errors and uncertainties identified in these comments, the Alliance does not support the proposal to establish a separate secondary NAAQS to protect visibility. It would be prudent to rely on the existing regulations and control programs to meet the primary NAAQS for PM and other pollutants and the Regional Haze Rule to continue to improve urban visibility while developing appropriate long-path and continuous PM measurement technologies so that a scientifically sound secondary NAAQS can be considered in the next review.

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[75] Ibid., at pp. 38970.
[76] PM ISA, supra note 3, at pp. 3-183 and 3-186.
[77] Proposed Rule, supra note 1, at pp. 38968.

Region >			All U.S.	Northeast	Southeast	Industrial Midwest	Upper Midwest	Southwest	Northwest	Southern California	Other Areas
Total # of counties with suitable data to calculate the indicator >			187	33	47	53	10	9	26	7	2
Standard		Statistic	Number of counties and percentage of counties with suitable data[2]								
Current Standards - $PM_{2.5}$ mass indicator											
Annual	24-Hour										
15 μg/m[3]	35 μg/m[3]	# counties	21	0	1	3	0	0	11	5	1
		% counties	11%	0%	2%	6%	0%	0%	42%	71%	50%
Alternative Standards – Calculated $PM_{2.5}$ Light Extinction Indicator											
Form[4]	Level (Mm^{-1})										
90th	25	# counties	122	26	28	49	4	0	8	6	1
		% counties	65%	79%	60%	92%	40%	0%	31%	86%	50%
90th	26	# counties	95	22	14	48	1	0	4	5	1
		% counties	51%	67%	30%	91%	10%	0%	15%	71%	50%
90th	27	# counties	72	16	5	42	0	0	3	5	1
		% counties	39%	48%	11%	79%	0%	0%	12%	71%	50%
90th	28	# counties	44	6	2	27	0	0	3	5	1
		% counties	24%	18%	4%	51%	0%	0%	12%	71%	50%

[2] Design values for comparison with the level of the standard were calculated based on approach T, using 2007-2009 monitoring data, if at least 2500 hours of 2005-2007 data were available. (See Appendix F for the description of approach T). Actual future outcomes may differ from these estimates due to changes in instrumentation, siting, and/or the specific procedure for calculating the indicator.
[3] 3-year average of annual 90th percentile 24-hour average PM2.5 light extinction.
[4] Design values for comparison with the level of the standard were calculated based on the approach specified in Table G-2 using 2007-2009 monitoring data. Actual future outcomes may differ from these estimates due to changes in instrumentation, siting, and/or the specific procedure for calculating the indicator.

Table 3. Predicted number of counties not likely to meet current secondary $PM_{2.5}$ NAAQS and potential alternative secondary NAAQS based on a 24-hour average calculated $PM_{2.5}$ light extinction indicator.[3]