Comments of the American Lung Association on EPA's
Policy Assessment
for the Review of the Particulate Matter
National Ambient Air Quality Standards
Second External Review Draft
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Prepared by
Deborah Shprentz
Consultant to the American Lung Association
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The American Lung Association offers these additional comments on EPA's second draft Policy Assessment for the Review of the Particulate Matter (PM) National Ambient Air Quality Standards (NAAQS).

The Clean Air Act requires EPA to set NAAQS that protect public health with an adequate margin of safety, including the health of sensitive populations. Protection of public health is the only consideration permitted under the Clean Air Act for the NAAQS.

Annual Average Fine Particle Standards

The Lung Association is pleased that EPA is pressing forward expeditiously with the review of the PM standards. In the last review, EPA failed to follow the advice of its staff scientists and the Clean Air Science Advisory Committee (CASAC) to tighten the annual average standard for $PM_{2.5}$. The American Lung Association and a number of States successfully challenged the final rule in court; the D.C. Circuit remanded the primary annual $PM_{2.5}$ standard to EPA for reconsideration.

The draft Policy Assessment (PA) lays out a strong case for strengthening the annual average NAAQS for fine particles to protect public health based upon the scientific record. The Integrated Science Assessment (ISA) concludes that long-term exposures to $PM_{2.5}$ are causally related to mortality and cardiovascular effects, and are likely to be causal for respiratory effects. (PA Table 2-1).

The American Lung Association strongly supports the EPA staff's conclusion that the current annual $PM_{2.5}$ standard is inadequate to protect public health. The evidence of serious adverse effects -- including increased risk of premature death -- at levels well below the current standard is compelling.

New multi-city studies undertaken since the last review (e.g. the WHI cohort study and Medicare cohort study), and extensions of the American Cancer Society Cohort (ACS) study and the Harvard Six City Study confirm earlier research linking fine particle pollution to premature death. As PM concentrations have declined over time in response to cleanup efforts, the association between particle pollution and mortality persists down to the lowest concentrations studied. The new and extended studies not only confirm earlier findings, but also find that the risks extend down to these lower levels of PM pollution. The concentration-response relationship is linear, and elevated risks are evident below the level of the current annual standard. With a causal concentration-response relationship evident at lower concentrations, the mortality risks of PM exposure are even greater than previously understood.

Accordingly, EPA's Risk and Exposure Assessment (REA) reports that a greater number of premature deaths are attributable to fine particle pollution than previously recognized. Specifically, a national scale analysis presented in the RA estimates that total $PM_{2.5}$-related premature deaths range from 63,000 to 88,000, depending on whether the risk function is derived from the ACS cohort (Krewski et al. 2009) or the Six-Cities cohort (Laden et al. 2006). These risks are estimated down to the lowest measured levels in each study.

Table G-1 from the risk assessment provides more detail, and presents the substantially higher risk estimates, if calculated down to the policy-relevant background concentration.

Table G-1 Estimated $PM_{2.5}$-related premature mortality associated with incremental air quality differences between 2005 ambient mean $PM_{2.5}$ levels and lowest measured level from the epidemiology studies or policy relevant background (90th percentile confidence interval)

Air Quality Level	Estimates Based on Krewski et al. (2009)		Estimates Based on Laden et al. (2006) *(90th percentile confidence interval)*
	'79-'83 estimate (90th percentile confidence interval)	*'99-'00 estimate (90th percentile confidence interval)*	
10 μg/m³ (LML for Laden et al., 2006)	26,000 (16,000—36,000)	33,000 (22,000—44,000)	**88,000 (49,000—130,000)**
	Estimates Based on Krewski et al. (2009)		
5.8 μg/m³ (LML for Krewski et al., 2009)	**63,000 (39,000—87,000)**	**80,000 (54,000—110,000)**	210,000 (120,000—300,000)
Policy-Relevant Background	110,000 (68,000—150,000)	140,000 (94,000—180,000)	360,000 (200,000—500,000)

Bold indicates that the minimum air quality level used to calculate this estimate corresponds to the lowest measured level identified in the epidemiological study

These estimates show annual premature mortality on a national scale that is the equivalent of a small- to medium-sized city. Looked at another way, contemporary (e.g. 2005) concentrations of $PM_{2.5}$ cause more annual deaths than motor vehicle accidents (roughly 45,000 in 2005) or than suicide (roughly 32,600 in 2005)[1]—perhaps even combined. Given the public health implications, this national scale analysis should receive more emphasis in the risk assessment and policy assessment.

The EPA risk assessment of 15 metropolitan areas further supports the need for a lower annual and 24-hour $PM_{2.5}$ standard. Risk assessment data in PA Table 2.2 estimates that more than 7,000 premature deaths from ischemic heart disease are associated with exposure to $PM_{2.5}$, based on 1999-2000 air quality data. Approximately 2300 hospitalizations for cardiovascular disease are attributed to short-term $PM_{2.5}$ exposures, based on 2007 air quality (PA Table 2-3).

Data on annual mean air quality concentrations from both the short- and the long-term studies should inform the selection of a level for the long-term standard. Examining concentrations one standard deviation below the mean provides a principled guideline for

[1] Centers for Disease Control and Prevention. National Vital Statistics System.
Number of deaths from 113 selected causes by 10-year age groups, race and sex: United States, 2005. Accessed at http://205.207.175.93/VitalStats/TableViewer/tableView.aspx?ReportId=26041 on August 16, 2010..

standard-setting. This one standard deviation is not arbitrary: on the contrary, the bulk of the data contributing to finding of an effect at a mean concentration comes from values one standard deviation above and below the mean. Furthermore, this statistic is readily available in the scientific literature and does not require extrapolation from other data sets; epidemiological studies almost always report mean air quality concentrations plus or minus one standard deviation. Other statistics may be reported by some studies, but are not consistently reported.

The draft PA also discusses another approach for deriving recommended standards from the epidemiological studies. That approach involves looking at the confidence intervals around the concentration-response relationship. Some have argued that the confidence bounds widen with lower PM concentrations. But the reverse is also true: the confidence bounds also widen at higher concentrations. This is a function of the quantity of data available at various concentrations. It is not a useful metric for determining standards.

The Lung Association is concerned that even the most stringent option proposed in the draft PA, that of 30 $\mu g/m^3$ daily combined with 11 $\mu g/m^3$ annual, will not offer optimal protection for the most susceptible populations. We cite two additional arguments that offer the case for considering an annual average standard level of 10 $\mu g/m^3$, as proposed in the first draft PA: the conclusions of the World Health Organization and evidence from EPA's March 2010 analysis of air quality data.

First, we note that the World Health Organization (WHO) recommends more protective annual mean and 24-hour mean standards for $PM_{2.5}$ and PM_{10} than those under consideration in the second draft PA. These guidelines are established after an extensive review of the scientific literature by an international panel of eminent scientists. The WHO guideline values, as indicated in the table below, should be referenced and discussed in the PA.

World Health Organization Guideline Values

$PM_{2.5}$	**PM_{10}**
10 $\mu g/m^3$ annual mean 25 $\mu g/m^3$ 24-hour mean	20 $\mu g/m^3$ annual mean 50 $\mu g/m^3$ 24-hour mean

Source: http://www.who.int/mediacentre/factsheets/fs313/en/index.html

In addition, EPA's March 29, 2010 analysis of air quality data evaluates several measures: author reported study-specific area mean; EPA composite monitor approach; and EPA maximum value approach.[2] Several representative long-term and short-term exposure studies are analyzed. Figure 1 of the March 29, 2010 memo shows that in most cases mean concentrations are below the current annual $PM_{2.5}$ standard of 15 $\mu g/m^3$.

[2] U.S. EPA memo re Analyses of $PM_{2.5}$ Data for the PM NAAQS Review, March 29, 2010.

Looking at one standard deviation below the mean suggests that an annual standard of 10 $\mu g/m^3$ may be needed to protect public health with an adequate margin of safety.

Form of the Annual Average Fine Particle Standard

The Lung Association supports the elimination of spatial averaging to assess compliance with the annual average standard. Spatial averaging could potentially allow areas with hotspots of particulate matter concentrations to avoid nonattainment designations and cleanup requirements. This is an environmental justice concern because poor people are more likely to live near roads, depots, factories, ports, and other pollution sources. However, merely changing the form of the standard to eliminate spatial averaging may have little real world effect and is not sufficient to address vulnerable populations and environmental justice concerns. EPA needs to consider disproportionate exposures when selecting the level of the standards and determining monitoring strategies.

Daily Fine Particle Standard

There is strong evidence of the adverse effects of short-term exposure to $PM_{2.5}$. The Integrated Science Assessment (ISA) concluded that there was a causal relationship between short-term $PM_{2.5}$ exposures and cardiovascular effects and mortality, and a likely causal relationship with respiratory effects.

Figure 2 of the March 29, 2010 memo indicates that one standard deviation below the study-specific area 98th percentiles shows that a 24-hour standard of 30 $\mu g/m^3$ or below may be necessary to protect public health with a margin of safety.

The draft Policy Assessment allows that it might be appropriate to consider a tighter daily standard to protect against strong local or seasonal sources of emissions that result in high daily concentrations, despite the annual average standard. More specifically, the draft PA considers a more protective 24-hour $PM_{2.5}$ standard of 30 $\mu g/m^3$, but only in conjunction with the more protective option of an annual standard of 11 $\mu g/m^3$. Lower 24-hour standards should be considered in combination with all annual average standard options.

We do not agree that EPA should consider a tighter 24-hour standard of 30 $\mu g/m^3$ only in conjunction with the most stringent annual standard under consideration; that is, only with an annual standard of 11 $\mu g/m^3$. If daily concentrations are of concern with a standard of 11, they are even more so of concern with an annual standard of 12 or 13 $\mu g/m^3$. A higher annual standard will be even less effective at moderating 24-hour peaks than a lower standard.

The justifications offered by the draft Policy Assessment do not hold up. First, the draft states that the annual standard should be controlling. This argument that one of the two standards must be "controlling" standard has no statutory basis in the Clean Air Act and is not germane to selecting standards. The National Ambient Air Quality Standards must

protect public health and EPA cannot base the selection of the standards on whether one standard or the other is likely to be attained in an area. .

Second, the draft policy assessment purports to set a 24-hour standard based on the average peak-to-mean ratio of 2.5 in most, but not all regions of the country. (In the Northwest, the peak-to-mean ratio is approximately 3.5). The Policy Assessment states that it is reasonable to focus on 24-hour standards that are at least 2.5 times the annual standard. This is used to argue that the current level of the standard of 35 $\mu g/m^3$ meets this criterion. But again, the goal is to identify a level that will protect health, not to maintain the annual standard as controlling.

Different areas have different distributions of 24-hour exposures, with some places having fairly steady levels year-round and other areas having large variation between peak and average concentrations. The health effects associated with acute and chronic $PM_{2.5}$ exposures are distinct. EPA, therefore, must adopt standards that individually or collectively address both sets of exposures.

The draft Policy Assessment attempts to justify its failure to consider tightening the 24-hour standard based on regional considerations. EPA's analysis of air quality data shows that a standard of 11 $\mu g/m^3$ annual, and 30 $\mu g/m^3$ daily, would primarily impact the Northwestern region of the country, where emissions from wood-stoves and agricultural burning are problems. A standard of 30 or 25 $\mu g/m^3$ in conjunction with an annual standard of 13 or 12 $\mu g/m^3$ would affect additional regions of the country, where wood stoves and other sources may also be a problem.

This regional justification is not allowed under the Clean Air Act, and it is bad policy because it would fail to provide equal protection throughout the U.S.

Consequently, we disagree with EPA's interpretation of Figure 2-10 in the PA to argue that the 24-hour standard need only be lowered in conjunction with an annual average standard of 11 $\mu g/m^3$.

In addition, it is unclear why EPA considered a daily $PM_{2.5}$ standard of 25 $\mu g/m^3$ in the last review, and in the risk assessment, but not here. As daily standards are linked to air quality alerts, as well as used as regulatory targets, it is crucial that they represent levels that will protect health with an adequate margin of safety.

Coarse Particles

Coarse particles are emitted from a variety of sources including traffic, poorly controlled combustion, industrial sources, agricultural burning, construction and demolition. In rural areas, coarse particles may be contaminated by toxicants such as pesticides, polycyclic organic matter, metals, and endotoxin. Coarse particles are referred to as "thoracic" coarse particles because they can evade the body's defense mechanisms and be

breathed deep into the lungs. "Coarse" particles is a misnomer; we are talking about very tiny particles less than 10 microns in diameter.

Coarse particles are associated with a variety of adverse health effects including decreased lung function, increased respiratory symptoms in children, increased hospital admissions for heart and lung disease, increased doctors' visits for respiratory ailments, and premature death in people with heart or lung disease. We note that CASAC, in their May 17, 2010 comments on the first draft PA, found the evidence of coarse particle health effects was much stronger than in last review.

In light of the strengthened evidence of available since the last review, the option to merely retain or relax the coarse particle standard -- set in 1987 -- is unacceptable.

We note that the bulk of the coarse particle studies reviewed in the ISA reported positive associations. The most relevant studies to the setting of a PM_{10} standard are the thousands of studies that have reported adverse effects associated with PM_{10} pollution. However, the draft the draft PA concludes that it may or may not be appropriate to consider changes to the 1987 PM_{10} standard, despite the evidence showing that a stronger standard is needed. .

The conclusions that the PA reaches for coarse particles stem from a circular argument The ISA focuses its review of coarse particle health effects on studies of $PM_{10\text{-}2.5}$. The availability of such studies is limited relative to the vast literature available on the health effects of PM_{10}. Then, the PA suggests using PM_{10} as an indicator for the health standard for coarse particles, while relying only on the studies of $PM_{10\text{-}2.5}$ to determine the appropriate level and form for the standard. Given the relatively limited number of $PM_{10\text{-}2.5}$ studies available, that proved an understandably difficult hurdle. So having set up the review to use an assessment tool that was inadequate, the test failed.

Nevertheless, the evidence of harm for PM_{10} is clear. The bulk of the coarse particle studies reviewed in the ISA reported positive associations. There is no basis in the health literature for relaxing the PM_{10} standard.

Form and Indicator of the Coarse Particle Standard

With respect to the coarse particle standards, the draft Policy Assessment contemplates a change in form of the 24-hour standard. The current form of the standard is the "one expected exceedance" form (not to be exceeded more than once per year on average over 3 years). We are dismayed that the draft Policy Assessment suggests moving to a 98th percentile form. This change would represent a serious relaxation of the PM_{10} standard.

The goal of the 24-hour standard is to reduce peak daily exposures. A 98th percentile form of the standard excuses too many days of unhealthy air quality from the compliance determination -- seven days per year. The continued reliance on 1 in 6 day monitoring (or 1 in 3 day monitoring) is not a reason to move to a 98th percentile standard. Indeed it

is past time to require daily monitoring of PM_{10} concentrations. Daily monitoring is needed to determine compliance, as well as for conducting epidemiological studies of daily exposures.

One justification the PA offers for recommending a 98th percentile form of the 24-hour PM_{10} standard is that other NAAQS have used this form. This is incorrect. The recently adopted hourly sulfur dioxide NAAQS uses a 99th percentile form.

Even if EPA lowers the level of the 24-hour standard to compensate for a more lenient form, it will impact implementation, leading to a delay in the delivery of health benefits.. A change in form will delay implementation for eight years. States will have to reclassify nonattainment areas, and develop new implementation plans, and the deadlines for attainment will be extended. Meanwhile, clean up efforts will be stalled.

That delay may be acceptable if the change in form increases the protectiveness of the standard. It is not acceptable simply to have the standards all have a similar form. The Lung Association has long argued against the 98th percentile as it allows so many days of unlimited levels to be excused, a critical concern for a standard seeking to reduce short-term exposures. We see it having the same impact in this case.

The draft Policy Assessment argues that the PM_{10} indicator for coarse particles is desirable because it will allow less coarse particle pollution in urban areas than in rural areas. The PA bases this argument on its unsupported conclusion that urban coarse particles are more toxic. Setting aside the issue of drawing lines between urban and rural (where do suburbs fall, we wonder?), this argument has serious flaws. Toxic coarse particles are present in rural areas as well as urban areas. Mobile, off road, and stationary combustion sources are located in rural and urban areas. Likewise, industrial sources of coarse particle emissions exist in less populated areas. Many electricity generating units, for example, are located in rural areas. Toxic pesticides and metals can contaminate coarse particles in rural areas. National standards must protect all citizens, urban and rural alike.

The draft Policy Assessment argues that fine particles are more prevalent in urban areas. Because the PM_{10} in urban areas is comprised of more fine particles than in rural areas, coarse particles must comprise a smaller fraction than in rural areas in this argument.. The PA concludes that this would render the PM_{10} standard more stringent in urban areas. The PM_{10}:$PM_{2.5}$ ratio varies from region to region; therefore a PM_{10} standard might similarly allow more coarse particle pollution in the West than in the East.

However, this argument has some fatal flaws. Most health studies of coarse particles have been conducted in urban areas, as the draft Policy Assessment states. This is because researchers can only conduct studies where monitoring data exists. Rural areas have relatively sparse monitors making the accurate assessment of their air quality impossible. Epidemiological studies must often look “under the lamppost” to find the data visible only in that light. .Using this lamp post effect does not mean that rural areas have less toxic coarse particles, merely that we have no way to see them. Without the

specious fraction argument, no support can be found in the ISA for the notion that rural particles are less toxic than urban.

Further, if EPA still holds to the the urban/rural inequities of a PM_{10} standard, it may be time to consider changing the indicator for the coarse particle standard to $PM_{10-2.5}$. A PM_{10} standard will provide uneven protection in different areas of the country. This is due to the differing ratios between PM_{10} and $PM_{2.5}$ in different areas of the country, as well as differences in "peakiness."

Level of the Coarse Particle Standard

We strongly disagree with the staff recommendation that favors adoption of a coarse particle standard at the upper end of the proposed range, that is 85 $\mu g/m^3$ 24-hour average standard. Some areas that would meet a PM_{10} standard of 85 $\mu g/m^3$ 98th percentile could have PM_{10} concentrations above the current standard of 150 $\mu g/m^3$ with no expected exceedances. A standard at the upper end of the range would effectively loosen the current standard.

The draft PA claims, that with a change in the form of the standard, a standard of 85 $\mu g/m^3$ 98th percentile would be roughly equivalent to the current standard. This is not supported by the Table 3-2 and Appendix 3A in the PA. Even if the same number of areas is likely to be classified as nonattainment relative to the current standard, these are not necessarily the same areas. They may be different areas, with different populations. The PA indicates that fewer people would be protected with a standard of 85 $\mu g/m^3$ 98th percentile, and even 80 $\mu g/m^3$, than with the current 150 $\mu g/m^3$ one expected exceedance standard.

Several health studies point to the need for a standard of 65 or below. For example, Zanobetti and Schwartz (2009) and Peng (2008) show health impacts remain with 98th percentile PM_{10} concentrations of 78 and 68 $\mu g/m^3$.

The Lung Association strongly opposes a change in the form of the PM_{10} standard. However, if such a change is proposed, we concur with a number of CASAC members that suggested that the upper end of the range be no higher than 75 $\mu g/m^3$.

Monitoring

Monitoring is as integral to standard setting as other key attributes discussed in the draft PA such as indicator, averaging time, level and form.

The PA dismisses the option of setting a coarse particle indicator as $PM_{10-2.5}$, claiming that a new monitoring network would be necessary. We believe the final PA needs to give full consideration to a $PM_{10-2.5}$ indicator. The choice of an indicator for coarse particles should not be constrained by the current monitoring network.

The lack of monitoring data often becomes a chicken and egg argument. For instance, EPA concludes in the draft PA that there is insufficient information to consider setting a standard for ultrafine particles. If no one is monitoring a particular pollutant, no one will find an effect. Similarly, lack of a coarse particle monitoring convention has impeded research. For example, numerous studies that examine the health effects of highway pollution must use distance from roadways as a surrogate exposure measure because there are so few monitors sited near roadways. These studies have not been included in the ISA because they did not specifically report PM concentrations. The limitations in the monitoring have other practical impediments to health research. Lack of daily monitoring of PM_{10} impedes studies of short-term effects. Continuous monitoring is needed to evaluate the effects of sub-daily exposures or of different species of particles.

We believe that the review of the PM standard must give full consideration to questions of monitoring technology, monitoring frequency, adequacy of network design, monitor siting, and other issues.