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Arthur N. Marin, Executive Director

April 11, 2006

Stephen L. Johnson
Mail Code 6102T
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Attention: Docket I.D. # EPA-HQ-OAR-2001-0017

Re: *Proposed Rule -- National Ambient Air Quality Standards for Particulate Matter*

Dear Administrator Johnson:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments on the U.S. Environmental Protection Agency's (EPA's) proposal, published on January 17, 2006 in the Federal Register, entitled *National Ambient Air Quality Standards for Particulate Matter* (71 FR 2620-2708). NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.

Primary Fine Particulate Matter Standards

The NESCAUM states agree with EPA that the primary fine particulate matter ($PM_{2.5}$) national ambient air quality standards (NAAQS) should be revised downward to afford more public health protection. We support more stringent standards than EPA's proposed $PM_{2.5}$ NAAQS of 15 $\mu g/m^3$ annual and a 35 $\mu g/m^3$ 24-hour (98th percentile form) levels. Given the significant health threat posed by $PM_{2.5}$, the preponderance of health studies supporting more stringent standards, and the Clean Air Act's mandate to set standards that protect public health with an adequate margin of safety,[1] we urge EPA to promulgate a 12 $\mu g/m^3$ annual and a 30 $\mu g/m^3$ 24-hour (98th percentile form) primary $PM_{2.5}$ standard.

In letters dated October 27, 2005 and December 16, 2005 (attached), five New England Commissioners and the New Jersey Environmental Commissioner, respectively, expressed the need for the more protective $PM_{2.5}$ standards articulated in our proposal. Throughout this PM NAAQS revision process, we have made several presentations to the Clean Air Scientific Advisory Committee (CASAC) and EPA, underscoring the need for such standards. Our detailed comments and recent peer-reviewed publications (attached) provide a public health rationale and technical documentation supporting our recommendation.

EPA's proposed primary $PM_{2.5}$ standards, which are nearly the least stringent in the range recommended by EPA staff and are less stringent than the range recommended by CASAC, would only take us part way to truly protective standard-setting. Adopting NESCAUM's proposed set of standards, 12 and 30 $\mu g/m^3$, could protect two and one-half times times as many people in the Northeast as the EPA proposal due to improved air quality resulting from emission control strategies. Over 20 million more people in the Northeast would receive public health protection than under EPA's proposal. Across the U.S., a combination of 12 and 30 $\mu g/m^3$ annual and 24-hour standards would nearly double the number of people in the US afforded protection from exposure to fine particulate matter.

[1] Section 109(b)(1)

Coarse Particulate Matter Standards

While the NESCAUM states support the adoption of a $PM_{10-2.5}$ (PM-coarse) standard, we do not support EPA's PM-coarse proposal. In particular, we are concerned with EPA's proposed exemptions for rural windblown dust, agricultural, mining, and "other similar" sources.[2] Proposing source-based exemptions is out of place in a rulemaking process to establish national health standards. If done at all, such exemptions should be the subject of a separate, more narrowly tailored rulemaking that focuses specifically on these source sectors. Therefore, EPA should remove these exemptions.

In addition, CASAC's advice does not recommend exempting agricultural, mining or any other source sector from the PM-coarse standard. The CASAC based its comments on agricultural sources in light of limited studies on health effects associated with particulate matter generated by these sources. The CASAC advice does not discuss mining sources. We note that the EPA Staff Paper states, "The limited evidence does not support either the existence or *the lack of causative associations* for community exposures to agricultural or mining industries" (p. 5-57, emphasis added). We understand that the available health studies focus on urban sources so that information on agricultural sources is more limited. The lack of information, however, does not then lead to the conclusion *a priori* that there are no health effects from these sources and should not be the basis for exempting source sectors from the NAAQS.

While the EPA Staff Paper cautions not to "potentially over-generalize the results of the limited available studies" (p. 5-58), the Clean Air Act has a clear statutory mandate for EPA to provide an adequate margin of safety for protecting public health. Therefore, the appropriate path forward is to retain all these source sectors until further studies clearly absolve them of harmful health effects, rather than absolving them now because there are few studies on the topic.

Furthermore, we do not support EPA's proposed siting criteria for monitors. The lack of monitors in non-urban areas would effectively result in there being no PM-coarse or PM_{10} standards in those areas. Available scientific data do not justify limiting PM-coarse or PM_{10} standards to urban areas with the possibility of exempting source categories. Moreover, the demarcation of an urban area for these purposes would be subject to considerable interpretation. Collecting ambient exposure data in non-urban areas is essential so that research on the health effects of those exposures can continue to be conducted. A prudent national public health policy includes concerns for those Americans living in non-urban areas. A standard setting approach that is not national in scope undermines the intent and purpose of the Clean Air Act, which mandates the protection of the entire nation's ambient air quality. At a minimum, EPA should retain the PM_{10} standards until these issues are resolved.

Secondary Fine Particulate Matter Standards

The NESCAUM states agree that EPA should revise the current secondary $PM_{2.5}$ NAAQS from its existing level of 65 $\mu g/m^3$, 24-hour average, 98th percentile. However, we disagree that the proposed

[2] "The standard for $PM_{10-2.5}$ includes any ambient mix of $PM_{10-2.5}$ that is dominated by resuspended dust from high-density traffic on paved roads and PM generated by industrial sources and construction sources, and excludes any ambient mix of $PM_{10-2.5}$ that is dominated by rural windblown dust and soils and PM generated by agricultural and mining sources. Agricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard" (see 71 FR 2698-2699).

secondary standard should be identical to the proposed primary NAAQS of 35 µg/m^3, 24-hour average, 98th percentile form. We recommend that EPA promulgate a sub-daily 4-hour (12 p.m. to 4 p.m.) secondary $PM_{2.5}$ standard for improving visibility that is consistent with the EPA staff and CASAC recommendations and provides greater visibility protection than EPA's proposed secondary standard. A reasonable selection for a secondary $PM_{2.5}$ standard is a sub-daily (12 p.m. to 4 p.m.) average in the range of 20 to 25 µg/m^3 at the 95th to 96th percentile level.

Design Value Calculation Methodology

We have reviewed EPA's method for calculating the daily PM design values in Part 50 (Appendix N for $PM_{2.5}$). Our work revealed that the existing and proposed methodology yields a lower (i.e., less stringent) value on average for a one-in-three-day frequency sample data-set compared to a daily sample data-set by approximately 1 µg/m^3. We recommend that EPA develop a more robust but equivalent statistical approach to calculating the daily PM design values, i.e., one that is free from the sample size or run-schedule bias contained in the proposed calculation method for $PM_{2.5}$ and PM-coarse.

Detailed comments are attached. If you or your staff has any questions regarding the issues raised in this letter, please contact Paul Miller at the NESCAUM office at 617-259-2016.

Sincerely,

Arthur N. Marin
Executive Director

Attachment A: Detailed Comments on the Primary $PM_{2.5}$ National Ambient Air Quality Standards
Attachment B: Detailed Comments on the PM-coarse National Ambient Air Quality Standards
Attachment C: Detailed Comments on the Secondary $PM_{2.5}$ National Ambient Air Quality Standards
Attachment D: October 27, 2005 Letter to Administrator Johnson from the New England Environmental Commissioners and December 16, 2005 Letter to Administrator Johnson from the New Jersey Environmental Commissioner
Attachment E: NESCAUM Peer-Reviewed Publications Relating to $PM_{2.5}$ National Ambient Air Quality Standards

Cc: NESCAUM Directors
Lydia Wegman, U.S. EPA
Erika Sasser, U.S. EPA

ATTACHMENT A
Detailed Comments on the Primary Fine Particulate Matter ($PM_{2.5}$)
National Ambient Air Quality Standards (NAAQS)

1. Public Health Standard Setting and NESCAUM's $PM_{2.5}$ NAAQS Recommendation

Since the 1952 London smog disaster, scientists have been developing increasingly sophisticated evidence to explain air pollution-associated risk. Many health studies have found that U.S. populations exposed to fine particles experience adverse cardiac and respiratory effects at or below present $PM_{2.5}$ standards. Health outcomes include the exacerbation of existing cardiopulmonary disease and premature mortality. Based on these studies, and because of the Clean Air Act's mandate to protect public health and susceptible populations with an adequate margin of safety, NESCAUM supports more stringent $PM_{2.5}$ standards than those promulgated during the previous NAAQS review cycle in 1997.

Since 1997, the scientific process has refined and improved epidemiology, toxicology, and exposure assessment tools used to understand associations between human health and fine particulate matter. Scientific research has answered many central questions. For example, time-series studies have largely put to rest questions about whether risk factors such as weather, influenza epidemics, short-term mortality "harvesting," and other air pollutants could be confounding variables. An exhaustive re-analysis of these studies continues to point to fine particles as a serious contributor to excess mortality in spite of earlier concerns about the use of certain statistical software functions. An exhaustive re-analysis of the major U.S. long-term cohort studies indicates that estimates of total mortality associated with chronic PM exposure appear to be much larger than those reported from time-series daily mortality PM studies. In fact, cohort risk estimates are one order of magnitude higher than estimates found in current time-series studies, which suggests that the burden of death and disease attributable to PM air pollution is substantial. Moreover, evidence has been developed to explain the biological mechanisms of particle toxicity that contribute to the pathology of cardiopulmonary disease. While work remains, the picture is clear enough to show that, because fine particles are ubiquitous, toxic, and detrimental to human respiratory and cardiac health, effective public health action is justified.[1]

In keeping with the Clean Air Act NAAQS provisions, EPA has a clear and strong mandate to establish health-based standards with a protective adequate margin of safety at a level that avoids unacceptable risks to all populations. Legislative history has interpreted the NAAQS margin of safety provision as requiring the protection of general and susceptible populations, including those among us who are most sensitive to air pollution.

Despite efforts over the past few decades to improve air quality, the use of regulatory standards to protect public health has been constrained by science's inability to confirm the existence of a fine particle threshold level of exposure below which populations are safe. This presents an important public health question because standard-setting is the fulcrum on which society decides how many people will be at increased health risk. Decision-makers face a challenge to protect sensitive subgroups in spite of uncertain thresholds.

In response to this uncertainty, major regulatory organizations set enforceable or target standard levels to limit $PM_{2.5}$ concentrations below those where epidemiologic evidence is most consistent and coherent, and where estimates of risk reductions associated with alternative annual and 24-hour standards are

[1] Colburn KA and Johnson PRS. 2003. Air Pollution Concerns not Changed by S-PLUS Flaw. *Science* 299(31):665-6. (see Attachment E)

considered most protective. This approach recognizes the strengths and the limitations of the full range of scientific and technical information on the health effects of PM, as well as associated uncertainties.

The current EPA NAAQS review process charged to select $PM_{2.5}$ primary standards delineates a range of annual and 24-hour mass-based concentration levels based, in part, on findings of health effects associated with chronic and acute exposure to $PM_{2.5}$ concentrations. **Table 1** facilitates a comparison of corresponding standard levels and forms in the U.S. and Canada. Differences in stringency may reflect the varying levels of health protection required by the controlling statute and the level of public health protection commitment.

Based on the preponderance of epidemiologic and risk assessment evidence supporting more stringent standards, and the Clean Air Act's mandate to set standards that protect public health with an adequate margin of safety, the NESCAUM states recommend that EPA promulgate a 12 $\mu g/m^3$ annual and a 30 $\mu g/m^3$ 24-hour (98^{th} percentile form) primary $PM_{2.5}$ standard. As shown in Table 1, EPA staff, CASAC, and other regulatory agencies support more stringent $PM_{2.5}$ standards. EPA's proposed standards (see 71 FR 2620-2708) are the least stringent when compared to EPA staff, CASAC, California, NESCAUM, and Canada.[2]

Table 1. $PM_{2.5}$ primary standards or position of selected regulatory agencies, scientific review panels, and governmental organizations in the U.S. and Canada

When	What	24-hour $PM_{2.5}$ ($\mu g/m^3$)	Annual $PM_{2.5}$ ($\mu g/m^3$)
2000	Canada-wide target standard [a]	30	n/a
2002	State of California	~18-20 [b]	11-11.5 [c]
2004	NESCAUM NAAQS recommendation	30	12
2005	U.S. EPA staff NAAQS recommendations	25-35 [d] 30-40 [e]	15 12-14 [e]
2005	CASAC NAAQS recommendation	30-35	13-14
2005	U.S. EPA NAAQS proposal	35	15

[a] Target implementation to be achieved by 2010 and ratified by ministers in June 2000.
[b] California 24-hour level normalized to reflect equivalent 98^{th} percentile form. CA proposed a new 24-hour average standard for $PM_{2.5}$ at 25 $\mu g/m^3$ (not to be exceeded form) in May 2002 but subsequently deferred a final decision.
[c] California annual level normalized to reflect equivalent 3-year mean form. CA's annual standard for $PM_{2.5}$ at 12 $\mu g/m^3$ (not to be exceeded form) amounts to new clean air goals for the state and took effect in June 2003.
[d] Based on a 98^{th} percentile form for a standard set at the middle to lower end of this range, or a 99^{th} percentile form for a standard set at the middle to upper end of this range.
[e] With either the annual or the 24-hour standard, or both, at the middle to lower end of these ranges.

2. NESCAUM Rationale for More Stringent Standards

The large body of scientific evidence accumulated over the last decade shows that significant health effects occur from exposure to ambient $PM_{2.5}$ concentrations at levels below current federal standards. Time-series epidemiological studies have found associations between PM and daily deaths, and cohort

[2] Johnson PRS and Graham JJ, 2005. Fine Particulate Matter National Ambient Air Quality Standards: Public Health Impact on Populations in the Northeastern United States. *Environmental Health Perspectives* 113(9):1140-7. (See Attachment E)

studies that incorporate risk associated with longer-term exposure report even higher risk estimates. In addition, clinical and epidemiological evidence now suggests that acute cardiac health effects may be associated with PM exposures with averaging times less than 24 hours.

During the last decade, regulatory agencies have increasingly recognized that persons sensitive or susceptible to PM are more numerous and diverse than once thought. These subgroups are potentially at increased risk and comprise a large fraction of the U.S. population, including people with respiratory disease, heart disease, or diabetes; older people; young children; and populations experiencing heightened exposure levels (e.g., involved in outdoor exercise, or living near high PM sources such as busy roadways). Given the likely heterogeneity of individual responses to air pollution, the severity of health effects experienced by a susceptible subgroup may be much greater than that experienced by the population at large. Therefore, varying host susceptibility factors may hinder adequate protection of an entire population, even at low exposure levels.

Standard setting judgments rest on the premise that more stringent standards lead to requirements for more extensive control strategies to reduce PM levels. Accordingly, reduction in ambient PM levels presumably reduces the public health toll exacted by PM pollution. This belief is supported by intervention studies in the U.S. and other countries that have related reductions in ambient PM to observed improvements in respiratory or cardiovascular health.

Even if attainment of the most stringent $PM_{2.5}$ NAAQS were achieved, health risks within the U.S. population would not be totally eliminated. Any non-zero PM standard represents the air pollution-related health burden that policy makers consider “acceptable.” Nevertheless, ambient air quality standards can ultimately determine the number of persons affected by air pollution. Incrementally more stringent standards would offer the expectation of increased public health protection from $PM_{2.5}$ exposures. This underscores the importance of setting appropriately stringent $PM_{2.5}$ standards to trigger control measures intended to reduce ambient $PM_{2.5}$.

In view of the Clean Air Act’s mandate to protect public health, including susceptible populations, with an adequate margin of safety, EPA staff and CASAC find that meeting this mandate requires more stringent $PM_{2.5}$ standards. As shown in Table 1, the recommended standard ranges correspond to levels believed necessary to protect public health based on epidemiologic and risk assessment evidence. This evidence indicates the likelihood that thousands of adverse health outcomes per year occur in urban areas across the U.S. even upon attainment of the current $PM_{2.5}$ standards. These outcomes include thousands of premature deaths and an even greater number of incidences of hospital admissions, emergency room visits, aggravation of asthma and other respiratory symptoms, and increased cardiac-related risk per year. More stringent standards would result in a substantial and appreciable reduction of long-term and short-term mortality and morbidity risks.

NESCAUM’s recommendation considers these health-based recommended standard ranges together with analyses of Northeast demographic and monitoring data. These analyses support our recommendation of an annual standard of 12 $\mu g/m^3$ and a 24-hour standard of 30 $\mu g/m^3$ (98^{th} percentile form) in order to ensure sufficient public health protection across the 8-state northeastern region. Within EPA staff’s range of recommended health-based $PM_{2.5}$ standards, a 12/30 $\mu g/m^3$ annual/24-hour suite would enable the Northeast states to implement more stringent controls to reduce emissions of $PM_{2.5}$ and its precursors. This would lower $PM_{2.5}$ concentrations to levels that EPA staff and other regulatory agencies conclude are required to adequately protect public health based on the best available science. In order to maximize public health protection in the Northeast and across the U.S., the annual and 24-hour standards also should be selected as “matching” standards. This will ensure consistent and adequate protection to the greatest number of Americans across varying spatial and temporal concentration scales. A 12/30 $\mu g/m^3$ combination adequately satisfies this requirement.

A 12/30 $\mu g/m^3$ standard has important consequences for the densely populated Northeast states. It would result in 84% of the NESCAUM region's population directly benefiting from improved air quality due to emission control strategies, including about five times more people in susceptible subgroups than at the current 15/65 $\mu g/m^3$ standard. Upwards of 50% of northeasterners are at increased risk to $PM_{2.5}$ and over 70% (30 million persons) of the total population live in areas that experience the region's highest air pollution levels.

The following technical remarks in support of more stringent standards make note of recently published NESCAUM materials relevant to understanding the behavior and protectiveness of alternative levels and forms of the $PM_{2.5}$ NAAQS.[3] These materials are based on analyses submitted in previous comments during the NAAQS review process.

Our demographic analysis[4] finds that a large fraction of the Northeast population is susceptible or vulnerable to PM air pollution based on age, disease prevalence, and exposure status. Combined, these indicators characterize the potential magnitude of $PM_{2.5}$ health impacts within the eight-state NESCAUM region. Specifically:

- About 38% of the NESCAUM region's total population is potentially susceptible to $PM_{2.5}$ based on age group (ages <18 or =65 yrs).
- For people in potentially susceptible subpopulations based on health status (e.g., people with pre-existing health conditions such as respiratory disease, heart disease, and diabetes), 4-18% of the total population of adults have cardiopulmonary or diabetes health conditions, and 12-15% of the total population of children have respiratory allergies or lifetime asthma.
- The population density of the NESCAUM region is among the highest in the nation, as five of eight states (CT, MA, NJ, NY, and RI) are among the six most densely populated states in the U.S.
- Thirty million persons, or more than 70% of the NESCAUM region's population (across child, adult, and elderly age groups), live in urban areas that combined consist of 6% of the total land mass.
- Age groups susceptible to PM exposure (ages <18 or =65 yrs) living in urban areas comprise 27% of the region's total population.
- Many of these urban populations are vulnerable to pollution-related effects because Northeast urban areas experience the region's highest PM levels and give rise to heightened exposure scenarios.

Our monitoring data analysis assessed how various annual and 24-hour combinations influence the distribution and level of $PM_{2.5}$ concentrations throughout the NESCAUM region. Such a method facilitates the percentage estimation of the total population living in areas that would be out of compliance at selected pollution levels. Areas that fail to attain $PM_{2.5}$ standards must take steps to reduce concentrations, thereby diminishing population exposures and associated adverse health outcomes. In addition, more stringent $PM_{2.5}$ standards would potentially benefit all populations, not just those living in nonattainment areas, since $PM_{2.5}$ is transported over long distances and lowering the $PM_{2.5}$ burden in one area will lower the $PM_{2.5}$ burden elsewhere to some extent. Findings include:

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[3] Colburn and Johnson, 2003; Johnson and Graham, 2005; Johnson PRS and Graham JJ,2006. Analysis of Primary Fine Particle National Ambient Air Quality Standard Metrics. *Journal of the Air & Waste Management Association* 56(2):206-18. (See Attachment E)

[4] Johnson and Graham, 2005, see footnote 2.

- In many areas of the U.S., lowering only one standard without a matching reduction of the other standard will result in a wide range of annual or 24-hour levels permitted for the non-controlling standard. Mismatched standards permit areas with high annual-to-24-hour $PM_{2.5}$ ratios – as well as high 24-hour-to-annual mean ratios – to experience levels at which health effects occur when the backstop standard fails to constrain $PM_{2.5}$ concentrations. This phenomenon demonstrates the need for protective long- and short-term standards, and argues against using a single controlling annual standard (or 24-hour standard) as practiced by EPA. Compared to EPA's proposed 15/35 $\mu g/m^3$ standard combination, a stringent matching annual/24-hour (98th percentile form) standard of 12/30 $\mu g/m^3$ would provide a more uniform level of protection across the largest monitored area possible.

- In the NESCAUM region, current $PM_{2.5}$ standards affect only 16% of the general population, who live in counties that do not meet the existing 15/65 $\mu g/m^3$ standard. A requirement to reduce emissions of $PM_{2.5}$ and its precursors in order to meet a 12/30 $\mu g/m^3$ standard would result in 84% of the NESCAUM region's population benefiting from improved air quality due to $PM_{2.5}$ emission control strategies (See **Figure 1**). By establishing this standard combination, about five times more people would benefit from improved air quality.

- Because 24-hour values in the NESCAUM region cluster within the 30-35 $\mu g/m^3$ range, the most substantial impact on nonattainment status in the region would occur if EPA lowered the 24-hour standard from the current 65 $\mu g/m^3$ to below 35 $\mu g/m^3$ (98th percentile form). For example, in the Northeast U.S., the difference between a 15/30 and 15/35 $\mu g/m^3$ standard amounts to a 50% difference in protectiveness. For the entire U.S., the difference is 24%. These differences decrease as the annual standard becomes more stringent, i.e., moving from 15 down to 12 $\mu g/m^3$, and make evident the limitations of EPA's proposed 15/35 $\mu g/m^3$ standard.

- EPA's recently proposed 15/35 $\mu g/m^3$ standard is nearly the least protective option that could have been selected among the recommended standard ranges offered by EPA staff and CASAC (See **Figure 1**). Were EPA to pair the 35 $\mu g/m^3$ 24-hour standard with more stringent annual standards of 14 or 13 $\mu g/m^3$ (as recommended by CASAC) 23% or 46% more people would be protected by non-attainment designations and required reductions in $PM_{2.5}$ ambient levels as compared to the 15/35 $\mu g/m^3$ standard. Were EPA to select CASAC's most stringent 13/30 recommendation, about 48 million more people in the U.S. would be protected. Were EPA to select NESCAUM's 12/30 recommendation, nearly 100% more people would be protected, or nearly doubling the number of people in the U.S. afforded protection.

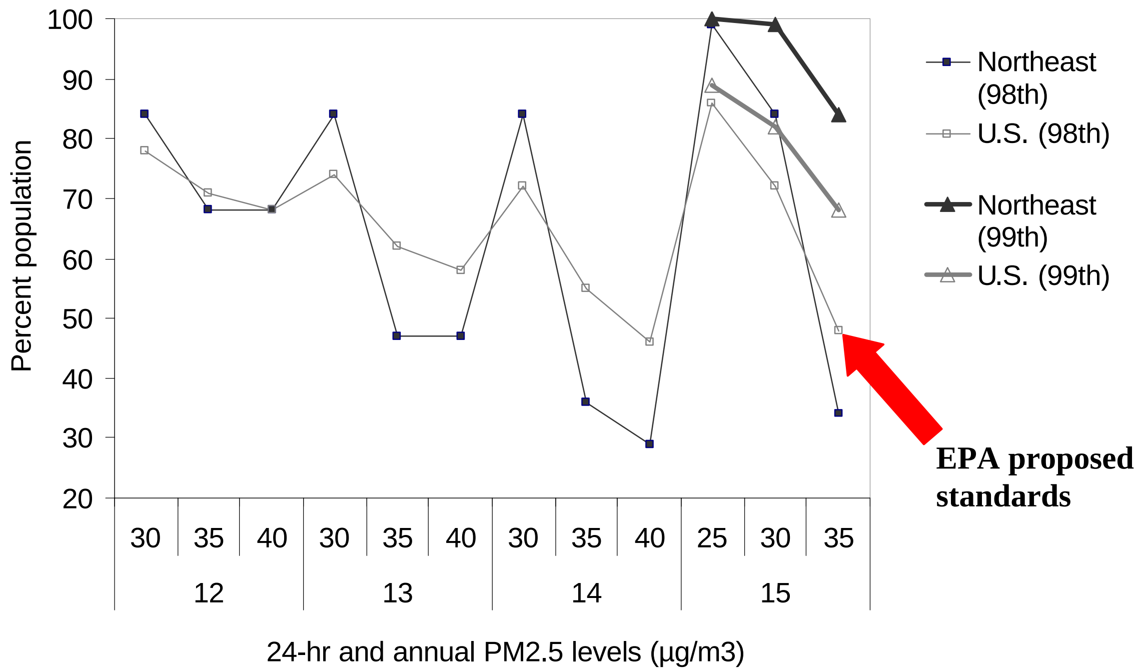
- In the Northeast U.S., a 12/30 $\mu g/m^3$ standard would result in protecting over 20 million more people, or more than double the number of people compared to EPA's 15/35 $\mu g/m^3$ proposal. This finding may be especially relevant to health studies suggesting the potential for heterogeneity in U.S. city-specific excess risk estimates for acute health effects, including higher mortality levels found in the Northeast than other parts of the country.

- The 12/30 $\mu g/m^3$ $PM_{2.5}$ standards NESCAUM has recommended are consistent with those currently in effect in California (12 $\mu g/m^3$ for the annual standard - not to be exceeded) and Canada (30 $\mu g/m^3$ for the 24-hour standard - 98th percentile). More protective $PM_{2.5}$ standards falling within normalized ranges recommended by California and Canada would protect 84-100% of the NESCAUM region's population.

- A suitably stringent 24-hour standard may lead to meaningful reductions in shorter-term hourly average concentrations, thus providing some degree of protection from acute elevated levels that may lead to a significant portion of an individual's daily exposure, and which have been associated with cardiac and pulmonary outcomes in high source environments such as along roadways or in urban areas that predominate in the Northeast

- Exempted natural event peak value days have the potential to contribute significantly to $PM_{2.5}$ concentrations. Populations experience these real-world exposures, which are not reflected in design value calculations used to determine compliance with $PM_{2.5}$ standards. For example, the impact of high peak day exemptions because of forest fires on $PM_{2.5}$ levels was found to be significant in some areas in the Northeast study area during 2002, a year with heavy upwind forest fire activity in Canada.

Figure 1. Estimated percent total population in New England, New Jersey, and New York counties (Northeast) vs. total U.S. county-level population that would benefit from compliance with alternative EPA staff and CASAC recommended 24-hour (98th and 99th percentile) and annual $PM_{2.5}$ standard ranges (µg/m3) (2000-2002 FRM Regions 1, 2 for Northeast; 2001-2003 FRM country-wide for total U.S.)[5]



3. Bias in Design Value Calculation Methodology

The EPA's present method of calculating the daily PM design values in Part 50 (Appendix N for $PM_{2.5}$) produces a lower -- or less stringent -- value on average for a one-in-three-day frequency sample dataset (i.e., every-third-day collection schedule) compared to a daily sample dataset by approximately 1 µg/m^3. We recommend that EPA develop a more robust but equivalent statistical approach to calculating the daily PM design values, i.e., one that is free from the sample size or run-schedule bias contained in the proposed calculation method for $PM_{2.5}$ and PM-coarse.

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[5] Johnson and Graham, 2006, see footnote 3.

NESCAUM analyzed data extracted from the Air Quality System (AQS) database for 102 daily $PM_{2.5}$ sampling sites from 2004 to investigate the effect the proposed calculation method would have on daily design values. The proposed method requires as input the number of valid ambient samples (N) at a site. This number is multiplied by 0.98, and the resulting value is truncated to an integer. This integer is incremented by one with the resulting value representing the rank of the daily measurement used to determine the standard. The daily values are sorted from least to greatest (1 to N).

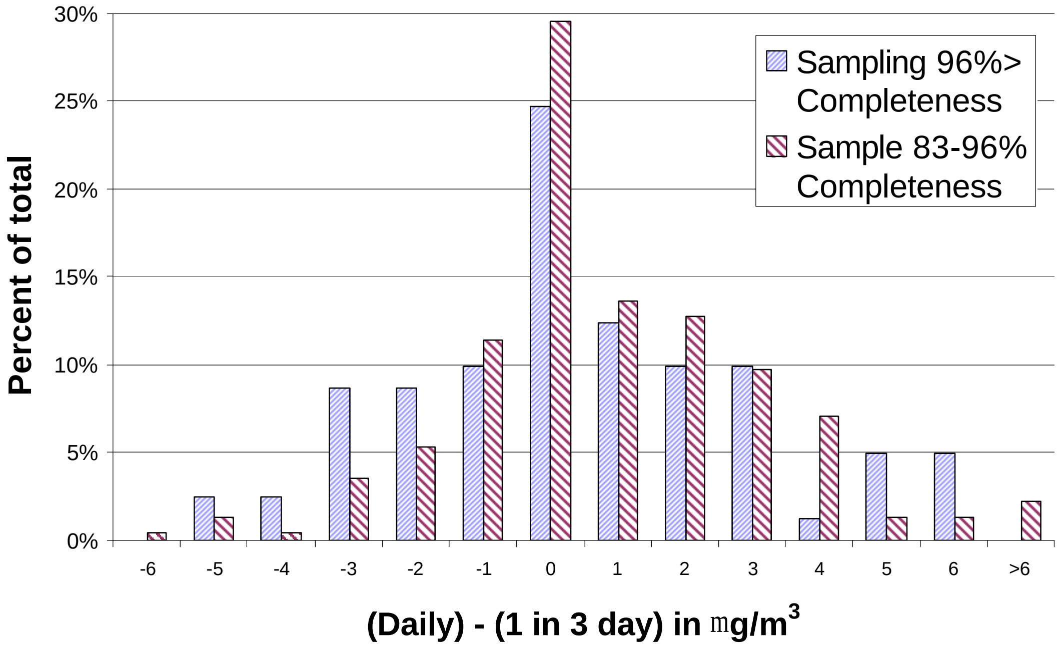
The 2004 dataset was split into two groups based on sample completeness: 26 sites collecting greater than 350 samples and 76 sites collecting 303 to 350 samples. Using the proposed formula, either the eighth or seventh highest value, for the two respective groups, becomes the value compared to the standard. These data were further divided into three subgroups, each representing a different possible one-in-three-day collection schedule. For these subgroups, the third highest value yields the level for standard comparison. Comparisons of the standard level from these subgroups were compared to the standard level determined from the parent everyday dataset, revealing the potential for substantial differences in design values depending upon sampling schedule and data completeness.

Figure 2 shows the distribution of these differences for the two sample completeness groupings. The x-axis represents the difference between the 98th percentile value as calculated from the full everyday dataset and each of the three every-third-day possibilities. The y-axis shows the occurrence of each difference as a percentage. Since there are three cases for each site, the differences plotted represent 78 and 228 (i.e., 3 * 26 and 3 * 76) values for the completeness groupings. The differences cover a wide range, with everyday as much as12 $\mu g/m^3$ greater or 6 $\mu g/m^3$ less than one of the corresponding one-in-three-day calculations. On average, everyday 98th percentile values are 0.24 or 0.89 $\mu g/m^3$ greater for the higher or lower data capture sites, respectively. In other words, using the proposed methodology to calculate the daily design value will tend to underestimate the true 98th percentile 3-year average value at a site if an every-third-day collection schedule is used relative to a daily collection schedule. The bias is more pronounced for a typical data capture percentage (on the order of 90%) than high data capture, as shown in the figure (26% versus 10% where bias represents the difference between the sum of the positive bars and the sum of the negative bars).

The bias exists due to the selection of a discrete measured value. For the typical case, the 98th percentile value at a daily monitor site would be the seventh highest monitored value. Were an every-third-day collection schedule used, the 98th percentile value would be third highest. By splitting a daily dataset into its three every-third-day components, three possible third-highest values can be compared to the seventh highest from the entire dataset. These third highest values may rank anywhere from third to ninth in the daily dataset. The rankings, however, are not equally likely. In fact, the ninth highest value must be one of the three third-highest values, while the everyday third highest represents the least likely value to be one of the every-third-day 98th percentiles. The most probable case reveals the seventh, eight, and ninth highest everyday values as the representative third-highest values on a one-in-three-day sampling schedule. While for an everyday schedule, the 98th percentile value will be the seventh highest, for an every-third-day schedule, the 98th percentile is more likely to be an eighth or ninth highest value, at best. There remains the probability of it being an even lower ranking value.

Given the potential bias demonstrated here and the resulting implication for non-attainment status, we recommend that EPA review the proposed daily PM design value calculation methodology and revise it such that the calculation becomes insensitive to data capture rate or sampling frequency. It should be noted that although the proposed daily design value calculation is similar to the existing approach under the current 24-hour PM NAAQS, its bias has not been an issue for the Northeast states because current 24-hour averages are well below the existing standard, thus well outside the magnitude of the bias we describe here. This is not the case with the proposed daily $PM_{2.5}$ NAAQS, which will be a controlling standard at many Northeast sites. Thus, the design value calculation bias now becomes an issue of concern.

Figure 2. Design Value Bias Introduced by EPA's 98th Percentile Calculation Methodology



4. Conclusion

During the 1997 and 2005 PM standard setting cycles, a central question has been which combination or suite of short-term and long-term primary $PM_{2.5}$ standards is needed to protect general and susceptible populations with an adequate margin of safety across a range of concentrations that vary spatially and temporally. Based on the best available health effects findings and regional demographic and monitoring data, NESCAUM recommends an annual $PM_{2.5}$ standard of 12 $\mu g/m^3$ and a 24-hour $PM_{2.5}$ standard of 30 $\mu g/m^3$ (98th percentile form) as necessary to protect public health across the eight-state Northeast region.

This strong level of protection is justifiable as it recognizes current unresolved issues concerning the existence or non-existence of a threshold, as well as the extent to which protection of all populations – including susceptible groups – can be achieved with an adequate margin of safety based on best available scientific evidence.

We recognize the considerable implications of promoting standards that will place the majority of the region's counties into $PM_{2.5}$ nonattainment based on currently monitored data. Nonetheless, we believe this is the appropriate public health action because of the corrective actions that will follow. Elevated levels of particulate matter from local sources and transported from upwind of the NESCAUM region can be found across broad areas of the Northeast, especially in its densely populated urban areas, where the possible magnitude of risk from environmental exposure to air pollution is significant.

The Northeast states are currently involved in a number of important activities to reduce local PM emissions and exposure beyond the requirements of the Clean Air Act. However, until EPA revises the standards to adequately protective levels, adverse health effects from exposure to concentrations near or below current and EPA's proposed standards will remain a serious public health concern, and our ability to lower these exposures will be significantly limited.

ATTACHMENT B
Detailed Comments on the $PM_{10-2.5}$ (PM-coarse) National Ambient Air Quality Standards

1. Defining the Coarse Particle Indicator

EPA invites comment on defining the coarse particle indicator in terms of particle size and categories of named sources and classes. The proposal states that the coarse particle standard "includes any ambient mix of PM-coarse that is dominated by re-suspended dust from high density traffic on paved roads, and PM generated by industrial sources and construction sources, and excludes any ambient mix of PM-coarse that is dominated by rural windblown dust and soils and PM generated by agriculture and mining sources. Agricultural sources, mining sources and similar sources of crustal material shall not be subject to control in meeting the standard" (see 71 FR 2668).

The proposal does not indicate how one should or can determine what sources "dominate" the PM mix. EPA indicates that it has been "mindful" of the need to separate where the mix is dominated by the emissions of PM from the listed sources and where it is not. In support of that need, EPA proposes a five-part test for determining the suitability of a site for comparison to the NAAQS. However, the exemptions for agriculture and mining and the specification that the PM composition be "dominated" by specific types of emissions, pose several monitoring problems. While the criteria EPA proposed for the five-part assessment accomplishes some things, they do not ensure that the intent of the standards will be met. This is in part because the intent itself is vague. What the five-part test appears to accomplish (through the first four criteria, at a minimum) is that the site will be population-oriented and not near any major sources. The net effect of this proposal is that sources located outside of urbanized areas will not be subject to direct regulation and sources within the area cannot be monitored. In practice, the proposal exempts everything except emissions associated with paved roads from influencing a site.

If an agency locates a monitor within a block that meets the proposed criteria, there is no reason to believe that any adjoining block would meet the requirements. This begs the question of how to determine the spatial extent of non-attainment. As proposed, the criteria would allow for "pockets" of attainment within a non-attainment area. Determining that a site is dominated by a particular source type would require analysis of the aerosol itself. In such cases, the mix would undoubtedly vary, based on a number of factors, e.g., the sources within the area, wind direction. There is no guidance on how to make such a determination, e.g., what to analyze for, how many samples are required, what constitutes "dominated." The process of determining what "dominates" a PM-coarse sample is poorly defined, overly complex and impractical to implement, and could ultimately lead to litigation.

Previous standards have relied upon definitions of particle classes that were basically defined by the monitoring methods. This was because the monitoring measurements were used in evaluating health outcomes and therefore constituted an appropriate indicator on which to base the standard. While there are problems with this approach, there is also an underlying rationality to it. There is also precedent in the $PM_{2.5}$ standard for limiting the type of site that is appropriate for determining compliance with the standards based on the type of sites used for relevant health studies. However, in those cases there was no implied assertion that particles in other size classes did not have varying degrees of health consequences, or that smaller scale sites did not record levels of concern. Those standards were set at more stringent levels because separating out all of the various size fractions, particle compositions, and spatial scales would have been impractical, and there was sufficient health basis for setting the standards on the selected indicators.

In EPA's current PM coarse proposal, components of the particles and site locations are excluded because of an apparent lack of evidence that they should be included, not a definitive analysis that shows they are innocuous. This is a paradigm shift -- away from EPA's previous standard-setting approach to protect sensitive portions of the population with an adequate margin of safety -- that we do not support. Taking EPA's proposed approach to its next step, EPA might posit that any source type not represented in the studies should be excluded. The limited number of sources identified and the large excluded classes in the proposed standard make it, along with the subsequent siting of monitors, either arbitrary, or intentionally biased to exclude even collecting data that could eventually determine whether the excluded sources are of importance.

There should be no exemption of emission sources by "class." We see no good reason to exclude agricultural dust, which may include inorganic or organic fertilizer, toxic heavy metals, pesticides, and bacteria or other biological residues. Similarly, mining emissions may contain asbestos, toxic metals, acids from extraction processes, residue from blasting, processing, refining, and sorting, or other hazardous materials. It appears these potentially unhealthy residues from agricultural and mining activities were excluded because monitoring sites near such sources were not included in the health studies used to support the standard. Little or no information has been provided in the proposed standard regarding studies on the health impact of agricultural and mining activities. EPA should not seek to exclude sources or classes of emissions without in-depth, unambiguous health oriented studies.

NESCAUM recognizes EPA staff and CASAC's recommendation to propose a PM-coarse 24-hour standard without an accompanying PM-coarse annual standard. We suggest that the next PM NAAQS revisit this decision. When sufficient monitoring data become available, analysis of the spatial and temporal behavior of PM-coarse levels could provide insight as to whether a short-term standard adequately protects populations from long-term exposures. Such an analysis would depend on whether future studies find health effects associations with chronic exposure to PM-coarse.

2. Transport and PM-coarse

EPA should revise the statement (71 FR 2625) that reads in part "…coarse particles generally deposit rapidly on the ground or other surfaces and are not readily transported across urban or broader areas…" This is an incorrect quote (p. IV-6) from the latest Criteria Document posted on EPA's web site and provides information that is out of context and distorts the original meaning. The quoted passage refers to "…the larger coarse particles (>10 µm)…." and describes how it is possible for the particles of interest ($PM_{10-2.5}$) to be transported across urban or broader areas. EPA should revise the language consistent with language on page IV-7 of the Criteria Document: "The atmospheric behavior of smaller 'coarse fraction' particles ($PM_{10-2.5}$) is intermediate between that of the large coarse particles and smaller fine particles. Thus, coarse fraction particles may have lifetimes on the order of days and travel distances of up to 100 km or more…."

We are concerned about the long range transport of coarse particles and the likelihood of their association with toxic material. In the aftermath of an intercontinental dust storm originating in the Gobi desert during April of 2001, researchers associated with the IMPROVE program noted that particulate matter reaching the U.S. during this event showed a "size distribution peak between 2-3 µm."[1] Another researcher noted the dust storm was associated with "the highest level of arsenic we ever saw in Nevada…." [2] This is but one example of toxic material in association with coarse particles that has been transported well over 100 km. EPA should rescind its position that such particles "are not readily transported across urban or broader areas."

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[1] See http://vista.cira.colostate.edu/improve/publications/NewsLetters/IMPNewsSpring2001.pdf
[2] See http://www.sciencemag.org/cgi/content/summary/294/5551/2469a

If EPA would like to exclude a class of natural events such as dust storms originating in "rural" areas from the coarse particle regulations, it might consider providing such exemption under its forthcoming "exceptional events" rules. However, that course should only be pursued with the proviso that adequate speciation measurements and health studies support those rules.

3. Use of Spatial Averaging and Other Issues with Design Value Calculations

With respect to the annual $PM_{2.5}$ standard, use of spatial averaging (see 71 FR 2685) results in unnecessary complexity with little or no benefit. EPA should employ data from the highest community-oriented monitor within an area with no allowance for spatial averaging.

For sites with high monitored concentrations, EPA proposes use of "a historically low" 24-hour value to populate a calendar quarter with less than 11 samples when calculating the three-year design value to determine non-attainment (see 71 FR 2686). The proposal would use the lowest historical value for the quarter in question for the most recent three year period. Although the use of only 11 samples per quarter is not desirable, the proposed approach has merit given two constraints: (1) no more than one quarter should be allowed data substitution for the three-year design value calculation and (2) this process should only be used to classify a site non-attainment, which otherwise would be unclassifiable for failing data completeness requirements. The absence of a significant amount of data (e.g., two or more quarters during a three year period) is an indication of site operator and/or equipment problems. Under such circumstances, a simple data substitution would ignore possible significant data quality problems.

Regarding use of the "applicable number of samples" versus the "actual number of samples" approach for calculating the annual $PM_{2.5}$ average, it is not clear if adopting the former approach would prevent the use of the "extra sample" approach currently allowed by EPA guidance to make up for missing samples. If the "applicable number" approach still allows for extra sampling at the end of a month to make up for missing samples, then we would deem it to be an acceptable approach.

The proposal to allow substitution of a "collocated" sample in place of a missing "regular" sample is a valid approach and should be implemented.

4. PM-coarse Federal Reference Method (FRM)

The EPA's proposed PM-coarse FRM of low-volume samplers that is based on the existing $PM_{2.5}$ FRM (see 71 FR 2687) is useful only for determining performance of Federal Equivalent Method (FEM) candidates (of any class). We agree with EPA that the difference method for PM-coarse is the most defendable approach for a reference measurement method. When highly skilled staff run exactly matched pairs of samplers and protocols in a well-controlled environment (field and lab), the difference method is the most definitive PM-coarse measurement with the fewest data quality ambiguities. Identical hardware for both systems must be used (with the exception of the lack of a $PM_{2.5}$ WINS impactor or VSC-cyclone in the "PM10c" sampler).

Our concern with this proposed FRM is degradation of PM-coarse data precision in areas where $PM_{2.5}$ is substantially greater than PM-coarse. This includes much of the eastern U.S., especially in the context of National Core Monitoring Network (NCore) spatial scale siting (neighborhood to urban scale, away from mid- and micro-scale PM-coarse sources). While we realize that EPA does not intend the FRM to be widely used for routine monitoring, the proposed regulations require that it will be used for audit purposes. We do not think this is appropriate.

NESCAUM scientific staff has outlined an approach to estimate what the PM-coarse precision would be using the difference method when the precision of a single sampler and the $PM_{2.5}$ to PM-coarse ratio is known.[3] In summary, multiply the single sampler precision by the square root of 2, and then multiply that result by the expected or mean $PM_{2.5}$ to PM-coarse ratio. In EPA's 1999-2001 Quality Assurance Report,[4] page x of the executive summary shows a 7.2% 3-year average precision (CV) for a single $PM_{2.5}$ FRM 24-hour sample. For 2003,[5] the reported single sampler CV across reporting sites ranges from 0.9 to 46%, the mean is 8.3%, and the median is 5.1%. Of the 157 reporting sites, 37 had CV of >10% for $PM_{2.5}$ FRM data, and 78 sites had precision better than 5%.

Assuming a $PM_{2.5}$ to PM-coarse ratio of 2 (a $PM_{2.5}$ to PM_{10} ratio of 0.67, which is a reasonable estimate for eastern NCore sites, urban or rural) and a single sampler precision of 5%, the estimated PM-coarse precision is 14%. If 7.2% single sampler precision is used, the PM-coarse precision for this scenario is 20%. If the goal of an audit (only a few samples) is to assess the performance of another monitor, the audit device precision must be better than 5%. This will be difficult or impossible to achieve with the proposed PM-coarse FRM at most eastern NCore sites. One solution to this is to allow the dichotomous sampler method (presently proposed to be a Class II FEM) to be used for audit purposes. While this approach is not currently allowed in the proposed regulations, we urge EPA to allow it for PM-coarse sampler audits.

In addition, we recommend that for PM-coarse, the acceptable average field blank value of 30 µg for the $PM_{2.5}$ FRM be lowered, since the existing value (1.25 $\mu g/m^3$ equivalent) can contribute to degraded precision of PM-coarse data. There is a wide range in mean and variation of field blanks[6] across different $PM_{2.5}$ FRMs. Any other process does not yield a useful field blank value, and should have some other name, such as "trip blank." Some methods routinely achieve mean field blanks in the range of 5 to 10 µg. We recommend that this specification be reduced to a maximum of 10 µg field blank mean for sampler pairs used for PM-coarse measurements.

5. Use of Negative Values

EPA discusses and minimizes the possibility of negative PM-coarse values when using the difference method because such values would likely occur only at low ambient concentrations (see 71 FR 2688). However, it is not clear when or if EPA considers negative PM-coarse values valid data. Negative values should not be allowed for use in a daily standard, and this point should be emphasized in Appendix O. However, for calculating non-NAAQS PM-coarse annual mean metrics, plausible negative values must remain in the dataset to avoid bias in the mean calculations.

6. Clarifications and Possible Typographical Errors

In the proposal, EPA discusses the range suggested in the Staff Paper (50-70 $\mu g/m^3$) for a 24-hour $PM_{10-2.5}$ standard, noting, "The upper end of this range is also below the 98th percentile $PM_{10-2.5}$ concentrations in the two mortality studies that reported statistically significant associations" (see 71 FR 2671). However, at 71 FR 2669, EPA states that "...in (the) mortality studies...the reported 98th percentile $PM_{10-2.5}$ values were all above 50 $\mu g/m^3$[.]" It is confusing to use the phrase "above 50 $\mu g/m^3$" if the actual 98th percentile values were above 70 $\mu g/m^3$ as the statement on page 2671 indicates. Or is the number "50" on page 2669 a typo? We would like this apparent inconsistency clarified.

[3] Allen et al., *Journal of the Air & Waste Management Association* 49: PM-133-141.
[4] See http://www.epa.gov/ttn/amtic/cy9901qa.html
[5] Communication with Mike Papp, EPA, OAQPS, January 17, 2006.
[6] In this context, a field blank is defined as a filter loaded into the sampler and left in place for the same duration as a normal sample (typically 48 hours or more).

In Part 3.0 (b) (see 71 FR 2701), EPA proposes that $PM_{2.5}$ data "be reported to one decimal place with additional digits to the right being truncated," whereas Part 3.0 (c) calls for truncation of "the insignificant digits to the right of the third decimal place." There appears to be a typo in subsection (c). This discrepancy also occurs on 71 FR 2707 in Sections 2.0(c) and (d).

We suggest that EPA clarify the phrase in Section 1.7 of Appendix O referring to "Class 1" equivalent methods that reads "significant but minor" (see 71 FR 2703). It is difficult to imagine a significant modification that is also minor.

ATTACHMENT C
Detailed Comments on the Secondary $PM_{2.5}$
National Ambient Air Quality Standards

The EPA proposes to revise the secondary $PM_{2.5}$ standard to be identical to the proposed primary standard of 35 µg/m^3, 24-hour average, 98th percentile form (71 FR 2675-2685). The NESCAUM states agree that EPA should revise the current secondary $PM_{2.5}$ NAAQS from its existing level of 65 µg/m^3, 24-hour average, 98th percentile. However, we disagree that the proposed secondary standard should be identical to the proposed primary NAAQS of 35 µg/m^3, 24-hour average, 98th percentile form. The NESCAUM states recommend that EPA promulgate a secondary $PM_{2.5}$ standard that provides greater visibility protection than EPA's proposed secondary standard and that is more consistent with its staff recommendation (*Review of the National Ambient Air Quality Standards for Particulate Matter: Policy Assessment of Scientific and Technical Information*, EPA-452/R-05-005a (December 2005) (EPA Staff Paper). We also note that CASAC "strongly supported" the EPA staff recommendation (with one dissenting view) (CASAC letter to EPA Administrator Stephen L. Johnson (June 6, 2005) p. 9) (CASAC letter). The NESCAUM states recommend a secondary $PM_{2.5}$ standard based on a sub-daily (12 p.m.-4 p.m.) average in the range of 20 to 25 µg/m^3 at the 95th to 96th percentile level averaged over three years.

Monitors in the NESCAUM region never exceed the current secondary $PM_{2.5}$ standard of 65 µg/m^3, 24-hour average, 98th percentile form, yet the CAMNET regional haze camera network routinely documents extremely hazy days obscuring city skylines and adjacent views.[1] This shows that virtually all of $PM_{2.5}$ effects on visibility in the Northeast are occurring below the present secondary standard, justifying EPA's proposal to revise the existing standard to a more stringent level adequately protective of public welfare. However, EPA's proposed new secondary standard is not adequate.

We agree with EPA's view that visibility relates most directly to sub-daily levels of $PM_{2.5}$ that can vary dramatically over a few hours. As noted in the EPA Staff Paper, this calls for a shorter-term standard of less than a 24-hour averaging period focused on daylight hours. Daylight hours are the most relevant for urban views, and the lower humidity during the day substantially diminishes much of the visibility difference between the eastern and western United States for an equivalent $PM_{2.5}$ dry mass concentration (see R. Poirot comments, CASAC letter, pp. C-24/25).

Survey findings cited by EPA demonstrate that the human eye is sensitive to $PM_{2.5}$ levels well below EPA's proposed primary $PM_{2.5}$ standard. The public survey methods cited by EPA in its proposal (71 FR 2678) amply and consistently demonstrate publicly acceptable visual ranges of 40 to 60 km, as also noted in EPA's Staff Paper (see p. 7-5). The publicly acceptable visual ranges consistently found in different cities correspond to $PM_{2.5}$ levels on a sub-daily basis well below the 35 µg/m^3 24-hour average proposed by EPA, which corresponds to a visual range of somewhat less than 20 km. For the 12 p.m. to 4 p.m. time period, a visual distance of 40 km corresponds to $PM_{2.5}$ levels around 17 µg/m^3, and 60 km corresponds to around 11 µg/m^3.[2]

We note that the public surveys cited by EPA are for western US cities and Lower Fraser Valley, British Columbia. While similar survey data are not, to our knowledge, available for eastern cities, the EPA Staff Paper points out that East/West differences are much smaller for urban areas than Class I areas with respect to visibility, and are further minimized during daylight hours when humidity is generally lower (EPA Staff Paper, p. 6-6). Therefore, the reduced East/West differences make feasible the establishment

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[1] See CAMNET, Realtime Air Pollution and Visibility Monitoring , at http://www.hazecam.net/
[2] EPA Memo by Mark Schmidt, et al., *Analysis of Particulate Matter (PM) Data for the PM NAAQS Review*, EPA OAQPS, June 30, 2005 (see figures on pp. 253 and 255).

of a national secondary standard for visibility that is based on already existing public survey data even if the data do not cover all parts of the country.

In addition, we do not believe the eastern public would substantially differ in its perception of acceptable visibility relative to the western public. Public surveys of acceptable visibility in New Hampshire's White Mountains find visibility ranges below about 20 deciviews (~50 km) unacceptable to half the respondents.[3] While this is a rural survey, it suggests that public perception of acceptable eastern visibility is not significantly out of line with the results of the western urban surveys (40-60 km).

Even if one were to assume that the eastern public values urban visibility less than the western public, the secondary standard recommended by the NESCAUM states is already conservative in this respect. The EPA Staff Paper states that 25 and 20 $\mu g/m^3$ correspond to visual range levels of 30 and 35 km, respectively (EPA Staff Paper, p. 7-8). These visual distances are below the minimum 40 km distance the public finds acceptable in the western urban areas and the ~50 km distance found acceptable in New Hampshire's White Mountains. Although the range of the NESCAUM recommended secondary standard will not initially achieve what is acceptable to the public according to the survey results, it is a more productive first step than the EPA proposal, and can be revised in the future as warranted by updated and refined public visibility valuation studies.

While EPA's Staff Paper asserts that the Clean Air Act "does not require that secondary standards be set to eliminate all risk of adverse welfare effects" (see p. 7-12), the Clean Air Act requires that secondary standards be set to eliminate *at least some of the risk* of adverse welfare effects in order to give meaning to the statutory language. Simply equating the primary to the secondary standard as sufficient to protect welfare renders the Clean Air Act's statutory language on secondary standards superfluous and meaningless, which is contrary to standard statutory interpretation.

A secondary standard will also complement EPA's regional haze rule and better address winter haze in Northeast cities and other urban areas. During the winter, haze events are often more local in nature,[4] thus the regional haze rule will not be adequate for visibility protection in urban areas, as it targets federal Class I areas primarily in rural regions.

The NESCAUM states question EPA's rationale for not proposing a sub-daily secondary standard. The EPA takes the proposed primary standard and compares it with a hypothetical standard of 30 $\mu g/m^3$ "toward the upper end of the range recommended in the Staff Paper"[5] coupled to the 95th percentile, "a form within the recommended range" of the Staff Paper, to find this sub-daily form would cover fewer counties than the proposed primary standard (24% vs. 27%) (See 71 FR 2681). This is only one possible combination amongst a wider range provided in the Staff Paper. Table 7A-1 of the Staff Paper provides a fuller range of possible standards. In light of the NESCAUM states' recommendation of a primary $PM_{2.5}$ standard of 30 $\mu g/m^3$, 24-hour, 98th percentile coupled to a 12 $\mu g/m^3$ annual average, a reasonable secondary standard providing some additional level of protection for welfare effects would be a sub-daily (12 p.m.-4 p.m.) 20-25 $\mu g/m^3$ average at the 95th-96th percentile level averaged over three years.

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[3] L.B. Hill, W. Harper, J.M. Halstead, T.H. Stevens, I. Porras, & K.D. Kimball, *Visitor Perceptions and Valuation of Visibility in the Great Gulf Wilderness, New Hampshire*, USDA Forest Service Proc. RMRS-P-15-VOL-5, pp. 304-311 (2000).

[4] *Regional Haze and Visibility in the Northeast and Mid-Atlantic States*, NESCAUM, Boston, MA, January 31, 2001.

[5] We note that EPA's characterization of 30 $\mu g/m^3$ as "toward the upper end of the range recommended in the Staff paper" is an understatement. It *is the upper end of the range* recommended in the Staff paper, hence it is the least possible protective standard recommended.

EPA's Staff Paper found that available information on visibility "may well provide a basis for a *distinctly* defined standard" (see p. 7-2, emphasis added). The NESCAUM states support this view, and note that our recommendation is consistent with the range of possible choices given by the EPA Staff Paper for a distinctly defined sub-daily secondary standard within the range of 20 to 30 $\mu g/m^3$ (71 FR 2680).

We also note that the EPA Staff Paper observed that "4-hour average $PM_{2.5}$ concentrations of approximately 30, 25, and 20 $\mu g/m^3$ correspond to the target visual range levels of 25, 30, and 35 km, respectively." While these fall short of the minimum 40 km visibility range derived from public perception surveys and local visibility standards (see Staff Paper, pp. 7-8/10), a revised secondary standard of 20 to 25 $\mu g/m^3$, as proposed by the NESCAUM states, would be a more meaningful step towards achieving publicly acceptable visibility than that ultimately proposed by EPA. EPA's proposed secondary standard of 35 $\mu g/m^3$ 24-hour average falls far short of any meaningful improvement in visibility as many $PM_{2.5}$ monitors in the Northeast already are at or just below EPA's proposed standard. It is also well outside the range deemed acceptable by the public.

Trends in monitoring also support a shift to a sub-daily secondary standard. There has been and continues to be a movement towards continuous hourly monitoring, rather than filter samples, nationwide. As the methods continue to mature and the ability of agencies to run these monitors increases, hourly data collection will be an increasingly routine activity with higher quality data. In addition to current trends in monitoring, the information EPA already has on hand and used in developing a range of possible sub-daily secondary standards (see Table 7A-1 of Staff Paper) demonstrates that there are monitoring data available now to support a sub-daily secondary standard.

Although the proposed rules do not specify what methods would be used to measure $PM_{2.5}$ for the purposes of demonstrating compliance with a sub-daily secondary standard, there is mention of this in the preamble to Part 50 in the text and footnote 87 at 71 FR 2680. Only data from a Class III continuous Federal Equivalent Method (FEM) $PM_{2.5}$ monitor could be used. The EPA proposes requirements for designating this class of monitor in Part 53.35 in the context of continuous monitoring for compliance with the $PM_{2.5}$ NAAQS (see 71 FR 2762).

ATTACHMENT D

October 27, 2005 Letter to Administrator Johnson from the New England Environmental Commissioners

December 16, 2005 Letter to Administrator Johnson from the New Jersey Environmental Commissioner

New England Environmental Commissioners

Gina McCarthy,
Commissioner
Connecticut Department of Environmental Protection

Dawn Gallagher,
Commissioner
Maine Department of Environmental Protection

Robert W. Golledge, Jr.,
Commissioner
Massachusetts Department of Environmental Protection

Michael Nolin,
Commissioner
New Hampshire Department of Environmental Services

W. Michael Sullivan,
Director
Rhode Island Department Environmental Management

October 27, 2005

Stephen L. Johnson, Administrator
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 1101A
Washington, DC 20460

Dear Administrator Johnson:

Fine particulate matter poses one of the greatest public health risks in our region and across the nation. The preponderance of health studies suggest that significant segments of the U.S. population are experiencing adverse health effects from exposures to ambient concentrations of fine particles ($PM_{2.5}$), even at levels at or below the current national ambient air quality standard (NAAQS). The U.S. Environmental Protection Agency (EPA) has the opportunity to greatly reduce this risk by adopting an appropriately protective NAAQS for fine particles. We write to offer our thoughts and urge you to act decisively on this critical public health issue.

A large portion of the Northeast population is vulnerable to the health effects of airborne particulate matter at the concentrations currently measured on many days across the region. Sensitive populations include people with cardiovascular and respiratory conditions, diabetes, the young and elderly. Further, the population density of our region is among the highest in the nation, with over 30 million persons living in urban areas that typically experience the highest particulate matter levels. These areas have asthma rates that are among the highest in the nation and asthmatics are particularly sensitive to particulate matter.

Given the Clean Air Act's mandate to protect public health—including susceptible populations—with an adequate margin of safety, the Northeast states believe that epidemiologic and risk assessment evidence clearly supports more stringent $PM_{2.5}$ standards. While both EPA and the Clean Air Scientific Advisory Committee (CASAC) have concluded that a more health protective particulate matter standard is warranted, the broad range of levels and forms proposed in the EPA Staff Paper could result in adoption of a suite of standards that will not be adequately protective in our region.

Based on the weight of evidence of health effects findings and regional demographic and monitoring data, the Northeast states believe that a 24-hr $PM_{2.5}$ standard of 30 $\mu g/m^3$ (98^{th} percentile form) and an annual $PM_{2.5}$ standard of 12 $\mu g/m^3$ are necessary to protect public health across the region. These levels are within the range offered in the EPA Staff Paper. A requirement to reduce current emissions of $PM_{2.5}$ and its precursors to meet a 12/30 $\mu g/m^3$ standard would result in 84 percent of the region's population directly benefiting from improved air quality, including about five times more people in susceptible subgroups than at current standard levels. The attached paper describes an analysis that NESCAUM conducted in support of our efforts to reach regional consensus on the appropriate level of the new PM NAAQS. We strongly believe that a more protective PM NAAQS is appropriate and needed to address this important public health risk. Your pending decision relative to revising the NAAQS for particulate matter is of critical importance. We urge you to propose $PM_{2.5}$ standards in line with the lower end of the range recommended in the EPA Staff Paper.

Sincerely,

THE UNDERSIGNED ENVIRONMENTAL COMMISSIONERS

Gina McCarthy, Commissioner
Connecticut Department of Environmental Protection

Dawn R. Gallagher, Commissioner
Maine Department of Environmental Protection

Robert W. Golledge, Jr, Commissioner
Massachusetts Department of Environmental Protection

Michael Nolin, Commissioner
New Hampshire Department of Environmental Services

W. Michael Sullivan, Director
Rhode Island Department of Environmental Management

CC: Robert W. Varney, Regional Administrator, EPA Region-1
William Wehrum, Acting Assistant Administrator, Office of Air and Radiation
Robert Brenner, Director, Office of Air and Radiation
Steve Page, Director, Office of Air Quality Planning and Standards
Lydia Wegman, Director, EPA OAQPS Air Quality Strategies and Standards Division
John Bachmann, Associate Director, Office of Air Quality Planning and Standards
Arthur Marin, Executive Director, NESCAUM

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Richard J. Codey
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Commissioner
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DEC 16 2005

The Honorable Stephen L. Johnson, Administrator
United States Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, D.C. 20460

Dear Administrator Johnson:

Fine particulate matter poses one of the greatest public health risks in New Jersey and across the nation. The preponderance of health studies suggest that significant segments of the United States population are experiencing adverse health effects from exposures to ambient concentrations of fine particulate matter ($PM_{2.5}$), even at levels below the current National Ambient Air Quality Standard (NAAQS). The U.S. Environmental Protection Agency (USEPA) has the opportunity to greatly reduce this risk by adopting an appropriately protective NAAQS for fine particles. New Jersey urges you to act decisively on this critical public health issue by decreasing the 24-hr $PM_{2.5}$ standard to 30 $\mu g/m^3$ and the annual $PM_{2.5}$ standard to 12 $\mu g/m^3$.

A large portion of the New Jersey population is vulnerable to the detrimental health effects of airborne particulate matter at the concentrations currently measured on many days across the region. Sensitive populations include people with cardiovascular and respiratory conditions, diabetes, the young and the elderly. The most urbanized states, like New Jersey, have asthma rates that are among the highest in the nation, and asthmatics are particularly sensitive to particulate matter.

Given the Clean Air Act's mandate to protect public health—including susceptible populations—with an adequate margin of safety, New Jersey believes that epidemiological and risk assessment evidence clearly supports more stringent $PM_{2.5}$ standards. While both the USEPA and the Clean Air Scientific Advisory Committee (CASAC) have concluded that a more health protective particulate matter standard is warranted.

Based on the weight of evidence of health effects findings and regional demographic and monitoring data, New Jersey believes that a 24-hr $PM_{2.5}$ standard of 30 $\mu g/m^3$ (98^{th} percentile form) and an annual $PM_{2.5}$ standard of 12 $\mu g/m^3$ are appropriate to protect public health across the region. These levels are within the range offered in the USEPA Staff Paper and provide an adequate margin of safety for the most sensitive of population as required by law. A requirement to reduce current emissions of $PM_{2.5}$ and its precursors to meet a 12/30 $\mu g/m^3$ annual/24-hour health standard would not only benefit the New Jersey population, but also benefit all citizens of the nation, especially those groups that are more sensitive to air pollution. In New Jersey we estimate that two to ten times more premature deaths would be prevented by meeting a 12 $\mu g/m^3$ annual health standard compared to meeting the 15 $\mu g/m^3$ level. This translates to 350 to 1,450 more lives saved per year.

Your pending decision relative to revising the NAAQS for particulate matter has long term important public health consequences. A $PM_{2.5}$ NAAQS is needed to address this important public health risk. We urge you to propose the $PM_{2.5}$ standards at the lower end of the range recommended in the USEPA Staff Paper to establish the standard at a level which is clearly protective of public health and the environment. Again, New Jersey strongly supports a 24-hr $PM_{2.5}$ standard of 30 $\mu g/m^3$ and an annual $PM_{2.5}$ standard of 12 $\mu g/m^3$.

Sincerely,

Bradley M. Campbell
Commissioner

c: The Honorable Bill Werhum, Assistant Administrator, USEPA
The Honorable Alan J. Steinberg, Administrator, USEPA Region II
The Honorable Peter C. Harvey, Attorney General, State of New Jersey

ATTACHMENT E

NESCAUM PEER-REVIEWED PUBLICATIONS RELATING TO $PM_{2.5}$ NATIONAL AMBIENT AIR QUALITY STANDARDS

Colburn KA and Johnson PRS. 2003. Air Pollution Concerns not Changed by S-PLUS Flaw. *Science* 299(31):665-6.

Johnson PRS and Graham JJ. 2005. Fine Particulate Matter National Ambient Air Quality Standards: Public Health Impact on Populations in the Northeastern United States. *Environmental Health Perspectives* 113(9):1140-7.

Johnson PRS and Graham JJ. 2006. Analysis of Primary Fine Particle National Ambient Air Quality Standard Metrics. *Journal of the Air & Waste Management Association* 56(2):206-18.

Air Pollution Concerns Not Changed by S-PLUS Flaw

Kenneth A. Colburn and Philip R. S. Johnson*

A large body of scientific evidence has accumulated over the last decade showing that significant health effects occur from exposure to ambient particulate matter (PM) concentrations near or below current federal standards that were presumably set to protect public health and the environment. This topic has recently been in the news because an analytical software issue surfaced that may modify the results of some epidemiological studies used by the U.S. Environmental Protection Agency (EPA) to evaluate PM standards. Unfortunately, a disproportionate amount of attention has been devoted to this concern that threatens to poison the public policy debate on PM air quality standards.

Annual and daily standards for particulate matter with an aerodynamic diameter of 2.5 micrometers or less ($PM_{2.5}$) are 15 μg/m^3 and 65 μg/m^3, respectively. Yet scientific evidence indicates that exposure to ambient levels of PM is causing tens of thousands of excess mortality outcomes and hundreds of thousands of excess morbidity outcomes annually in the United States. These effects include risk of premature mortality, increased hospital admissions for cardiopulmonary causes, acute and chronic bronchitis, asthma attacks and emergency room visits, decreased lung function, and increased incidence and duration of respiratory symptoms (*1–9*).

EPA was scheduled to review and possibly to revise the PM National Ambient Air Quality Standards (NAAQS) in 2002 until the announcement in May that use of a default setting in a statistical software program [the S-PLUS statistical package (*10*)] biased overall risk estimates upward in a major epidemiological time-series study (*11*). The S-PLUS software problem was identified by researchers analyzing the National Morbidity, Mortality, and Air Pollution Study (NMMAPS), one of the multicity studies used by EPA in consideration of new PM standards (*12*). EPA is currently facilitating the reanalysis of key epidemiological studies and expects to propose a final decision on PM NAAQS no sooner than November 2003. The time-series reanalysis effort that has occurred since May 2002 has led scientists to reevaluate modeling approaches and estimation procedures used for sensitivity analyses in short-term studies. In so doing, investigators reaffirmed that the development of the analytic models underlying time-series study results involved decisions and assumptions that, on the whole, showed a consistency of results across reasonable modeling choices (*13*). The software glitch in the S-PLUS statistical package has not changed what we have learned about particulate air pollution and human health during the last half-century. But controversy surrounding the problem has caused unwarranted confusion and uncertainty. Critics of the PM NAAQS review process have used the S-PLUS revelation as an opportunity not only to question time-series epidemiological methods, but also to challenge the scientific credibility of the current PM pollution standards (*14*).

NMMAPS risk estimates have been revised with a corrected S-PLUS application and an alternative model. The central findings remain unchanged by the S-PLUS flaw. Furthermore, other multicity time-series studies of airborne particulate consistently report higher risk rates for mortality than NMMAPS regardless of the model used. [See the table on this page; (*3, 4, 7, 15–17*)]. NMMAPS found evidence of an association between acute exposure to PM and daily mortality with a lag of 1 day between exposure and response across the United States. Strongest associations were found for respiratory and cardiovascular problems as the cause of death, as well as for hospital admissions for chronic obstructive pulmonary disease (COPD) and heart disease. These associations cannot be attributed to NO_2, CO, SO_2, or O_3 (*12*, *13*, *15*).

Over the past decade, time-series studies have answered questions about whether risk factors such as weather, influenza epidemics, and other air pollutants could be confounding variables (*18*). Critics have also questioned whether increased short-term mortality associated with higher pollution levels is restricted to very ill persons for whom life expectancy is already short. Single-city studies suggest that air pollution actually increases twofold the size of the pool of critically ill people over longer time scales by increasing the intensity of illness (*19–22*).

In addition, there is no clear evidence of an exposure threshold below which PM has no effect on population mortality. Schwartz *et al*. explored the relation between $PM_{2.5}$ concentrations and daily mortality in six U.S. cities and found an essentially linear relationship down to 2 μg/m^3 exposure levels. An association with traffic particles (which are primarily carbonaceous aerosols) also had no threshold and was somewhat steeper than the association with all $PM_{2.5}$, which indicates that a 1-μg/m^3 increase in the concentration of traffic particles in the United States, for

EFFECTS OF CORRECTIONS ON ESTIMATES OF MORTALITY AND MORBIDITY IN TIME-SERIES STUDIES OF SHORT-TERM PARTICULATE MATTER EXPOSURE

Study	Pollutant	Mortality/morbidity increase per 10 μg/m^3 increase in pollutant concentration (%)		
		S-PLUS (original)	S-PLUS (corrected)	Alternative
NMMAPS	PM_{10}			
Mortality		0.41	0.27	0.21
Cardiovascular disease		10.7	9.9	9.5
COPD		18.6	17.0	13.3
Pneumonia		18.7	16.9	5.6
Harvard Six-Cities (Schwartz reanalysis)	$PM_{2.5}$			
Mortality		1.5	1.4	1.2
APHEA-1, 2* (western European cities)	Black smoke†			
Mortality		0.6		0.6

*APHEA, Air Pollution and Health: A European Approach (*4, 7, 16*).

†"Black smoke" is small particulate matter that serves as a marker of traffic-related emissions in urban areas.

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example, could be associated with about 7000 additional early deaths per year (*23*).

Recently, more evidence has been developed to explain the biological mechanisms of particle toxicity that contribute to the pathology of cardiopulmonary disease. For example, elevated short-term exposure to particulate pollution has been associated with the triggering of acute myocardial infarctions (*24*), disruption of autonomic nervous system activity by decreased heart rate variability (*25*), and increases in the risk of potentially life-threatening cardiac arrhythmias (*26*). Suwa *et al*. found that repeated exposure to urban air particulates in rabbits caused a systemic inflammatory response and was associated with progression of the atherosclerotic process in the coronary arteries and aorta (*27*). Recent EPA research using human subjects has also helped to validate epidemiological PM health observations. Healthy elderly subjects placed in an exposure chamber containing ~40 $\mu g/m^3$ of concentrated ambient particulates for 2 hours showed adverse electrocardiogram changes (*28*).

Furthermore, reanalysis of the time-series studies in no way changes the underlying results of the major U.S. long-term cohort studies, which agreed in their findings of statistically significant positive associations between PM and mortality. The cohort studies, which estimate combined effects of acute and chronic exposure by comparing death rates across cities, indicate that the estimates of total mortality associated with chronic PM exposure appear to be much larger than those reported from time-series daily mortality PM studies. In fact, cohort risk estimates are one order of magnitude higher than estimates found in current time-series studies, which suggests that the burden of death and disease attributable to particulate air pollution may be substantial.

The Harvard Six-Cities Study published results for a 15-year prospectively followed cohort of ~8000 adults in six U.S. cities. The authors found that each 10 $\mu g/m^3$ elevation in $PM_{2.5}$ was associated with a 14, 19, and 21% increased risk of all-cause, cardiopulmonary, and lung cancer mortality, respectively (*1*, *6*). In a 16-year American Cancer Society (ACS) prospective study by Pope *et al.* of ~500,000 individuals in over 100 U.S. metropolitan areas, each 10 $\mu g/m^3$ elevation in $PM_{2.5}$ was associated with a 6, 9, and 14% increased risk of all-cause, cardiopulmonary, and lung cancer mortality, respectively (*2*, *8*). Krewski *et al*. reanalyzed and confirmed the original Harvard Six-Cities and ACS studies, concluding that the published findings of the investigators are based on substantially valid data sets and statistical analyses (*6*). Building on U.S. findings, a newly published study from the Netherlands assessed the association between long-term exposure to traffic-related pollution and mortality in a cohort of subjects aged 55 to 69 years living near major roads. Hoek *et al.* found high mortality risks among persons exposed to black smoke (traffic-related) particles (*29*).

Although time-series and cohort studies have suggested an association between particulate air pollution and mortality, a recent study in Ireland showed that an intervention reducing exposure to coal particles in Dublin resulted in a significant reduction in mortality (*30*). After the introduction of domestic coal-burning regulations in Dublin in 1990, researchers found decreases in the city's nontrauma death rates by 5.7%, decreases in estimated annual cardiovascular death rates by 10.3%, and decreases in estimated respiratory death rates by 15.5%. The study reported results similar to Pope *et al*.'s findings during a 13-month strike at a local steel mill in Utah Valley, where researchers found a reduction in total deaths after a reduction in PM_{10} concentrations (*31*).

Since the 1952 London smog disaster, scientists have been developing evidence to explain air pollution–associated risk. The recent S-PLUS revelation is simply the latest change in an advancing scientific process that over time continually refines and improves the tools used to understand associations between human health and air pollution. As science progresses, large numbers of epidemiological studies continue to find evidence that short-term and long-term exposures to low concentrations of particles are associated with sizable numbers of morbidity and mortality events in developed urban areas around the world.

The relevance of these findings for public health and preventative measures is a compelling argument for the EPA to continue to move forward in the PM NAAQS revision process. The Northeast States for Coordinated Air Use Management (NESCAUM) is an association of state regulatory agencies in New England, New York, and New Jersey whose mission is to protect the public and environment from exposure to unhealthy levels of air pollutants. Elevated levels of PM characterized by different sources—both local and transported from outside of the NESCAUM region—can be found across broad areas of the Northeast, especially in its densely populated urban areas, where the possible magnitude of risk from environmental exposure to air pollution is significant.

Recognizing these concerns, the Northeast states are currently involved in a number of important activities to reduce local PM emissions and exposure beyond the requirements of the Clean Air Act. These activities include retrofitting diesel engines, implementing more power plant pollution controls, and educating the public about health risks. But no state or group of states can regulate the sources beyond its borders. Until EPA moves to revise its currently inadequate PM NAAQS, risk of adverse health effects from exposure to concentrations near or below current standards will remain a serious public health concern and activities to lower these exposures will be limited.

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Fine Particulate Matter National Ambient Air Quality Standards: Public Health Impact on Populations in the Northeastern United States

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In this article we identify the magnitude of general and susceptible populations within the northeastern United States that would benefit from compliance with alternative U.S. Environmental Protection Agency (EPA) annual and 24-hr mass-based standards for particulate matter (PM) with an aerodynamic diameter ≤ 2.5 µm ($PM_{2.5}$). Understanding the scale of susceptibility in relation to the stringency or protectiveness of PM standards is important to achieving the public health protection required by the Clean Air Act of 1970. Evaluative tools are therefore necessary to place into regulatory context available health and monitoring data appropriate to the current review of the PM National Ambient Air Quality Standards (NAAQS). Within the New England, New Jersey, and New York study area, 38% of the total population are < 18 or ≥ 65 years of age, 4–18% of adults have cardiopulmonary or diabetes health conditions, 12–15% of children have respiratory allergies or lifetime asthma, and 72% of all persons (across child, adult, and elderly age groups) live in densely populated urban areas with elevated $PM_{2.5}$ concentrations likely creating heightened exposure scenarios. The analysis combined a number of data sets to show that compliance with a range of alternative annual and 24-hr $PM_{2.5}$ standard groupings would affect a large fraction of the total population in the Northeast. This work finds that current $PM_{2.5}$ standards in the eight-state study area affect only 16% of the general population, who live in counties that do not meet the existing annual/24-hr standard of 15/65 µg/m^3. More protective $PM_{2.5}$ standards recommended or enacted by California and Canada would protect 84–100% of the Northeast population. Standards falling within current ranges recommended by the U.S. EPA would protect 29–100% of the Northeast population. These considerations suggest that the size of general and susceptible populations affected by the stringency of alternative PM standards has broad implications for risk management and direct bearing on the U.S. EPA's current NAAQS review and implementation. *Key words:* air pollution, National Ambient Air Quality Standards, northeastern United States, particulate matter, $PM_{2.5}$, populations, public health, sensitive, susceptible. *Environ Health Perspect* 113:1140–1147 (2005). doi:10.1289/ehp.7822 available via *http://dx.doi.org/* [Online 10 May 2005]

Exposure to ambient fine particulate matter [particulate matter (PM) with an aerodynamic diameter ≤ 2.5 µm ($PM_{2.5}$)] has been associated with a wide range of PM-related human health effects in general populations, including the aggravation of heart and lung disease and premature mortality (Brook et al. 2004; Holgate et al. 1999; Samet et al. 2000). The Clean Air Act of 1970 (CAA 1970) mandates the U.S. Environmental Protection Agency (EPA) to set health-based National Ambient Air Quality Standards (NAAQS) for certain pollutants known to be hazardous to human health, including PM. NAAQS provisions require the U.S. EPA to establish standards requisite to protect public health with an adequate margin of safety at a level that avoids unacceptable risks. Legislative history has interpreted the PM NAAQS margin of safety provision as requiring the protection of both general populations and sensitive subpopulations, or those subgroups potentially at increased risk for ambient particle health effects (National Air Quality Standards Act of 1970). Accordingly, the PM NAAQS—which are currently under review by the U.S. EPA—are intended to protect the health of the most sensitive members of society as well as the general population.

During the last decade, regulatory agencies have increasingly recognized that persons sensitive or susceptible to PM are more numerous and diverse than once thought. To achieve the public health protection called for by the CAA, the National Research Council (NRC) has recommended that subpopulations at increased risk from PM pollution should be identified and the nature and magnitude of their risk understood in the context of standard setting (NRC 2004). These groups comprise a large fraction of the U.S. population, including people with respiratory disease, heart disease, or diabetes; older people; young children; and populations experiencing heightened exposure levels (e.g., those engaged in outdoor work or exercise) [California Air Resources Board (CARB) 2002; U.S. EPA 2004a, 2004b].

Despite regulatory efforts over the past 40 years to improve air quality, the protection of public health with an adequate margin of safety is constrained by the inability of scientists to determine a safe level of exposure to $PM_{2.5}$ below which populations are safe (Daniels et al. 2004; DiBattista and Brown 2003; Schwartz et al. 2002). The American Thoracic Society's (ATS) statement on the nature of an adverse health effect of air pollution notes that although the NAAQS affords health protection to subgroups with increased susceptibility to air pollution using a margin of safety provision, this margin has not been quantified (ATS 2000). Given the likely heterogeneity of individual responses to air pollution, the severity of health effects experienced by a susceptible subgroup may be much greater than that experienced by the population at large (Zanobetti et al. 2000). Therefore, varying host susceptibility factors may hinder adequate protection of an entire population, even at low exposure levels [ATS 2000; Peters et al. 2004; World Health Organization (WHO) 2004].

Notwithstanding the limitations of current standard-setting methods, ambient air quality standards do ultimately determine the number of persons affected by air pollution (Deck et al. 2001). The more stringent the standard, the greater the emission reduction required and the more extensive the control strategies used to reduce PM concentrations. Reduction in ambient PM levels presumably reduces the public health toll exacted by PM pollution. However, given the current lack of an accepted threshold level for adverse health effects, any nonzero PM standard represents the air-pollution–related health burden that policy makers consider "acceptable" (Peters et al. 2004). This presents an important and challenging public health question because PM standards are the fulcrum on which society decides how many people will be at increased health risk to ambient PM. Furthermore, there may be variation in PM–health outcome associations for different subgroups and for different geographic regions, including the northeastern United States, which require consideration in the standard-setting process.

We assessed the extent to which compliance with various combinations of alternative $PM_{2.5}$ standards would provide supplemental protection to general populations and susceptible subgroups in the northeastern United States. We first conducted a state-of-knowledge review of key regulatory and research

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organizations in the United States and Canada to determine which subgroups were considered to be at elevated risk to PM. We then integrated existing demographic and disease or health condition prevalence databases from the U.S. Census Bureau and Centers for Disease Control and Prevention (CDC) with various combinations of $PM_{2.5}$ annual and 24-hr U.S. EPA design values generated from a network of air pollution monitoring sites across an eight-state Northeast study region. This analysis estimated the number of general population and susceptible subgroups in the northeastern United States that would benefit from compliance with alternative U.S. EPA annual and 24-hr mass-based $PM_{2.5}$ standards. We believe the methodologic approach used provides an evaluative tool that may help decision makers place into regulatory context health data appropriate to the current review of the PM NAAQS. The analysis makes evident the public health implications of selecting among alternative $PM_{2.5}$ standards with different degrees of health protection.

Materials and Methods

We identified subpopulations considered potentially at elevated risk for adverse health effects related to PM by reviewing recent health assessment reviews and research reports. These included the Canadian Council of Ministers of the Environment's (CCME) human health effects of $PM_{2.5}$ report in support of the Canada-wide standards (CCME 2004); the CARB's staff report to consider amendments to the ambient air quality standards for PM and sulfates (CARB 2002); the U.S. EPA's PM criteria document (U.S. EPA 2004b), PM staff paper (U.S. EPA 2005), and Particulate Matter Research Program progress report (U.S. EPA 2004a); and comments provided by the NRC's fourth report on research priorities for airborne PM (NRC 2004). To the extent that the four organizations identified or commented on subgroups likely or possibly at increased risk to PM, we estimated the magnitude of these subgroups for an eight-state study area (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont) where data were sufficient. Common subgroups identified included susceptibility by age group, preexisting disease or health condition, heightened exposure, and socioeconomic status. Sufficient demographic and health prevalence data allowed for the estimation of subgroup size using age group and preexisting disease or health condition indicators. To a lesser extent, heightened exposure subgroups were also estimated using population density data.

We calculated age subgroup sizes from the 2000 Census (U.S. Census Bureau 2000) and matched preexisting disease or health condition indicators to available prevalence rates generated by recently published CDC health surveys desegregated by either state or Northeast region. Adult ($\geq$18 years) self-reported asthma rates (ever) were obtained from the 2002 Behavioral Risk Factor Surveillance System (BRFSS), which was state specific. Lifetime asthma was defined as an affirmative response to the question "Have you ever been told by a doctor (nurse or other health professional) that you have asthma?" (CDC 2002a). We calculated the mean lifetime asthma prevalence rate for the eight states in the study area from each state-level prevalence rate. Adult sinusitis rates (preceding 12 months) and chronic bronchitis rates were obtained from the 2000 U.S. Adult National Health Interview Survey (NHIS) for the northeastern United States. The NHIS defines the northeastern United States as the six New England states, plus New Jersey, New York, and Pennsylvania. Respondents were asked in separate questions whether they had been told by a doctor or other health professional in the past 12 months that they had sinusitis or bronchitis (CDC 2003a).

We acquired adult cardiac prevalence rates from the 2000 NHIS for the northeastern United States (CDC 2003a). In separate questions, respondents were asked if they had ever been told by a doctor or other health professional that they had hypertension (or high blood pressure), coronary heart disease, angina (or angina pectoris), heart attack (or myocardial infarction), or any other heart condition or disease not already mentioned. Persons had to have been told on two or more different visits that they had hypertension, or high blood pressure, to be classified as hypertensive. Heart disease was defined to include coronary heart disease, angina pectoris, heart attack, or any other heart condition or disease (CDC 2003a). We obtained adult diabetes prevalence rates (ever) from the 2001 BRFSS report, which was state specific. Diabetes was defined as an affirmative response to the question "Have you ever been told by a doctor that you have diabetes?" (CDC 2002b).

We acquired child (< 18 years) respiratory allergies (preceding 12 months) and asthma (ever) prevalence rates from the 2001 U.S. Children NHIS for the northeastern United States (CDC 2003b). Allergy rates were based on the following questions: "During the past 12 months, has [child's name] had any of the following conditions? Hay fever? Any kind of respiratory allergy?" Asthma rates were based on the question "Has a doctor or other health professional ever told you that [child's name] has asthma?" (CDC 2003b).

To integrate demographic and health prevalence databases with various combinations of $PM_{2.5}$ annual and 24-hr U.S. EPA design values generated from a network of air pollution monitoring sites, federal reference method (FRM) $PM_{2.5}$ air pollution data from 2000, 2001, and 2002 were obtained from the U.S. EPA's air quality system in August 2003 for 127 FRM monitors in U.S. EPA Region 1 (six New England states) and Region 2 (New Jersey, New York), 65 FRM monitors outside these regions in bordering states (Delaware, Maryland, and Pennsylvania, as well as the District of Columbia), and three Interagency Monitoring of Protected Visual Environments (IMPROVE) sites in Regions 1 and 2 [U.S. EPA 2003a; Visibility Information Exchange Web System (VIEWS) 2003]. Within the 2000–2002 period, 192 PM monitoring sites had data in all 12 quarters. Data flagged with the forest fire exemption for 2002 were removed. More than 75% of the 192 sites had better than 50% data capture within each quarter. Data completeness affecting the remaining sites was primarily isolated to one quarter. For sites with collocated monitors, the primary monitor at a site was used to determine the $PM_{2.5}$ concentration (27 pairs of 192 monitors). Although less than half of the primary monitors satisfied the 75% data completeness criteria, no substitution from collocated monitors was attempted.

To determine whether data completeness would affect the relationship between the annual and 24-hr standards at each site, the 81 sites meeting the U.S. EPA's strict 75% completeness requirement for 12 consecutive quarters were compared with 111 sites that did not meet completeness requirements. Regression equations and slopes between the two monitoring data sets were statistically indistinguishable. The regression (where y is the level of the 24-hr standard and x is the level of the annual standard) for the subset of monitors with complete data was $y = 1.86x + 10.43$ ($R^2 = 0.76$). The regression for the subset of monitors with incomplete data was $y = 1.82x + 10.90$ ($R^2 = 0.78$). One data point was excluded from the linear regression because of its undue influence by virtue of its extreme value pair. Inclusion of this point changed the regression to $y = 2.00x + 8.79$ (although this slope is also statistically equivalent to that of the incomplete data).

To estimate the number of persons living in counties not likely to meet different combinations of alternative annual and 24-hr $PM_{2.5}$ standards, 3-year average annual and 24-hr design values were calculated for all counties (150) in the eight-state study area and integrated with Census county-level population data using ArcGIS software (version 8.2; ESRI, Redlands, CA). Design values for state data were generated in adherence with the U.S. EPA's criteria for determination of design values (U.S. EPA 1997, 1999). Alternative standard combinations were put forward for annual standards ranging from 11 to 15 µg/m^3 (1-µg/m^3 intervals) and for 24-hr

(98th percentile) standards ranging from 20 to 65 µg/m^3 (5-µg/m^3 intervals). These ranges were selected to encompass recent California, U.S. EPA, and CCME recommended $PM_{2.5}$ ranges or selected standards.

Design values for the 70 counties with monitors were assigned from the highest monitored levels in each county for 2000–2002. Design values for 80 counties lacking monitors were generated by interpolating county-level monitored design value data from 104 monitors within the eight-state study region and 61 monitors outside the region for border counties. An interpolation scheme was employed using inverse distance-squared weighting for the six nearest monitors within a 111-km radius (corresponding to 1° latitude). Massachusetts and New Hampshire had very few sites with complete data for the 3-year period, requiring an approximation of design values for counties in those states. For the other counties in the eight-state study region, the annual design values used were generally within 0.2 µg/m^3 of those reported by the U.S. EPA using customary guidelines for data substitution and completeness determinations (U.S. EPA 2003b).

We calculated the number of susceptible persons identified as potentially at elevated risk to PM living in counties with $PM_{2.5}$ levels exceeding various annual/24-hr standard combinations for age subgroups and persons with preexisting health conditions using Census age demographic and BRFSS and NHIS health survey prevalence data (CDC 2002a, 2002b, 2003a, 2003b; U.S. Census Bureau 2000). Prevalence rates were multiplied by the number of persons in respective adult and child age groups estimated to be living in counties with $PM_{2.5}$ levels exceeding $PM_{2.5}$ standard combinations.

Differing forms of $PM_{2.5}$ annual and 24-hr primary standards of selected U.S. and Canadian government agencies were normalized to facilitate general comparisons across agencies. This allows for the estimation of how other agency's standard levels correspond to the U.S. EPA's standard level. Relationships were generated using 2000–2002 data from 192 PM monitors located in the eight states and border states of the study region. To compare California's 1-year not-to-be-exceeded (NTBE) target annual standard with the U.S. EPA's 3-year mean annual standard, the relationship between the 3-year annual average and the individual annual averages from the 3 years was reviewed. The highest 3-year average annual value for which no individual year exceeded the California standard was 11.5 µg/m^3. However, several sites showed a 3-year average lower than this where an individual year had exceeded 12 µg/m^3. There were no annual excursions above the 12 µg/m^3 level for a site when the 3-year annual average was < 11.0 µg/m^3. These values (11.0–11.5 µg/m^3) represent a reasonable range of equivalency between a 3-year annual average and a 1-year annual average NTBE standard form.

The relationship between California's proposed 1-year NTBE target 24-hr standard and the U.S. EPA's 3-year mean 98th percentile 24-hr standard was also derived from the 3-year data set (U.S. EPA 2003a; VIEWS 2003). Unlike the annual standard, California's 24-hr standard is structured to allow the exclusion of one extreme day per year over 3 years. To account for these potential extreme day exclusions, the 24-hr values were ranked over 3 years and exclusions were permitted based on total available collected samples; for each 365 sample days, the highest concentration value was excluded. For most sites that sampled on a 1-in-3-day schedule, no exclusions were allowed. For 24-hr sampling sites, generally the top 2 concentration days were excluded, leaving the third highest day as the 24-hr standard level. Because the lowest maximum 24-hr value for any site was > 25 µg/m^3, a conservative corresponding 98th percentile form value (18 µg/m^3) was extrapolated from the linear regression between the maximum value at a site (after exclusion) over 3 years and the 3-year average 98th percentile value. A second approach relied on the regression relationship of the 3-year average of the year-specific maximum values and the 3-year average 98th percentile, yielding 20 µg/m^3. This approach is roughly equivalent to excluding 1 extreme day over 3 years. These values were used to establish the tabulated 98th percentile range of 18–20 µg/m^3 that corresponds to the 25-µg/m^3 24-hr maximum.

Results

We conducted a review of recent PM reports from CARB, the U.S. EPA, CCME, and NRC to assess whether ambient PM is believed to have a disproportionate effect or increased risk on certain populations. This was accomplished by comparing how the various organizations conceived of sensitive populations and defined determinants of sensitivity among subgroups. Previous research on sensitivity or susceptibility has noted varying conceptual approaches to defining the terms and subgroups, given different interpretations of the state of knowledge (ATS 2000; ATS Committee 1996; Parkin and Balbus 2000; Pope 2000). The ATS has broadly defined "susceptibility" as including extrinsic factors, such as the profile of exposure to other pollutants, and intrinsic factors, such as genotype. As scientific advances more precisely identify those at risk within the distribution of the degree of susceptibility, it may become increasingly challenging to regulate outdoor air pollution to assure protection for all individuals against adverse health effects. Such effects may already or eventually include biomarker changes, health-related quality of life, physiologic impact, symptoms, clinical outcomes, and mortality (ATS 2000).

The U.S. EPA and NRC each provided definitions of susceptibility and construed the term differently. The U.S. EPA's PM criteria document defined susceptibility as generally encompassing "innate or acquired factors that make individuals more likely to experience effects with exposure to pollutants" (U.S. EPA 2004b). Innate susceptibility can entail genetic or developmental factors, whereas acquired susceptibility may result from age, disease, or personal risk factors such as smoking, diet, or exercise. The U.S. EPA also referred to the concept of increased vulnerability to pollution-related effects, as distinct from susceptibility, because of factors including socioeconomic status or experiencing "particularly elevated exposure levels" (U.S. EPA 2004b). NRC's Committee on Research Priorities for Airborne Particulate Matter was charged to gauge research progress on susceptible subpopulations by evaluating new evidence that has appeared since 1998. NRC commented on a broadening scope of health concerns, including an increasing number of adverse health outcomes associated with PM and related susceptible subpopulations. The committee referred to groups as "particularly susceptible" to the effects of air pollution based on one or more of the following factors: *a*) increased exposure due to longer-duration and/or higher-than-normal pollution concentrations, *b*) higher delivered dose due to physiologic factors, and *c*) a greater health response than the general population to a given dose of air pollution (NRC 2004).

Overall, the current list of subgroups for which PM likely or possibly has disproportionate health effects is reasonably congruent across the four organizations. Six categories or determinates of susceptibility were identified: age, preexisting disease, heightened exposure, genetic makeup, sex, and socioeconomic status. The level of scientific understanding associated with research findings for these categories was characterized by groups to which exposure to PM likely or possibly has disproportionate health effects and groups to which exposure to PM is of concern, but overall evidence is insufficient or limited.

Two categories listed as likely or possibly affected by PM were identified explicitly in all four reports. These categories comprised population subgroups defined by age (infants, children, and persons ≥ 65 years of age) and by preexisting disease (cardiopulmonary disease and diabetes). The category defined by heightened exposure levels (e.g., populations involved in outdoor exercise, outdoor work, and living near high PM sources) was either listed as likely or possibly affected by PM or was not considered explicitly.

The NRC and U.S. EPA identified population subgroups defined by heightened exposure levels as likely or possibly affected by PM in report sections devoted specifically to assessing susceptible or vulnerable subpopulations (NRC 2004; U.S. EPA 2004b). However, both the U.S. EPA and NRC offered different interpretations of whether these groups are "susceptible" or "vulnerable." The NRC defined groups with heightened exposure status—such as proximity to source or outdoor exercise—as susceptible, whereas the U.S. EPA defined these groups as vulnerable. CARB and CCME reports recognized the potential impact of heightened exposures on subpopulations, but not within sections specifically devoted to susceptible or vulnerable populations (CARB 2002; CCME 2004). Heightened exposure as a determinate of increased risk was instead discussed in other sections (e.g., human exposure assessment) or by reference to scientific investigations in sections devoted to epidemiologic field studies.

The U.S. EPA characterized socioeconomic status as both likely and possibly having disproportionate health effects and of concern, but with insufficient or limited overall evidence (U.S. EPA 2004b). This divergence of outcomes relates to long-term epidemiologic studies that find PM–mortality risk may be greater for those with lower socioeconomic status, whereas time-series epidemiologic studies provide less evidence of effect modification for short-term exposure effects by socioeconomic status.

Finally, four categories were either not considered in all the research reports or, if listed, were believed to be of concern but with insufficient evidence. These subgroup categories were defined by age (fetus), genetic makeup, sex, and socioeconomic status (for time-series studies).

Based on the framework of susceptibility criteria established in the review, age, preexisting disease, heightened exposure, and socioeconomic categories were identified as likely or possibly at increased risk to PM. In the eight-state northeastern U.S. study area, data were analyzed to estimate the magnitude of susceptible groups in the age and preexisting disease categories, and to a lesser extent to estimate the heightened exposure category. Tables 1 and 2 illustrate that subgroups susceptible to PM represent a large fraction of the northeastern U.S. population. Table 1 shows the population age group distributions for the eight-state study region. The number and percentage of persons in age-related susceptible subgroups are indicated for < 3-year, 3- to 17-year, and ≥ 65-year age classes. Thirty-eight percent or 15.6 million persons of the region's total population (41.3 million persons) were infants, children, or older adults.

Table 2 summarizes information on the prevalence of chronic cardiopulmonary conditions and diabetes in the northeastern U.S. population. The number of adults (≥ 18 years of age) and children (< 18 years of age) in the northeastern United States with cardiac and respiratory conditions and diabetes was estimated by compiling recent BRFSS and NHIS surveys on disease or health condition prevalence between 2000 and 2002 (CDC 2002a, 2002b, 2003a, 2003b). Adults with preexisting heart and lung conditions ranged from approximately 4 to 18% of the total northeastern adult population. For respiratory conditions, 15% have been told by a doctor or other health professional they have sinusitis (preceding 12 months), 13% asthma (ever), and 4% chronic bronchitis (preceding 12 months). For circulatory conditions, 10% of the adult population has received a diagnosis of heart disease (ever) and 18% hypertension (ever). The percentage of adults with hypertension was likely > 18% because persons may have a silent or undiagnosed condition. The CDC's National Health and Nutrition Examination Survey found that measured hypertension (physical examination) in the United States among persons ≥ 20 years of age is 30% (National Center for Health Statistics 2003). Six percent of adults in the northeastern United States have ever been told by a doctor they have diabetes. Twelve percent of children have been diagnosed with respiratory allergies (preceding 12 months). Fifteen percent of children have been diagnosed with asthma at some point in their life. Comparing across age groups, cardiovascular conditions were more common among older age groups, whereas asthma prevalence was higher in children.

Given the need to identify the nature and magnitude of susceptible population risk in the context of standard setting (NRC 2004), compliance with various combinations of alternative PM standards could benefit general populations and especially benefit susceptible populations in the northeastern United States. Figures 1–4 reflect the benefits from improved air quality as a result of additional $PM_{2.5}$ control strategies.

Figure 1 shows the percentage of the eight-state total population living in U.S. EPA Regions 1 and 2 counties with $PM_{2.5}$ concentrations less or greater than various combinations of annual and 24-hr (98th percentile) alternative standards and levels for 2000–2002. The U.S. EPA's current annual and 24-hr $PM_{2.5}$ standards are 15 and 65 $\mu g/m^3$ (98th percentile), respectively. As indicated in Figure 1, 16% of the region's population currently lives in counties that do not meet the existing annual/24-hr standard of 15/65 $\mu g/m^3$. Were the revised annual standard of 15 $\mu g/m^3$ to remain unchanged, the percentage of the total population living in counties not meeting annual/24-hr standards would change only after the 24-hr standard is lowered to < 40 $\mu g/m^3$. A 24-hr standard of 30 $\mu g/m^3$ coupled with an annual standard of 12, 13, 14, or 15 $\mu g/m^3$ would result in 84% of the population living in counties that would not meet the regulation. As depicted in Figure 1, compliance with alternative annual/24-hr standard setting in U.S. EPA Regions 1 and 2 would benefit populations if the annual standard moved to < 15 $\mu g/m^3$ or the 24-hr standard moved to < 40 $\mu g/m^3$. An annual standard of 12 $\mu g/m^3$ would result in 68% of the population living in counties that would not meet the regulation, whereas a 24-hr standard of 20 $\mu g/m^3$ would result in 100% of the population living in counties not meeting the regulation.

Figures 2–4 condense the analysis to combinations of an annual standard of 15 $\mu g/m^3$ with alternative 24-hr standards ranging from 65 down to 20 $\mu g/m^3$ (98th percentile). The condensed annual/24-hr range of alternatives captures the entire sphere of all annual 11–15 $\mu g/m^3$/24-hr 20–65 $\mu g/m^3$ ranges with respect to affected populations. As presented in Table 1, 38% of the eight-state region's population is composed of infant, children, and older adult subgroups considered susceptible to PM. Figure 2 shows the percentage of these subgroups living in counties with $PM_{2.5}$ concentrations less or greater than various combinations of annual and 24-hr (98th percentile) alternative standards and levels for 2000–2002. In Figure 2, the current annual/24-hr standard of 15/65 $\mu g/m^3$ results in 15% of the region's susceptible age groups living in counties with $PM_{2.5}$ levels at or above the standard. Compliance with

Table 1. Number and percentage of age subgroups living in the northeastern United States.

Age group (years)	No.	Percent
< 3	1,574,903	4
3–17	8,550,659	21
≥65	5,453,117	13
Total (< 18, ≥65)	15,578,679	38
18–64	25,734,645	62
Total (all ages)	41,313,324	100

Table 2. Prevalence and number of children and adults with specific preexisting disease conditions living in the northeastern United States.

Age group and health condition	Prevalence rate (%)	No.
< 18 years		10,125,562
Respiratory allergies (preceding 12 months)	12.2	1,235,319
Asthma (ever)	14.8	1,498,583
≥18 years		31,187,762
Sinusitis (preceding12 months)	14.7	4,584,601
Asthma (ever)	12.8	3,992,034
Chronic bronchitis (preceding 12 months)	3.9	1,216,323
Hypertension (ever)	17.9	5,582,609
Heart disease (ever)	10.4	3,243,527
Diabetes (ever)	6.2	1,933,641

a revised annual/24-hr $PM_{2.5}$ standard of 15/30 μg/m^3 would especially benefit 84% of the region's susceptible age groups with improved air quality.

Figures 3 and 4 show adult and children subgroups with preexisting health conditions considered to be determinates of susceptibility, by ages ≥ 18 years and < 18, respectively, as a percentage of the total population. These subgroups live in counties with $PM_{2.5}$ concentrations less or greater than various combinations of annual and 24-hr (98th percentile) alternative standards and levels for 2000–2002. In Figure 3, adult populations with preexisting health conditions contributing to susceptibility represent 0.6–3% of the total adult population living in counties with $PM_{2.5}$ levels above the current annual/24-hr standard of 15/65 μg/m^3. A revised annual/24-hr $PM_{2.5}$ standard of 15/20 μg/m^3 would especially benefit about 4–18% of the total population, or 100% of all adults in the northeastern region currently estimated to have these health conditions. In Figure 4, child populations with preexisting respiratory conditions represent 2–2.4% of the total children population living in counties with $PM_{2.5}$ levels above the current annual/24-hr standard of 15/65 μg/m^3. A revised annual/24-hr $PM_{2.5}$ standard of 15/20 would especially benefit about 12–15% of the total population, or 100% of all children in the northeastern region currently estimated to have these health conditions.

In addition to age and preexisting disease or health condition indicators, heightened air pollution exposure status represents another category of susceptibility wherein populations are possibly or likely at increased risk to PM. Possible subpopulations affected include outdoor workers, children and adults physically active outdoors, and people living near high-intensity sources. Presently, there is no universal indicator used to quantify the number of persons that may be at risk because of heightened exposure status. Given that combustion-source particulate air pollution is common to many urban environments, these areas may function as examples of environments in which populations commonly experience heightened PM levels. Urban airsheds in the northeastern United States experience elevated 24-hr average and annual mean PM concentrations and are home to numerous intense sources [Cass et al. 1999; NARSTO (formerly North American Research Strategy for Tropospheric Ozone) 2004].

Using population density as an indicator of an urban-scale demographic, 2000 U.S. Census data are presented in Table 3. The northeastern region's urban areas, defined as having census tract population densities greater than 1,000 persons/miles^2, consisted of 6% of the total land mass and were home to about 30 million persons or 72% of the region's total population of 41.3 million persons. The percentage of child, adult, and elderly age subgroups living in urban areas was nearly identical, ranging from 71 to 73% across groups, and comprised 27% of the region's total population. The density of this eight-state region is among the highest in the nation, because five of eight states (New Jersey, Rhode Island, Massachusetts, Connecticut, New York) are among the six most densely populated states in the United States. Thus, most persons—across child, adult, and elderly age groups—in the northeastern United States live in densely populated urban areas that are also characterized by elevated PM levels and heightened exposure scenarios.

Discussion

This study draws attention to public health issues facing regulators charged to minimize the harmful impact of ambient $PM_{2.5}$ on populations. Our analysis of northeastern U.S. monitoring and demographic data suggests the population size of susceptible groups—a key indicator of the potential impact of $PM_{2.5}$ exposure on public health—is extensive. Although additional knowledge is needed about the biologic mechanisms and host characteristics involved in susceptibility, a variety of groups are likely more susceptible or vulnerable to PM. Within the eight-state study area, 38% of the total population are < 18 or ≥ 65 years of age, 4–18% of adults have cardiopulmonary or diabetes health conditions, 12–15% of children have respiratory allergies or lifetime asthma, and 72% of all persons (across child, adult, and elderly age groups) live in densely populated urban areas with elevated $PM_{2.5}$ concentrations likely creating heightened exposure scenarios. In addition, current $PM_{2.5}$ standards in the eight-state study area affect only 16% of the general population, who live in counties that do not meet the existing

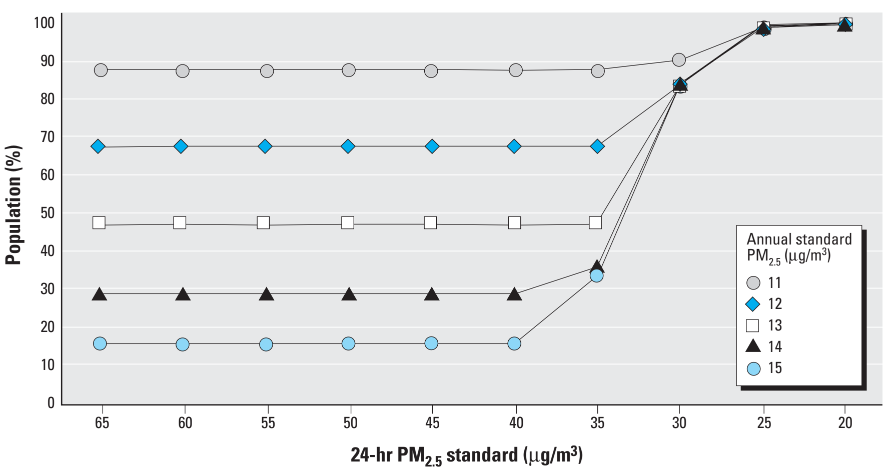

Figure 1. Percentage of the northeastern population that would benefit from compliance with alternative annual/24-hr $PM_{2.5}$ (98th percentile) standards.

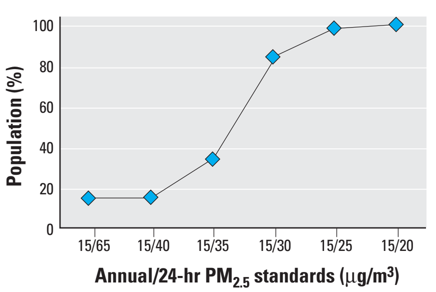

Figure 2. Percentage of northeastern susceptible age subgroups that would especially benefit from compliance with alternative annual/24-hr $PM_{2.5}$ (98th percentile) standards.

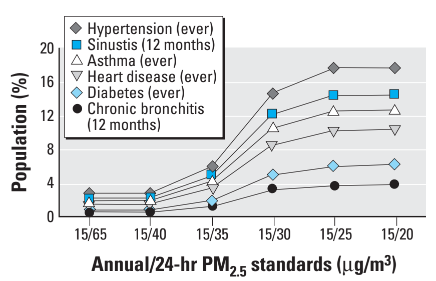

Figure 3. Percentage of all adults that would especially benefit (members of subgroups with preexisting health conditions) from compliance with alternative annual/24-hr $PM_{2.5}$ (98th percentile) standards.

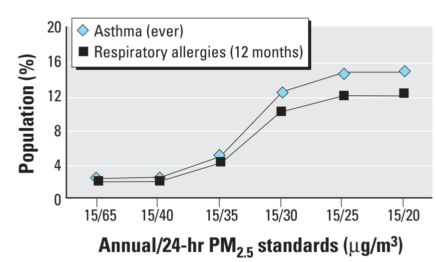

Figure 4. Percentage of all children that would especially benefit (members of subgroups with preexisting health conditions) from compliance with alternative annual/24-hr $PM_{2.5}$ (98th percentile) standards.

annual/24-hr standard of 15/65 µg/m^3. A combination of more stringent annual/24-hr standards would result in a larger percentage of the population living in counties that would not meet the regulation; these populations would therefore benefit from greater emission reduction requirements and more extensive control strategies to reduce PM concentrations.

When taking into account susceptible subgroups, it is difficult to set standards consistent with the intent of the CAA—which stipulates that the U.S. EPA establish primary NAAQS at a level that protects sensitive populations—because of science's inability to confirm the existence of a $PM_{2.5}$ threshold level under which there are no health effects. In response, major regulatory organizations in the United States and Canada set enforceable or target standard levels to limit $PM_{2.5}$ concentrations below those where epidemiologic evidence is most consistent and coherent. This approach recognizes both the strengths and the limitations of the full range of scientific and technical information on the health effects of PM, as well as associated uncertainties.

The interpretation of available data by different standard-setting bodies may reflect the varying levels of health protection required by the controlling statute and the level of public health protection commitment. Table 4 estimates the relationship among current or recently recommended California, Canada, and U.S. $PM_{2.5}$ standards by normalizing differing annual and 24-hr forms. This facilitates a comparison of corresponding standard levels and forms that differ among the three agencies. Both Canada and the U.S. EPA currently use a 98th percentile 3-year average form for the 24-hr $PM_{2.5}$ standard. Canada's 24-hr standard of 30 µg/m^3 would result in 84% of the eight-state Northeast study area population living in counties that would not meet the regulation. Although Canada does not have an annual standard, the U.S. EPA's annual $PM_{2.5}$ standard form is expressed as the annual arithmetic mean averaged over 3 years.

California's proposed (later deferred) 24-hr and adopted annual standard form are based on year-to-year NTBE values, which include maximum monitoring values and are more stringent than 3-year and 98th percentile forms. Were California's proposed 24-hr standard of 25 µg/m^3 (NTBE) converted into a 98th percentile form, the standard would range from 18 to 20 µg/m^3. This 24-hr standard would result in 100% of the eight-state Northeast study area population living in counties that would not meet the regulation. Were California's adopted annual standard of 12 µg/m^3 (NTBE) converted into the U.S. EPA's form, the standard would range from 11 to 11.5 µg/m^3. An annual standard of 11 µg/m^3 would result in 88% of the eight-state Northeast study area population living in counties that would not meet the regulation.

Although differences in health-related PM air pollution standard setting are common across agencies (Benner 2004), $PM_{2.5}$ exposure associations with adverse health effects may well extend to levels lower than the most stringent recommended target standards. Even if $PM_{2.5}$ NAAQS attainment were reached, health risks within the U.S. population would not be totally eliminated. As demonstrated by this study, however, the stringency of $PM_{2.5}$ standards can determine the magnitude of the $PM_{2.5}$-related health burden that decision makers choose to place on the population. Within the framework of standard-setting logic, incrementally more stringent standards would offer the expectation of increased public health protection from $PM_{2.5}$ exposures. Epidemiologic evidence shows that large-scale interventions and natural reductions in ambient PM have resulted in decreases in disease and death (Clancy et al. 2002; Laden et al. 2001; Pope 1991). This underscores the importance of setting appropriately stringent $PM_{2.5}$ standards to trigger control measures intended to reduce ambient $PM_{2.5}$.

A central limitation of the study was its inability to generate additive estimates of total susceptibility across the eight-state study region. The population as a whole is considered diverse in its susceptibility to inhaled pollutants, and persons may be represented in multiple categories of susceptibility. The range of sensitivity among persons is uncertain because variations in PM exposure, PM dose, and host-related factors can cause exposed people to be more susceptible.

The study could have benefited from more refined estimates of factors determining susceptibility in urban populations, including those experiencing heightened exposures such as outdoor worker, child, athlete, other exercising adult and child, and commuter subgroups. The study also did not account for other potential susceptibility indicators, such as socioeconomic status, which may influence exposure scenarios and health disparities, especially among urban populations (American Lung Association 2001). Moreover, a consideration of projected demographic shift and epidemiologic transitions likely would have augmented the import of study findings. For example, in the U.S. populations ≥ 65 years of age are projected to increase from 12.4% in 2000 to 19.6% in 2030, or from about 35 million to 71 million, respectively. Approximately 80% of all persons in this age cohort have at least one chronic condition, 50% have at least two, and overall chronic diseases such as diabetes and heart disease affect older adults disproportionately (Anderson and Smith 2003; Goulding et al. 2003).

In addition, the study did not quantify the potential for a varying profile of susceptibility to PM across spatial scales. The NHIS study findings were regional and included the eight-state study area and Pennsylvania (CDC 2003a, 2003b). The BRFSS asthma and diabetes surveys provided prevalence rates by state, but only for adults (CDC 2002a, 2002b). Regional and state resolution scales

Table 3. Distribution of population age groups by nonurban and urban population density scales (persons/mi^2 land area) in the northeastern United States.

	0–1,000 (94% of total land mass)		> 1,000 (6% of total land mass)		
Age (years)	No.	Percent total	No.	Percent total	Percent age group
< 18	2,915,526	7	7,210,036	17	71
18–64	7,008,390	17	18,726,255	45	73
≥65	1,460,005	4	3,993,112	10	71
Total	11,383,921	28	29,929,403	72	72

Table 4. $PM_{2.5}$ primary standards of selected government agencies.

	California		Canada	U.S. EPA	
	2003, target[a]	2002, deferred[b]	2000, target[c]	1997, final	2005, recommended range[d]
24-hr standard					
Level (µg/m^3)	NA	25	30	65	25–40
Form		NTBE of 98th percentile	3-year average of 98th percentile	3-year average of 98th percentile	3-year average of 98th or 99th percentile
Normalized		~18–20	30	65	25–40
Annual standard					
Level (µg/m^3)	12		NA	15	12–15
Form	NTBE			3-year average	3-year average
Normalized	~11–11.5			15	12–15

NA, not applicable.
[a]California's new state standards amount to new clean air goals for the state and took effect in June 2003 (CARB 2002). [b]California proposed a new 24-hr average standard for $PM_{2.5}$ at 25 µg/m^3, NTBE, in May 2002 but subsequently deferred a final decision (CARB 2002). [c]Target implementation to be achieved by 2010 and ratified by ministers on June 2000. [d]U.S. EPA (2005).

do not enable one to distinguish prevalence rates between, for example, urban and nonurban populations with respect to specific states or other geographic scales.

Concerning the integration of prevalence rate data with design value estimates, the uniform application of CDC prevalence rate data to populations living in counties not meeting alternative $PM_{2.5}$ standards assumes that CDC data for the region are representative of those counties. With respect to the study's use of monitoring data, the assessment followed U.S. EPA methods by assigning the highest annual or 24-hr design values as the design values for the entire county (U.S. EPA 1999). Likewise, for those counties without monitors, the highest annual or 24-hr interpolated levels were used from counties with monitors. This method could overestimate the number of persons exposed to $PM_{2.5}$ concentrations at the county level. However, the study applied county-level population estimates to achieve greater resolution and accuracy. The U.S. EPA currently defines attainment/nonattainment areas by consolidated metropolitan statistical areas that aggregate counties (Holmstead 2003). Finally, application of a 3-year data set (2000–2002) incorporating a wide range of monitoring sites and concentration values allowed us to establish the relationship between various $PM_{2.5}$ standard metrics. The inclusion of additional years to the analysis probably would not materially change this relationship unless factors driving PM concentrations across the northeastern region were suddenly to change. Since 2002, this has not happened.

The above limitations recommend more definitive data collection efforts, as future research using this study's integrative analytical approach would benefit from improved knowledge about susceptible subpopulations and the use of highly spatially resolved monitoring data. This might be fostered by the U.S. EPA and U.S. Department of Health and Human Services cross-agency research platforms guiding future investigations, and further broadening of problem definitions in each organization. For example, the CDC and U.S. EPA might develop a common health survey framework to *a*) augment our understanding of specific subpopulations by exploring disease, vital, and behavioral variability among regions (or even states or metropolitan areas) across all age groups; *b*) provide information about urban-scale (and other scales, e.g., rural) health impacts—rather than gross national or regional-scale impacts; *c*) help explain putative heterogeneity of health effects in urban areas across U.S. regions as reported by epidemiologic studies; and *d*) gain insight into populations at high risk residing near source-dominated environments. These suggested approaches would provide policy makers with a greater understanding of how the U.S. EPA's PM NAAQS recommendation will affect public health.

In conclusion, this study was conducted to assess the public health implications of the current PM NAAQS revision process. Using susceptibility criteria compiled from major regulatory and research reports, we found that a significant percentage of the eight-state region's population is potentially susceptible to $PM_{2.5}$, including 38% of the total population by age group and 4–18% of adults and 12–15% of children by preexisting health condition. More than 70% of the child, adult, and elderly population age groups in the study area live in urban areas that experience elevated $PM_{2.5}$ concentrations and heightened exposure scenarios. This finding may be relevant to studies suggesting the potential for heterogeneity in U.S. city-specific excess risk estimates for acute health effects, including higher mortality coefficients in the Northeast (Dominici et al. 2002). We also devised an evaluative method that uniformly applied CDC prevalence rates for selected health conditions and Census age distributions to the number of persons living in areas with $PM_{2.5}$ concentrations above annual/24-hr standard combinations. We found that currently only 16% of the eight-state region's general population lives in counties that do not meet the annual/24-hr $PM_{2.5}$ standards. However, a large fraction of the region's total population would benefit and a large number of adult and children populations with chronic health conditions would especially benefit from compliance with $PM_{2.5}$ levels less or greater than various combinations of annual and 24-hr average (98th percentile) concentrations currently under review by the U.S. EPA. More protective $PM_{2.5}$ standards falling within ranges recommended by California and Canada would protect 84–100% of the general population.

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Analysis of Primary Fine Particle National Ambient Air Quality Standard Metrics

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ABSTRACT

In accordance with the Clean Air Act, the U.S. Environmental Protection Agency (EPA) is currently reviewing its National Ambient Air Quality Standards for particulate matter, which are required to provide an adequate margin of safety to populations, including susceptible subgroups. Based on the latest scientific, health, and technical information about particle pollution, EPA staff recommends establishing more protective health-based fine particle standards. Since the last standards review, epidemiologic studies have continued to find associations between short-term and long-term exposure to particulate matter and cardiopulmonary morbidity and mortality at current pollution levels. This study analyzed the spatial and temporal variability of fine particulate ($PM_{2.5}$) monitoring data for the Northeast and the continental United States to assess the protectiveness of various levels, forms, and combinations of 24-hr and annual health-based standards currently recommended by EPA staff and the Clean Air Scientific Advisory Committee. Recommended standards have the potential for modest or substantial increases in protection in the Northeast, ranging from an additional 13–83% of the population of the region who are living in areas not likely to meet new standards and thereby benefiting from compliance with more protective air pollution controls. Within recommended standard ranges, an optimal 24-hr (98th percentile)/annual standard suite occurs at 30/12 $\mu g/m^3$, providing short- and long-term health protection for a substantial percentage of both Northeast (84%) and U.S. (78%) populations. In addition, the Northeast region will not benefit as widely as the nation as a whole if less stringent standards are selected. Should the 24-hr (98th percentile) standard be set at 35 $\mu g/m^3$, Northeast and U.S. populations will receive 16–48% and 7–17% less protection than a 30 $\mu g/m^3$ standard, respectively, depending on the level of the annual standard. A 30/12 $\mu g/m^3$ standard suite also provides nearly equivalent 24-hr and annual control of $PM_{2.5}$ distributions across the United States, thereby ensuring a more uniform and consistent level of protection than unmatched or "controlling" and "backstop" standards. This could occur even within EPA staff's recommended range of standard suites, where 22–43% of the monitors in the country could meet a controlling standard but fail to meet the combined backstop standard, resulting in inconsistent short- and long-term protection across the country. An equivalent standards combination of 30/12 $\mu g/m^3$ would minimize the wide variation of protectiveness of 24-hr and annual $PM_{2.5}$ concentrations. Furthermore, given recent associations of subdaily exposures and acute adverse health effects, in the absence of a subdaily averaging metric, a stringent 24-hr standard will more effectively control maximum hourly and multihourly peak concentrations than a weaker standard.

IMPLICATIONS

The Clean Air Act calls on EPA to establish ambient air quality standards that protect public health with an adequate margin of safety. With respect to the forthcoming decision of EPA on whether to revise current $PM_{2.5}$ standards, this paper provides a set of methodological tools for regulatory agencies and decision-makers to determine which level, form, and combination of currently recommended health-based $PM_{2.5}$ 24-hr and annual standards would best protect populations in the Northeast and continental United States. Selecting an equivalent and stringent standards suite would ensure the broadest short- and long-term protection across the $PM_{2.5}$ monitoring network.

INTRODUCTION

The Clean Air Act mandates the U.S. Environmental Protection Agency (EPA) to set health-based National Ambient Air Quality Standards (NAAQS) for particulate matter ≤2.5 μm ($PM_{2.5}$). NAAQS provisions require EPA to establish standards stringent enough to protect public health with an adequate margin of safety, at a level that avoids unacceptable risks to both general and susceptible populations. Over the past quarter century, a growing body of scientific evidence has found associations between short-term and long-term exposure to airborne particulate matter (PM) and cardiopulmonary health outcomes, including increased symptoms, hospital admissions, emergency department visits, and premature death.[1–4] Population subgroups that have been identified as potentially susceptible to health effects as a result of PM exposure include children, older adults, and people with existing heart and lung diseases and diabetes. In addition, population subgroups may have increased vulnerability to pollution-related effects because of factors including socioeconomic status or elevated exposure levels.[5] EPA is required to periodically review the PM NAAQS, last revised in 1997,[6] to ensure that they provide adequate health and environmental protection reflecting the latest scientific and technical information about PM. EPA expects to propose final mass-based $PM_{2.5}$ 24-hr and annual primary standards by the end of 2005.

The primary objective of this study was to provide methodological tools to determine the degree to which the recent $PM_{2.5}$ NAAQS recommendations of EPA staff and the PM Clean Air Scientific Advisory Committee (CASAC) will protect populations across the Northeast and continental United States. Using $PM_{2.5}$ concentrations measured by the Federal Reference Method (FRM) monitoring network, we assessed the protectiveness of various standard levels, forms, and combination choices. EPA uses the FRM network to determine whether or not monitoring areas are in compliance (attainment) with the PM NAAQS. Areas not in compliance (nonattainment) must take steps to reduce $PM_{2.5}$ concentrations, which presumably lowers the level of pollutants to which populations are exposed, thereby decreasing adverse health outcomes. The methodological approach of this study does not determine whether various NAAQS recommendations protect public health with an adequate margin of safety, a question beyond the capacity of this research. However, the study does assess which currently recommended EPA staff and CASAC standard levels, forms, and combinations would provide the most protection to the public by lowering fine particle concentrations across the broadest FRM monitoring network area.

EPA justification for the 1997 $PM_{2.5}$ standard level and averaging time was in large part attributable to available health effects evidence, including short- and long-term epidemiologic studies finding associations between increased PM and adverse health effects among populations living in urban areas.[7–9] The current PM NAAQS review also has emphasized the importance of findings of health effects associated with acute and chronic exposure to $PM_{2.5}$ concentrations, including those characterized in time-series and cohort epidemiologic studies.[10] Since 1997, multicity research has reported consistent associations of health effects across differing exposure time scales. Time-series epidemiologic studies have found associations between particulate air pollution and daily deaths, especially those using daily monitoring data.[11,12] Multiday effects of exposure appear to accumulate over time,[13,14] and cohort studies that incorporate risk associated with longer-term exposure report even higher risk estimates.[15,16] Together, these studies suggest the need for more stringent 24-hr and annual standards. But because of the inability of the majority of these studies to identify the existence or nonexistence of any justifiable threshold concentration below which effects are not detectable,[17] selecting primary standards that protect susceptible populations with an adequate margin of safety, as mandated by the Clean Air Act, is largely a public health policy judgment.

During both the 1997 and 2005 NAAQS review cycles, in addition to determining what 24-hr and annual $PM_{2.5}$ standard levels and averaging times are appropriate, a central question has been what combination of 24-hr and annual standards can best protect the entire country, given the spatial and temporal variability of concentrations in the United States. During the previous review cycle, EPA concluded that both 24-hr and annual standards could effectively control PM concentration levels and distributions, thereby providing public health protection for short-term (from <1 day to ≤ 5 days) and long-term (seasonal to several years) exposures to $PM_{2.5}$. In determining optimal 24-hr and annual standard combinations, an argument was made to treat the annual standard as the generally controlling metric for lowering both short- and long-term $PM_{2.5}$ concentrations across the monitoring network. A supplemental or backstop 24-hr standard would serve to provide protection against days with high peak $PM_{2.5}$ concentrations, localized "hot spots," and risks arising from seasonal emissions that would not be well controlled by a national annual standard.[6]

Since 1997, understanding of the behavior of $PM_{2.5}$ levels in the United States has increased because of deployment of the FRM national monitoring network in 1999, providing a wealth of new data. At present, an important question is whether $PM_{2.5}$ standard levels, forms, and combinations other than EPA current 24-hr and annual standards would be more protective of public health. The current controlling annual standard level of 15 $\mu g/m^3$ is based on the 3-yr average of annual arithmetic mean $PM_{2.5}$ concentrations from single or multiple community-oriented monitors. This standard is combined with a supplemental 24-hr standard level of 65 $\mu g/m^3$, which is based on the 3-yr average of the 98th percentile (form) of 24-hr $PM_{2.5}$ concentrations at each population-oriented monitor within an area. The current 98th percentile form represents the daily value from a year of monitoring data below which 98% of all values in the group fall. This allows the 7 highest $PM_{2.5}$ concentration days per year to exceed the 24-hr standard level. A more stringent 99th percentile form would exclude only the 3 highest concentration days.

Both EPA staff and CASAC now recommend that EPA administrator propose more stringent $PM_{2.5}$ NAAQS.[10,18] As shown in Table 1, EPA staff provides 2 alternative options to establishing more protective suites of 24-hr and annual $PM_{2.5}$ standards. "Option A" would revise the 24-hr standard, within the range of 30–40 $\mu g/m^3$, combined with a revised annual standard in the range of 12–14 $\mu g/m^3$, with either the 24-hr or the annual standard, or both, at the middle-to-lower end of these ranges. "Option B" would revise the 24-hr standard, within the range of 25–35 $\mu g/m^3$ (based on a 98th percentile form for a standard set at the middle-to-lower end of this range, or

Table 1. Recommended primary $PM_{2.5}$ NAAQS 24-hr and annual ranges for EPA (option A and option B) and CASAC.

Annual ($\mu g/m^3$)	24-hr ($\mu g/m^3$) 25	30	35	40	65
12		EPA A[a]	EPA A	EPA A	
13		EPA A / CASAC	EPA A / CASAC	EPA A	
14		EPA A / CASAC	EPA A / CASAC	EPA A	
15	EPA B[b]	EPA B	EPA B		EPA current[c]

[a]EPA option A: 24-hr, annual, or both at the middle to lower end of these ranges; [b]EPA option B: 24-hr 98th percentile at the middle to lower end of this range or a 99th percentile at the middle to upper end of this range; [c]EPA current 24-hr (98th percentile)/annual standard.

a 99th percentile form for a standard set at the middle-to-upper end of this range), combined with a retained annual standard of 15 μg/m^3. CASAC recommends setting a 24-hr standard at concentrations in the range of 30–35 μg/m^3 with the 98th percentile form, combined with an annual standard in the range of 13–14 μg/m^3.

The second objective of this study was to assess the extent to which current 24-hr standard averaging metrics are sufficient to control hourly and multihourly levels. During the 1997 standard setting review, EPA selected the current $PM_{2.5}$ 24-hr and annual standard averaging metrics based on epidemiologic studies using 24-hr integrated samples that reported health effects associated with short-term and long-term exposures. Earlier health studies used 24-hr integrated samples, because most PM concentration measurements were collected in this form, often only with once every 3-day and every 6-day sampling frequency. At the time, although most reported effects had been associated with daily or longer average measures of PM, epidemiologic and toxicological evidence suggested that some effects might be associated with PM exposures <24 hr.[19]

Since the last PM NAAQS review by EPA, advances in $PM_{2.5}$ monitoring have facilitated the collection of highly time-resolved fine particle data and its use in health studies. The increasing use of monitoring equipment capable of measuring PM in near-continuous time intervals has begun to improve our understanding of exposure to airborne PM as a continuous or "real-time" experience. The importance of short-duration and peak versus 24-hr exposure has been reported by recent studies finding adverse health outcomes in subdaily exposure periods.[20–25] Using continuous $PM_{2.5}$ data, clinical and epidemiologic evidence now suggests that acute cardiac health effects may be associated with PM exposures of durations with averaging times of 1 hr to several hours.[26] Studies have also determined that exposures at hourly or minute scales experienced in microenvironments with elevated PM levels may lead to a significant portion of an individual's daily exposure.[27–31] Such findings call into question the suitability of the current EPA 24-hr and annual standards in protecting populations from acute peak exposure periods that occur in subdaily time frames. This points to the importance of understanding the degree to which 24-hr and annual $PM_{2.5}$ standards can control subdaily peak levels and provide an adequate margin of safety.

In the course of both the 1997 and current PM NAAQS review, the question of peak exposures and their relation to overall risk has played a role in considerations over the selection of 24-hr/annual standard level and forms. Based on its 1996 and 2005 PM risk assessments, EPA has concluded that much, if not most, of the aggregate annual risk associated with short-term exposures results from the large number of days during which 24-hr average concentrations are in the low-to-middle range. This, in part, provided the rationale for the agency to select a controlling annual standard and a weaker backstop 24-hr standard.[6,10,32,33] As noted recently by some PM CASAC members, however, another interpretation of the EPA evidence might find that 24-hr mortality per concentration day actually increases as $PM_{2.5}$ concentrations increase. Such a finding might suggest that higher concentration levels are important to consider for mortality-related health risks.[18] Although the current EPA 24-hr average and statistical forms conceive of short-term exposure (and thereby facilitate the assessment of health risk) in terms of low-, middle-, or high-range daily 24-hr averages, subdaily hourly averaged data may lead to a different characterization of exposure health risk. EPA does not believe enough quantitative evidence currently exists to support a subdaily standard,[10] but the issue likely will play a dominate role in the next PM NAAQS review cycle. Therefore, for the time being, in the absence of a shorter averaging metric, it is important to understand to what extent a 24-hr average metric can control subdaily levels. These findings have the potential to inform the selection of a 24-hr standard form, level, and combination.

METHODS

FRM $PM_{2.5}$ air pollution data from 2000, 2001, and 2002 were obtained for a Northeast dataset from EPA Air Quality System in August 2003 from 127 FRM monitors in EPA Region 1 (6 New England states) and Region 2 (New Jersey and New York), and 65 FRM monitors outside these regions in bordering states (Delaware, Washington, DC, Maryland, and Pennsylvania). Data for the same period were retrieved for three Northeast Interagency Monitoring of Protected Visual Environments sites from the Visibility Information Exchange Web System. Countrywide data for the years 2000–2002 were obtained from EPA AirData.[34–36]

Within the 2000–2002 period for the Northeast dataset, 192 PM monitoring sites had data in all 12 quarters. Data flagged with the forest fire exemption for 2002 were removed. More than 75% of the 192 sites had >50% data capture within each quarter. Data completeness affecting the remaining sites was primarily isolated to one calendar quarter. For sites with collocated monitors, the primary monitor at a site was used to determine the $PM_{2.5}$ concentration (27 pairs of 192 monitors). Although fewer than half of the primary monitors satisfied the 75% data completeness criteria, no substitution from collocated monitors was conducted. The relationship between the 24-hr and annual averages was not dependent on data completeness at the site, as determined by regression analysis. (The regression where y is the level of the 24-hr average and x is the level of the annual average for the subset of monitors with complete data was $y = 1.86x + 10.43$ [$n = 81$, $R^2 = 0.76$] and for the subset of monitors with incomplete data was $y = 1.82x + 10.90$ [$n = 111$, $R^2 = 0.78$]).

To estimate the number of persons living in counties not likely to meet different combinations of alternative 24-hr and annual $PM_{2.5}$ standards, design values were calculated for all counties[150] in the eight-state study area and integrated with 2000 U.S. Census county-level population data using ArcGIS v8.2 software.[37] A design value is a statistic that describes the air quality status of a given area relative to the level of the NAAQS. Design values are typically used to classify nonattainment areas, assess progress toward meeting the NAAQS, and develop control strategies. Design values were calculated in adherence with EPA criteria for determination by calculating 3-yr averages of 24-hr 98th percentiles and annual means based on the maximum monitor within an urban area.[6,38]

Design values for the 70 counties with monitors were assigned from the highest monitored levels in each county for 2000–2002. Design values for 80 counties lacking monitors were generated by interpolating county-level monitored data from 104 monitors within the eight-state study region and 61 monitors outside the region for border counties. An interpolation scheme was employed using inverse distance squared weighting for the six nearest monitors within a 111-km radius (corresponding to 1° latitude). Massachusetts and New Hampshire had very few sites with complete data for the 3-yr period, requiring an approximation of design values for counties in those states. For the other counties in the eight-state study region, the annual design values used were generally within ±0.2 μg/m^3 of those reported by EPA using customary guidelines for data substitution and completeness determinations.[38]

The analysis of continuous $PM_{2.5}$ data (50 °C Tapered Element Oscillating Microbalance [TEOM] method and Beta Attenuation Monitor) used 2001 and 2002 data collected from EPA Region 1, 2, and 3 monitoring networks. The 50 °C TEOM method daily or subdaily data are subject to large errors because of a substantial loss of semivolatile mass. Therefore, $PM_{2.5}$ levels are likely to be underestimated on winter days with high $PM_{2.5}$ concentrations or during hours with the highest local mobile source influence. In general, data with highest temporal resolution (e.g., 1-hr data) have the greatest potential to underestimate $PM_{2.5}$ relative to "FRM-like" levels.

Analysis of maximum 1-, 3-, 4-, and 6-hr average and 24-hr average continuous data was conducted to assess the extent to which the 24-hr average metric controls subdaily maximum hourly averages. Cumulative frequency plots used year-round 2001 data from Regions 1 and 2 and border state monitoring networks. The analysis considered the 24-hr average of a day valid if 16 hourly values were reported. Rolling 3-, 4-, and 6-hr averages were calculated, and the maximum average for each interval was tabulated for each day. Valid averages required 3 or 4 hr for those averaging periods, respectively, whereas a valid 6-hr average required ≥5 valid hourly values. The analysis is insensitive to the TEOM method bias, because it relies on relationships among different averaging times rather than absolute monitored concentration.

RESULTS

Northeast and continental U.S. FRM $PM_{2.5}$ data were analyzed to assess the protectiveness of currently recommended EPA staff and CASAC $PM_{2.5}$ 24-hr and annual standard levels, forms, averaging times, and combinations. This facilitated an understanding of the various ways that different standards may reduce ambient $PM_{2.5}$ concentrations and thereby protect populations from exposure to fine particles. Results are organized into three subsections covering the protectiveness of standard levels, forms, and combinations; 24-hr and annual standard equivalency; and 24-hr and subdaily averaging metrics.

Protectiveness of $PM_{2.5}$ Standard Levels, Forms, and Combinations

The study found that either 24-hr or annual standard levels can lower the entire $PM_{2.5}$ distribution curve (including maxima), decreasing 24-hr average and annual mean concentrations. Figure 1 shows the distribution for 24-hr (98th percentile) and annual average concentrations in the Northeastern United States. Each distribution covers the entire data range (with the area under the curve = 1) and is normalized to reflect the total number of monitored days in every grouping. This relationship also applies to the 24-hr 99th percentile form, which is 4–5 μg/m^3 more stringent than the equivalent 98th percentile form (Figure 2).

The study also found that both 24-hr 98th and 99th percentile forms control $PM_{2.5}$ maxima. However, use of the 99th percentile form would allow fewer days above the 24-hr standard than use of the 98th percentile. Table 2 estimates the number of days that $PM_{2.5}$ values exceed the 98th or 99th form ≥5 μg/m^3 of the 24-hr level. A 5-μg threshold was selected because the EPA-recommended 24-hr standard levels are in 5-μg increments. For both percentile forms, more than half the days above the standard are within 5 μg/m^{3}of the standard, corresponding to <3 days

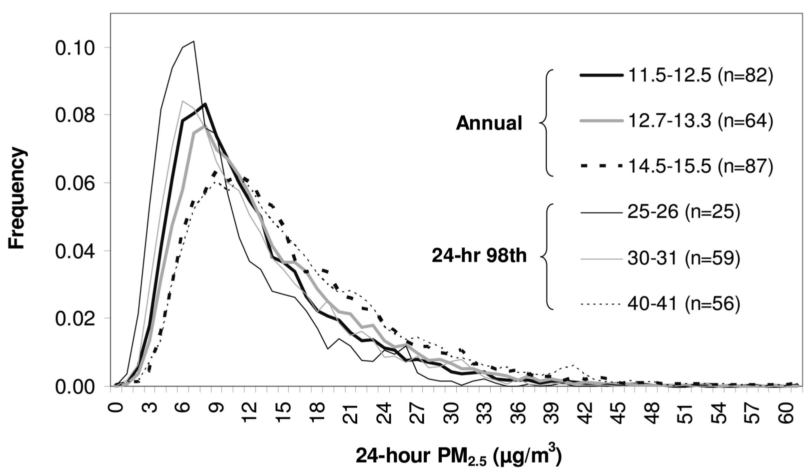

Figure 1. Distribution of selected 24-hr (98th percentile) and annual $PM_{2.5}$ ranges (μg/m^3; 2000–2002 FRM Regions 1, 2, and Delaware, Washington DC, Maryland, and Pennsylvania).

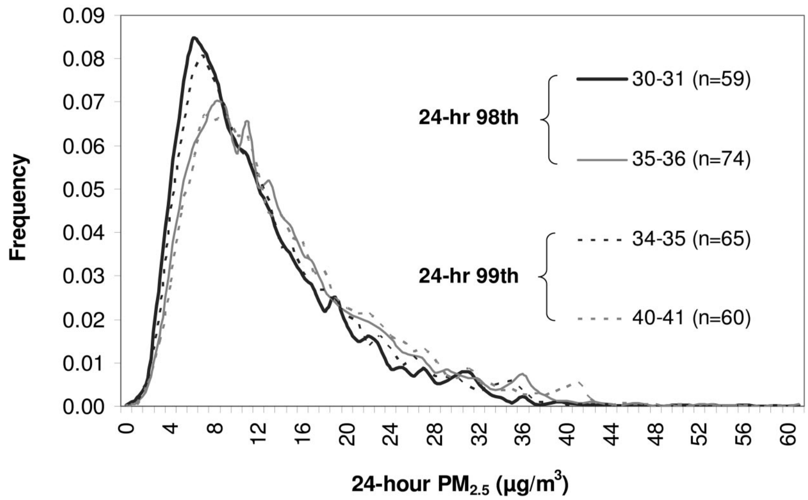

Figure 2. Distribution of selected 24-hr (98th and 99th percentile) and annual $PM_{2.5}$ ranges (μg/m^3; 2000–2002 FRM Regions 1, 2, and Delaware, Washington DC, Maryland, and Pennsylvania).

and 1 day more than 5 μg/m^3 for the 98th and 99th percentile forms, respectively. For example, at a daily concentration of 30–31 μg/m^3, for 5 of 7 days (or 71% of the time) the excluded values exceed this daily level by ≤5 μg/m^3. The remaining 2 days exceed the level by >5 μg/m^3.

Within the currently recommended EPA staff and CASAC range of standards, the final $PM_{2.5}$ standards proposed by the EPA Administrator may result in either modest or substantial additional protection to the Northeast, varying from 13 to 83% of the region populations living in areas that would not meet the standards. As shown in Figure 3, increasingly stringent 24-hr and annual standard levels and forms result in a greater percentage of the total population living in nonattainment areas that would require increased control measures to lower $PM_{2.5}$ concentrations, thereby benefiting public health by reducing exposure levels. By meeting the current 24-hr (98th percentile)/annual standard of 65/15 μg/m^3, 16% of the region population benefits from $PM_{2.5}$ emission control strategies. Regarding the EPA staff "Option A" recommendation, the least-stringent 40/14 μg/m^3 standard (98th percentile) would result in 29% of the population of the region being in nonattainment, whereas the most-stringent 30/12 μg/m^3 standard (98th percentile) would result in 84% of the population in nonattainment, or 68% more than afforded by the current standard. For the EPA staff "Option B" recommendation, the least-stringent 35/15 μg/m^3 (99th percentile) would result in 84% nonattainment, whereas the most-stringent 25/15 μg/m^3 (98th percentile) would result in 99% nonattainment. Overall, the range of protection within both options is 29–99%, or 13–83% more than the current standard. Within the CASAC recommendation, the overall range of protection is 36–84%, or 20–68% beyond the current standard. (The 99th percentile levels are 5 μg/m^3 approximations based on the average relationship between the 98th and 99th percentiles from Figure 2.)

Table 2. Number of days $PM_{2.5}$ values exceed 98th or 99th percentile form ≥5 μg/m^3 of the 24-hr level (2000–2002 FRM Regions 1, 2, and Delaware, Washington DC, Maryland, and Pennsylvania).

	Number of Days Above 24-hr Standard			
	98th Percentile Form		99th Percentile Form	
24-h Average Concentration (μg/m^3)	No. Days ≤5 μg/m^3 of Level	No. Days >5 μg/m^3 of Level	No. Days ≤5 μg/m^3 of Level	No. Days >5 μg/m^3 of Level
25–26	3.9	3.1		
27–29	4.3	2.7		
30–31	5.0	2.0	1.9	1.1
32–33	4.3	2.7	2.0	1.0
34–35	4.8	2.2	2.1	0.9
35–36	4.6	2.4		
36–37	4.1	2.9	1.9	1.1
38–39	3.9	3.1	1.7	1.3
40–41	4.4	2.6	1.7	1.3
Average # days	4.4	2.6	1.9	1.1

Figure 3 also illustrates the levels at which currently recommended 24-hr and annual standard combinations become controlling in the eight-state Northeast study area. Because most Northeast monitoring site 24-hr (98th percentile) averages cluster in the 30–35 μg/m^3 range, a sharp increase in protection occurs below a 24-hr level of 35 μg/m^3 in combination with annual levels ranging from 12 to 15 μg/m^3. A 24-hr (98th percentile) standard level of 30 μg/m^3 behaves as a controlling standard, resulting in a 68% increase in nonattainment protection for Northeast populations compared with the current standard, regardless of whether the combined annual level is 12–15 μg/m^3. Conversely, 24-hr (98th percentile) levels set at ≥35 μg/m^3 would result in an 18–52% increase in protection, depending where the 12–15 μg/m^3 annual level was set. This finding makes clear the implications of selecting a 24-hr standard ≥35 μg/m^3, especially in combination with less-stringent annual standards. For example, were the current 24-hr 98th percentile standard reduced from 65 to 40 μg/m^3 in combination with an annual standard of 15 μg/m^3, no additional protection would be realized in the Northeast study area. Of interest, an 11-μg/m^3 annual standard level, although not under

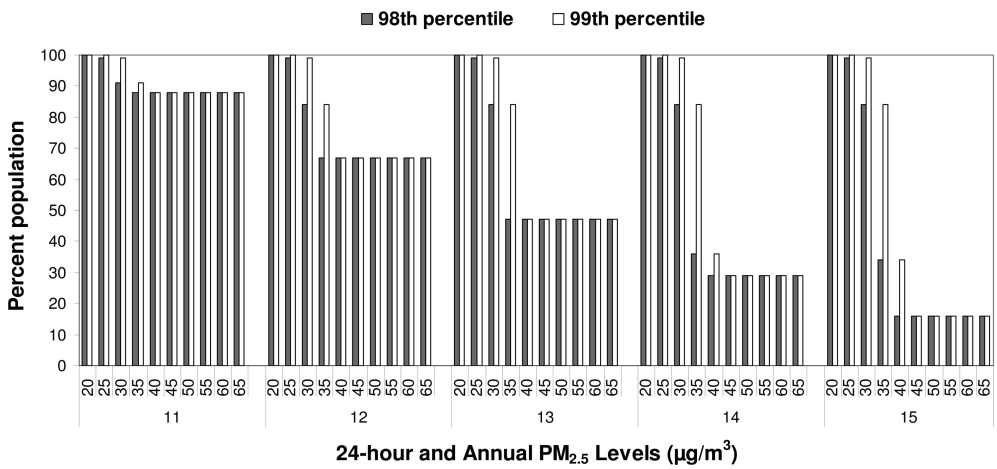

Figure 3. Estimated percent total population in New England, New Jersey, and New York that would benefit from compliance with alternative 24-hr (98th and 99th percentile) and annual $PM_{2.5}$ standards (μg/m^3; 2000–2002 FRM Regions 1, 2).

consideration, would control $PM_{2.5}$ levels over the lower range of 24-hr levels considered.

Expanding the preceding Northeast analysis to the entire U.S. monitoring network (using comparatively similar EPA calculations; ref. [10]) finds that within the recommended primary 24-hr/annual health-based ranges of EPA staff and CASAC, the difference between a 24-hr (98th percentile) standard of 30 and 35 μg/m^3 would have a disproportionate effect on the protectiveness of Northeast versus U.S. populations. As shown in Figure 4, a 24-hr (98th percentile)/annual standard combination of 30/14 μg/m^3 would protect 48% more of the Northeast population than a combination of 35/14 μg/m^3. A combination of 30/13 μg/m^3 would protect 37% more of the Northeast population than a 35/13 μg/m^3 pairing. This 48% and 37% Northeast difference compares to a 17% and 12% respective difference for the entire United States. Thus, the Northeast region will not benefit as widely as the nation as a whole unless $PM_{2.5}$ standards are set at or below a 24-hr (98th percentile)/annual 30/12 μg/m^3 level. Within EPA staff recommended ranges were the annual standard set between 12 and 14 μg/m^3, the difference between selecting a 24-hr (98th percentile) standard of 30 μg/m^3 and 35 μg/m^3 amounts to a 16–48% difference in the Northeast and 7–17% difference in the United States. However, a 30/12 μg/m^3 98th percentile standard would result in more even countrywide protectiveness, with 84% of the Northeast and 78% of the U.S. populations living in areas that would not meet the new standards.

24-hr and Annual Standard Equivalency

Although the preceding findings show that both 24-hr (98th and 99th percentile) and annual standards recommended by EPA staff and CASAC can control the distribution of $PM_{2.5}$ levels, the study has also found that neither standard in isolation is sufficient to ensure maximum protection across the United States for both 24-hr short-term and annual long-term exposure time scales. As shown in the following figures, the spatial and temporal variability of $PM_{2.5}$ concentrations across the U.S. FRM monitoring network results in a wide variation of 24-hr and annual levels. Unequal standards providing either weak 24-hr or annual protection in the form of less-stringent standards may lead to inadequate protection of populations across either averaging metric. When set at an appropriately stringent level, equivalent or matching

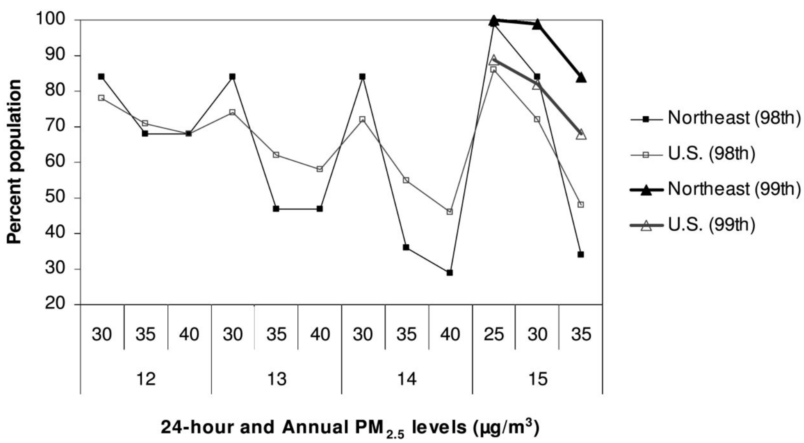

Figure 4. Estimated percent total population in New England, New Jersey, and New York (Northeast) vs. total U.S. population that would benefit from compliance with alternative EPA staff and CASAC recommended 24-hr (98th and 99th percentile) and annual $PM_{2.5}$ standard ranges (μg/m^3; 2000–2002 FRM Regions 1, 2 for Northeast; 2001–2003 FRM country-wide for total U.S.; ref. 10).

combinations of 24-hr and annual standards would, together, provide more uniform and consistent protection across the country than unequal standard combinations by minimizing the variation of short- and long-term exposures.

Figure 5 illustrates the short- and long-term variability of $PM_{2.5}$ concentrations across the U.S. FRM network. The figure plots the site-by-site relationship between 3-yr average 24-hr (98th percentile) and annual average levels for selected U.S. urban areas, showing that many monitoring areas will experience a wide range of $PM_{2.5}$ concentrations on a 24-hr or annual basis when satisfying one or the other standard. Using an example 24-hr/annual standard of 14/35 $\mu g/m^3$ (as provided by vertical and horizontal lines on the figure), data in Figure 5 fall into four categories of monitor levels that do the following: (1) meet both 24-hr/annual standards; (2) miss the annual standard; (3) miss the 24-hr standard; and (4) miss both standards. Monitoring sites in the upper right quadrant would miss both standards. Sites in the lower left quadrant would meet both standards. Sites in the upper left quadrant would miss the 24-hr standard but would meet the annual standard. Sites in the lower right quadrant would miss the annual standard but meet the 24-hr standard. For example, at monitoring sites in Seattle, a stringent controlling annual standard of 11.8 $\mu g/m^3$ would experience gradually less stringent backstop 24-hr levels ranging from 31 to 42 $\mu g/m^3$. If a stringent annual standard of 12 $\mu g/m^3$ were combined with a less-stringent 24-hr standard of 40 $\mu g/m^3$, the annual standard would effectively protect populations from long-term exposure, but the weaker 24-hr standard would allow exposures $\leq$40 $\mu g/m^3$.

Findings presented in Figure 6 suggest that the optimal $PM_{2.5}$ standard selection would use both 24-hr and annual standard levels to provide consistent and uniform protection by minimizing short- and long-term $PM_{2.5}$ variability, thereby maximizing protection across the broadest FRM monitoring network area. The figure aggregates 24-hr (98th percentile) and annual $PM_{2.5}$ levels for the entire U.S. network (1137 monitors) to show the magnitude of various standard combinations falling into the

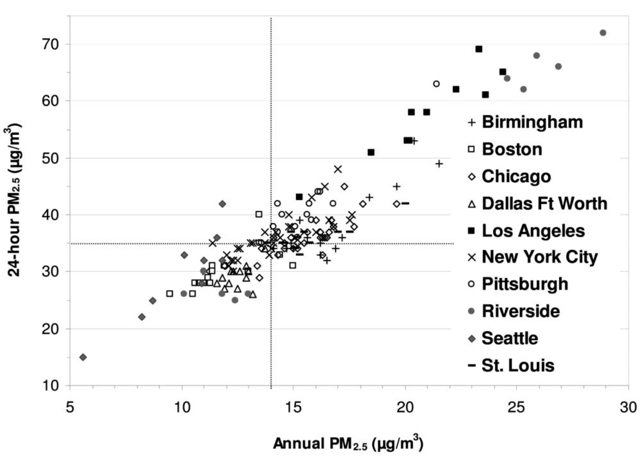

Figure 5. Relationship between 24-hr (98th percentile) and annual $PM_{2.5}$ levels ($\mu g/m^3$; 2000–2002 selected FRM country-wide monitors). Using an example 24-hr/annual standard of 14/35 $\mu g/m^3$ (as provided by vertical and horizontal lines on the figure), data in the figure fall into four categories: monitor levels that (1) meet both 24-hr/annual standards; (2) miss the annual standard; (3) miss the 24-hr standard; and (4) miss both standards.

same four categories (monitors that meet both standards, either the 24-hr or annual standard, or neither standard). Results are presented across a range of five annual levels (11–15 $\mu g/m^3$), within which are nested a range of five 24-hr levels (25–45 $\mu g/m^3$). Annual and 24-hr ranges were purposely selected outside of EPA staff and CASAC recommended ranges to extend the analysis beyond the bounds of the recommended ranges. The lower portion or first segment of the bars represents the percentage of monitors that meet both 24-hr and annual standards. The next segment represents monitors that miss the annual but meet the 24-hr standard. The third segment represents monitors that miss both standards. The top portion or fourth segment of the bars represents monitors that miss the 24-hr but meet the annual standard.

Across all five of the 24-hr/annual groupings, Figure 6 shows that as 24-hr and annual standard levels increase in stringency (i.e., move from 15 to 11 $\mu g/m^3$ or from 45 to 25 $\mu g/m^3$, respectively), more monitors miss either the annual or 24-hr standards or miss both standards. Within each grouping, as the 24-hr standard becomes less stringent (i.e., moves from 25 to 45 $\mu g/m^3$), fewer monitors miss the 24-hr standard, with a greater percentage missing only the annual standard. Thus, more "control" is ceded to the annual standard within the 11–13 $\mu g/m^3$ range when combined with a 24-hr standard ranging from 35 to 45 $\mu g/m^3$. Conversely, as the 24-hr standard becomes more stringent, more control is ceded to the 24-hr standard as a higher percentage of monitors miss only the 24-hr standard. Across the five groupings, a 25–30 $\mu g/m^3$ 24-hr standard range would control nearly all of the monitors regardless of the annual standard level.

Figure 6 suggests that an optimal standard combination would occur when the number of sites that miss the 24-hr standard equals the number of sites that miss the annual standard. Such matching of 24-hr and annual standards would minimize the occurrence of monitored areas experiencing elevated backstop 24-hr or annual levels relative to a controlling standard. This analysis should not be construed as implying that matching standards are acceptable regardless of the level at which they are set. We assume that both standards levels would be set at a defensible level of health protection as established by EPA staff and CASAC. The more stringent the standards, the more health protection they will afford.

Table 3 shows a subset of data graphed in Figure 6 and illustrates the concepts of controlling, backstop, and equivalent standards encompassing the CASAC recommended $PM_{2.5}$ standard range, which lies in the middle of the EPA staff range. The table demonstrates the contrast between a controlling/backstop combination versus a matched pair of standards. In this case, the controlling annual level, 12 $\mu g/m^3$, is paired with a backstop 24-hr level of 40 $\mu g/m^3$. Alternatively, a controlling 24-hr of 30 $\mu g/m^3$ is paired with a backstop annual of 14 $\mu g/m^3$. These two combinations seem to offer similar levels of protection, with 58% and 59% of the monitors failing to meet either standard pairing. However, under the matching standard scenario, an additional 9% or 8% of monitors would fail to meet the paired standards, thus providing more extensive protection.

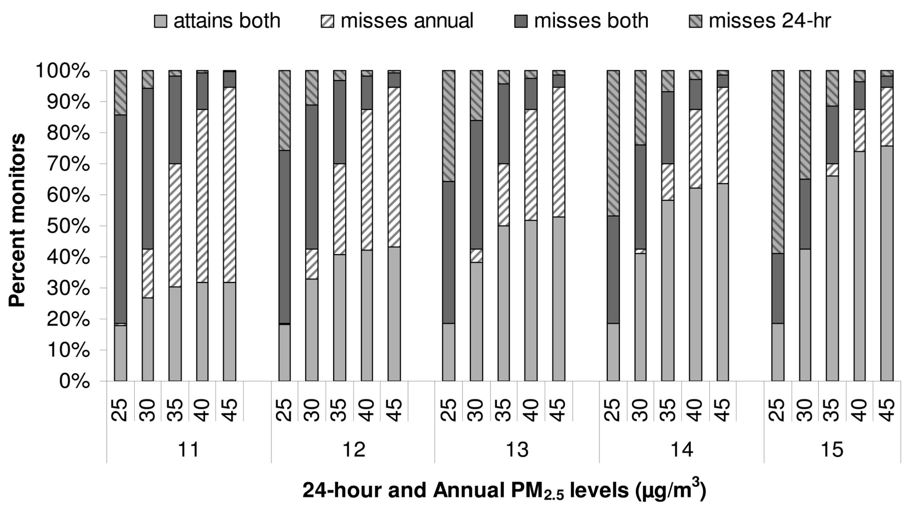

Figure 6. Estimated percent of U.S. FRM monitors (n = 1137) that attain or miss alternative 24-hr 98th percentile (25–45 μg/m^3) and annual (11–15 μg/m^3) $PM_{2.5}$ standards (μg/m^3; 2000–2002 FRM country-wide monitors).

In addition, a significant percentage of monitors that do not meet the controlling standard but that do meet the less-stringent backstop standard would potentially realize additional health benefits by complying with a more-stringent equivalent standard. For example, within the 40/12 μg/m^3 standards combination, there is a 43% difference between those monitors that miss the backstop 24-hr (98th percentile; 2%) and those that miss the controlling annual (45%); within the 30/14 μg/m^3 combination, there is a 22% difference between the controlling 24-hr (98th percentile; 24%) and backstop annual (2%). Alternatively, the difference between equivalent 30/12 μg/m^3 standards is only 1%. In this manner, equivalent or matching standards have the effect of minimizing the wide variation of short- and long-term $PM_{2.5}$ concentrations within the EPA staff recommended standard range on both 24-hr and annual time scales from 22 to 43% to 1% across the FRM $PM_{2.5}$ network, thus ensuring consistent and uniform protection for both standard time scales.

Figures 7 and 8 show how unmatched 24-hr and annual standards may lead to inadequate protection of populations. Whereas a controlling standard can ensure protection across its respective 24-hr or annual time scale, the companion noncontrolling or backstop standard will allow a wide variation of either short- or long-term exposures to occur. In Figure 7, the x-axis represents 24-hr ranges of 5 μg/m^3 centered about integer mass values from 23 to 52 μg/m^3. Six annual average range categories are used to create the bar chart; each bin is centered around annual levels (11–15) in 1-μg/m^3 intervals. The y-axis gives the percentage of monitors in each annual range that fall in each 24-hr range on the x-axis. In Figure 8, the x-axis represents annual ranges of 1 μg/m^3 centered about integer mass values from 8 to 20. Six 24-hr average range categories are used to create the bar chart; five of the bins are centered around 24-hr levels in 5-μg intervals (25, 30, 35, 40, and 45) with a sixth bin representing values $\geq$48 μg/m^3. The y-axis gives the percentage of monitors in each 24-hr range that fall in each annual range on the x axis.

With respect to EPA staff–recommended $PM_{2.5}$ standard ranges, about two-thirds of U.S. sites in Figure 7 with an annual range of 11.5–12.49 μg/m^3 experience 24-hr averages between 28 and 42 μg/m^3. An additional 6% of U.S. sites are >42 μg/m^3. In Figure 8, about one-half of U.S. sites with a 24-hr range of 28–32 μg/m^3 experience annual averages between 11.5 and 14.49 μg/m^3. An additional 11% of U.S. sites are >14.5 μg/m^3. This indicates that within EPA staff-recommended 24-hr and annual standard combinations, neither standard alone is sufficient to constrain both short- and long-term $PM_{2.5}$ concentrations across a substantial percentage of the monitoring network. Matching 24-hr and annual standard levels, however, would effectively constrain the upper distributions of 24-hr and annual ranges, thereby providing more-uniform protection across the country.

The preceding figures suggest that within EPA staff and CASAC recommended standard ranges, an optimal pairing occurs with a 24-hr (98th percentile)/annual standard combination of 30/12 μg/m^3. This analysis finds that an appropriately stringent 24-hr standard and an appropriately stringent annual standard, when combined with

Table 3. Estimated percentage of U.S. FRM monitors (n = 1137) that attain or miss alternative 24-hr 98th percentile (30, 40 μg/m^3) and annual (12, 14 μg/m^3) $PM_{2.5}$ standards (μg/m^3) (2000–2002 FRM country-wide monitors).

Standard Metric	Annual (μg/m^3)	24-hr (μg/m^3)	Attains Both (%)	Misses Annual (%)	Misses Both (%)	Misses 24-hr (%)
Controlling annual	12	40	42	45	11	2
Matching standards	12	30	33	10	46	11
Controlling 24-hr	14	30	41	2	33	24

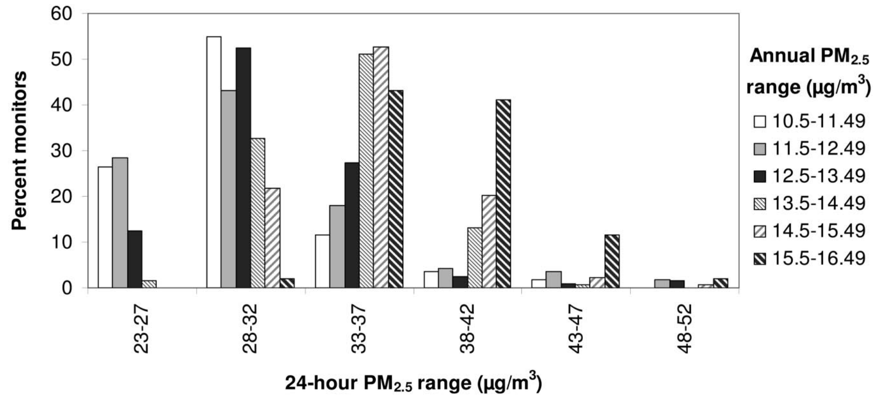

Figure 7. Frequency of alternative 24-hr (98th percentile) and annual $PM_{2.5}$ levels for monitoring sites in United States ($\mu g/m^3$; 2000–2002 FRM country-wide monitors).

equivalence, appear to provide superior protection compared with other standard levels and combinations throughout the entire distribution of the $PM_{2.5}$ FRM monitoring network.

24-hr and Subdaily Averaging Metrics

Although current $PM_{2.5}$ standards are intended to protect populations from both short-term and long-term exposures, the use of 24-hr average and annual mean metrics may require reevaluation because of the growing body of studies finding effects associated with exposure periods <24 hr (e.g., 1 hr to several hours) and characterizing high subdaily excursions.[39,40,41,42] At this time, the EPA NAAQS review is not considering a primary $PM_{2.5}$ subdaily standard. Therefore, in the absence of a subdaily standard option, the question arises as to what extent a 24-hr or annual $PM_{2.5}$ standard will provide protection against peak excursions experienced by populations on subdaily hourly scales.

We conducted an exploratory analysis of $PM_{2.5}$ continuous data from Region 1, 2, and bordering states continuous monitoring sites (2001 and 2002) to assess the relationship between 24-hr concentrations and subdaily concentrations, assuming that the annual metric is less effective at controlling the distribution of maximum $PM_{2.5}$ levels.[43] The study found that increasingly stringent 24-hr average standards will lower subdaily maximum hourly average levels, as depicted in Figure 9. The figure shows the distribution of maximum 3-hr averages associated with 24-hr averages within a discrete range for year-round 2001 values. The cumulative frequency of the 3-hr maximum values is plotted for each of the 24-hr average bins centered around 5-$\mu g/m^3$ breakpoints of 15, 20, 25, 30, 35, and 40, with the number of days about each of these values in parentheses in the figure legend. The solid horizontal line demarks a 1-day/week frequency. An estimate of the 3-hr maximum level experienced at a monitor once per week can be read from the graph by dropping a vertical line from the intersection of the horizontal solid line with the 24-hr average cumulative curve. For example, the line that represents days around a 19–21 $\mu g/m^3$ 24-hr average will experience a 3-hr maximum level of ≥ 38 $\mu g/m^3$ once per week. The analysis was also conducted for 1-, 4-, and 6-hr averages (data not presented), finding structurally similar behavior.

The analysis of continuous $PM_{2.5}$ data also found that the 24-hr average metric smoothes subdaily peak $PM_{2.5}$ levels across the entire distribution of 24-hr levels, thereby masking exposure variability during low, moderate, and high 24-hr average time periods. Figure 10 plots

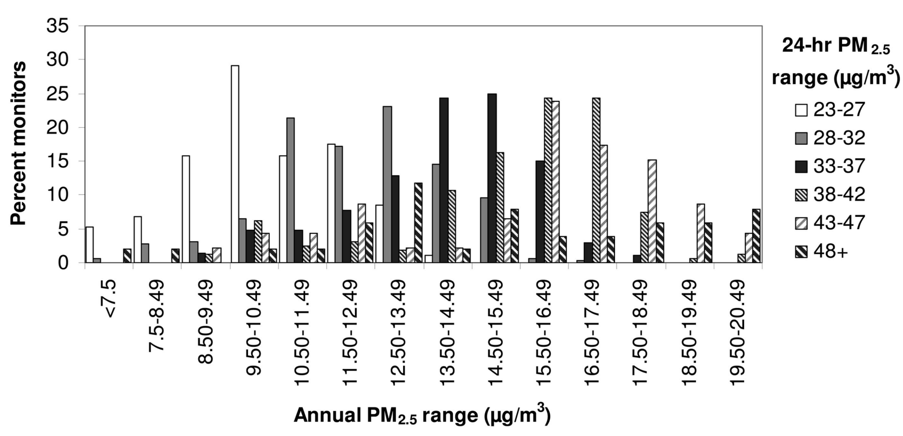

Figure 8. Frequency of alternative annual and 24-hr (98th percentile) $PM_{2.5}$ levels for monitoring sites in United States ($\mu g/m^3$; 2000–2002 FRM country-wide monitors).

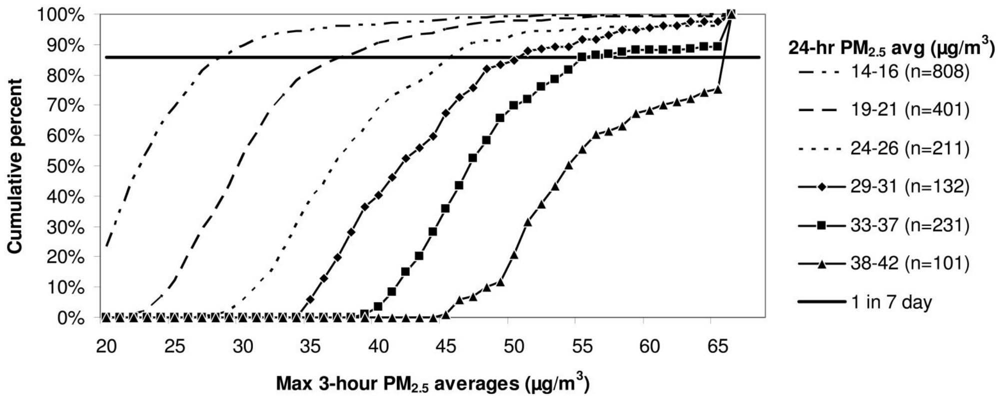

Figure 9. Relationship of maximum 3-hr and 24-hr (98th percentile) $PM_{2.5}$ averages ($\mu g/m^3$; 2001 Region 1, 2, and border state continuous monitoring sites).

ascending 24-hr averages relative to corresponding 1-hr and 6-hr maximum averages between May and September 2002 from 39 sites in the Northeast and adjacent states, illustrating the limitations of conceiving of peak exposures in terms of 24-hr averaging periods. Only summertime values were plotted to enhance visual resolution, although similar behavior was observed for wintertime data. The figure suggests that a more realistic conception of exposure might characterize peak exposures by minutes or hours, because receptors may experience a series of episodic bursts throughout a 24-hr period depending on their activity patterns and proximity to sources.

Figures 9 and 10 indicate that subdaily peak concentrations across individual days are frequent across the entire range of 24-hr average concentration days at Northeast urban sites. This finding is in contrast to the conventional characterization of 24-hr peak concentrations as being limited and infrequent across the total distribution of low, medium, and high concentration days.[32,33] Given these results, a 24-hr averaging metric, although capable of reducing maximum hourly averages, may not be the most effective and efficient way to control subdaily peaking.

DISCUSSION

The current PM NAAQS review process charged to select $PM_{2.5}$ primary standards that are adequate to protect public health delineates a range of 24-hr and annual standards recommended by EPA staff and CASAC. This study has attempted to contribute to the understanding of how the combination and the stringency of the level and form of various 24-hr and annual standards can be selected to protect exposed populations. The analysis also assesses the extent to which current standard 24-hr averaging metrics can protect populations from subdaily exposures.

With respect to the Northeast study area (New England, New Jersey, New York, and border state monitors), a central study finding is that the final selection of $PM_{2.5}$ NAAQS could result in a modest or substantial percentage of the Northeast population benefiting from revised standards through increased nonattainment designations triggering more stringent pollution control measures. Whether the size of populations protected is modest or substantial depends on how stringent the 24-hr and annual standard levels are. Because 24-hr $PM_{2.5}$ values in the Northeast cluster within the 30–35 $\mu g/m^3$ range, the population of the region would receive minimal additional protection unless a 24-hr 98th percentile standard were

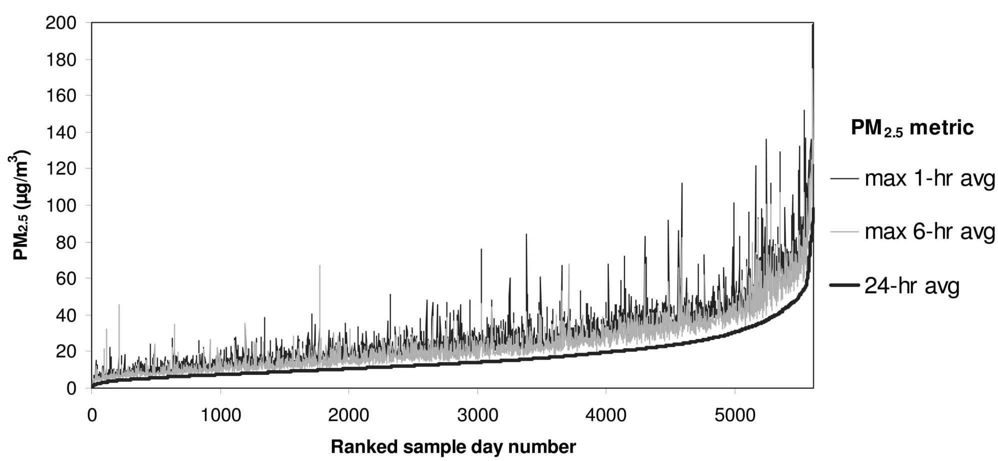

Figure 10. Maximum 1-, 6-, and 24-hr $PM_{2.5}$ concentrations ($\mu g/m^3$; 2002 summertime from 39 Northeast monitoring sites in Region 1, 2, and border states).

tightened from the current 65 μg/m^3 to <40 μg/m^3, were the 15 μg/m^3 annual standard retained. As shown in Figures 3 and 4, across the current recommended annual standard range (12–15 μg/m^3) the most substantial impact on Northeast nonattainment status would occur were the 24-hr (98th percentile) standard lowered to ≤30 μg/m^3 and annual concentration lowered to 12 μg/m^3.

If standards are selected at the less-stringent end of the EPA staff and CASAC recommended range, the Northeast region will not benefit as widely as the nation as a whole. Were the annual standard set between the EPA staff 12–14 μg/m^3 range, the difference between selecting a 24-hr (98th percentile) standard of 30 μg/m^3 and 35 μg/m^3 in the Northeast amounts to a 16–48% difference in population living in areas that would not meet the new standards. This difference is less pronounced for the United States, where only 7–17% of the population live in areas that would not meet the new standards. Within the more narrowly recommended standard ranges of the CASAC, the difference between a 24-hr (98th percentile) standard of 30 μg/m^3 and 35 μg/m^3 within the annual standard range of 13–14 μg/m^3 is a 37–48% increase in the Northeast and 12–17% in the United States of populations living in areas that would not meet the new standards. The consequences of this disparity in protection are of public health concern to the Northeast, because the majority of the populations of the region that would benefit from more-stringent standards live in the most densely populated region of the United States, an urban corridor that experiences the highest $PM_{2.5}$ concentrations of the region.[5] A 30/12 μg/m^3 24-hr (98th percentile)/annual standard would result in more congruent protection across the country, with 84% of the Northeast and 78% of the U.S. populations living in areas that would not meet the new standards.

This study also found that a standard-setting approach that selects matching or equivalent standards would ensure the broadest possible protective coverage in most U.S. areas given the substantial variability of concentrations across the country where 24-hr and annual averages are not well-correlated. Within the recommended range of standards, findings indicate that an appropriately stringent 24-hr standard and an appropriately stringent annual standard, such as 30/12 μg/m^3 (98th percentile), when combined, together provide superior protection throughout the entire U.S. distribution of $PM_{2.5}$ 24-hr and annual levels.

Conversely, the former 1997 NAAQS decision by the EPA setting the current 65/15 μg/m^3 24-hr (98th percentile)/annual $PM_{2.5}$ standard used a controlling and backstop approach, wherein the annual standard controlled the distribution of measured concentrations while the 24-hr standard served as a weaker or backstop standard to limit peak 24-hr average concentrations. Although both standards can effectively shift the low- and middle-range $PM_{2.5}$ levels within the total distribution curve, these mismatched standards have permitted areas with high 24-hr-to-annual mean $PM_{2.5}$ ratios to experience levels at which health effects occur when the backstop standard fails to constrain $PM_{2.5}$ concentrations.

The selection of 24-hr standard percentile forms also has bearing on the level of public health protection afforded by recommended $PM_{2.5}$ standards. During the 1997 and current PM NAAQS review, two competing factors were considered when deciding whether to choose a 98th percentile form or a 99th form. The first factor relates to the importance of a more stable metric in minimizing year-to-year exceedances as they pertain to determining the attainment status of an area, which a 98th percentile form evidently offers. The second factor relates to the importance of providing public health protection from peak $PM_{2.5}$ concentrations, especially at sites with periodic high seasonal peaks, source-oriented peaks, and localized hot spots. Presumably, reducing the number of excluded peak 24-hr average days that populations are exposed to would benefit public health, such that a 99th percentile form would be more protective than a 98th percentile form.

As shown in Table 2, in the Northeast United States, the majority (~65%) of excluded days above both 24-hr average 98th and 99th percentile form levels are within 5 μg/m^3 of this level. This finding indicates that peak 24-hr concentrations typically lie close to the standard cut point and suggests that either percentile form can control $PM_{2.5}$ 24-hr maxima. However, in Figures 2 and 3, the 99th percentile form generates a 24-hr $PM_{2.5}$ standard ~5 μg/m^3 lower or more stringent than a 98th form by removing four additional peak days. Thus, to achieve an equivalent 24-hr average, a 98th percentile form 24-hr standard would need to be ~5 μg/m^3 more stringent than a comparable 99th percentile form standard. Even if removing the 99th percentile form from consideration effectively decreases the number of 24-hr level alternatives available to decision-makers, a 98th form can offer the same level of public health protection, in terms of exposure to 24-hr levels, assuming it is comparably stringent and the range of 24-hr 98th percentile levels encompasses an absolute level of stringency provided by the 99th percentile range.

Although the current 98th percentile form is intended to balance the dual needs of limiting periodic peak values and increasing stability in 24-hr standard nonattainment designations, it is worth noting that exempted natural event peak value days have the potential to contribute significantly to $PM_{2.5}$ concentrations. Populations experience these real-world exposures, which are not reflected in design value calculations used to determine compliance with $PM_{2.5}$ standards. As shown in Table 4, the impact of high peak day exemptions because of forest fires on $PM_{2.5}$ levels was found to be significant in some areas in the Northeast study area during 2002, a year with heavy upwind forest fire activity in Canada. The table

Table 4. Reduction in 24-hr and annual $PM_{2.5}$ from peak concentration forest fire exemptions (2002 FRM Regions 1, 2, and Delaware, Washington DC, Maryland, and Pennsylvania).

Reduction	24-hr (μg/m^3)	Annual (μg/m^3)
Maximum	23.60	1.03
95th percentile	11.56	0.74
75th percentile	4.50	0.58
Median	1.90	0.51
Average	3.36	0.48
25th percentile	0.70	0.38
5th percentile	0.00	0.17
Minimum	0.00	0.08

shows the potential impact of peak $PM_{2.5}$ concentration exemptions in reporting 24-hr and annual levels. For 129 of 192 sites that exempted $PM_{2.5}$ data, annual means were as much as 1 $\mu g/m^3$ lower and on average ~0.5 $\mu g/m^3$ lower. For the 24-hr average, data removal resulted in an average change of ~4 $\mu g/m^3$. The maximum change was ~24 $\mu g/m^3$.

With respect to recent scientific evidence indicating that adverse health effects are associated with subdaily exposures, in the absence of a new subdaily PM NAAQS averaging metric, this study set out to determine to what extent a 24-hr metric can control subdaily excursions. The study found that suitably stringent 24-hr levels, such as a 30-$\mu g/m^3$ standard, are more effective at constraining subdaily hourly and multihourly averages than weaker 24-hr levels, as shown in Figure 9. Figure 10, however, shows how current 24-hr standard averaging metrics reduce the distribution of continuous excursions into one composite 24-hr average, leveling peak variability across all of the 24-hr average periods, regardless of concentration. These findings suggest that populations are exposed to peak subdaily levels that may contribute to aggregate health risk across much of the 24-hr average distribution, including more frequently occurring "typical" days, as well as less-regular high days. This indicates that populations could receive relatively high subdaily peak exposures even on low 24-hr average days. In addition, high-risk scenarios could occur wherein physically active outdoor populations are exposed to nearby high-source environments (e.g., roadways) during peak excursion periods (e.g., morning rush hour).

These considerations suggest that different scales of exposure should be taken into account when selecting future averaging periods for PM standards. The extent to which multiplicative subdaily peak exposures occur across the entire range of 24-hr averages over the course of days, weeks, and years may inform the toxicological and epidemiologic study of acute health events and help to connect specific activity patterns and exposure events with emissions sources. Additional research into continuous exposure variability should be conducted to determine whether a subdaily standard is more effective in protecting populations from short-term exposures. For the time being, until additional health studies based on continuous $PM_{2.5}$ data additionally inform these initial findings, the most effective way to limit subdaily exposures is to set the most stringent 24-hr standard possible.

This analysis of $PM_{2.5}$ standard metrics was subject to analytical limitations. With respect to the use of monitoring data, the assessment followed EPA methods by assigning the highest annual or 24-hr design values as the design values for the entire county. Likewise, for those counties without monitors, the highest annual or 24-hr interpolated levels from counties with monitors were used. This method could result in an overestimation of the number of persons exposed to $PM_{2.5}$ concentrations at the county level. However, the study applied county-level population estimates to include all persons in the study region. EPA currently defines attainment/nonattainment areas by consolidated metropolitan statistical areas that aggregate counties. The study did not take into account upwind areas designated as nonattainment when estimating the percentage of populations living in counties with PM levels above standard combinations.

Application of a 3-yr dataset (2000–2002) incorporating a wide range of monitoring sites and concentration values allowed us to establish the relationship between various $PM_{2.5}$ standard metrics. The inclusion of additional years to the analysis likely would not materially change this relationship, unless factors driving PM concentrations across the Northeastern region were suddenly to change. Since 2002, this has not happened. Nonetheless, the percentage estimates of nonattainment areas in various 24-hr/annual standard combinations pertain to 2000–2002 only and may not be identical to estimates generated using more recent monitoring data. Recognizing the difficulty in determining absolute population numbers or pollution levels, the study focused on establishing data structure and inherent relationships between the 24-hr and annual metric and the potential impact that these standards and their relative stringency have on the level of public health.

In conclusion, study findings show that within the EPA staff and CASAC recommended range of primary $PM_{2.5}$ standards, the most appropriate 24-hr (98th percentile)/annual standards would be 30/12 $\mu g/m^3$. The standard is low enough to provide a stringent level of short- and long-term protection for a substantial percentage of both the Northeast and the U.S. populations. This level of protection is justifiable, because it recognizes current unresolved issues concerning the existence or nonexistence of a $PM_{2.5}$ health effects threshold, as well as the extent to which protection of all populations, including susceptible groups, can be protected with an adequate margin of safety. The standard also provides nearly equivalent 24-hr and annual coverage across the most monitoring areas, thereby providing a more uniform level of short- and long-term protection across the largest area possible. This finding contrasts with the current PM NAAQS controlling and backstop approach, where neither standard alone is sufficient to ensure maximum protection across broad areas of the United States. Furthermore, given recent associations of subdaily exposures and acute adverse health effects, in the absence of a subdaily averaging metric, a stringent 24-hr standard will more effectively control maximum hourly and multihourly peak $PM_{2.5}$ levels than a weaker standard.

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