TESTIMONY OF THE NATIONAL MINING ASSOCIATION

ON

EPA'S PROPOSED REVISIONS TO

THE NATIONAL AMBIENT AIR QUALITY STANDARDS

FOR PARTICULATE MATTER

71 FED. REG. 2620-2708 (JAN. 17, 2006)

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GLOSSARY

µm	Micrometers, equal to one one-millionth of a meter.
1982 CD	Air Quality Criteria for Particulate Matter (EPA 1982)
1996 CD	Air Quality Criteria for Particulate Matter (EPA 1996)
2004 CD	Air Quality Criteria for Particulate Matter (EPA 2004)
BACT	Best Available Control Technology, referring to the control technology-based level of air pollutant emissions which must be achieved by any source which must obtain a PSD permit under the program for the Prevention of Significant Deterioration.
BS	British Smoke, a measure of the darkness of PM collected, estimated at approximately PM3.5-4.5, prior to modern PM controls.
CAA	Clean Air Act
CASAC	The Clean Air Scientific Advisory Committee, which reviews EPA proposals for ambient air quality standards and provides advice and reactions to EPA.
CO	Carbon Monoxide
D_{50}	Due to the engineering difficulties of designing a sampling instrument with an absolute size cutoff, PM samplers are designed to have a 50% collection efficiency at a specified size (e.g., 10 microns), which then results in increasing collection efficiencies (up to ~100%) of smaller particles and decreasing collection (down to 0%) of larger particles. This is commonly referred to as the "D_{50}" of the particular sampler, e.g., D_{50}=10µm.
NAAQS	National Ambient Air Quality Standards
NMA	National Mining Association
OSHA	Occupational Safety and Health Administration
PM	Particulate matter

PM_{coarse} — Coarse particulate matter, consisting of crustal material, including dust from surface mining, construction, agriculture, forestry and wind erosion (as well as sea salt and plant particles). Nearly all PM_{coarse} has an aerodynamic diameter greater than 1 μm, but EPA's rule was $PM_{2.5}$ as a size indicator to distinguish between PM_{fine} and PM_{coarse}.

PM_{fine} — Fine particulate matter, consisting of such products of combustion as the atmospheric conversion of combustion gases such as sulfur oxides and nitrogen oxides into sulfates and nitrates, tobacco smoke and soot. Almost all PM_{fine} has an aerodynamic diameter of 1 μm or less, but EPA's rule uses $PM_{2.5}$ as a size indicator to distinguish between PM_{fine} and PM_{coarse}.

$PM_{2.5,}$ $PM_{3.5,}$ PM_{10}, etc. — Particulate matter collected by an instrument with a 50 percent sampling efficiency at the aerodynamic sampling diameter specified by the sub-number in micrometers; e.g., PM_{10} is the PM collected by an instrument with a 50% sampling efficiency at a particle size of 10 μm. (See definition of D_{50}).

PNOR — Particles not otherwise regulated, used by OSHA to mean non-chemical specific air-borne particles, for certain sizes of which OSHA has adopted workplace standards.

PSD — Prevention of Significant Deterioration, referring to an EPA program designed to prevent deterioration of the air quality in areas in which levels of pollution are below the NAAQS.

SP — EPA's "Staff Paper" – EPA's staff review, analysis and recommendations of PM NAAQS based on the CD.

TSP — Total Suspended Particulate Matter, as measured by an EPA reference instrument, which captures PM with aerodynamic diameters in the range of PM_{25} to PM_{45}, based on wind speed and direction.

TWA — Time Weighted Average

I. Introduction

National Mining Association (NMA) appreciates the opportunity to provide testimony on the Environmental Protection Agency's ("EPA") proposed rule, which seeks to revise the National Ambient Air Quality Standards ("NAAQS") for particulate matter ("PM"). NMA is a national trade association of mining and mineral processing companies whose membership encompasses producers of most of the United States' metals, coal, uranium, and industrial and agricultural minerals; manufactures of mining and mineral processing machinery, equipment and supplies; and engineering consulting, transportation and financial institutions that provide services to the mining industry.

Neither NMA nor its members seek to roll back dust controls. Indeed, coarse PM emissions from mining operations are subject to pervasive regulation and control of coarse PM based on Best Available Control Technology ("BACT") and Best Management Practices ("BMPs") embodied in federal, state, and local control regulations, New Source Performance Standards ("NSPS"), permit conditions, and federally enforceable State Implementation Plans, that are also enforceable by citizen's suit under the Clean Air Act. These requirements will remain in place regardless of whether the EPA adopts a coarse PM NAAQS at this time.

The types of controls employed at mining operations include: watering roads or applying other dust suppressants to them; covering and/or applying wet suppression to crushers, belt conveyors, stockpiles, and batch-drop unloading facilities; and utilizing baghouses where emission can be routed through a duct or vent – to name a few. NMA's comments focus on the irreducible, minimal impacts of such dust that remain after applying controls. Technology-based, reasonable and feasible fugitive dust control measures have been in the past, and must continue to be in the future, the basis for controlling fugitive coarse PM from mining operations.

The amounts of fugitive dust remaining after controls from mining operations have never been demonstrated to have adverse impacts on health at ambient levels. Such dust is similar to that from county roads, highway construction, earth-moving of all kinds, and numerous other surface-disturbance activities. Because such dust has been generally agreed by health experts not to have substantial health or welfare effects at ambient concentrations, historically EPA guidance, policies and exemptions (detailed below) have not included it in making determinations of ambient compliance. Over the last more than 30 years, EPA has excluded such dusts in making "attainment" determinations of compliance with the PM NAAQS, has determined not to list surface mines because of the lack of such effects, created the "fugitive dust exemption" to exclude it from ambient determinations under the Prevention of Significant Deterioration ("PSD") program, discounted it under its "rural fugitive dust policy," and excluded it under various "natural events" policies from being considered in determining compliance with the PM NAAQS. The proposed rule's exclusion of coarse PM from agriculture and mining from the coarse PM NAAQS continues EPA's historic, scientifically-based, policy and practice of excluding such coarse PM from the PM NAAQS.

The fugitive dusts from mining operations, are by scientific definition "coarse particulate matter," namely particles derived from "mechanical division" of earthen and other materials. Fine particulate matter, on the other hand, is derived from the primary and secondary results of combustion and other chemical processes.

II. The Basis for the PM NAAQS

The critical feature of the Particulate Matter NAAQS, namely its concentration term, has, from its inception, been based on "British Smoke," ("BS") measurements, 62 Fed. Reg. 38659 (July 18, 1997). BS is a measure of the "blackness" of smoke produced by combustion appearing on a filter paper. Such material is dominantly below PM_1, only rarely "accumulating" in foggy atmospheres to $PM_{2.5}$. The concentration term of virtually all of the PM NAAQS promulgated from the Clean Air Act's enactment forward and in effect from 1970 through 1997, was the BS data from a 1952 London smog, stagnation incident. It found associations with adverse health effects at 24-hour concentrations of 500 $\mu g/m^3$ of BS and above (in combination with high levels of sulfur oxides), and, for instance, in 1987, took approximately 1/3 of this amount, namely 150 $\mu g/m^3$ as the basis for the PM_{10} standard. *Id.* It was not based on PM_{10} data, nor on Total Suspended Particulate ("TSP") data, but on British Smoke data. It was not based on coarse PM data, and should not, scientifically, be applied to coarse PM, or used as a metric for determining the concentration at which coarse PM in the ambient air may be harmful.

Unfortunately, from the beginning, EPA has not based the "indicator" term of the PM NAAQS on the data from which it was derived, namely BS (estimated at the time as $PM_{3.5}$-$PM_{4.5}$). Instead, in the early 1970s EPA adopted TSP, which collected particles generally as large as PM_{35} to PM_{45}, based on its belief that some particles of that size might get into the nose and mouth and might contribute to health effects.

In 1987, EPA excluded particles above PM_{10} from the PM NAAQS, because particles larger than 10 micrometers do not penetrate to the thoracic or alveolar areas of the lung, and thus do not present health concerns at ambient concentrations. However, PM_{10} still included coarse PM above the BS size indicator, on the possibility that further research and studies might show substantial health effects due to the fact that such particles had the potential to penetrate into primarily the upper airways of the human respiratory system. The material above PM_{10}, between PM_{10} and PM_{35}-PM_{45}, was discarded from the standard. There was no evidence indicating that material was producing adverse health effects, yet it was constituting most of the mass in arid, western atmospheres. Including it in the standard distorted and misdirected control efforts, producing no substantial environmental benefit. Several health scientists, environmental and industry groups argued that the particle indicator for the PM NAAQS should have been PM_1 or $PM_{2.5}$, because including particles above those sizes departed from the evidence of adverse health effects on which the PM NAAQS were based, and diluted and misdirected control efforts to particles with no substantial health or welfare effects.

NMA submits that after years of study, the clear, preponderant weight of the evidence continues to support EPA's historic conclusion that fugitive dusts at ambient concentrations do not present substantial health concerns that would justify the adoption of a coarse PM ambient air quality standard. The best and only indicator necessary for ambient regulation of particulate matter is one that best represents fine PM.

The 1997 PM NAAQS. None of the PM NAAQS adopted prior to 1997 had recognized the fundamental disjunction between the data that supported the concentration term of the PM NAAQS, namely BS, which was virtually entirely fine PM, and the coarse PM that EPA had included in the indicator term of the standard. In 1997 EPA recognized the fundamental difference between fine and coarse PM, and created a fine $PM_{2.5}$ standard. While EPA initially proposed not to adopt a 24-hour coarse PM standard, in the final rule it did adopt such a standard. That coarse PM10 standard was, however, set at 150 $\mu g/m^3$, a concentration level quantified and derived from fine PM, BS data. The only concentration data discussed as the basis for this standard was at concentration levels well above 1000 $\mu g/m^3$ and included both fine and coarse PM. (Hefflin, 1991; Gordian, 1996).

The 1997 coarse PM_{10} standard was vacated and set aside as confounded, because it included both fine and coarse PM. The Court also found that EPA's lack of a rationale for the concentration term of the standards constituted an unconstitutional delegation of authority from Congress (a ruling later reversed by the U.S. Supreme Court). The result is that there has never been a valid coarse PM standard based on coarse PM evidence, nor a sustaining rationale of any kind connecting the 150 µg/m3 concentration term of that standard with any health studies based on coarse PM effects at those concentrations.

EPA's and CASAC's Controversial Review on Remand of the Vacated Coarse PM_{10} Standard. CASAC's review of the coarse PM standard over the last three years has been marked by controversy, abrupt and unexplained changes of position, last-minute changes in possible theoretical bases for such a standard, and an unprecedented failure by CASAC even to review EPA's Final Staff Paper and reach "Closure" on its scientific basis for the coarse PM standard before that document and its recommendations to the EPA Administrator were finalized and released. CASAC reviewed that scientific basis only after that document had become final.

After several years of review and deliberation, several members of CASAC, including its then Chair and its leading health scientists, had expressed the view that EPA's Criteria Document and drafts of its Staff Paper did not provide an adequate basis for a coarse PM standard. Indeed, CASAC's May 11, 2005 draft letter to the Administrator stated that "the setting of this [coarse PM] standard be set aside until further deliberations on the appropriate metric can be made."

At its April 2005 meeting, CASAC had suggested a potential new rationale for a coarse PM standard that EPA might substitute for its past, unsuccessful efforts to provide a basis for a coarse PM standard. This new concept was based not on the health effects of coarse PM, but its possible contamination by toxic urban contaminants that might be absorbed and carried by coarse PM in urban areas. EPA was urged to substitute this new concept for the years of work that had gone into the Criteria Document and two drafts of its Staff Paper that CASAC had found wanting. After a teleconference on its May 11, 2005 draft letter on May 18, 2005, CASAC wrote a final letter to the EPA Administrator stating that although "the evidence for a standard for coarse-mode particles was weaker than for the $PM_{2.5}$, the Panel agreed that a 24-hour NAAQS for $PM_{10-2.5}$ was appropriate, especially in urban areas, with caveats to make exceptions for those types of rural dusts thought to have low toxicity."

EPA's Final Staff Paper. EPA issued its final Staff Paper on PM NAAQS revision at the end of June 2005. It recommended an "urban" coarse PM standard. Significantly, the Staff Paper noted that the studies and data on which it based its proposal were weak, uncertain, limited, and not even adequate to support a health risk assessment, since they did not fulfill the minimum requirements for such assessments. That remains the case. EPA also stated that a coarse PM standard might be based on providing protection somehow "equivalent" to the 1987 24-hour PM_{10} standard, whose concentration term was based on fine PM, not coarse PM.

III. EPA's Proposed Revisions to the PM NAAQS.

On January 17, 2006, EPA published its proposed revisions for the PM NAAQS. 71 Fed. Reg. 2620-2708. The coarse PM standard it proposed is a 24-hour $PM_{10-2.5}$ standard "qualified so as to include 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." 71 Fed. Reg. 2620. The indicator for this standard "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." *Id.* In addition, it states that "[a]gricultural sources, mining sources, and other similar sources of crustal material shall not be subject to control in meeting this standard." *Id*. at 2698-99. The concentration term of the proposed coarse PM standard is 70 $\mu g/m^3$. That level, EPA says, is intended to provide a "generally equivalent level of protection" to the 1987 PM_{10} standard.

IV. The Exclusion of Coarse PM from Agricultural and Mining, and of Crustal Material from Similar Sources Is Consistent with the Preponderance of the Scientific Evidence, and the Determinations of EPA, Congress and the Courts Since the Inception of the Clean Air Act.

As noted above, fugitive dusts have been consistently determined not to present substantial health or welfare effects, and have been excluded from PM NAAQS determinations, PSD and NNSR permit applicability determinations, and discounted or not counted under exemptions ranging from the fugitive dust exemption to the rural fugitive dust policy for more than 30 years. These determinations and policies have been upheld by the courts, and endorsed by Congress on several occasions. CASAC counseled EPA to "make exceptions for rural dust thought to have low toxicity." This section provides specific reference for this history.

By the time of the CAA Amendments of 1977, it was well-known that coarse PM dusts, generally referred to as "fugitive dust," from natural sources and activities, such as surface mining, agriculture, dirt roads, forestry, construction and earth-moving, routinely exceeded the PM NAAQS in the arid West. In the same Amendments, Congress added the Prevention of Significant Deterioration (PSD) program into the statute, requiring all new or expanded sources of 250 tons/year or more of PM to demonstrate not only that the PM NAAQS were met, but that PSD PM increments, set at levels approximately one-fifth of the PM NAAQS, also were met. 42 U.S.C. §7460-69. It was apparent that if the PM NAAQS and increments were applied to new or expanded activities producing fugitive dust, those activities would be drastically reduced or prohibited because their emissions were projected to exceed those PM standards, even after the application of Best Available Control Technology(BACT).[1]

Based on this uncontroverted assessment, EPA determined that fugitive dust should be excluded from the application of the PM NAAQS and increments, noting several factors cited at the time by the mining industry, namely:

> that a large majority of the associated particulate matter is nonrespirable; that mining activity occurs in areas with limited population; that the particulate matter arises at ground level and falls out within very short distances; that visibility is not affected because the light scattering which hinders visibility is caused by smaller particles; and that even after the application of BACT, short-term particulate standards for NAAQS and PSD increments might not be met.

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[1] See studies recited in fn. 3, col. 2, 43 Fed. Reg. 26395 (June 19, 1978) and EPA Region VIII Interim Policy Paper on Air Quality Review of Surface Mining Operations (1978).

> In view of these comments and other studies, EPA has decided to exclude from any air quality impact assessment of a source or modification any fugitive dust that would emanate from it.
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> Additional support for this exclusion can be found in the legislative history. It points to the utilization of 'administrative good sense' regarding fugitive dust (*see* S. Rep. No. 95-127, at 98 (1977)) and suggests that Congress did not intend PSD to prohibit surface mines of an economically viable size (*see* H. Rep. No. 95-294, at 165-66 (1977)).

43 Fed. Reg. 26395 (June 19, 1978).

EPA routinely classified "nonattainment" areas exceeding the PM NAAQS due to fugitive dust as "attainment" areas, applying its "rural fugitive dust policy," e.g., 45 Fed. Reg. 78122 (Nov. 25, 1980), 56 Fed. Reg. 37564 (August 8, 1991).

As Judge Leventhal noted in this Court's decision on fugitive PM issues in *Alabama Power Co. v. Costle*, 636 F.2d 323(D.C. Cir. 1979):

> EPA's regulation of fugitive emissions has been of special concern to the mining and forestry industries which contend, without serious opposition, that they are incapable of meeting the strict limitations on the emission of particulate matter set by the PSD provisions.

Id. at 369. The Court in this case held that fugitive emissions could not be included in determining applicability until EPA had performed a rulemaking to include them pursuant to section 302(j) of the Clean Air Act. Perhaps as or more important, the Court noted that:

> "EPA has discretion to define the pollutant termed 'particulate matter' to exclude particles of a size or composition determined not to present substantial public health or welfare concerns."

Id. at 369-70, fn. 134. It went on to explain how those particles could remain subject to reasonable controls under other provisions of the Clean Air Act. The Court made this explanation in the context of its decision to vacate the fugitive dust exemption. In deciding that such an exemption was invalid, the Court went to considerable lengths to point the way to a solution to the problem posed by not excluding harmless fugitive dust emissions from the PM NAAQS.

Congress, in deciding not to enact a statutory exclusion of fugitive dusts, made very clear that EPA was expected to use its "administrative good sense" to exclude it:

> Because of the imprecision inherent in the total suspended particulates standards, background dust in such States can cause levels in excess of the particulate standards. Fortunately, the logical dilemma posed by the shortcomings of the present particulates standards can be overcome by administrative good sense until such time as modification of the standards are adopted. *The States and EPA have begun to recognize this problem of background particulates and should discount its effects where the problem involves particulates not generally of the substances and respirable sizes thought to affect public health.* The Environmental Protection Agency has used this approach in its current policy, and the committee endorses it. *In calculating baseline levels for the purposes of the nondeterioration requirements, and in making determination of attainment and nonattainment of ambient particulate standards, the committee would expect that this administrative good sense would apply.* (Emphasis supplied). S. Rep. No. 95-127, 95th Cong., 1st Sess. 98 (1977).

EPA came to the same conclusion as this Court and Congress concerning coarse PM from surface coal mining. Following this Court's remand in *Sierra Club v. Gorsuch,* 715 F.2d 653 (D.C. Cir. 1983), EPA proposed to list such mines as sources whose fugitive dust emissions must be included in determining whether they are major stationary sources under the PSD program. It concluded that mine fugitive dust emission should not be included and surface mines should not be listed because of (1) the lack of substantial health or welfare effects from such coarse PM emissions, and (2) the prohibitive effect on the mining industry that including such coarse particle fugitive dust would have. 54 Fed. Reg. 48870 (November 28, 1989).

Finally, as support for the current proposed coarse PM NAAQS, EPA cites health effect studies performed in several cities. As EPA recognizes, coarse crustal particles from mining and similar sources would not have been present in significant quantities in any of those cities. Therefore, even if one were to ignore the serious issues with those studies (which we will discuss later), they provide no information at all about health effects from coarse crustal particles from mining or similar sources.

In summary, EPA's proposal to exclude coarse PM from agriculture, mining and similar sources is in keeping with past determinations of Congress, the courts and EPA itself.

V. The Preponderance of the Scientific Evidence Continues to Demonstrate That Fugitive Dust from Agricultural and Mining Operations Presents No Substantial Health or Welfare Concerns.

Over the last 30 years, the consensus opinion of the many eminent and experienced medical and public health experts in respiratory disease epidemiology, toxicology and clinical treatment has been that coarse PM has never been demonstrated to have adverse health effects at ambient levels. This section summarizes that evidence.

After many years of study, Benjamin G. Ferris, Jr., M.D., a nationally known expert in research on the effects of PM and other criteria pollutants on health, Professor of Environmental Health and Safety, Department of Environmental Science and Physiology, head of the Respiratory Epidemiology Program of the Harvard School of Public Health, and a principal author of the Harvard Six City Study stated this conclusion clearly in an unsolicited letter to EPA Administrator Lee M. Thomas dated August 27, 1987:

> Throughout my forty years of studying the associations between air pollution and public health, which includes my personal involvement and observations of our Harvard Air Pollution Respiratory Health study (Six-City Study), and numerous epidemiological studies reported by a number of excellent investigators, it appears that the fine particle fraction and its reactive constituents comprise the source of potential adverse effects of particulate matter. The fine fraction may include carcinogenic agents, toxic trace metals, and other organic and acidic components associated with combustion processes.
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> EPA's fugitive dust policy traditionally reflected the fact that standards for particulate matter were routinely exceeded by coarse particle fugitive dust from natural sources, agriculture, unpaved roads, mining, construction, and other sources, especially in the arid areas of the western U.S.A. **This fugitive dust at the levels measured in ambient air in the western and other parts of the United States over the years has never been documented to have had adverse effects on human health.** We began to realize this from

> research on particle deposition and clearance, showing that coarse insoluble particles deposited primarily in the upper airways while the fine soluble particles deposited primarily in the intrathoracic region. **Toxicological work in animals and clinical studies on humans further support the conclusion that fugitive dust at ambient concentrations poses little risk of adverse health effects to the public.** (Emphasis added).

Chatten C. Cowherd of the Midwest Research Institute, who has spent much of a distinguished scientific career in the study and characterization of PM, and authored much of EPA's work on fugitive dust, stated much the same opinion:

> Fugitive dust emissions, whether from mining, agriculture, or unpaved public roads, consist largely of coarse particles which settle out of the atmosphere close to the source. These particles do not account for any known adverse effects to health or welfare other than localized nuisance problems usually associated with periods of dry, windy weather.

Dale A. Lundgren, an eminent professor, scientist and industrial hygienist, who often advises EPA on PM issues, concluded, after a thorough review, that "coarse particles are not of significant health effect at levels found in the ambient air. . ."

Professor David L. Swift of Johns Hopkins University School of Public Health, one of the country's leading authorities on PM for more than 20 years, also conducted a comprehensive review and weighing of all of the scientific evidence in 1996. He concluded:

> It is concluded that the regulation of CF [coarse fraction] at ambient levels discussed in the SP [EPA Staff Paper] and preamble [to the EPA proposal to revise the PM standard] do not provide any substantial health benefit. By definition, CF is composed primarily of particles which are formed by mechanical processes from larger particles or bulk material. Such crustal particles, because of their lack of health effects at ambient levels well above the proposed standard, should be excluded from any PM standard.

NMA submits that this substantial body of medical and public health expert opinion, as well as the rationale and basis of EPA's practice for more than three decades excluding coarse PM from PM standard determinations, should be accorded substantial weight.

To this must be added the weight of the recent reviews of Criteria Document and Staff Paper science by Dr. Jonathan Borak of Yale University School of Medicine. Dr. Borak's qualifications included expertise in toxicology, epidemiology and occupational health exposure to pollutants. His first review dated May 4, 2005 of the limited studies that EPA cited as showing an association of coarse PM with morbidity found "a general lack of scientific support for a proposed NAAQS for $PM_{10-2.5}$," while his second review dated August 10, 2005 of additional studies cited by EPA in its Staff Paper, found that such studies "do not sustain quantitative risk assessment." He also noted that "[i]mportant data deficiencies currently obstruct the setting of such a [coarse] PM standard, noting that "further "data and research are necessary to determine whether there is a need for a coarse PM [standard] to address public health risks at ambient concentrations, and to characterize the indicator and concentration."

The lack of a basis for quantitative risk assessment, which EPA Staff itself has noted, is a fatal flaw in the basis for a standard. Without that analysis it is not possible to quantify the concentration term of a coarse PM standard.

VI. EPA's Proposal of an "Urban-Type" Coarse PM Indicator and PM NAAQS Is Not Based on Sound Science.

The new concept for development of a coarse PM standard based on its potential role in urban areas (where the hypothesis posits that it has the potential to combine with other substances that may be hazardous, such as industrial emissions, construction emissions, or mobile source emission components) is a novel one, first put forward in April of 2005, and now articulated in some detail with a proposed rationale in the January 17, 2006 Federal Register notice. The notice also asks for comment on a number of alternatives, including the alternative of not adopting a coarse PM standard at this time. NMA submits that the concept and hypothesis advanced by EPA as a justification for the proposed coarse PM NAAQS are just that, and no more. They cannot serve as the justification for adopting a health-based standard at a specific concentration level, such as that proposed, especially when that standard is nearly double the stringency of the prior PM_{10} standard in atmospheres dominated by coarse particles.

NMA submits that EPA has not provided the scientific support to demonstrate that a coarse PM standard is necessary to protect public health or welfare, even in urban areas with other contaminants present. In fact, as EPA itself notes, when PM fine or other criteria pollutants are considered, even the marginal statistical associations in a few anomalous, one-pollutant studies disappear. 71 Fed. Reg. 2671-2672.

In presenting its proposed 24-hour coarse $PM_{10-2.5}$ standard, EPA places primary reliance on four studies that it claims provided the support necessary for demonstrating the necessity of controlling coarse PM to a concentration of 70 μg/m^3, 71 Fed. Reg. 2655-2568. It states that these studies show significant associations of coarse $PM_{10-2.5}$ with mortality and morbidity at this concentration. The severe problems that militate against any reliance on these four studies are not discussed in EPA's discussion of them as its basis for the proposed coarse PM standard. However, in a later discussion of a possible "alternative interpretation" of the health evidence, EPA does acknowledge the fatal flaws in the four studies. Its treatment of them bears full quotation and careful consideration:

> "Having decided to propose the 24-hour $PM_{10-2.5}$ standard described above, the Administrator recognizes that there are important views on the information relating to the effects of coarse fraction PM that warrant consideration. For example, **an alternative interpretation of the available health evidence presented in the Criteria Document and the Staff Paper questions the conclusions about $PM_{10-2.5}$ associations drawn from one-pollutant models**. This interpretation of the available epidemiological evidence suggests that the results from one-pollutant $PM_{10-2.5}$ models are confounded by fine particles and gaseous co-pollutants.
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> The key $PM_{10-2.5}$ epidemiologic results discussed in the Criteria Document and Staff Paper are drawn from one-pollutant models; i.e., $PM_{10-2.5}$ is the only variable used in the statistical model reflecting exposure to air pollution. **There are four studies cited in these documents as being suggestive of a statistically significant role for $PM_{10-2.5}$ in the reported associations: Ito (2003), Burnett et al. (1997), Mar et al. (2003), and Ostro et al. (2003).** However, there is strong evidence that adverse health effects similar to those observed in these studies, including both cardiovascular and/or respiratory health effects are associated with exposure to $PM_{2.5}$. The authors of several of these studies focus on fine particles (and in some cases one or more of the gaseous pollutants) as playing an important role in 'explaining' the association between PM and various health endpoints. For example, in these key epidemiologic studies, the correlation coefficients between $PM_{2.5}$ and $PM_{10-2.5}$ concentrations range from moderate to high (i.e., 0.4 to 0.7), which increases the likelihood that associations between health effects and $PM_{10-2.5}$ identified in one-pollutant

models may instead simply reflect the effects of exposure to $PM_{2.5}$ rather than independent health effects. With the positive correlations between pollutants and similar health effects, **it generally would be appropriate for any assessment of the effect of exposure to $PM_{10-2.5}$ to control for exposure to the $PM_{2.5}$.**

In this light, it is important to review how the authors of the four key $PM_{10-2.5}$ epidemiology studies have accounted for co-pollutants in their analysis. Ito (2003) noted significant estimates of the health effects of associations in one-pollutant models, but **in a two-pollutant model with $PM_{2.5}$ the $PM_{10-2.5}$ associations lost statistical significance. Burnett et al. (1997) concluded that the effect of $PM_{10-2.5}$ in a one-pollutant model could be explained by gaseous co-pollutants. Mar et al. (2003)** found $PM_{10-2.5}$ to be positively associated with adverse health effects in a one-pollutant model, but also **found similar associations with a range of other air pollutants**. In addition, Mar et al. (2003) noted that even though all PM mass metrics included in the study were associated with an excess risk of cardiovascular death, the strongest associations were with $PM_{2.5}$, followed by PM_{10} and $PM_{10-2.5}$. **Ostro et al. (2003) used a one-pollutant model to estimate the association between $PM_{10-2.5}$ on mortality using an effectively linear construct of PM_{10} (as observed in Indio, CA) to represent $PM_{10-2.5}$ for the entire study area. By using such a construct of PM_{10}, the estimated associations simply reflect a PM_{10} association (i.e., the construct does not provide additional information on the effect of $PM_{10-2.5}$)**. Moreover, roughly 75 percent of the cardiovascular mortality in this study occurred in or near Palm Springs, CA and PM characteristics differ significantly between Palm Springs and Indio (e.g., average PM_{10} concentrations are roughly 30 percent lower in Palm Springs and $PM_{2.5}$ represents a higher fraction of PM_{10}, with a correlation coefficient between $PM_{2.5}$ and $PM_{10-2.5}$ of 0.46 in Palm Springs). Thus, the Ostro et al. (2003) study suggests a positive association between PM_{10} monitored in Indio and mortality in Palm Springs, but **some view this study as offering little basis for attributing significant**

mortality association to $PM_{10-2.5}$ as observed in either city.

The Criteria Document and Staff Paper also present and discuss other epidemiology studies in support of the proposal for both the $PM_{2.5}$ and $PM_{10-2.5}$ standards (as shown in Figure 2 and discussed in Section III.A above): Burnett (1997), Fairley (2003), Ito (2003), Lipfert et al (2000), Mar et al (2003), Moolgavkar (2000), Sheppard et al (2003), Thurston et al (1994), Burnett (2000, 2003), Klemm and Mason (2003), and Schwartz and Neas (2000). However, these studies report positive statistically significant associations with $PM_{2.5}$ that are more consistent and robust than the associations thus far identified for $PM_{10-2.5}$. Indeed, **several of these and other studies that specifically considered $PM_{10-2.5}$, but did not find statistically significant associations, including Schwartz et al (1996), Thurston et al. (1994), Sheppard et al. (2003), Fairley (2003), Schwartz et al (1996) and Lipfert et al. (2000). With respect to mortality effects in the Six-City study, Schwartz et al. (1996) concluded that the PM associations (in the six metropolitan areas – including Steubenville) were specifically associated with $PM_{2.5}$, with little additional contribution from the $PM_{10-2.5}$.** Sheppard et al. (2003) noted that bias in model selection and reporting can result in inflated excess risk estimates for PM. Fairley (1999) noted that $PM_{10-2.5}$ effects become negative and insignificant when modeled jointly with $PM_{2.5}$. Lipfert et al. (2000) showed insignificant effects for $PM_{10-2.5}$ in one- and two-pollutant models with O_3. The authors also caution against drawing causal interpretations from results when comparing health effects from one region in a metropolitan area to air quality observations in another region. In addition, several of these studies also report positive, statistically significant associations with one or more of the gaseous pollutants. **Both Thurston et al. (1994) and Burnett et al. (1997) reported substantial confounding with gaseous co-pollutants in Toronto, and Thurston et al. (1994, p. 282) reported that "it seems clear that these apparent associations were merely a statistical by-product of interpollutant confounding resulting from the shared day-to-**

> **day variations in dispersion conditions."** In addition, Burnett et al. (2000) concluded that gaseous pollutants played an important role in explaining the effect of urban air pollution on health. Similarly, Moolgavkar (2000) concludes that gases were more strongly associated with respiratory effects than PM in Los Angeles.
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> Taken as a whole, evidence from $PM_{10-2.5}$ epidemiologic studies could be interpreted to suggest that one-pollutant $PM_{10-2.5}$ models suffer from bias due to omitting co-pollutants in the statistical model, especially given the much stronger evidence (discussed above) that these effects are associated with exposure to $PM_{2.5}$. As noted by many of the aforementioned authors, while significant health associations may be noted for coarse fraction PM in one-pollutant models, the actual association may be insignificant from zero due to confounding co-pollutants. Of course, the Administrator must conclude in the final rule that the evidence about the health effects of $PM_{10-2.5}$ is sufficiently robust to finalize a standard for $PM_{10-2.5}$.
>
> The Administrator, recognizing notably large uncertainties in the underlying evidence and information that formed the basis for this proposal as well as the challenges associated with moving toward a new $PM_{10-2.5}$ indicator and a related new monitoring network, solicits comment on this and other alternative interpretations of the available health evidence and alternative policy responses. Several such alternative interpretations and policy responses are discussed below.

71 Fed. Reg. 2671-2672. (Emphasis added.)

What should be clear is that the rationale for the proposed coarse PM standard is not at all supported by the four studies. This passage states that "it generally would be appropriate for any assessment of the effect of exposure to $PM_{10-2.5}$ to control for exposure to the $PM_{2.5}$." In the primary study on which EPA placed reliance to support an "urban" $PM_{10-2.5}$ standard, namely that of Detroit (Ito 2003), it notes that when $PM_{2.5}$ is considered "the $PM_{10-2.5}$ associations lost statistical significance." In the Toronto study (Burnett 1997), the apparent association of health effects with coarse $PM_{10-2.5}$ "disappeared after adjustment for O_3, NO_2, and SO_2." In addition, the Toronto study did not find statistically significant associations between monitored cardiac and respiratory effects and coarse particulate matter. In

Phoenix (Mar 2003), only single pollutant models were used, and only a "marginally significant (p<.10)" association was found. Anomalously, Mar found no significant association between total mortality and $PM_{2.5}$, contrary to virtually all of the other epidemiological studies cited by EPA. Any reliance on the Coachella Valley (Ostro, 2003) study also seems entirely unjustified. Not only does it attribute deaths in Palm Springs to exposure measured in the city of Indio, but it finds no association between fine PM and health effects, contrary to virtually all other EPA studies. In addition it models 24-hour concentrations for the 75% of the period for which it has no $PM_{2.5}$ data.

Even more misleading is the preamble text's treatment of the Six Cities Study as supportive of a finding of an association of coarse PM with mortality and morbidity as a basis for its proposed coarse PM standard. 71 Fed. Reg. 2655, col. 3. Buried in a footnote to this passage, EPA admits that upon reanalysis to correct errors, "the association for Steubenville was not statistically significant in most models reported in the two reanalyses . . ." 71 Fed. Reg. 2655, col. 3, fn. 49. Indeed, in the Schwartz review of the effects of coarse PM in the Six Cities Study, as well as the reanalyses, no significant associations with mortality were found in five of the six cities, and in the one city where coarse PM was a significant proportion of the PM_{10} measured, Topeka, Kansas, there was a negative association with mortality. (Schwartz, 1996). The Six Cities Study likewise did not find associations with morbidity in five of the six cities, and only with cough in one of the six cities, St. Louis. Surely it is misleading by omission to cite the Six Cities Study for the proposition that it supports findings of associations with mortality and morbidity.

Even more egregious is the failure to consider and weigh the far larger number of studies with much larger and more powerful databases and longer duration that specifically considered $PM_{10-2.5}$, but did not find statistically significant associations. (Schwartz 1996), (Thurston 1994), (Sheppard 2003), (Fairley 2003), (Schwartz 1996), and (Lipfert 2000).

Any fair and sound scientific weighing of the evidence on coarse PM would, NMA submits, determine that the preponderance of that evidence does not support the finding that a coarse PM standard is necessary to protect public health. The preponderance of scientific evidence does not show any significant association with health effects at ambient concentrations. Those few studies purporting to show an association with coarse PM health effects either do not support that characterization, or are so fatally flawed that they are contrary to virtually all of the other evidence considered.

VII. Neither (1)"Protection Equivalent to the 1987 PM10 Standard," (2) Potential Effects of Deposition of Some Coarse PM in the Lung, Nor (3) Toxicology, Provides a Rational Basis for the Proposed 70 µg/m3 Coarse PM Standard.

EPA asserts several other justifications for its proposed 70 µg/m^3 coarse $PM_{10-2.5}$ standard. Chief among this is its assertion that that concentration is "equivalent" to the 150 µg/m3 1987 PM_{10} 24-hour standard, and would therefore provide public health protection "equivalent" to that provided by the 1987 PM_{10} standard. That proposition will not bear scrutiny.

First, the 1987 PM_{10} standard was based on fine PM, namely British Smoke measurements, not coarse PM. 62 Fed. Reg. 38659 (July 18, 1997). Fine PM and coarse PM are separate subpollutants, in no way equivalent. It would be arbitrary to equate them.

Second, PM_{10} is made up of different mixes of fine and coarse PM in different sections of the country. In arid, southwestern cities, coarse PM often constitutes 80% or more of PM_{10}, while in humid eastern cities, fine PM may constitute 80% or more of PM_{10}. 100 µg/m^3 measured in an eastern city with such a ratio of fine to coarse PM would have 20 µg/m^3 of coarse PM, while 100 µg/m^3 in a southwestern city would have 80 µg/m3 of coarse PM. With exactly the same amount of PM_{10}, the eastern city would be in compliance with the 70 µg/m^3 standard proposed, while the southwestern city would be in violation. Again, not only are the two situations not equivalent, but the western cities where coarse PM predominates are discriminated against. This is particularly ironic in view of EPA's reliance on studies from Toronto, Detroit, Steubenville, and other humid, largely eastern cities to support its health effects contentions. Those cities would not be subject to any controls as a result of the doubling of the stringency of the 1987 PM_{10} standard of 150 µg/m^3 to 70 µg/m^3, while arid western cities, where the evidence is to the contrary, may be expected to exceed it.

Third, the Court in the *American Trucking Assn.* case found that PM_{10} was confounded by including indeterminate amounts of fine and coarse PM. The fundamental reasoning of the case negates any possibility of equating PM_{10} with one of the two indeterminate components of PM_{10}.

Some coarse PM particles, particularly under mouth-breathing, may get into the upper and lower regions of the lung and have the potential to cause health effects; EPA treats this fact as a rationale for the coarse PM standard. Similarly, EPA treats toxicology as demonstrating that there is a mechanism by which coarse PM deposited in the lung in animal studies has been demonstrated to cause health effects at high dosages. Neither of these propositions is at all controversial. In fact, they are well-established, and furnished a justification for including coarse particles in the TSP and PM_{10} standards for many years. But just as clearly, neither consideration furnishes any basis for quantifying or deriving the concentration term of a PM coarse standard.

It has been undisputed for decades that coarse PM at high concentrations can cause adverse health effects. That evidence derives from occupational health studies that, while not directly relevant to ambient exposure of the general population is nonetheless edifying.

Occupational health standards also regulate fine and coarse PM separately. OSHA standards for PM fall into two categories, standards for specific substances, such as asbestos and arsenic, and standards for general, "Particles Not Otherwise Regulated" (PNOR). PNOR and inert or nuisance dusts are regulated in two categories, one the "respirable fraction," 5,000 $\mu g/m^3$, and one for "total dust," 15,000 $\mu g/m^3$. The "respirable fraction" is a $PM_{3.5}$ standard that is close, if not identical, in function and purpose to EPA's new $PM_{2.5}$ fine particle standard while the "total dust" standard ($\sim PM_{100}$) is more akin to the purported purpose of the proposed coarse PM standard.

During 1988-89, OSHA proposed to tighten the 15,000 $\mu g/m^3$ 8-hour TWA for several PM substances to 10,000 $\mu g/m^3$. The changes were vacated because the agency failed to establish that the existing exposure limits presented significant risk of material health impairment or that the new standards eliminated or substantially reduced the risk. *AFL-CIO v. OSHA,* 965 F.2d 962 (11th Cir. 1992).

NMA submits that one will look entirely in vain for any substantial study supporting the health effects of coarse PM in the ambient air at 70 $\mu g/m^3$, a concentration that is less than 5 one-thousands of the concentration of the total dust occupational health standard serving an equivalent purpose. Indeed, the only two studies cited by EPA in support of its coarse PM_{10} standard (Hefflin, 1991; Gordian 1996) were at concentrations well above 1,000 $\mu g/m^3$, while several studies have shown no effects from exposure to concentrations well above 10,000 $\mu g/m^3$.

VIII. Because Coarse PM Falls Out of the Atmosphere Over Relatively Short Distances, and is a "Local" Pollutant, Central Monitors Do Not Reflect or Even Approximate the Exposure of Residents in Surrounding Communities and Metropolitan Areas, and Thus Cannot Support the Conclusions of Studies That Assume Such Representative and Uniform Exposure.

The case EPA attempts to make in support of a coarse PM standard relies on deposition of coarse PM particles in the lung, toxicology in animals at high concentrations showing mechanisms for health effects at high concentrations, and EPA's assertion that those circumstances make the results of the epidemiological studies it selectively cites in support of its proposed coarse PM standard plausible. EPA recognizes the high spatial variability of coarse PM over short distances and the fact that coarse PM is a local pollutant, but contends that these considerations go only to the "precision" and not to the validity of its conclusions and reliance on the epidemiological studies. 71 Fed. Reg. 2660.

NMA submits that the spatial variability of coarse PM renders even the few, limited, uncertain epidemiological studies that have been cited by EPA invalid, as well as imprecise. Exposure to a local coarse PM source in downtown Indio simply has nothing to do with a patient living several miles away in Palm Springs admitted for a respiratory condition or indeed dying of such a condition. The same is of course true of the studies in Phoenix, Tucson, and Reno/Sparks. The coarse PM measured or modeled in these localities is patently unrepresentative of the population exposure reflected in the hospital admissions studied. Aggravating the unrepresentativeness of the central monitor measurements that serve as the basis for the epidemiological studies is the fact that coarse PM does not penetrate indoors as fine PM does. Indoor exposure constitutes most of human exposure.

IX. Conclusion

For all of the reasons discussed above, NMA submits that there is not a sound or adequate basis for the adoption of a coarse PM standard at this time. It supports the alternative of not adopting a coarse PM standard for ambient exposure. There has never been a valid coarse PM standard in the past, and coarse PM health effects have not been the basis for past controls of fugitive dust. Continued control of fugitive dust from mining operations is not dependent on the adoption of a coarse PM NAAQS. If, however, EPA chooses to implement a coarse PM NAAQS, EPA must exclude coarse PM from agricultural and mining, and of crustal material from similar sources, in order to be consistent with the preponderance of the scientific evidence, and the determinations of EPA, Congress and the Courts concerning these sources since the inception of the Clean Air Act.