

Fontaine, Roslyn B - MSHA

From: Watzman, Bruce [BWatzman@nma.org]
Sent: Monday, June 20, 2011 1:58 PM
To: zzMSHA-Standards - Comments to Fed Reg Group
Subject: RIN 1219-AB64

Attachments: 6-20-11 dust comments.pdf; Exhibit 1.pdf; Exhibit 2.pdf; Exhibit 3.pdf; Exhibit 4.pdf; Exhibit 5.pdf; Exhibit 6.pdf; Exhibit 7.pdf; Exhibit 8.pdf; Exhibit 9.pdf; Exhibit 10.pdf; Exhibit 11.pdf; Exhibit 12.pdf; Exhibit 13.pdf; Exhibit 14.pdf; Exhibit 15.pdf; Exhibit 16.pdf; Exhibit 17.pdf

Dear Ms. Fontaine:

Attached are the comments of the National Mining Association in response to the proposed rule, "Lowering Miner's Exposure to Respirable Coal Mine Dust, including Continuous Personal Dust Monitors.

Sincerely

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June 20, 2011

Ms. Roslyn Fontaine
Acting Director
Office of Standards, Regulations, and Variances
Mine Safety and Health Administration
Office of Standards, Regulations, and Variances
1100 Wilson Boulevard, Room 2350
Arlington, Virginia 22209-3939

Re: **RIN 1219-AB64; Comments on MSHA Proposed Rule for Lowering Miners Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors**

Dear Ms. Fontaine:

The National Mining Association (NMA) offers the following comments to the Mine Safety and Health Administration (MSHA) concerning its proposed rule for Lowering Miners' Exposure to Respirable Coal Mine Dust, 75 Fed. Reg. 64,412 (Oct. 19, 2010). This letter, together with the attached detailed comments and exhibits comprise our comments.

Introduction & Summary

The National Mining Association is the national trade association whose members produce most of the nation's coal, metals and minerals. NMA's membership also includes the manufacturers of mining machinery and equipment. NMA has a long history of engagement in efforts to eliminate lung diseases in miners, including coal workers pneumoconiosis (CWP). We have worked and continue to work with MSHA and others to examine new technologies and techniques to protect miners' health.

We request MSHA to withdraw the proposed rule because it: 1) lacks support in the record and best available science; 2) relies on a selective and non-transparent review of the current science on miners' health; 3) does not address directly the health concerns illuminated in the science; and 4) utilizes a limited and incomplete approach to improving worker health. Our comments include recommendations to improve the existing dust control and sampling program that should be incorporated as part of a new rule making.

I. The Proposed Standard Lacks Support in the Record and is Contrary to the Latest and Best Scientific Evidence

National Institute for Occupational Safety and Health (NIOSH) disease prevalence data, MSHA exposure monitoring data, and the evidence NMA witnesses submitted are clear. Nationally, under current conditions and standards, the incidence of pneumoconiosis among coal workers is declining dramatically and is approaching the background rate pneumoconiosis of general population.(Exhibit 1) Analysis of all available NIOSH data demonstrates that MSHA's contrary position is based on selective, interpreted data and that its regulatory conclusion is wrong. Detailed examination of CDC data demonstrate that predicted cases of CWP are not occurring other than in limited specific areas. (Exhibit 2) This data and a recent study by Dr. Eva Suarhana and her colleagues (Exhibit 3) provide critical information for the design of an effective regulatory strategy not present in the proposed rule. Dr. Suarhana's study reinforces and validates the industry's position that the industry-wide proposed rule is not supported by science and does not meet the statutory requirement that the rule shall be based upon "the latest available scientific data..."

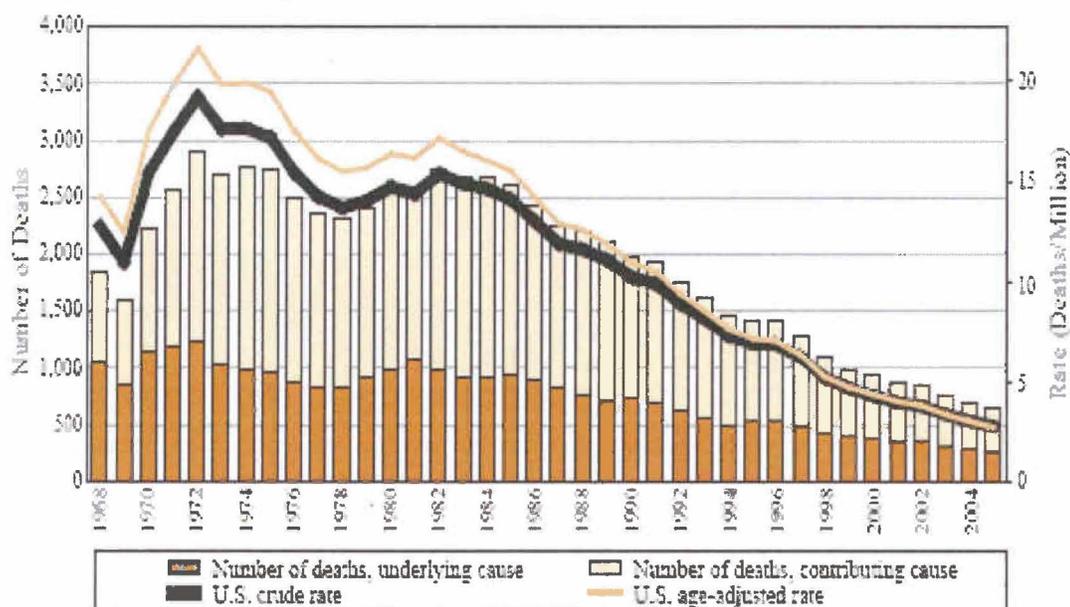
The NIOSH data from the enhanced x-ray surveillance program provide a road map for eradicating CWP by focusing on the limited areas of West Virginia, Kentucky and Virginia where new cases were identified (hot spots) as the underlying reason for the proposed rules. Published data (Exhibit 4) also demonstrate that excessive silica exposure in these limited areas and coal rank, not coal dust exposure nationwide, has led to an isolated increase in cases identified by MSHA, as clearly described by the testimony of Glen and Gamble. Exhibit 5.

The MSHA proposal to universally lower the coal mine dust exposure limit by 50 percent (and more for extended shifts) is not supported by the science as needed to reduce health risk or to provide health benefits. Instead, a focused approach can be designed to address identified problems and solve them. This view was shared by Dr. David Rosenberg, who concluded in his *Evidence Based Review of the Literature Supporting the Mine Safety and Health Administration Proposed Coal Mine Dust Rule* (Exhibit 6) that, "...the need for a dramatic change in the PEL for coal mine dust has not been appropriately documented in a manner that comports with the best science or best epidemiological methodologies or that the proposed reduction will positively impact the health of US miners." See also the comments of the National Mining Association in response to the Centers for Disease Control publication "A Review of Information Published Since 1995 on Coal Mine Dust Exposures and Associated Health Outcomes." (Exhibit 7)

Contrary to its statutory duties to protect against significant risk of material impairment of health with standards based on the latest and best scientific evidence, the proposed rule ignores the source of its identified problem and increases regulation where no risk exists and where no benefit can be expected. As demonstrated in the following chart, deaths from pneumoconiosis continue their historic decline and, absent the questionable phenomenon identified in the "hot spot" area (Exhibit 8), the evidence demonstrates that this decline will continue directly refuting the basis and need for the proposed rule.

Of additional significance, accepting as we do that we must eliminate every case of occupational induced CWP, there must be the recognition that some level of CWP not attributable to workplace exposures will likely be incorrectly deemed as workplace related. Per 2009 CWHSP data, the prevalence of lung disease in miners was below 2.0 percent while the "background prevalence" of opacities in non-exposed populations is 0.21 to 11.7 percent with an overall pooled prevalence (non-exposed) of 5.3 percent. (Exhibit 1) This raises serious questions regarding the scientific basis for and expected benefit of the proposed rule.

Coal workers' pneumoconiosis: Number of deaths, crude and age-adjusted death rates, U.S. residents age 15 and over, 1968–2005



NOTE: See selected limitations for general cautions regarding inferences based on small numbers of deaths, and see appendices for source description, methods, and ICD codes.

SOURCE: National Center for Health Statistics; multiple cause-of-death data. Population estimates from U.S. Census Bureau.

II. The Proposed Rules are Counterproductive to Health Protection

Apart from the lack of support for the lowering of the dust limits nationwide, the proposed rule also fails in several other critical respects. First, the proposal will not improve miners' health. Second, the proposed rule ignores sound, current, transparent science that has been subjected to independent peer review. Third, the

proposed revisions will not restore confidence in the dust sampling program. For these reasons as well, the proposal must be withdrawn.

a. Health Protection Requires Mandatory X-Ray Surveillance

MSHA's proposal to expand the coal miners' medical surveillance program to include spirometry testing fails to fully protect miners because of the agency's decision not to impose a mandatory X-Ray surveillance program for all workers. Experts agree that early diagnosis is the best tool to prevent disease progression. It is the foundation upon which the 30 CFR Part 90 protection program is premised. Unfortunately, participation in the voluntary coal worker's x-ray surveillance program, administered by the National Institute for Occupational Safety and Health, has not succeeded as an early diagnostic screening tool due to the low participation rates. This fact was recognized by current Deputy Assistant Secretary for Mine Safety and Health, Dr. Gregory Wagner, who as a NIOSH employee assisting the members of the 1996 Advisory Committee on the Elimination of Pneumoconiosis among Coal Workers reported "... the voluntary participation rate in the CWXSP was estimated at 20-35 percent during Round 5. **Dr. Wagner indicated that this rate of participation in unsatisfactory...**" (emphasis added) Excluding current workers from mandatory participation in the medical surveillance program eliminates the opportunity for them and their medical providers to work with mine operators to implement intervention measures. History has proven that the CWXSP will remain a failure until such time as the agency requires mandatory participation by all miners.

Moreover, excluding current workers violates Section 101(a)(6)(A) of the Mine Act, which requires MSHA to set standards "which most adequately assure...that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life." It is clearly within MSHA's mandate to impose such a requirement, and the failure to do so completely undermines efforts to understand and address this problem.

b. Health Protection Requires Adoption of "The Hierarchy of Controls"

As described in attached Exhibit 9, "hierarchy of controls" is an accepted industrial hygiene concept and an accepted safety and health practice, adopted by MSHA in other regulations and by OSHA. The protection strategy prefers engineering controls, if feasible, but recognizes administrative controls as acceptable, and reserves the use of respirators for circumstances where engineering and administrative controls are not feasible or able to provide the desired level of protection. The strategy's purpose is to produce health protection in a feasible and effective manner. MSHA's rejection of this time-tested strategy, except for permitting administrative controls for an unnecessarily limited period of time, is counterproductive to miners' health and should be revised to permit operators to utilize the entire suite of controls to protect miners' health.

c. Protection Requires Acceptance Of Personal Engineering Controls

The proposed rule's rejection of the safe, effective use of modern personal engineering controls (PECs), such as filtered air helmets, as a primary protective tool for compliance with dust limits is counterproductive to miners' health. As a result, it violates MSHA's statutory duty to set standards that most adequately assure protection against material impairment of health. The prohibition on the use of filtered air helmets as a primary compliance method stems from older, full face-sealed, respirator technology, considered uncomfortable and thereby unreliable. Not considering advanced, comfortable PECs as "respirators" and denying their effective role as primary compliance controls is illogical and arbitrary.

Moreover, rejecting these engineering controls as a means of compliance also violates the Act's mandates to use the latest scientific evidence and technologically feasible controls. These advanced, comfortable and effective personal engineering controls provide clean air curtains over the person's breathing zone and substitute an integrated multiple protective device for the hard hat, cap light, battery and safety glasses. PECs have been proven fully effective for health protection. As engineered today, PEC technology can be far more effective in many mining applications than continuing decades of costly experiments with attempted mining engineering controls in ever changing mining conditions, as mandated by the MSHA proposal. MSHA's proposed regulation, rejecting PECs as primary controls, is the same approach that led to the health issues that it believes necessitates the proposed rule.

MSHA's own data analysis of current compliance with existing exposure limits in longwall mines demonstrates that even the most advanced engineering on some of the latest, safest and most productive equipment, combined with maximum ventilation cannot achieve compliance under current rules. Person wearable engineering controls achieve protection and maintain the viability of mines challenged by dust control. Where these PECs can be used, they represent the latest, most effective, best and cost effective protection methods. MSHA's rejection of these advanced devices is counterproductive to achieving the goal of protecting miners. MSHA should reevaluate its position on this issue and include as part of a new rule, provisions that recognize and encourage PECs whenever these devices are feasible.

III. Accurate Sampling Is Critical, but the Rule Relies upon a Device that Does Not Provide Accurate Results

The MSHA coal dust limits are based on British research that measured the effect of "respirable" dust on lung disease risk. Respirable dust is dust of a particular size that can enter the lungs and cause harm. Gaining the ability to measure that dust, and thereby design methods to limit its adverse impact on miners, has been one of the great success stories in the field of occupational health. For that reason, Congress mandated that MSHA coal dust limits and enforcement be based on

“accurate” coal dust sampling. The proposed rule, however, fails to achieve this goal. In fact, the proposal mandates dust sampling procedures that will increase errors in sampling results and sacrifice “accurate” results to administrative convenience.

The testimony of NMA witnesses demonstrates that the mandated new sampling device, while helpful to provide an instantaneous indicator of relative dust levels needs additional development to assure it can provide accurate results. Side-by-side samples collected in coal mines varied greatly, and we support more field testing before adopting the continuous personal dust monitor (CPDM) as the industry compliance tool. Under any circumstance, the CPDM was never intended to be used as a single-shift compliance device, and this approach should be scrapped in its entirety. The proposed rule’s sampling mandates will create a massive false enforcement problem, without any benefits, and with substantial adverse impacts on underground coal mining, as shown by the NMA testimony. (Exhibit 10)

In public hearing testimony, both the United Mine Workers of America (UMWA) and NMA suggested that the new sampling technology (CPDM) be tested extensively in the mines before developing a proposal for its use for enforcement. Specifically, the UMWA suggested that “MSHA move forward with the use of the CPDM to gather true sample readings of what miners are being exposed to today with the current extended work shifts and various coal seams before we actually determine what is protective and what can be realistically achieved.”¹ MSHA must withdraw the proposal and re-propose a new rule after widespread testing of the CPDM is conducted.

IV. Other Substantive and Procedural Flaws Require a New Proposed Rule

Our detailed comments and those of our experts, submitted for the record with this summary and in our public hearing testimony, set forth a series of additional rulemaking failures that result in a proposal that does not serve the goal of protecting miners’ health. Among the flaws leading to this result and providing guidance for the steps needed to prepare a new rulemaking, are:

- 1) The failure to conduct congressionally-mandated joint rulemaking with NIOSH to support a finding that single-shift samples provide accurate results;
- 2) The failure to realistically evaluate the technological and economic feasibility of the new exposure limits, the new sampler, single-shift sampling, and other proposals such as those that will prohibit the continued use of accepted and safe mining/ventilation practices, i.e. eliminating “super sections.” (Exhibit 11);

¹ See Transcript Proceedings in the December 7, 2010 hearing in Beckley, West Virginia, (Beck. Tr.) at 54 (emphasis added). A copy of the transcript is available at: <http://www.msha.gov?REGS/Comments/2010-25249/Transcripts/20101207BeckleyWV.pdf>

- 3) The failure to determine the true costs and benefits of the proposed rule and the incorrect certification of its lack of a significant impact; and
- 4) The failure to consider alternatives, identify and address shortcomings of the existing program to improve miners' health while reducing burdens.

V. Confidence in Health Protection Must Be Achieved With a New Rulemaking That More Effectively Addresses Miners' Health

Unfortunately, confidence in coal mine dust sampling, and the regulatory system for the protection of miners' health, will not be restored by the proposed rules. These proposals continue a legacy of rejected agency actions to achieve illogical results, contradicted by sound science and demonstrated to be neither technologically nor economically feasible. Without properly evaluating the need for and benefits of the proposals or their impact and feasibility, the agency proposed the use of a new sampler, a substantially reduced dust exposure limit, a new single-shift compliance determination, and a new series of operating mandates.

MSHA must revoke this arbitrary proposal. A new rulemaking should then be evaluated to include:

- Mandates for X-ray surveillance for all current miners;
- A focused, consensus-based silica emphasis program for the "hot spots" with suspected increased disease risks;
- Acceptance of the hierarchy of controls concept, permitting the use of administrative controls to protect miners' health;
- Recognition, acceptance and encouragement of personal engineering controls, such as clean air helmets for protection and compliance;
- Further testing, development and improvement of the new instantaneous dust sampler before its use is mandated as a compliance tool; and
- Changes to existing sampling procedures to ensure that samples better represent miner's exposures. (Exhibit 17)

Again, we request the agency to withdraw the proposal. NMA stands ready to participate in a dialogue with all stakeholders to develop a more effective program for protecting miners.

Sincerely,



Bruce Watzman

ADDITIONAL & DETAILED COMMENTS

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I. The Proposed Regulatory Changes Are Not Based On A Significant Risk, Do Not Provide Significant Benefits, And Are Not Based on the Best and Latest Scientific Evidence

The Federal Mine Safety and Health Act of 1977, as amended (Mine Act), requires that the promulgation of a revised health standard cannot reduce protection and must be based on the identification of hazards and the quantification of risks and benefits, *i.e.* a determination of whether working lifetime exposures to the hazards are significant enough to cause miners to "suffer material impairment of health or functional capacity." Section 101)(a)(6)(A)

In describing a "significant risk", the majority of the Supreme Court in *Indus. Union Dept., AFL-CIO v. Petroleum Inst.*, 448 U.S. 607 (1980) held that "the burden [is] on the Agency [OSHA] to show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to [an air contaminant at a specific concentration level] presents a significant risk of material health impairment." *Id.* at 653

The majority of the Court held that, "...before [the Secretary] can promulgate *any* permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe – in the sense that significant risks are present and can be eliminated or lessened by a change in practices." (emphasis in original) *Id.* at 642. Initially, we fundamentally disagree with the basis for the MSHA determination of "risk:"

[b]ased on recent data from the National Institute for Occupational Safety and Health (NIOSH), the prevalence rate of black lung is increasing in our nation's coal miners.

75 Fed. Reg. at 64413.

The latest and best scientific evidence, reviewed by NMA experts in reports attached to these comments and made a part hereof, overwhelmingly demonstrates that there are neither risks nor benefits to support the proposal's massive and burdensome industry-wide changes to the dust regulations.

a) The Purported Basis for the New Standard is Not Supported by the Latest and Best Scientific Evidence

MSHA asserts that the current standard is not sufficiently protective to prevent coal miners from developing Coal Worker's Pneumoconiosis (CWP) and Chronic Obstructive Pulmonary Disease (COPD), which includes emphysema and chronic bronchitis. According to MSHA, its proposal is based on three data sources:

- A 1995 NIOSH criteria document on health effects of coal mine dust;
- A NIOSH report on studies published since 1995; and
- Medical surveillance studies of coal miners.

The 1995 NIOSH criteria document is outdated and not reliable for use in rulemaking. Moreover, no NIOSH criteria document has ever been adopted by MSHA or OSHA, due to NIOSH's historical zero risk philosophy and lack of realistic feasibility determinations. It simply does not constitute the best and latest scientific evidence and research that MSHA is required to use as the basis for new standards. For example, the NIOSH (and MSHA) conclusions do not consider the 2007 HHS Work Related Lung Disease Surveillance Report, and updates to the report, nor the years of data that should have been analyzed for this rulemaking. Instead, MSHA makes these assumptions to reach inaccurate risk/benefit conclusions:

- After a long period of declining CWP, prevalence is rising;
- Miners are developing severe CWP at relatively young ages;
- Early CWP development is manifested as premature mortality;
- CWP increase is concentrated in "hot spots" in southern West Virginia, eastern Kentucky, and western Virginia;
- The cause of this resurgence in disease is likely multifactorial and includes:
 - Excess exposure to crystalline silica;
 - The mining of higher rank coal;
 - Excess exposure to coal mine dust, both in intensity and duration;
 - Longer working hours; and
 - Insufficient dust control at some mines.

A thorough examination illustrates that MSHA has misinterpreted the underlying science, failed to consider the latest available scientific data as required under §101(a)(6)(A) of the Mine Act and unlawfully proposes a new compliance system, without having met its statutory requirements.

MSHA's rationale for lowering the permissible exposure level for coal mine dust is that in the past decade there have been reports of a slight increase in the prevalence of (CWP) and cases, as reported by the Center for Disease Control, National Institute for Occupational Safety and Health of Rapidly Progressive Coal Workers Pneumoconiosis. MSHA suggests that this is occurring in younger miners and also in miners that have been exposed to respirable coal dust for a shorter duration. Based on NIOSH studies, MSHA has determined that new exposure response estimates predict an increased occurrence of CWP at various cumulative

exposure levels and that the risk is greater than previously indicated. MSHA is wrong. Unfortunately, the agency analyzed only part of the NIOSH data, omitting the latest scientific data (required to be considered by the Mine Act), and improperly interpreted its selective data, ignoring the "best" scientific evidence mandated for rulemaking. (Exhibit 12)

NIOSH – RPCWP Studies

Beginning in the mid-1990s, NIOSH identified an increase in more severe cases of CWP. The change in prevalence and severity (onset of disease) was identified as a sentinel health event and was described as Rapid Progression Coal Workers Pneumoconiosis (RPCWP). An initial study of the increase in RPCWP cases was conducted in two counties in western Virginia, Wise and Lee County, and reported in the Morbidity Mortality Weekly Reporter, a CDC publication.² The study's authors proposed several hypotheses as the cause for their observations: (1) the coal mine dust standard is too high; (2) dust levels are actually above the MSHA standard; and (3) silica might be a contributing factor. NIOSH's continued examination of this phenomenon identified a cluster of cases in the southern Appalachian region of western Virginia, southern West Virginia, and eastern Kentucky.

Looking closely at the NIOSH data, a hypothesis can be drawn that silica exposure is causing the noted incidents of disease but even that generalization is of questionable validity (Exhibit 8). Coal mine dust levels in those two counties were, on average, below the permissible standard from 1972 to 2005 and were, on average; below the NIOSH recommended exposure limit (1 mg/m³) since 1995. Thus, long-term exposure to concentrations of coal dust in excess of the PEL were likely not the cause of the RPCWP. As described by Glenn (Exhibit 5) and Hall (Exhibit 16) the observed RPCWP cases were more characteristic of silicosis than CWP and are associated with R-type opacities on the chest radiograph. The ILO classification for chest films for the pneumoconiosis defines two shape factors of rounded opacities and irregular opacities. Rounded opacities are more consistent with an etiology of coal dust or silica whereas irregular opacities are more consistent with a fiber exposure such as asbestos. NIOSH has determined from pathology studies that R-type opacities are more frequently seen with silicosis.

For the southern Appalachian region, the prevalence of both R-type opacities and progressive massive fibrosis increased with each decade that was examined. The effect of this increase is particularly pronounced in mines with fewer than 50 miners. The evidence is convincing that increased quartz exposure is an important, if not the explanatory factor, in these cases of RPCWP.

This conclusion becomes even more likely when considered in light of the silica samples collected by MSHA indicating concentration levels above the 0.1 mg/m³ silica standard during this same timeframe. In light of this, it is likely that silica is the major factor in the prevalence of RPCWP in southern Appalachia. Perhaps, most importantly, the study most relied on by MSHA, *Rapidly progressive coal*

² VC Antao, EL Petsonk & MD Attfield, *Advanced Cases of Coal Workers' Pneumoconiosis -- Two Counties, Virginia, 2006*, MORBIDITY MORTALITY WEEKLY REPORTER 55(33):910-912 (Aug. 25, 2006).

workers' pneumoconiosis in the United States; geographic clustering and other factors, (Antao 2005) concluded:

Although the prevalence of CWP is declining in the USA, severe and rapidly progressive cases of the disease continue to occur among young miners. Cases of rapidly progressive CWP appear to be clustered in eastern Kentucky and western Virginia.

(Emphasis added.)

A more recent study (Exhibit 4), examining disease prevalence in the "hot spot" areas concluded that:

The increasing prevalence of pneumoconiosis ... and the change in the epidemiology and disease profile documented in this and other recent studies implies that coal miners are being exposed to excessive amounts of respirable crystalline silica.

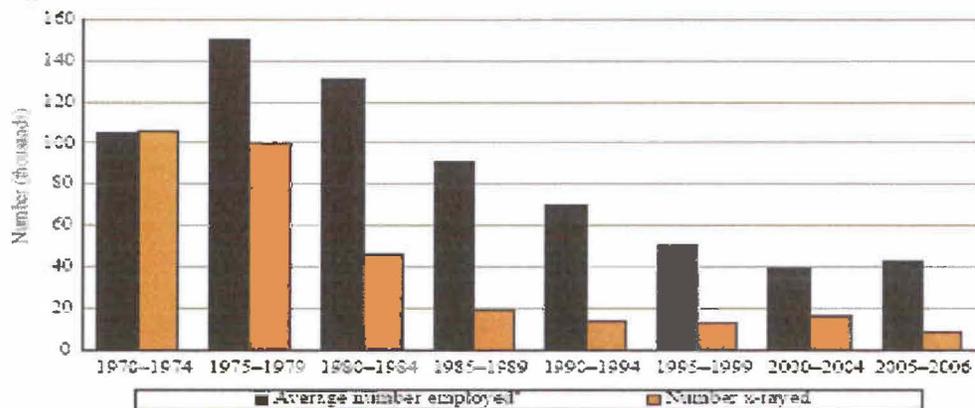
(Emphasis added.)

Compelling evidence indicates that the cases of rapidly progressive pneumoconiosis reported by MSHA to support its proposed rules are coal rank and silicosis related, not prevalent throughout the industry, but rather occurring in a limited geographic area under specific silica exposure conditions.

MSHA Reliance on Suspect Science to Support Its Conclusions

Since the early 1970's NIOSH has overseen a voluntary x-ray surveillance program intended to provide a database from which disease prevalence determinations can be made. Unfortunately, as demonstrated below, the program has been hampered by an extremely low participation rate resulting in questions regarding selection bias. This has resulted in concerns being raised regarding the representativeness of those participating compared to the miner population as a whole. Consequently, to the extent MSHA justifies its risk conclusions on NIOSH x-ray studies; they represent only a small snapshot of the health status of a few miners and are not representative of the entire miner population and do not support the proposed massive regulatory changes.

Figure 2-5. CWXSP: Estimated number of actively employed workers at underground mines and number of miners examined, 1970–2006



* Average number employed during the period, based upon quarterly reports by coal mine operators to the Mine Safety and Health Administration (MSHA). Because of hiring and layoffs, the total number of individuals who worked at underground mines in any period exceeds the average employment.

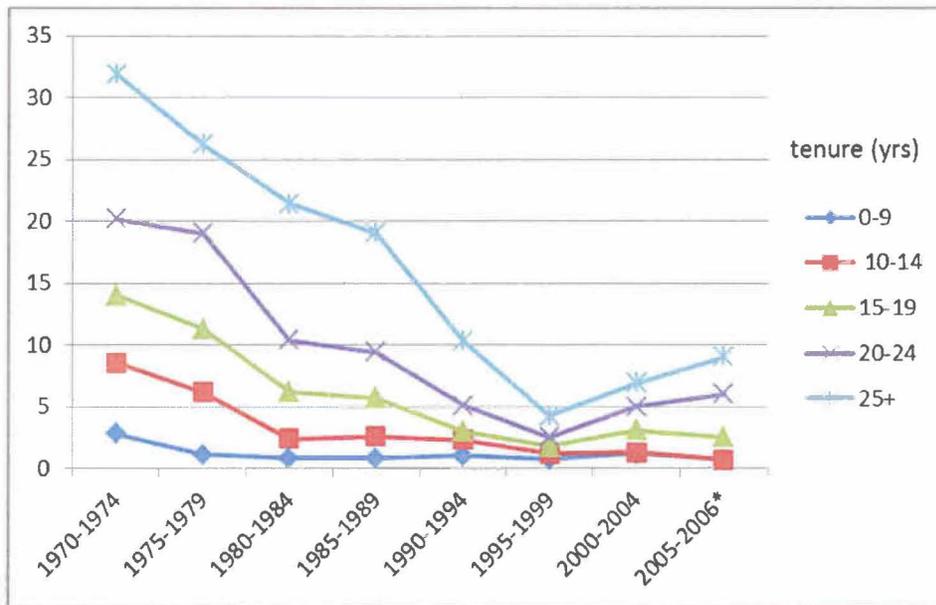
NOTE: See appendices for source description and methods.

SOURCE: NIOSH Coal Workers' X-ray Surveillance Program (CWXSP), MSHA coal mine employment data.

Second, as explained by former high ranking NIOSH officials testifying at the public hearings as expert witnesses, Gamble and Glen, the studies relied on by MSHA do not adequately consider exposure-response relationships in explaining lung disease. Credible exposure-response studies must be used to determine the thresholds for the onset of disease. Yet, exposures were underestimated in the NIOSH studies relied upon by MSHA, which therefore overestimate disease risk at lower exposure levels. For example, the studies relied upon include miners exposed prior to 1970, when coal mine dust levels were much higher than current exposures, resulting from new equipment and current regulations in place over the last 40 years.

Moreover, the latest and best scientific evidence and risk assessment procedures recognize the role of very high exposures in creating disease risk, as described by the expert testimony of Dr. Anthony Cox. (Exhibit 12 and 16) The MSHA analysis ignores this critical risk assessment concept and thereby assigns risk to very low exposures that do not exist. This is exemplified by the MSHA risk analysis proving a four-fold risk increase of disease for zero exposure, as described by Dr. Cox in his testimony.

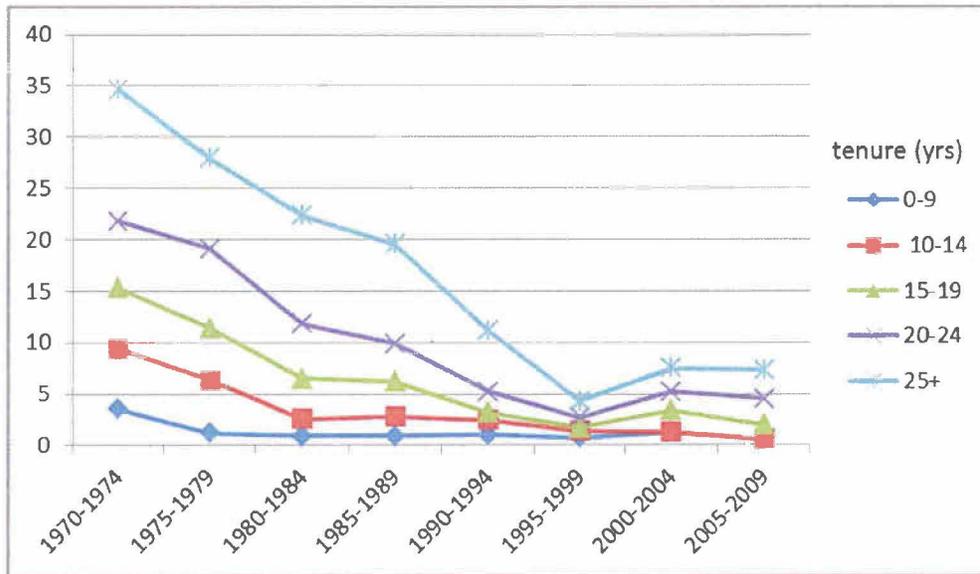
Third, MSHA's selective use of data is not justified. The chart below, proffered by MSHA as proof of increasing disease risk, is misleading and not based on "the latest available scientific data." It eliminates both the long term trend shown above by decades of CDC data, and the data collected over the last four years:



Source: NIOSH World Report, 2007

A more robust analysis, (Exhibit 13) and as demonstrated in the following charts, using available NIOSH data, indicates that CWP prevalence trends have reversed in

all age groups and are heading downward, as they were for the last thirty years. Taken together these, in and of themselves: (1) invalidate MSHA's premise for the rule; (2) demonstrate the agency's failure to comply with its statutory obligations as required in § 101 (a)(6)(A); and (3) are sufficient to require that the proposed rule be withdrawn.



Source: NIOSH CWHSP Data Query System, 2011

MSHA's analysis and characterization of prevalence of CWP suffers from three fundamental flaws, each of which is shown below:

- The agency has ignored, as shown below, the "hot spot" effect on prevalence;

The First Problem: A “Hot Spot” Focus in 2006 Enhanced Coal Workers’ Health Surveillance Program (ECWHSP)

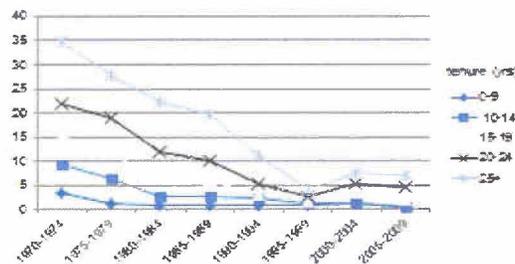
MSHA district	year	# of days	# of miners employed	disease prevalence (%)
01	2006	58	32	10
02	2007	687	4150	2
03	2008	1693	4122	2
04	2007	1677	7072	7
05	2006	649	2456	8
06	2006	379	3740	13
07	2006	442	2562	8
08	2007	707	1928	3
09	2007	808	3833	3
010	2009	242	1770	2
011	2007	637	2198	2

- Early phases of program targeted Central Appalachian “hot-spot” areas where regional clusters of rapidly progressive cases of disease have been observed.
- District 5 (Southwest VA), District 6 (Eastern KY) and District 7 (Southeast KY) surveyed in 2006.
- 2005-2006 period influenced by ECWHSP focus on Central Appalachian region in 2006 and is not representative of the entire mining industry.



- The MSHA analysis excludes the results of x-ray data collected and analyzed from 2007-2009

The Second Problem: Data from 2007-2009 was Excluded Percentage of Examined Miners with CWP (category 1/0+) by Tenure in Mining, (1970-2009)

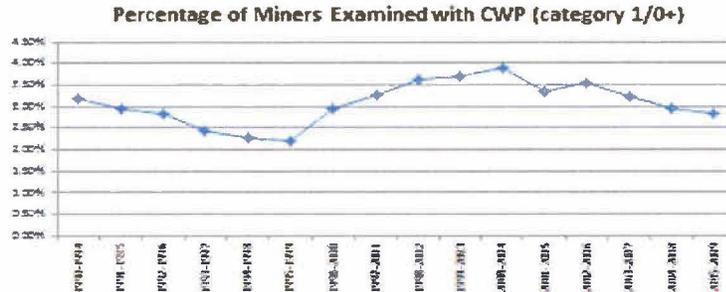


- Chart created using NIOSH Coal Workers’ Health Surveillance Program (CWHSP) Data Query System. NIOSH released summary data on February 22, 2011, but continues to refuse to release the complete data-set despite FOIA requests.
- Presents decreasing trend in CWP prevalence since 2000.
- 2005-2009 reported as a full period; reduces influence of Central Appalachian region from 2006 ECWHSP.



- Methodology changes starting in 2000, including an almost doubling of the number of x-rays performed, produced a significant year over year increase of prevalence in the Coal Worker Health Surveillance Program Data Set.

The Third Problem: Methodology Change in 2000 Percentage of Examined Miners with CWP (category 1/0+) by Five Year Period (1990-2009)

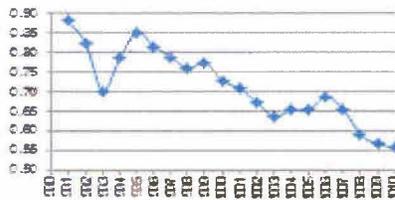


- Miners across the country are generally offered x-rays in five year cycles.
- Examination of 5 year periods reveals a significant year over year increase in 2000. The change in 2000 affects results over a 5 year period.

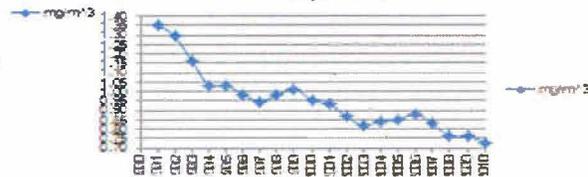


No Correlation Between Dust Exposure and Lung Disease Prevalence

Avg Dust Concentrations; All Occupation Codes



Avg Dust Concentrations; Occupation Code 36 - CM Operator



- Concentrations of respirable coal mine dust, as measured by MSHA and operators, have steadily declined since 1995.



Lastly, as shown above, MSHA and operator sampling data demonstrate a 39 percent reduction in exposures in the last two decades, and a 13 percent reduction since 2006. Without any regulatory changes, MSHA can safely predict that the long-term trend of improving conditions will continue, as will the trend of declining incidents of coal workers disease and mortality.

II. The Latest MSHA Proposed Single Shift Sample Accuracy Finding is Again Contrary to Statutory Mandates and Would Reduce Protection

a) Single-Shift Sampling Finding Lacks Authority or Justification.

Section 202(b)(2) of the Mine Act requires coal mine operators to “continuously maintain the average concentration of respirable dust in the mine atmosphere during each shift ... at or below 2.0 milligrams of respirable dust per cubic meter of air.” 30 U.S.C. § 842(b)(2). The Mine Act goes on to define “average concentration” as:

a determination which accurately represents the atmospheric conditions with regard to respirable dust to which each miner in the active workings of a mine is exposed (1) as measured, during the 18 month period following the date of enactment of this Act, over a number of continuous production shifts to be determined by the Secretary and the Secretary of Health, Education, and Welfare, and (2) as measured thereafter, over a single shift only, unless the Secretary and the Secretary of Health, Education, and Welfare ***find, in accordance with the provisions of section 101 of this Act, that such single shift measurement will not, after applying valid statistical techniques to such measurement, accurately represent*** such atmospheric conditions during such shift.

Id. § 842(f) (emphasis added)

On July 17, 1971, MSHA’s predecessor issued a proposed “Notice of Finding That Single Shift Measurements of Respirable Dust Will Not Accurately Represent Atmospheric Conditions During Such Shift.” 36 Fed. Reg. 13286. Issued jointly by the Secretary of the Interior and the Secretary of Health, Education, and Welfare, the notice stated that pursuant to Section 101 of the Federal Coal Mine Health and Safety Act of 1969, the Secretaries were planning to jointly issue a proposed notice of finding “that single shift measurement of respirable dust will not, after applying valid statistical techniques to such measurement, accurately represent the atmospheric conditions to which the miner is continuously exposed.” *Id.* Accordingly, the proposed finding would alter the definition of “average concentration” found in Section 202(f) of the Coal Act.³

³ “Section 202(f) of the Mine Act is taken essentially verbatim from § 202(f) of the Coal Act.” *MSHA v. Excel Mining LLC*, 334 F.3d 1, 4 (D.C. Cir. 2003). “Pursuant to Mine Act § 301(b)(1) and (c)(2), all

On February 23, 1972, the agencies issued their "Notice of Finding That a Single Shift Measurements of Respirable Dust Will Not Accurately Represent Atmospheric Conditions During Such Shift" (the 1972 Joint Finding). 37 Fed. Reg. 3833. Concluding that their statistical technique was valid and that their data was accurate and supported the finding, the Secretaries adopted the finding that "a measurement of respirable dust over a single shift only, will not, after applying valid statistical techniques to such measurement, accurately represent the atmospheric conditions to which the miner under consideration is continuously exposed." *Id.* at 3834. NMA's response to the Finding included an expert review conducted by Sciences International, Inc. that raised serious questions regarding the agencies statistical methodologies concluding, among other things, that agencies actions will "lead to decisions of non-compliance when the samples actually demonstrate compliance with the respirable dust standard." (Exhibit 14)

MSHA twice attempted to overturn the 1972 Joint Finding without proper rulemaking and was rebuffed by the courts each time. In 1991, MSHA instituted a spot inspection program. Under the program, if a mine's multiple, single-shift samples average did not exceed the respirable dust standard, the inspector would review the single, full-shift samples. If any of the single, full-shift samples exceeded the standard by an amount determined by MSHA, the operator was issued a citation for noncompliance. 75 Fed. Reg. at 64414 (Oct. 19, 2010). This practice was challenged and ultimately terminated following the Commission's decision in *MSHA v. Keystone Coal Mining Corp.*, 16 FMSHRC 6 (Jan. 4, 1994), rejecting the MSHA single shift enforcement efforts. Ruling in favor of the mine operator, the Commission concluded that the 1972 Joint Finding remained in full force and effect, and that the attempt to rescind the Joint Finding was improper because the rescission was not undertaken through formal rulemaking. *Id.* at 12. The Commission rejected an MSHA argument that rulemaking was not necessary to rescind the 1972 Finding, by holding that "Congress's evident intent, that [a finding rejecting single-shift sampling] be made in accordance with notice-and-comment rulemaking, bespeaks an equal intent that, once such a finding is made, it may be **rescinded only through the same formal process.**" *Id.* at 13 (citation omitted, emphasis added).

Rebuffed by *Keystone*, but still determined to rescind the 1972 Joint Finding, MSHA and the Secretary of Health and Human Services ("HHS")⁴ jointly published a notice stating their plan to rescind the 1972 Joint Finding. 59 Fed. Reg. 8357 (Feb. 18, 1994) (the proposed joint notice). Concurrently, MSHA issued a notice announcing its "intention to use single, full-shift respirable dust measurements" for compliance purposes. 59 Fed. Reg. 8356 (Feb. 18, 1994). Public comment on the notices, originally slated to conclude on April 19, 1994, was extended several times. 59 Fed. Reg. 16958 (Apr. 8, 1994); 59 Fed. Reg. 29348 (June 6, 1994); 59 Fed. Reg.

standards, decisions, determinations, and regulations issued under the Coal Act remain in effect under the Mine Act until modified or set aside." *Id.* (citing 30 U.S.C. § 961(b)(1), (c)(2)).

⁴ The Department of Health, Education, and Welfare split into the Department of Education and the Department of Health and Human Services in 1979.

38988 (Aug. 1, 1994). Additionally, MSHA and NIOSH⁵ held two public hearings on the proposed joint notice. 59 Fed. Reg. 29348. Following the hearings, the agencies supplemented the record and again extended the comment period until November 30, 1994. 59 Fed. Reg. 50007 (Sept. 30, 1994). Determining, based on comments submitted and other information on the record, that the term “accurately represents,” as used in Section 202(f) of the Mine Act needed to be defined, the agencies reopened the record “to submit a definition of accuracy, [and] to supply new data and statistical analyses on the precision of coal mine respirable dust measurements obtained using approved sampling equipment...” 61 Fed. Reg. 10012 (Mar. 12, 1996).⁶ In light of the new definition and information, the comment period was reopened, originally until April 11, 1996, but was extended until June 10, 1996, and two more hearings were held. 61 Fed. Reg. 16123 (Apr. 11, 1996).

Notably, commenters raised concerns about the procedures used by the agencies in rescinding the 1972 Joint Finding and instituting a new finding permitting single-shift sampling. The commenters asserted that such action could only be taken through notice and comment rulemaking. 63 Fed. Reg. 5669 (Feb. 3, 1998). Despite these procedural concerns, MSHA and HHS determined that their actions were consistent with the requirements of Section 202(f) – “[b]ecause this is not a mandatory safety and health standard, there is no need for the Secretaries to publish the finding as a proposed rule, or to address feasibility, for example, which would be required under section 101(a)(6)(A) when a mandatory safety or health standard is promulgated.” *Id.* MSHA and HHS jointly published their “Final notice of joint finding” (the New Finding) on February 3, 1998, purporting to rescind the 1972 Joint Finding. *Id.* at 5664.

The National Mining Association and the Alabama Coal Association, petitioned the 11th Circuit Court of Appeals to review the New Finding. *Nat’l Mining Assoc. v. Secretary of Labor*, 153 F.3d 1264 (11th Cir. 1998). In vacating the New Finding, the court first concluded that despite the agencies’ conclusion to the contrary, the “[u]se of single-shift measurements by MSHA is ... an ‘improved mandatory health standard’” and therefore must be promulgated in accordance with Section 101 of the Mine Act, 30 U.S.C. § 811. *Id.* at 1268 (citing *United Mine Workers v. Dole*, 870 F.2d 662, 671 (D.C. Cir. 1989) (emphasis in original)).

30 U.S.C. § 811 “requires notice, the opportunity for public comment, public hearings if requested, and final publication in the Federal Register.” *Id.* However, MSHA must also comply with the requirements of § 811(a)(6), which require it to demonstrate that the new standard: “(a) adequately assures that no miner will suffer a material impairment of health, on the basis of the best available evidence; (b) uses the latest available scientific data in the field; (c) is feasible; and (d) is based on experience gained under the Mine Act and other health and safety laws.”

⁵ The National Institute for Occupational Safety and Health is a part of the Centers for Disease Control and Prevention, which is within HHS.

⁶ The agency proposed application of the NIOSH Accuracy Criterion, which provides that to be considered “accurate,” “sampling and analytical methods need to produce results that fall within 25% of the true value 95 times out of 100.” 75 Fed. Reg. 64447 (Oct. 19, 2010).

Nat'l Mining Assoc., 152 F. 3d at 1269. Holding that the rulemaking record contained no finding of feasibility, the court vacated the New Finding. *Id.*

In response to the 11th Circuit's holding, on July 7, 2000, MSHA and HHS jointly instituted a rulemaking action (the "2000 Proposed Finding") that again proposed rescinding the 1972 Joint Finding and instead finding "that the average concentration of respirable dust to which each miner in the active workings of a coal mine is exposed can be accurately measured over a single shift." 65 Fed. Reg. 42068 (Jul. 7, 2000). A series of public hearings was held on the 2000 Proposed Finding and the comment period was extended until September 8, 2000. 65 Fed. Reg. 49215 (Aug. 11, 2000).

In 2003, three years after close of the comment period, the agencies reopened the record for the 2000 Proposed Finding to allow interested parties an additional opportunity for comment. 68 Fed. Reg. 10940 (Mar. 6, 2003). The comment period was extended once until July 7, 2003 (68 Fed. Reg. 32005 (May 29, 2003)), and additional hearings were held. In August 2003, the record was reopened and extended indefinitely to "obtain further information on Personal Dust Monitors (PDMs), a new technology which is currently being tested by NIOSH." 68 Fed. Reg. 47886 (Aug. 12, 2003).⁷ The 2000 joint rulemaking Proposed Finding continues in its dormant state today.

b) MSHA's Current Single Shift Accuracy Finding Violates The Mine Act

On October 19, 2010, MSHA alone issued its proposed rule for "Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors." 75 Fed. Reg. 64412 (Oct. 19, 2010)⁸. The proposal incorporated numerous prior rulemaking actions that were never completed, including the 2000 Proposed Finding. Through this October 2010 rulemaking, MSHA again attempts to rescind the 1972 Joint Finding, but this time does so without the involvement of NIOSH. The current rulemaking fails to comply with the requirements of the Mine Act and the Administrative Procedures Act, 5 U.S.C. § 501 *et seq.* (APA) because:

- The proposed finding is by MSHA alone, without HHS, as required by §202(f) of the Mine Act;
- The proposed finding is not based on the best or latest data and science;
- Neither a significant risk of material impairment of health nor a significant benefit support the proposal;

⁷ MSHA and NIOSH jointly published a final rule revising approval requirements for coal mine dust personal samplers in 2010. 75 Fed. Reg. 17512 (Apr. 6, 2010).

⁸ MSHA's previous rulemaking attempts to rescind the 1972 Joint Finding were joint efforts with HHS. However, based upon the absence of any mention of HHS joining in this proposal in the MSHA federal register notice of the proposed rule, as well as the absence of any proposed finding in HHS's unified regulatory agenda, this proposed finding is not a regulatory action by HHS. Executive Order 12866, issued by President Clinton on September 30, 1993, requires each agency to "prepare an agenda of all regulations under development or review" 58 Fed. Reg. 51738

- MSHA's use of dormant rulemaking and stale data is arbitrary and capricious;
- MSHA failed to analyze alternatives to the proposed finding; and
- MSHA did not properly analyze the feasibility of the proposed finding.

Failure to conduct a joint rulemaking with HHS/NIOSH, and to allow the rulemaking and the interested parties to be informed by NIOSH expertise, violates the APA and the Mine Act. The critical role of NIOSH previously was recognized by MSHA when the agencies reopened the record "to ... supply new data and statistical analyses on the precision of coal mine respirable dust measurements obtained using [the old] approved sampling equipment." 61 Fed. Reg. 10012 (Mar. 12, 1996). The current solo MSHA proposed rule/finding seeks to mandate single shift sampling, and a new sampling device that did not exist in 1996 or 2000, during NIOSH's last rulemaking efforts.

NIOSH's absence from this rulemaking renders the solo MSHA finding and proposed rule scientifically suspect and legally invalid. The rulemaking and its proposed finding should be withdrawn.

c) The Scientific Evidence Contradicts the Proposed Finding

The latest and best science and data should have resulted from a simple, but extensive MSHA test of the proposed dust samplers to determine their mine worthiness and accuracy. While MSHA was faulted for not conducting such tests prior to this rulemaking, by industry and the UMWA, NMA representatives presented their own evidence conclusively demonstrating the inaccuracy of single shift sampling results. Almost 1000 "side by side" samples were collected by Alliance Coal that demonstrated single-shift sample variability.

Alliance CPDM Program

Date	Cass #	CMDPSU	CPDM	Difference	Abs. Difference	% Difference
6/3/2010	51091032	0.61	0.403	0.207	0.207	33.93%
7/21/2010	51079248	0.849	1.052	-0.203	0.203	23.91%
9/15/2010	51090008	1.049	2.038	-0.989	0.989	94.28%
9/28/2010	51087242	2.141	1.13	1.011	1.011	47.22%
10/8/2010	51094423	0.547	1.058	-0.511	0.511	93.42%
12/1/2010	510943391	1.216	0.710	0.506	0.506	41.61%
Average				0.035	0.571	55.73%

Due to + / - the average does not reflect the difference between individual CMDPSU and CPDM samples.

By taking the absolute value of the difference, a better measure of the variability in individual samples is given.

- **This is sample data taken from over 955 data points.**

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Alliance CPDM Results

- **NIOSH Accuracy Definition**
 - **Accurate within 25% of actual concentration 95% of the time**
- **Actual Performance Data**
 - **554 Samples (58%) within 25% of CMDPSU**
 - **401 Samples (42%) greater than 25% of CMDPSU**
- **CMDPSU and CPDM Fail NIOSH Accuracy Definition**
- **CMDPSU and CPDM Fail Common Definition of Accuracy And Can Not Meet The Mine Act's Required Finding Of Accurate Single Shift Sample Results**

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In contrast, MSHA's limited analysis of accuracy for both the single shift sample finding and the accuracy and feasibility of the new sampler, seek to support the proposal by comparing the averages of multiple samples, thereby "smoothing" errors and variability.

To declare single shift sample results accurate, MSHA had to go beyond reinventing the English language by re-defining the term "accurate" ($\pm 25\%$ of the true value, 95% of the time), and smoothing the data by comparing average results. It ignored the accepted scientific concept of calculating the impact of compounding errors. MSHA did not analyze or consider the significant errors associated with silica analysis on its accuracy finding, even though it reduces its coal mine dust standard for silica content, significantly impacting coal mine dust sampling accuracy. Similarly, MSHA did not evaluate increased errors and inaccuracy at the proposed lower levels of variable coal dust PELs, mandated by the proposed adjustment for shift lengths, nor the proposed silica content PEL reduction adjustment. Nor did MSHA analyze its accuracy finding at the lower levels of coal mine dust reported by current MSHA sampling data, acknowledged by the scientific literature to create greater levels of measurement inaccuracy than higher levels. And, as demonstrated by the analysis of Industrial Hygiene Specialty Resources (Exhibit 14), MSHA improperly calculated the MRE equivalency of the new sampler, and proposes to adopt area sampling, both of which adversely impact the accuracy of single shift samples for representing miner exposure.

Finally, MSHA relies on NIOSH Reports RI 9663 and RI 9669 to declare the accuracy and precision of the new sampler. RI 9663 states:

"The accuracy and precision were calculated from the data pairs of individual PDM mass measurements to the average gravimetric reference standard....the average value for triplicate gravimetric reference mass..." The individual concentration ratios were then averaged over all laboratory data..." Bias was then calculated based on the mean concentration minus one..." RI 9663 at 7-8.

RI 9669 states:

The mass collected by the samplers in each time group was used to determine the average reference gravimetric dust massIn addition there were three blank control filters for each test...Final test filter weights were corrected using the average control filter mass change." RI-9669 at 12.

It must be recognized that these averages and corrections for control filters are not related to the reality of the accuracy or precision of the samplers since the samplers are not used in triplicate nor do they subtract the weight gain of three control filters before reporting results. The accuracy, precision and bias calculations relied upon by MSHA are false, based on how they were determined, and proven false by the Alliance side by side analysis that sets forth actual accuracy and precision data.

d) Mandating Single Sample Compliance Determinations Will Reduce Miner Protection, and is Not Based on Mine Act § 101 Mandates

Dust sample results from the current and proposed sampler are only estimates of actual dust exposures, dependent on the performance of the sampler, the impact of the conditions under which the sample is collected, and the accuracy of the analysis and weighing of the collected sample. There can be no doubt that accurate dust

sampling results are important in evaluating health risks and taking protective actions when necessary, underlying the Congressional mandate for the use of accurate sample results to judge compliance with dust limits. There also can be no doubt that the current five-sample average system produces a more accurate representation of the dust to which a miner is exposed than the results of a single shift sample.

Making health risk and protection decisions on less accurate data provides less protection than making decisions on more accurate data. The MSHA proposed single sample accuracy finding will likely result in reduced miner health protection. The proposed finding and the proposed rules mandate to use a single sample for compliance determinations according to the data in the record and the accepted definition of accuracy in the English language violates the Mine Act's prohibition on reducing miner protection.

Unfortunately, MSHA attempts the single shift accuracy finding without basing the proposal on the factors mandated by Mine Act § 101. MSHA has not grounded its proposed finding on any evaluation or declaration of increased risk of material impairment of health resulting from the 1972 Joint finding currently in effect, nor any health benefits resulting from the implementation of the proposed finding.

Similarly, MSHA's analysis of the proposed finding ignores its own data base of 2010 sampling results, that clearly predicts hundreds of thousands of single shift sample, non-compliance determinations, regardless of the absence of health risks, and their technological and economic cost impacts. This analysis of predicted single shift sample enforcement results was set forth by Alliance and other NMA member companies in their comments and testimony, demonstrating the lack of economic and technological feasibility of the proposed finding.

e) The Inaccuracy of Single-Shift Sampling Has Been Demonstrated by Industry, But Not Properly Evaluated by MSHA For Its Impact on the Proposed Finding, Feasibility, or the Scientific Basis of the Rule

Because MSHA proposed a single-shift sampling compliance determination, as well as a multiple shift compliance determination using the new sampler, its reliance on average concentrations and/or the results of the current sampler, are misplaced and mask the infeasibility of the proposed rule. To determine the accuracy and the feasibility of single-shift sample determinations, MSHA must analyze single-shift results, not averages, which smooth inaccuracies and reduce the variability of single-shift results. This accuracy analysis was not conducted for both the CMDPSU and CPDM sampling methods for the proposed 1 mg/m³ limit, the extended shift reduced limits (.8 mg/m³ for 10-hour shifts and .67 mg/m³ for 12-hour shifts), and silica content reduced limits.

Moreover, MSHA must consider whether single-shift sampling provides any benefit to miner health, or reduces protections, or whether it simply makes compliance more difficult and costly without corresponding benefits.

An analysis of the 71,959 sample results in the MSHA sampling data-base for 2010, presented by Alliance, demonstrates the likely results of single shift compliance determinations under the proposed rule. Of the samples collected in 2010, 1,876

8-hour single-shift samples (2.6%) exceeded 2 mg/m³ and 10,506 (15%) exceeded 1 mg/m³.

Predictably, as the count of concentration decreases, samples out of compliance increase. 22 percent of all samples exceeded 0.8 mg/m³ and 40 percent exceeded 0.5 mg/m³. When low weight gain samples are discounted, the percentages change again with 3 percent exceeding 2 mg/m³, 17 percent exceeding 1 mg/m³, 25 percent exceeding 0.8 mg/m³, and 46 percent exceeding 0.5 mg/m³. *Id.* at 45.

For designation occupation (DO) samples gathered in 2010, 4.6 percent exceeded 2 mg/m³, 23 percent exceeded 1 mg/m³, 33 percent exceeded 0.8 mg/m³, and 55 percent exceeded 0.5 mg/m³. *Id.* Again, excluding the low weight gain samples, the percentages are 4.8 percent exceeded 2 mg/m³, 24 percent exceeded 1 mg/m³, 35 percent exceeded 0.8 mg/m³, and 58 percent exceeded 0.5 mg/m³. *Id.* Among DO and other designation occupation ("ODO") samples, excluding low weight gain samples, 3.9 percent exceeded 2 mg/m³, 21 percent exceeded 1 mg/m³, 31 percent exceeded 0.8 mg/m³, and 55 percent exceeded 0.5 mg/m³. *Id.* at 46.

Annual Estimate of DO Samples Under Proposed Rule

2010 Actual	Proposed Rule	% Increase	Description
	568,400		Total # of DO and Part 90 samples, from PREA pg 127
	42,250		Total # of Part 90 samples; 169 Part 90 miners, 250 shifts
27,865	526,150	1888%	Total # of DO Samples (Annual); Excluding Low-Weight Gain
	10.00		Run-Hrs Per Shift (Estimate)
	1.00		Proposed Standard (mg / m ³)
	0.80		Reduced Standard Due to Shift Length (mg / m ³)
34.4%	34.4%		% of Samples Above 0.8 mg/m ³ (Nationwide)
9,587	181,023	1888%	# of Samples Above 0.8 mg/m ³ (Nationwide)

Estimate based on 2010 results:

- 526,150 annual DO samples required
- 181,023 violations would be assessed for DO's

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Applying the rulemaking proposal to 2010 sampling, operators would have been required to take 526,150 DO samples, as compared to 27,865 valid samples actually taken in 2010 – a 1,939 percent increase. *Id.* Based upon the 2010 sampling results and considering an industry-average shift of 10 hours (resulting in

⁹ See Transcript of Proceedings in the February 15, 2011 hearing in Washington, D.C. at 44. Additional citations to this transcript in the comments are denoted by "Tr." At the beginning of the citations followed by the relevant page numbers.

a 0.8 mg/m³ standard), 34.4 percent of DO samples would exceed the permissible level, resulting in 181,023 violations assessed for designated occupations. *Id.* at 47. Similarly, application of the proposed rulemaking would require 215,432 ODO samples, as compared to 11,038 valid samples taken in 2010, and would result in 50,725 violations. *Id.* **This would result in a total of 231,748 violations under the proposed rulemaking, as compared to the 133 dust violations assessed by MSHA in 2010.** Even without adjusting the compliance limit or adjusting for shift length, the imposition of single-shift sampling for compliance purposes would have resulted in 27,500 violations in 2010 for DO and ODO samples. *Id.* at 48.

If MSHA determines that it will use weekly averaged results produced by the new sampler to determine compliance, in addition to single shift sample results, this will produce additional noncompliance determinations. Also, the differences in sample weights reported for the CPDM have the potential vastly increase out of compliance results, an issue demanding additional MSHA research and evaluation before the agency inadvertently causes massive disruption in the industry.

Alliance CPDM Results

➤ **Distribution of Differences Between CMDPSU and CPDM (mg/m³) (955 samples)**

Difference	Number of Samples (%)
CPDM > CMDPSU	396 (41.5%)
CMDPSU > CPDM	555 (58.1%)
CMDPSU = CPDM	4 (0.4%)
> 0.25 mg/m ³	306 (32.0%)

In its simplest terms, a regulatory scheme that results in highly variable, inaccurate and incorrect non-compliance results cannot be feasible. Preparing for compliance requires tremendous capital costs and each violation requires operators to submit a plan change, results in a penalty, and likely will entail downtime and production losses. No MSHA evaluation and representative survey of mine conditions and dust control technology has been performed to identify new technology to prevent or abate the new violations that would arise from the proposed rule. Only sweeping MSHA conclusions have been offered that existing technology can achieve compliance. Yet, MSHA has not analyzed the accuracy or feasibility of these outcomes, demonstrated by the agency's own data base.

f) A Case Study Demonstrating Economic and Technological Infeasibility of Single Shift Sampling Under the Proposed Rule

Taking the example of Mine 6 presented by Alliance at the February 15, 2011 hearing, the costs to operators are staggering. Testimony suggests that CPDMs can only be used one shift per day, in light of the numerous technical issues encountered when using the CPDMs and the required charging time between uses. Mine 6 would need to have 108 CPDMs on hand to be in compliance with the proposed rulemaking's DO and ODO sampling requirements.¹⁰ *Tr. At 58* At a cost of \$15,775 per unit, this results in initial capital costs of \$1.7 million. *Id.*

Currently, Mine 6 employs 1 dust technician per 10 CPDMs. The use of 108 CPDMs would require 11 new employees at a combined annual salary of approximately \$1.1 million per year. *Id.* Additionally, the dust filters for the units would cost approximately \$95,000 per year, resulting in annual costs of \$1.2 million. *Id. at 59.* These figures do not include plan preparation and submission, training and certification costs, record keeping and related equipment and staffing, the replacement of damaged equipment, and annual equipment maintenance costs.

Mine 6 will have to take 14,688 samples per year. *Id.* If you assume a 96 percent compliance rate,¹¹ Mine 6 will have 588 non-compliant samples, which will result in an average of 2 plan changes per day. *Id. at 59-60.* Each plan change will likely result in 1 shift of production downtime for 1 MMU. Assuming, that each production shift results in 1,000 tons of coal, Mine 6's 588 lost production shifts would result in a loss of \$30.2 million for a single year. *Id. at 60.* Such a result cannot be considered feasible under any definition.¹²

MSHA has not addressed whether it is feasible for mining companies and agency District Managers to handle the massive influx of proposed ventilation plan changes that will result from the increased number of violations. Furthermore, with its immense case backlog and the nearly two-year average for a contested citation to go from issuance to resolution, MSHA cannot seriously assert that enforcement of the proposed rulemaking would be feasible. In 2010, 26.7 percent of all citations

¹⁰ This does not account for designated areas ("DA") or intake sampling, or any additional ODOs that may be required by the District Manager (proposed 30 C.F.R. § 70.208(b)).

¹¹ Current national dust compliance based upon the 2.0 mg/m³ standard is 96.3%. Given the absence of identified new technology to assist operators in complying with the proposed reduced standard, the compliance rate would likely be considerably lower.

¹² MSHA raised issue with these figures during the February 15, 2011 hearing, asking whether these figures really represented the number of time the standard was exceeded, not necessarily the number of citations to which the operator would be subjected. *See Tr. at 167.* MSHA explained that "[i]f the agency would issue a citation based on a weekly exposure your single shifts exposures are already accounted for in the weekly, so you would not be getting cited twice for the same thing. . . . There's never two citations issued for a single exposure on respired dust." *Id. at 167-68.* Upon further questioning, MSHA explained, "the weekly citation is the preferred citation," and "[u]nder normal circumstances, . . . if the weekly exposure is under the weekly limit then there will only be at the most one citation per MMU." *Id. at 170.* However, as was pointed out at the hearing, these "normal circumstances," or an abnormal circumstance meriting additional citations is not explained in the rule. *Id.*

issued (166,420) were contested.¹³ Assuming 231,748 dust violations that would have been issued in 2010 under the proposed rulemaking, MSHA would have been faced with nearly 62,000 additional violations being contested for dust issues alone – a dramatic increase over the total of 44,464 penalties contested in 2010 for all standards and all sectors of the mining industry.

g) Single Shift Finding Conclusion

The agency's repeated attempts to implement an administratively convenient dust sampling enforcement system, at the cost of accurate sampling results, continues to violate its statutory duties to protect miners and conduct proper rulemaking. If MSHA continues its insistence on adopting a single shift coal mine dust sampling standard, it must conduct rulemaking with NIOSH, and the proposed rule can not reduce protections, but instead must be based on the mandatory rulemaking elements of Section 101 of the Mine Act.

III. Resurrecting Stale Data To Justify Current Rulemaking Is Improper

Much of the information relied upon by MSHA to support the proposed accuracy finding, its risk assessment findings, and its proposed rule provisions is contained in the 1995 NIOSH Criteria Document update of an older version, and its 1996 Dust Advisory Committee Report. Both are stale and agency reliance upon them is arbitrary and capricious.

Other agencies have demonstrated that the proper course of action for stale rulemaking materials is to abandon them. In 1978, the Federal Communications Commission (FCC) terminated a rulemaking that had begun in 1968. Specifically, the Commission observed:

The comments filed in this Docket are now stale and a number of changes in the nature of our regulations have been made since the proceeding was commenced so that the record does not provide an adequate basis for the adoption of rules. Of particular importance is the lack of a record concerning the technical details involved in cable television carriage of broadcast STV programming.

WWHT, Inc. v. Fed. Communications Comm'n, 656 F.2d 807, 810-11 (D.C. Cir. 1981) (quoting 69 F.C.C.2d 1622-23 (1978)). See also, *In re Special Const. of Lines and Special Serv. Arrangements Provided by Common Carriers*, 5 F.C.C.R. 5410 (1990) (terminating a 5-year-old rulemaking effort, finding that "[d]uring that period, there have been significant changes in the telephone communications marketplace and in our regulation of common carriers... In light of these developments, we conclude that the record compiled in this proceeding has become stale.").

¹³ MSHA Number of Penalties Assessed and Percent Contested January 2007 – December 2010.

The problems that that led to the FCC's termination of its 10-year-old rulemaking effort are replicated by MSHA's current rulemaking, but to a far greater degree. The current MSHA proposed finding and rulemaking started with several failed efforts, declared contrary to law by the courts. The 2000 Proposed Finding relied upon the prior illegal efforts and the 1995 Criteria Document and a 1996 Dust Committee Report. Over ten years have passed since the tainted 2000 rulemaking was initiated. Numerous technological advancements (e.g. the proposed new sampler) and new scientific research (including MSHA and NIOSH data through 2010) are critically important to the rulemaking outcome, but did not exist at the commencement or updating of the stale rulemaking. Yet, MSHA continues to rely upon the same documents it did eleven years ago to support imposition of single-shift sampling.

Although MSHA solicited additional comments on the stale rulemaking, and admitted that new science changed the basis of the proposal¹⁴, there is no evidence that MSHA reexamined the Criteria Document or Dust Committee Report, or the updates it used for this rulemaking, in light of the latest scientific research, such as: (a) 2006-2010 NIOSH prevalence and MSHA exposure data; (b) technological advances like the deployment of the new sampler; and (c) published studies targeting silica as the cause of the geographically limited new CWP cases. There is no evidence that MSHA considered whether its stale rulemaking materials required new field testing and/or analysis due to these critical developments and MSHA's failure to engage in this analysis is arbitrary and capricious.

IV. The Personal Dust Monitor (PDM) Provides Benefits, But Needs Improvements and Testing Under Actual Mine Conditions Before it can be used for Compliance Purposes.

a) Testing Shows PDM Massive Inaccuracy and Non Compliance Results

NMA testimony demonstrates that the PDM can beneficially affect worker behavior and, therefore, can provide benefits. The PDM provides comparative dust exposure information that empowers miners to make adjustments to lower exposures. PDMs have been deployed voluntarily, and after extensive testing and needed corrections, their industry-wide use should be expanded, wherever feasible.

However, as described above, and in NMA hearing testimony, the technology is not sufficient to provide reliable and accurate dust sampling results. If the proposed rule is adopted, Mr. Watson's testimony demonstrated, through analysis of the most recent MSHA sampling data (2010), that the single shift sample finding, along

¹⁴ MSHA previously suspended the rulemaking to "obtain further information on Personal Dust Monitors (PDMs), a new technology which is currently being tested by NIOSH." 68 Fed. Reg. 47886 (Aug. 12, 2003). However, the proposed finding has not been updated to reflect this new development and the actual impact PDMs have on the accuracy and feasibility of single-shift sampling. Notably, the rule for which MSHA halted the 2000 Proposed Finding did not reference, and did not consider the impact of PDMs, which were described at length by NMA witnesses and resulted in the UMWA seeking pre-regulation testing.

with the mandated use of the CPDM, will cause hundreds of thousands of dust standard violations per year, as compared to 191 in 2010. See Tr. At 41-50.

The difference between MSHA's analysis and Watson's analysis is Watson's use of actual 2010 sampling results in the MSHA data base, and his comparison of each single shift result, to the proposed standard to be applied at mines working 10 hour shifts, instead of the MSHA analysis of older data, *average* results.

Estimate of Samples Above Proposed Limit, Based on 2010 Compliance Sampling

- 40,520 eight hour single shift samples in 2010 for DO and ODO occupations
- 1510 of those samples exceeded the 2.0 mg/m³ standard
- 133 total dust violations assessed by MSHA in 2010: 70.100(a), 70.101 and 71.1 violations
- At least 27,500 total violations would be assessed annually for DO and ODO samples alone based on proposed single shift sampling frequency without adjusting for shift lengths or reducing compliance limits. (2.0 mg/m³ standard)
- At least 51,000 total violations would be assessed annually for DO and ODO samples alone based on proposed single shift sampling adjusted for shift length without reducing compliance limits. (1.6 mg/m³ standard)
- At least 220,000 violations would be assessed annually under the proposed rule for DO and ODO samples alone using the CPDM single shift sample and reduced limit proposal. (0.8 mg/m³ standard)
- Each violation requires a plan change, a penalty, and likely will entail non operating time and production losses.
- No new technology has been identified to prevent or abate these new violations created by the proposed rule.

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b. New Samplers Are Improperly Mandated, Without Consideration as Beneficial, Non-Compliance Tools To Enhance Protection

In promulgating its final rule for approval criteria for the new CPDM, MSHA lauded CPDMs as "allow[ing] mine operators to promptly identify and respond to dust exposures exceeding the applicable MSHA standards. With this new technology, operators could evaluate causes of overexposures, implement control measures to reduce exposures, and adjust such controls as necessary." 75 Fed. Reg. 17512 (April 6, 2010). However, just six months after promulgating approval regulations for this new technology, MSHA's new proposal will eradicate the benefits of the CPDMs by converting them into an occupational compliance device – without the benefit of needed improvements or evaluating the impact. The real advantage of the CPDM is its ability to measure the relative real-time exposure of individual miners who can then manage their own practices to reduce their own exposures.

Executive Order 12866 (58 Fed. Reg. 51735 (Oct. 4, 1993)) provides that:

Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made

necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.

(Emphasis added.)

As Mark Watson, and Glen and Gamble explained to the agency during its February 15, 2011 hearing, the industry has made great strides towards eliminating the incidence of coal dust disease, supporting alternatives to the MSHA proposal mandating lower limits and massive changes to the dust sampling system. See Tr. At 105-136

The CPDM is a major step change in technology from the existing systems, providing relatively instant results, but introducing new and unresolved issues. See Tr. At 35-36

Of specific concern:

- The new cyclone employed by the CPDMs collects different "dust" particle size distributions than those that penetrate the lung collected with the current cyclone, rendering the new sampler inconsistent with prior definitions of "hazardous" respirable dust that supports the underlying risk and benefit research;
- The CPDM uses a filter to collect the dust for measurement without the blank cassette analysis used in today's system to protect against the known deficiencies in the filter system that cause false weight gains.
- There is mine calibration analysis for the new sampler, which uses changes in vibration measurements to determine mass weight of collected dust. MSHA currently employs a national standard weight to calibrate accurate weight scales for determining the result of the current samples;
- MSHA currently employs procedures in the sample analytical lab to prevent contamination-induced false results, such as "oversized", non-respirable particles or sample contamination from other sources. Such protections will no longer be available if the CPDMs are adopted as a compliance mechanism because CPDMs use an electronic vibration measurement to determine sample weight and the collection filters are not examined by any laboratory for reasons that void large numbers of current samples;
- Based on limited experimentation, a new but suspect conversion factor (1.05 CPDM vs. 1.38 CMPDSU) is used to relate CPDM results to the British

MRE sampler upon which U.S. health-based dust risks, benefits and limits were based;

- Repeated, current lab quality control procedures, audits and checks to help reduce error are not employed for the CPDM; and
- Lab examinations to determine sample discoloration or evidence of rock dust or other contaminants is eliminated, increasing the probability of inaccurate exposure assessments.

While the CPDM provides greatly desired real time relative measurements, there needs to be a better more thorough analysis and understanding of the meaning of those measurements, in terms of accuracy, precision, reliability and feasibility. By mandating the CPDM for compliance without a thorough evaluation of the above listed items the proposed rule reduces the CPDM's usefulness and protective benefits, contrary to Mine Act mandates.

Before finalizing a rule mandating the CPDM sampling as a compliance tool, MSHA must consider industry studies that raise concerns about the use of CPDMs and their fitness for mining operations. At a public hearing on February 15, 2011, representatives of Alliance Coal presented the results of what is believed to be the most extensive analysis of CPDMs to date. See Tr. At 50-57. The company owns approximately one-third of all of the operator-owned CPDMs currently in the marketplace and operates them throughout six mines. They have collected over 1,000 CPDM samples, the vast majority of which have traditional sampling result counterparts from the MSHA lab.

Alliance CPDM Results

➤ Distribution of Differences Between CMDPSU and CPDM (mg/m³) (955 samples)

All Samples	CPDM / CMDPSU	Avg. CMDPSU	Avg. CPDM	Count
Mine 1	1.27	0.81	0.94	272
Mine 2	0.92	0.90	0.83	40
Mine 3	1.30	0.93	1.11	33
Mine 4	1.08	1.00	1.02	157
Mine 5 - 9 Seam	.96	0.85	0.77	54
Mine 5 - 11 Seam	1.62	0.70	0.88	58
Mine 6 - 9 Seam	0.92	0.82	0.65	180
Mine 6 - 11 Seam	0.77	0.73	0.52	161

Overall, the performance of the CPDMs in the active mining environment has been of concern and complicates their immediate use for compliance purposes. The differences in results between side-by-side single-shift samples collected with the CPDM and current sampler is problematic and of concern given the sampling protocol contained in the proposed rule. The Alliance results document the need for additional in-mine testing of the CPDM to determine the source of the bias (high or low) before decisions are made regarding use of the CPDM for compliance sampling purposes.

In addition, of the 40 CPDMs purchased and analyzed by Alliance,¹⁵ 14 (35%) were returned to the manufacturer for repair over a 10-month period¹⁶ and five of the units had to be returned to the manufacturer multiple times. For example, of the over one thousand samples conducted, more than 20 percent had an instantaneous error displayed on the dust data cards and over 6 percent had multiple errors. In addition, the analysis encountered numerous diagnostic failures with the CPDM units.¹⁷

¹⁵ The company actually owns 60 CPDMs, but data was only collected from 40 units for purposes of its February 15, 2011 presentation.

¹⁶ This does not take into account the number of units receiving in-house repair during the same period and does not consider the number of units that were returned before the company began tracking its repair returns.

¹⁷ The CPDM does not produce a record of its diagnostic failures, including failures occasioned by intentional manipulation of the unit, but instead simply stops sampling when a failure occurs. In light of this, the precise number of diagnostic failures encountered cannot be tracked. CONSOL Energy reported similar equipment and diagnostic issues with the equipment including software issues caused by daylight savings time, melted pins on charging plugs, filters not precisely installed, and diagnostic failures on startup that are not detected until warm-up or in the next program or early into the

Alliance CPDM Program

- **CPDMs sent off for Repair, in addition to in-house repairs:**
 - **Of 40 CPDMs, 14 (35.0%) have been sent back to the manufacturer in the last 10 months.**
 - **5 have been sent back multiple times.**
- **CPDM Instantaneous Errors**
 - **218 out of 1,019 (21.4%) had an instantaneous error displayed on the dust data card**
 - **63 (6.2%) showed multiple errors**
- **Diagnostic Failures**
 - **Produces no hard copy or electronic copy**
 - **Stops Sampling**
 - **Diagnostic failures are not included in this data due to lack of any supporting documentation**
 - **Intentional Manipulation by user can also create a Diagnostic Failure**

Repairs and errors aside, there are serious concerns about the use of the CPDM sampling as a compliance tool for single shift sampling.

The Alliance analysis raises questions that need to be addressed before a determination is made regarding the readiness of the CPDM for compliance sampling. For example:

- does the CPDMs produce reproducible, consistent, precise and accurate measurements;
- are CPDM results consistent from unit to unit;
- do CPDM's and gravimetric samplers produce consistent results within an accepted margin of error; and
- is the accuracy and reliability of the CPDM precise enough for it to be used to make single-shift samples compliance determinations?

Similarly, as was presented at the February 15, 2011 hearing, Consol Energy has also experienced serious issues with CPDM data, including unchanging Mass 0 numbers over several hours without a corresponding reduction in cumulative concentration, instances where Mass 0 numbers have changed, but the cumulative concentration has remained unchanged, and numerous occasions where the end of

sampling shift after the sample has been taken underground, resulting in error files. The proposed rule is not clear as to how such equipment and diagnostic errors would be addressed.

shift concentration is not changing. See Tr. At 65-69. Each of these observed problems create sampling result errors that adversely impact compliance determinations and health protection evaluations, particularly for single-shift sampling under the proposed rule.

Not only has MSHA not considered further improvements and testing of CPDMs before mandating their use as compliance tools, MSHA also has not considered the failure of its own proposal to tie results to health risks and benefits. The MSHA proposed mandates would require a sampler to be transferred, from employee to employee, when multiple individuals perform the same job function but rotate during a shift. This mandate eviscerates the power and utility of the CPDM to allow individuals to know what their exposure is and to take intervention actions during their shifts. It also creates area sampling results, without health risk meaning, from a personal sampler designed to reduce risks. Sampling the exposure of a particular work position, rather than the exposure of individual miners, does not aid in the protection of miner health and is unnecessary. Simply put, the rule is not structured in a manner that allows operators and miners to maximize protection of individual miner's health, which proper use of the CPDM would permit.

c) Extensive Testing of the PDM is needed before Mandating Its Use

NMA joins the UMWA in urging MSHA to use the CPDM to "gather true sample readings of what miners are being exposed to today with the current extended work shifts and the various coal seams before we actually determine what is protective and what can be realistically achieved."

When the UMWA's Dennis O'Dell testified to this need at a West Virginia public hearing, he concluded: "it's important that before the proposed rule is placed in the industry, that we have real time data that can be provided to understand what can actually be achieved." Beck, Tr. at 61. NMA again urges MSHA and NIOSH to join with the interested parties in a data gathering study, using both the CPDM and the current dust sampling and analysis system to determine exposures, compare results and examine the accuracy of measurements, and current exposure levels, before determining the feasibility and need for new regulations on how compliance will be determined.

V. The Proposed Rules Are Not Authorized, Warranted or Feasible

a) NMA Experts Show the Fallacies in the Scientific Basis of the Rule

MSHA's proposed rules lower the maximum exposure limit for respirable coal mine dust (CMD) by 50 percent, from the existing standard and far more, for shifts longer than 8 hours and/or samples containing more than 5 percent silica. Moreover, MSHA's proposed rule restricts, prohibits or will result in the closure of the most productive mining sections (e.g. longwall equipment and supersections).

MSHA seeks to impose new engineering experimentation mandates to meet the reduced standards throughout an industry whose jobs are under siege by

environmental regulations, threatened by new legislation, and condemned by various public interest groups seeking to stop US coal use.

Concurrently, MSHA proposes the new instantaneous read sampling device, for single shift compliance determinations, without extensive testing sought by the UMWA and industry, while abandoning the five shift sample averages deemed necessary for accuracy for 40 years.

MSHA proposes the new device regardless of its collection of different dust characteristics to determine compliance, its new and as yet unrefined technology and performance characteristics not tied properly to historical scientific research regarding health risks. MSHA simply ignores the fact that the new sampling device also abandons the protections against inaccurate samples currently used by MSHA to protect against false readings (e.g. due to lack of regular calibration, contaminated samples, "non-respirable dust," low weight gain samples or cassette gas induced weight gains).

NMA asserts that the experience under the current rules contradict the limited and suspect MSHA risk findings supporting this proposal, as well as the MSHA potential benefit findings resulting from the proposal.

The scientific evidence supporting NMA's conclusion is addressed in the testimony and comments of experts Dr. Tony Cox (risk assessment) (See Tr. At 77-105), Robert Glenn and Dr. John Gamble (former HHS NIOSH scientists and epidemiology and industrial hygiene experts) (See Tr. At 105-136), Dr. Tom Hall (occupational health, epidemiology and biostatistical experts) and Mark Watson, et al, of Alliance Coal (See Tr. at 41-61). The following is a summary of some of the main points of their testimony.

In its purported risk assessment, MSHA did not use accepted risk assessment science to analyze risk and benefits, nor the latest and best scientific methods in determining that risks and benefits justify its proposed rule.

Dr. Cox points out that:

[i]n fact, embarrassingly enough, some of the models do show a 4.4 fold relative risk even when there's zero exposure. Oops. An appendix of the QRA says you have to be really cautious in using these numbers. I agree with that except I'd say don't use them. You know what, if you're attributing risks and when there's zero exposure, it's probably not a good model to be using. *Tr. at 92-93.*

Drs. Hall and Chase describe the inappropriate mandate for "area samples" by the MSHA proposal the results of which do not represent personal exposures or health risks. They also describe the incorrect statistical calculations by MSHA of errors and variability, underlying the MSHA single sample finding and the rule's compliance determination methods. (Exhibit 15)

Dr. Gamble and Mr. Glenn, former leading NIOSH researchers and management officials, extensively reviewed the health risk data and NIOSH reports used by MSHA in its risk analysis, and concluded that MSHA missed the focus of the research and reached a sweeping and unsupported conclusion that the incidence of

CWP is increasing. Instead, Glenn and Gamble demonstrated the geographic limits and silica exposure cause of the limited cases observed by NIOSH, creating an easily identifiable target for regulatory improvement, if needed, as opposed to the unsupported sweeping changes proposed by MSHA. (Exhibit 5)

In addition, Gamble and Glenn reviewed the MSHA proposal from the perspective of the accepted scientific theory of the "hierarchy of controls," and conclude that MSHA selectively failed to adopt this protective concept for the proposed coal mine dust standards, in contrast to OSHA and other MSHA standards. In so doing, MSHA reduces protection for miners by not recognizing accepted administrative controls as compliance mechanisms. (Exhibit 9)

Alliance Coal experts, Mark Watson, et al, provided a comprehensive analysis of the MSHA proposed rule, its risk analysis and technological and economic feasibility analysis. Alliance has conducted the most comprehensive tests to date of the new and existing samplers, including almost 1000 side-by-side samples, evaluating accuracy, precision, durability, reliability and feasibility of both samplers, and applying the sample collection results to the 2010 MSHA data-base to determine predicted compliance and non-compliance rates and expected noncompliance determinations under the terms of the proposed new standards demonstrate the lack of accuracy and feasibility of the proposed rules (Exhibit 10).

b) Science & Evidence Mandates Are Not Met By MSHA

In promulgating standards for "toxic materials or harmful physical agents," the Secretary is required to "set standards which most adequately assure on the basis of the *best available evidence*..." 30 U.S.C. § 811(a)(6)(A) (emphasis added).

The agency must base standards on "research, demonstrations, experiments ... and consider 'the latest available scientific data in the field...'" *Id.* MSHA fails to abide by these mandates with its use of stale and outdated science and its failure to conduct its own simple field tests or current data analysis. As discussed earlier, NIOSH's 1995 Criteria Document and the 1996 Advisory Committee Report are stale and outdated and do not constitute the "best available evidence" or "the latest available scientific data in the field." MSHA's reliance on them in this rulemaking is misplaced.

MSHA should have undertaken or arranged for sound "research, demonstrations, experiments..." to determine: (1) whether mandating CPDM is feasible, supported by its performance and justified by health risks throughout the industry; and (2) whether its latest data base of sampling results supports feasibility findings for lowering the coal dust limit by 50 percent, and more for reduced standards due to silica or extended work shifts. Similarly, MSHA should have undertaken a scientifically accepted risk assessment procedure, as described in text books and published papers cited by Dr. Cox, to determine if the broad based proposed rule provisions are warranted by current risks and will provide significant benefits.

In a case interpreting similar rulemaking provisions under the Occupational Safety and Health Act (Act),¹⁸ the Fifth Circuit determined that OSHA's reliance upon "dated, inconclusive data" failed to satisfy the rulemaking mandates of the Act. *Am. Petroleum Inst. v. OSHA*, 581 F.2d 493, 507 (5th Cir. 1978), *aff'd on other grounds, Indus. Union Dept, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 662 (1980). Specifically, OSHA had promulgated a final rule prohibiting dermal contact with benzene, but admitted "the record evidence on the effect of benzene on the skin is 'extremely limited' and that the few studies in the area 'are not definitive.'" *Id.* at 505. Given the sparse record support for a prohibition against contact, the plaintiff challenged the rule as not being supported by "best available evidence." *Id.* at 506. OSHA had relied upon studies conducted between 1946 and 1961. *Id.* A handful of the studies found that benzene was not absorbed through the skin. *Id.* However, the 1961 study found that some absorption did occur. *Id.* The record contained NIOSH's opinion that benzene could be absorbed through the skin, but the conclusions were not supported by reference to any particular study. *Id.* One dermatologist testified on the record that he did not know whether benzene was absorbed through the skin, that the majority of studies concluded it was not, and one study found that it did. *Id.* at 506-07. However, although the dermatologist testified that he did not know whether absorption occurred through the skin, he went on to state:

Today we have a much simpler and a much more direct way of answering this ... because now radio-active benzene is available, and one simply would apply radioactive benzene, some Carbon 14 benzene, to the skin of the arm of an appropriate animal that has permeability characteristics similar to the people in this room ... and then would simply look for the radioactivity excreted into the urine, the feces and the breath.

This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would then tell us definitively, without argument, and efficiently, just how much of any benzene penetrates the skin.

Id. at 507.

¹⁸ 29 U.S.C. § 655(b)(5) requires:

The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which must adequately assure, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

He went on to testify that the experiment he was proposing could be concluded in a relatively short time span. *Id.*

Because of the availability of a relatively quick and effective method that was not included in the earlier studies that OSHA relied upon, the court determined that OSHA failed to meet its statutory mandate "to promulgate standards on the basis of the 'best available evidence,' 'research, demonstrations, experiments, and such other information as may be appropriate,' and 'the latest available scientific data in the field.'" *Id.* Specifically, the court distinguished this from cases where "there is testimony that additional sophisticated research could be attempted, but might not shed new light on a subject." *Id.* Instead, the evidence showed that there was a relatively simple technique available that could produce accurate information on OSHA's unresolved factual issues in the rulemaking. *Id.* "When such factual information is so readily available, [the Act] requires OSHA to acquire that information before promulgating regulations which would require an established industry to change long-followed work processes that are not demonstrably unsafe." *Id.* at 508.

Interpreting similar language found in the Endangered Species Act (the ESA),¹⁹ the Supreme Court determined that the obvious purpose of the "best available" requirement "is to ensure that [legislation] not be implemented haphazardly, on the basis of speculation or surmise. . . [and] another objective (if not indeed the primary one) is to avoid needless economic dislocation produced by agency officials zealously but unintelligently pursuing their environmental objectives." *Bennett v. Spear*, 520 U.S. 154, 176-77 (1997). While courts interpreting the ESA have found that "[t]he 'best available data' requirement makes it clear that the Secretary has no obligation to conduct independent studies," it does "prohibit[] the Secretary from disregarding available scientific evidence that is in some way better than the evidence he relies on." *Southwest Center for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000).

Here, MSHA's failure to evaluate and consider easily available scientific evidence or "research, demonstrations, experiments, and such other information" was described at length in the testimony of Robert Glenn, Mark Watson, Dr. Tony Cox and other NMA witnesses. Specifically, MSHA has not researched or evaluated the evidence contained in NIOSH records or its own sampling data. Nor has MSHA used the latest scientific methods to perform a scientifically accepted risk assessment. Instead, it relied on flawed assessments that, among many errors and improper assumptions, found a fourfold increase in risk at zero exposure. See e.g. Tr. at 91-94.

For example, MSHA has data contained in its own sampling data base regarding the silica content of the samples taken at all mines, including those mines where miners recently have been identified as suffering from coal dust related disease. Rather than examining its own silica exposure data, particularly in light of NIOSH

¹⁹ 16 U.S.C. § 1536(a)(2) requires each agency, utilizing "the best scientific and commercial data available," to insure that its planned destruction or modification of a habitat will not jeopardize the continued existence of any endangered or threatened species.

allegations of silica causation of recent disease cases, to determine if the disease resulted from excessive silica exposures, MSHA concluded that coal dust was the cause and uses this conclusion to justify its proposed rule. Analyzing data in its own possession and comparing that data to the disease cases relied upon for this rulemaking as CWP, is precisely the type of failure to conduct a simple scientific analysis that caused the courts to overturn an OSHA standard.

Similarly, the record contains a number of problems encountered with the mandated new personal dust monitor and the single shift accuracy finding that should have resulted in MSHA conducting simple research, including examining: (1) extensive results that are inconsistent with and higher than the current dust sampler; (2) the impact of humidity on the new sampler's results causing increased readings due to weighing of moisture; (3) the lack of a method, comparable or better than current laboratory examinations, to protect against new sampler inaccuracies from non-respirable, large particles of dust on collection filters; (4) the lack of weighing calibration for each sample result; (5) the lack of "blank" comparison filters and examinations of suspect filters; and (6) reported electronic, pump, battery and heating failures of the new sampler.

The testimony of NMA witnesses set forth an analysis of the MSHA data-base, demonstrating the inaccuracy of the proposed rule, its lack of a scientific basis and the massive disruption that the proposal will create. MSHA should have tested and evaluated these easily identifiable issues.

VI. The Quantitative Risk Assessment Is Flawed

As described by Dr. Anthony Cox (Exhibits 12 & 16), the Quantitative Risk Assessment (QRA)²⁰ does not contain a hazard identification, wherein MSHA addresses whether the currently permitted exposure levels cause incremental harm to miner health. Specifically, there is no toxicological, epidemiological, or clinical evidence concerning the effect of current levels on miner health.

Additionally, the exposure response relationship is lacking in the QRA. In other words, if exposure is changed, what impact will that have on future risks?

The QRA is also missing an adequate uncertainty characterization. The graph provided in the QRA does not include confidence bands, model uncertainty, or sensitivity analysis.

The MSHA flawed analysis assumes that reducing the permitted exposure will result in fewer deaths. However, the perception created by this flawed analysis is not reality. There is a massive uncertainty omitted from the QRA and it does not establish that by mandating a reduced exposure limit nationally risk will be reduced.

In the last eight years, the understanding of the toxicology of inflammatory and inflammation mediated lung disease has increased dramatically and the QRA does

²⁰ An in-depth analysis of the issues facing the QRA was presented by Louis Anthony (Tony) Cox, Jr. at the February 15, 2011 hearing and are contained in his "Comments on MSHA's Quantitative Risk Assessment (QRA) for RCMD," a copy of which is attached to these comments as Exhibit 14.

not account for this new scientific understanding. Specifically, high cumulative exposures for a long period of time results in damage to individuals' lungs. The mean level of exposure does not cause the damage; rather damage can be attributed to variability around the mean level, which translates into cumulative exposure.

Despite this understanding, the QRA focuses on mean exposures and MSHA acknowledges its assumption that mean cumulative exposure drives risk. Such a position is toxicologically inaccurate.

Instead, MSHA should consider the proportion of the distribution that is in the high risk or response region. That relevant exposure metric has not been quantified in the QRA. Moreover, while the available epidemiological evidence is consistent with the conclusion that reducing high levels of exposure protects worker health, it is ambiguous on the effects of reducing low levels of exposure.

To have a meaningful analysis, the distribution of exposures must be considered against a dose response model. Without looking at exposures through this lens, MSHA cannot say what would happen if present standards were unchanged but enforced (e.g. silica limits) and what impact that would have on future risks.

Throughout the QRA, MSHA states that past exposures have been underestimated. If this is true, then past dose response relations overestimated the potency of past exposures. If past exposures were twice as high in reality as they were thought to be and they produced a certain number of illnesses, then the potency of that exposure was about half of what it was thought to be because it still produced that total number of illnesses. It is simply nonsensical to increase your exposure estimates and not counter adjust your dose response estimates.

The QRA makes an attribution determination, which differs materially from causation. A retrospective attributable risk analysis attributes a seemingly arbitrary proportion of risk to coal dust. Instead, MSHA should employ causal modeling that considers the epidemiological impact on lung disease of a toxicological change. Without this necessary adjustment, those high-risk areas are going to be systematically attributed to lower mean exposures. Fortunately, the effects of this measurement error can be easily corrected, a task that MSHA should undertake before it proceeds with the current rulemaking.

Risk characterization must also be undertaken. What are the frequency and the severity of health effects with and without the proposed rule? MSHA's failure to conduct this analysis is illustrated by the occurrence of a 4.4 fold relative risk in some of the models where there is a zero exposure. Additionally, the MSHA models do not take into account the confounding effects of smoking, arguments about how risk should be attributed or how risk should be predicted.

Without this risk characterization analysis, the predictions are not accurate or validated, MSHA cannot support the reduced standards in the current rulemaking, and its efforts to reduce exposure levels are arbitrary and capricious. Additionally, by misinterpreting the statistical meaning of the analysis contained in the QRA, MSHA falls into the trap of making bogus claims about the potential impact of decreased exposure levels. The risk characterization should be extended to address realistic frequency distributions of exposure history. The effects of confounders,

such as smoking or time, should be removed. Statistical tools should be employed to account for estimation errors.

MSHA's use of regression analysis in the QRA is misplaced. When one trend variable is regressed against another, there will always be a strong correlation and a strong regression relation between them. The fact that both are trending means that high values of one tend to co-occur with high values of the other, and that low values of one tend to co-occur with low values of the other. However, looking at these correlations alone, without taking into account that time itself is playing a confounding role, results in worthless correlations. The QRA relies upon previously published regression models that regress one trend against the other without doing the causal analysis of the relationship between the exposure and risk, which is necessary to consider the impact of one against the other without the confounding effects of time.

The work necessary to determine the causal contribution is not reflected in the QRA. MSHA's applied methodology in the QRA contaminates their regression models with spurious regression and does not adequately characterize the risk presented by coal dust. For time series data, such analysis may include Granger Sims analysis and for non-time series data (cross-sectional data), it may include conditional independence tests for causality.

VII. The Proposed Rule Violated Statutory Requirements

Section 101(a)(6)(A) of the Mine Act requires that in developing "mandatory standards dealing with toxic materials or harmful physical agents," the agency must consider the "feasibility of the standards." 30 U.S.C. § 811(a)(6)(A). Consideration of feasibility is mandatory, not discretionary, and encompasses both technological and economic feasibility. See *Nat'l Mining Ass'n v. Secretary of Labor*, 153 F.3d 1264, 1268 and 1269 n.5 (11th Cir. 1998). MSHA's current rulemaking effort fails to properly analyze feasibility and disregards the infeasibility of the proposal. Moreover, MSHA's certification that the rule will not have a major impact on the economy also is wrong. Both the MSHA feasibility and significant impact conclusions require that the rule be re-analyzed to determine its actual economic feasibility and impacts.

In order for an agency's rules to be deemed feasible, the agency must establish "a reasonable possibility that the typical firm will be able to develop and install engineering and work practice controls that can meet the [standard] in most of its operations." *Kennecott Greens Creek Min. Co. v. MSHA*, 476 F.3d 946, 957 (D.C. Cir. 2007) (quoting *Am. Iron & Steel Inst. v. OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991)).

Given the large number of mines operating on extended shifts beyond 8 hours, and mines already operating on a reduced standard due to silica, almost all of the mines will be required to meet a standard lower than the 1mg/m³ purported to be analyzed by the MSHA analysis. Such a flawed analysis of feasibility is improper, even if it were conducted properly, which it was not.

The Alliance case study and data analysis reported above demonstrates that the proposed rule is not economically feasible, or using today's suite of engineering controls, or any that are on the horizon, technologically feasible. Hundreds of thousands of citations per year will result from MSHA's proposal, as documented by Alliance evaluation.

At page 26 of the MSHA Preliminary Regulatory Economic Analysis for Lowering Miners' Exposure to Respirable Coal Mine Dust Including Continuous Personal Dust Monitors (PREA), the agency states:

However, sampling data (see Table IV-1) indicate that not only are mine operators keeping miners' exposures at or below the levels required under the existing standards, but dust exposures at most operations **average** less than the proposed standard of 1.0 mg/m³. Thus the majority of miners' exposures are at or below the limits in the proposed rule. MSHA understands that these data reflect measurements under the existing sampling program and that requirements under the proposed rule (e.g. use of single full-shift samples to determine noncompliance, change in the definition of normal production shift) would result in higher exposures compared to the existing sampling program. However, existing engineering controls including ventilation, sprays and environmentally controlled cabs along with changes in work practices can be used to further reduce dust levels.

(Emphasis added).

While MSHA admits that the new sampler and the new proposed regulations will "result in higher measured exposures," 75 Fed. Reg. at 64477, it incorrectly determines feasibility based on *average* exposures, even though it proposes single shift sample compliance determinations. Moreover, it does so without any studies, evidence or analysis to support its conclusion that: "existing engineering controls along with changes in work practices can be used to further reduce dust levels." PREA at 26.

MSHA declares the rule feasible in one paragraph of the Federal Register notice by using a revenue screening test—whether the annualized compliance costs of a regulation are less than 1 percent of revenues, or are negative (i.e., provide net cost savings)—to establish presumptively that compliance with the regulation is economically feasible for the mining industry. 75 Fed. Reg. at 64477. Basing feasibility of a rule on this test is illogical since it does not consider the impact of costs on competition from other fuel types or non-US coal sources, profit or loss levels, the availability and cost of investment dollars to the industry, or other factors that determine the feasibility of absorbing the costs of the rule.

Using this MSHA "test," the agency could determine that it was feasible for AIG to acquire a new corporate headquarters, during the height of the recession, because its "annualized cost" was "less than 1% of revenues." MSHA was wrong to declare this rule economically feasible, both because its method of determining feasibility is

wrong, and its cost estimates are a fraction of actual costs, as shown in the NMA testimony of Mark Watson.

MSHA estimates the annualized costs of the rule for underground coal mines as \$35.6M to \$39.7M, and because in MSHA's view this estimate is 0.2 percent of the industry's \$17 billion in revenues, the rule is economically feasible for underground coal. 75 Fed. Reg. at 64477. In fact, this estimate is almost equal to the cost for one mine, as reported in the reported case study above.

b) MSHA's Diversionary Analysis Can Not Succeed in Proving Feasibility

Using single shift samples for compliance determinations, along with the highly variable and biased performance of the dust samplers, demonstrates that the proposed rule is neither technologically nor economically feasible by the sheer number of noncompliance determinations they will produce. By relying on average historical sampling results to declare the single shift finding and the other portions of the rule, dependent on the sampling, economically and technologically feasible; MSHA diverts attention from actual feasibility facts with feasibility fiction. The MSHA PREA demonstrates this analysis when it states, at page 28:

At underground mines, **average** concentrations ranged from 0.748 mg/m³ for non-longwall DOs to 1.206 mg/m³ for longwall DOs, while the percentage of individual samples below 1.0 mg/m³ ranged from a high of 77% to a low of 40%.

(Emphasis added).

VIII. MSHA Failed To Analyze Regulatory Alternatives

Under multiple accepted principles of agency rulemaking, agencies are required to analyze alternatives to their proposed regulatory approaches. This requirement arises in the context of the APA, Executive Order 12866, the Regulatory Flexibility Act (the RFA) and the Small Business Regulatory Enforcement Fairness Act (SBREFA). As demonstrated below, MSHA improperly concluded that the Executive Order and the RFA are not applicable to this rulemaking, and failed to consider effective regulatory alternatives.

The APA governs the way in which federal agencies conduct regulatory rulemaking and the ability of the federal courts to review agency regulations, as supplemented or amended by specific statutory provisions such the rulemaking provisions in the Mine Act. 5 U.S.C. § 553(c) requires agencies to "incorporate in the rules adopted a concise general statement of their basis and purpose." Where a court finds an agency action to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," the court can set aside the agency action. 5 U.S.C. § 706(2)(A). "To be regarded as rational, an agency must also consider significant alternatives to the course it ultimately chooses." *Allied Local and Reg. Mfrs. Caucus v. U.S. Evtl. Prot. Agency*, 215 F.3d 61, 80 (D.C. Cir. 2000) (citing *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29,

48-51 (1983)). Numerous courts have set aside agency action as arbitrary and capricious based upon an agency's failure to consider alternatives to regulation.²¹

In *Motor Vehicle Mfrs.*, the Supreme Court considered an agency's rescission of a previously promulgated standard. Applying the same arbitrary and capricious analysis to the rescission as it would to the review of an agency rule, the court considered whether the agency had "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of United States, Inc. v. State Farm Mut. Auto. Inc. Co.*, 463 U.S. 29, 42-32 (1983). (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). Specifically, the court considered the plaintiff's argument that the agency had failed to consider an alternative approach to rescission – modifying the standard to require the use of airbag technology. *Id.* at 46. Remanding the issue to the agency for further consideration, the court noted that agencies are not required:

to consider all policy alternatives in reaching decision. It is true that a rulemaking 'cannot be found wanting simply because the agency failed to include every alternative device and thought conceivable by the mind of man ... regardless of how uncommon or unknown that alternative may have been ...'

Id. at 51 (quoting *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 551 (1978) (omissions in original)).

However, here, the alternative not addressed by the agency was more than simply a policy alternative, "it [was] a technological alternative within the ambit of the existing standard." *Id.* The agency's failure to consider the alternative was fatal to its attempt to rescind the regulation. *Id.*

Similarly, in *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795 (D.C. Cir. 1983), the plaintiffs alleged that agency's rescission of agency regulation in light of the agency's failure to consider alternatives to rescission was arbitrary and capricious. The case involved rescission of a "long-standing" agency policy. *Id.* at 813. The court found that the agency's failure "to provide any explanation for [its] implicit rejection of alternatives to elimination of restrictions" rendered the agency's action arbitrary and capricious. *Id.* at 815. "[I]n addition to requiring rational consideration of alternatives, the APA demands an adequate explanation when these alternatives are rejected." *Id.* at 817. There was little dispute about the availability of alternatives to rescission – two of which were contained in the agency's notice of hearings on the proposed action. *Id.* at 815. "[T]he agency's consideration of some alternatives does not free it from considering other obvious alternatives." *Id.* at 816 n.41. Acknowledging that an agency is not required to consider every possible alternative, "the options ignored by the Secretary in this case certainly cannot be characterized as 'uncommon or unknown.' These options

²¹ Moreover, courts have set aside agency action where flawed agency methodology resulted in an overestimation of the benefit analysis. See *U.S. Air Tour Ass'n v. FAA*, 298 F.3d 997, 1018-19 (D.C. Cir. 2002).

were specifically mentioned in the notice of hearings and the comments received by the Secretary, and would be an obvious response to the concerns expressed by the Secretary." *Id.* at 817. The agency was required to "address common and known or otherwise reasonable options, and to explain any decision to reject such options." *Id.* at 818. In light of the agency's failure to address these alternatives, the court vacated the agency's rescission of the previous restrictions. *Id.*

Finally, in *Public Citizen v. Steed*, 733 F.2d 93 (D.C. Cir. 1984), the court held that "when the action involves a change in a settled course of agency behavior, . . . 'we will demand that the [agency] consider reasonably obvious alternative[s] . . . and explain its reasons for rejecting alternatives in sufficient detail to permit judicial review.'" *Id.* at 99 (quoting *Nat'l Resources Defense Council v. SEC*, 606 F.2d 1031, 1053 (D.C. Cir. 1979)). Here, the agency failed to consider available and known alternatives to testing procedure deficiencies that were readily correctable prior to suspending a component of a tire testing program. "NHTSA failed to give serious consideration to specific measures that could correct the variability problems which it relied upon to justify the suspension." *Id.* at 105. Given this failure to consider alternatives, the agency's suspension was deemed arbitrary and capricious.

The current rulemaking includes a discussion of "various alternatives to key provisions in the proposal," and solicits the submission through public comment of "other alternatives including detailed rationale and supporting documentation." 75 Fed. Reg. 64415-16.²² Although a final rule would not be considered unlawful if MSHA were to fail to consider every possible alternative, if MSHA were to fail to consider and provide its rationale for rejecting known or obvious alternatives, particularly those alternatives raised in the comments, the final rule could be challenged under the APA. In its current rulemaking, MSHA fails to consider alternatives such as regulating only the "hot spots" evidencing problems, adopting the hierarchy of controls, accepting the protection of supplied air helmets, and the other alternatives suggested by NMA.

IX. MSHA Violated Presidential Regulatory Reform and Transparency Orders

On January 21, 2009, the day after being sworn into office, the President issued a *Memorandum for the Heads of Executive Departments and Agencies* concerning administration of the Freedom of Information Act.²³ He set a course for a new era of accountability and transparency. In so doing, the President directed that agencies "adopt a presumption in favor of disclosure" where "in the face of doubt, openness prevails."

²² The request for the submission of alternatives also appears at 75 Fed. Reg. 64418, 64419, 64423, 64434, 64436, 64446, and 64477. Additionally, it discusses additional consideration of alternatives at 75 Fed. Reg. 64426 (yearly and biennial recertification); 64432 (noncompliance when any single-shift measurement exceeds the applicable dust standard by any amount); and 64475 (estimation of monetized benefits under alternative assumptions to illustrate uncertainty in estimates).

²³ Available at <http://www.whitehouse.gov/thepressoffice/FreedomofInformationAct/>

The President's directive was followed by a memorandum from the Attorney General (March 19, 2009).²⁴ In this memorandum, he reminded agencies of the President's view that, "The Government should not keep information confidential merely because public officials might be embarrassed by disclosure, because errors or failures might be revealed, or because of speculative or abstract fears." Indeed, the Attorney General recognized that exemptions to protect "national security, personal privacy, privileged records and law enforcement interests" are a necessary but limiting factor when reviewing FOIA document requests.

On October 25, 2010 and November 11, 2010, NMA sent Freedom of Information Act requests to MSHA and the NIOSH, respectively to obtain information critical to the review of the proposed rule. On Nov. 4, NMA received a response from DOL's FOIA Officer indicating that a response would be delivered "within 45 days of the date of this letter." On April 8, nearly 6-months from the date of the original FOIA request, MSHA's Freedom of Information Act Officer responded, repeatedly claiming FOIA's deliberative process privilege in denying the release of more than "20,000 pages ... of documents" regarding the proposed rule. Our appeal of the deliberative process exemption, with the Solicitor of Labor, remains pending as of the date of these comments.

On January 18, 2011, the President issued an Executive Order, *Improving Regulations and Regulatory Review*. The President ordered regulatory agencies to follow basic principles in the development of regulations, including:

Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.

(Emphasis added)

MSHA has violated the philosophies and values of accountability and transparency embodied in the President's and Attorney General's orders and memoranda. The agency's actions deny stakeholders access to documents critical to a thorough evaluation of the proposed rule and deprive miners' of a rule that is, as required by the Section 101(a)(6)(A) of the Mine Act informed by "... the latest available scientific data in the field [and] the feasibility of the standards..."

a) Executive Order 12866

In 1993, President Clinton issued Executive Order 12866 (EO 12866), which was aimed at reforming the regulatory process. 58 Fed. Reg. 51735 (Oct. 4, 1993). EO 12866 contains a statement of regulatory philosophy and principles, which directs:

In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating...

²⁴ Available at <http://www.justice.gov/ag/foia-memo-march2009.pdf>

Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach...

To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(3) Each agency shall identify and assess available alternatives to direct regulation;

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity; and

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

EO 12866 § 1, 58 Fed. Reg. at 51735-36.

b) Significant Regulatory Action

With these principles in mind, EO 12866 established a process for the review of significant regulatory actions by the Office of Information and Regulatory Affairs (OIRA). *Id.* at § 6(a)(3), 58 Fed. Reg. at 51740-41. Those planned regulatory actions not deemed to be significant by the agency are not reviewed by OIRA unless, within 10 days of the agency's submission, OIRA notifies the agency that OIRA has determined the planned regulation to be significant. *Id.* EO 12866 defines a significant regulatory action as any regulatory action likely to result in a rule that may:

- 1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- 2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

- 3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- 4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Id. at § 3(f), 58 Fed. Reg. at 51738. Where a proposed regulation is designated or identified as significant, the agency is required to provide additional information to OIRA, including:

An assessment, including the underlying analysis of costs and benefits of potentially effective and reasonable feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable non-regulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

Id. at § 6(a)(3)(C)(ii), 58 Fed. Reg. 51741.

The principles of EO 12866 were reaffirmed in President Obama's Executive Order 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011).²⁵ "Our regulatory system ... must identify and use the best, most innovative and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative."

c) OMB Guidance

When an agency does determine that a proposed rule is an economically significant regulatory action, the Office of Management and Budget provides guidance through its Circular A-4 Regulatory Analysis (Sept. 17, 2003).²⁶

Circular A-4 discusses the evaluation of alternatives by agencies in rulemaking. Circular A-4 instructs agencies to "carefully consider all appropriate alternatives for the key attributes or provisions of the rule." *Id.*

Where there is a "continuum" of alternatives for a standard (such as the level of stringency), [an agency] generally should analyze at least

²⁵ "This order ... reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866 ... each agency must among other things: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify; ... (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); ... (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public."

²⁶ Available at http://www.whitehouse.gov/omb/circulars_a004_a-4/

three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

In some cases, a regulatory program will focus on an option that is near or at the limit of technical feasibility. In this case, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

Id. at 16-17.

Additionally, where the primary benefit of the rulemaking is improved public health and safety, the guidelines direct agencies to conduct both a benefit-cost analysis and cost-effectiveness analysis.

d) MSHA's Determination under EO 12866 Is Invalid

In accordance with agency rulemaking requirements, MSHA prepared a Preliminary Regulatory Economic Analysis for Lowering Miners' Exposure to Respirable Coal Mine Dust Including Continuous Personal Dust Monitors (the PREA). Its analysis included a finding "that the proposed rule is not an economically significant regulatory action in terms of compliance costs under § 3(f)(1) of Executive Order 12866." PREA at 5.²⁷ This determination is at odds with the information presented at the February 15, 2011 hearing by Alliance and by other NMA members who reinforced the massive costs that will be imposed by the proposed rule. Specifically, with respect to the example of Mine 6, Alliance demonstrated that it would have initial capital costs of at least \$1.7 million, annual maintenance costs of \$1.2 million, and production losses of over \$30 million. Tr. At 59-60 Their analysis did not take into account the civil penalties that would result from each of the 588 expected citations. Clearly, if one mine can expect to encounter costs of \$33 million, the proposed regulation will not only have "an annual effect on the

²⁷ As was discussed at the February 15, 2011 hearing, one glaring omission from the PREA is the absence of any costs associated with lost or decreased production associated with compliance with or enforcement of the proposed rule.

economy of \$100 million or more," but it will also undoubtedly "adversely affect in a material way the economy, a sector of the economy, productivity, competition, [or] jobs ..." In light of this, MSHA's determination that the current rulemaking is not a significant regulatory action is not based on fact and unless the rule and the analysis is withdrawn, it will be subject to court review and likely held invalid.

However, because MSHA conveniently determined that the rulemaking is not a "significant regulatory action," it decided not to comply with the guidance set forth in Circular A-4. Despite this, the rulemaking makes multiple references to Circular A-4 when discussing its conclusion that the proposed rule is not an economically significant regulatory cost action pursuant to EO 12866. See 75 Fed. Reg. 64474-75.

Although there may be no private right of action under EO 12866 to challenge MSHA's determination that this is not a significant regulatory action, any party aggrieved by MSHA's final action in the respirable dust rulemaking (and the Agency's analysis of the compliance costs contained therein) may still challenge the action under the APA and the Mine Act.

e) MSHA Violated RFA and SBREFA

Signed into law on September 19, 1980, RFA, 5 U.S.C. §§ 601 *et seq.*, imposes both analytical and procedural requirements on federal agencies. The analytical components require agencies to consider carefully the economic impacts that rules will have on small entities. The procedural requirements are intended to ensure that small entities have a voice when federal agencies make policy determinations in shaping its rules. SBREFA, Pub Law No. 104-121, signed into law on March 29, 1996, amended RFA to require "covered agenc[ies]"²⁸ to convene a small business advocacy review panel prior to proposing any rule that will have a significant economic impact on a substantial number of small entities. It also added a provision that allows small entities adversely affected by a final rule to challenge the agency's compliance with RFA's requirements in court.

Specifically, RFA and SBREFA (collectively the Regulatory Acts), require an agency, when promulgating a rule, to prepare an initial and a final regulatory flexibility analysis, which must contain:

- (1) a statement of the need for, and objectives of, the rule;
- (2) a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- (3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;
- (4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate

²⁸ A "covered agency" includes the Environmental Protection Agency and the Occupational Safety and Health Administration. 5 U.S.C. § 609(d).

of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and (5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes...

See 5 U.S.C. §§ 603, 604.

5 U.S.C. § 605 provides an exception to this requirement. That is, a regulatory agency does not have to prepare a final regulatory flexibility analysis if the head of the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities." 5 U.S.C. § 605(b). If the head of the agency makes such a certification, the agency is required to publish such certification in the Federal Register at the time of publication of the final rule, along with a statement providing the factual basis for such certification.

f) The Statutes Apply to MSHA

The bulk of the requirements under the Regulatory Acts apply to "agencies" generally, with a very few additional requirements which only apply to "covered agenc[ies.]" By way of definition, an "agency" under the Regulatory Acts means any federal agency that is covered by 5 U.S.C. § 551(1) of the APA. See 5 U.S.C. § 601(1). Under the APA, an "agency" is defined as "each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include: (A) the Congress; (B) the courts of the United States; (C) the governments of the territories or possessions of the United States; (D) the government of the District of Columbia." Clearly, this definition of "agency" encompasses MSHA.

There are certain, *additional* requirements set forth in 5 U.S.C. § 609²⁹, which apply only to a "covered agency," for this purpose, such as OSHA, but not MSHA.

g) Impact on MSHA's Respirable Coal Dust Rulemaking

In its current rulemaking, MSHA analyzed the compliance costs of the proposed rule on small entities. Based on that analysis, MSHA determined and certified that the proposed rule would not have a significant economic impact on a substantial

²⁹ These additional activities include notifying the Small Business Administration ("SBA") about the proposed rule to allow the SBA an opportunity to "identify individuals representative of affected small entities for the purpose of obtaining advice and recommendations from those individuals about the potential impacts of the proposed rule," convening a review panel consisting wholly of full time Federal employees of the office within the agency responsible for carrying out the proposed rule, the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel, prior to publishing an initial regulatory flexibility analysis. 5 U.S.C. § 609(b). The review panel is responsible for collecting the advice and recommendations of the individuals identified by the SBA and for submitting a report on its findings. *Id.*

number of small entities. 75 Fed. Reg. at 64477. As a result, MSHA certified that it was not required to develop a regulatory flexibility analysis.³⁰

MSHA's analysis is simply wrong. A realistic analysis of the actual MSHA sampling database and of the ramifications of the changes to Part 75 demonstrates that the economic impacts of the proposed rule will be far greater than the agency's analysis contemplates and that the proposed rule will in fact have a significant economic impact on a substantial number of small entities and on the economy. MSHA's current analysis is based upon its erroneous assumption that most of the industry is already in compliance with the proposal. This assumption is based upon an averaging of multiple samples to make it appear as though the industry is already in compliance. However, when the actual MSHA dust sampling database of over 1 million samples is examined in light of the proposed rule, the stark reality is that the proposed rule will result in hundreds of millions of dollars in costs, the issuance of hundreds of thousands of violations and penalties, and required plan changes for each and every violation.

h) Without Withdrawing the Proposed Rule and Its Improper Certification, MSHA Faces Judicial Review of Its Flexibility Analysis

For any agency rule that is subject to the Regulatory Acts, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of the Regulatory Acts, including compliance with Section 605(b) (which allows an agency to avoid preparing a final regulatory flexibility analysis if the head of the agency certifies that the rule "will not, if promulgated, have a significant economic impact on a substantial number of small entities"). See 5 U.S.C. § 611(a). Thus, if a small entity or group of small entities believes that compliance with MSHA's respirable coal dust rule *will* have a significant economic impact on a substantial number of small entities, the entity or entities may seek judicial review of MSHA's compliance with Sections 603, 604, and 605(b) of the Regulatory Acts, once the final rule is published.³¹

Judicial review of final agency action is available in any court having jurisdiction to review such action for compliance with 5 U.S.C. § 553, the rulemaking provision of the APA, Pub L. 79-404. Pursuant to Section 611(a)(3)(A), a small entity may seek

³⁰ Interestingly, this position is contrary to the position that MSHA has taken with regard to single-shift sampling beginning in 1994. From Spring 1994 until Spring 2005, each time MSHA included single-shift sampling in the semi-annual Unified Agenda (RIN 1219-AA82 and RIN 1219-AB18), it indicated that a Regulatory Flexibility Analysis was required. See, e.g., 66 Fed. Reg. 25717 (May 14, 2001). Between Fall 2005 and Spring 2009, the Unified Agenda reflected that it was "undetermined" whether Regulatory Flexibility Analysis was required or not. See, e.g., 70 Fed. Reg. 64919 (Oct. 31, 2005). Only beginning in Fall 2009 did MSHA take the position that a Regulatory Flexibility Analysis was not required for the single-shift sampling rulemaking.

³¹ Section 101(d) of the Mine Act provides the exclusive means of challenging the validity of a mandatory health or safety standard. 30 U.S.C. § 811(d). Persons "adversely affected" by a standard may challenge its validity by filing a petition for review with the United States Court of Appeals for the District of Columbia Circuit, or the circuit where the aggrieved person resides or his his/her principle place of business, within sixty days after the standard is promulgated.

judicial review "during the period beginning on the date of final agency action and ending one year later, except that where a provision of law requires that an action challenging a final agency action be commenced before the expiration of one year, such lesser period shall apply."

MSHA's rulemaking continues today as a proposed rule, subject to public comment and revision, and is not yet a final agency action. If, after the final rule is published, a small entity is aggrieved, then the entity can seek judicial review consistent with Section 611.

i) The Agency Burden Under RFA and SBREFA Likely Requires Re-Analysis

The Regulatory Acts were passed in an effort to "encourage administrative agencies to consider the potential impact of nascent federal regulations on small businesses." *Associated Fisheries of Maine, Inc. v. Daley*, 127 F.3d 104, 111 (1st Cir. 1997). A "reasonable, good-faith effort to carry out [RFA's] mandate" is required. *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001) (quoting *Alenco Communications, Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000)). The Acts do not require agencies to take specific action, but instead require consideration of alternatives.

[T]his provision does not require that an agency adopt a rule establishing differing compliance standards, exemptions, or any other alternative to the proposed rule. It requires that an agency, having identified and analyzed significant alternative proposals, describe those it considered and explain its rejection of any which, if adopted, would have been substantially less burdensome on the specified entities. *Associated Fisheries*, at 114 (quoting 121 Cong. Rec. at S21,459-60).

Under the standard for judicial review of compliance with RFA, a court reviews whether the agency conducted a complete IRFA and FRFA. *ACE Lobster Co., Inc. v. Evans*, 165 F. Supp. 2d 148, 185 (D. R.I. 2001) "The point is not whether the Secretary's judgments are beyond reproach, but whether he made a reasonable, good-faith effort to canvass major options and weigh their probable effects." *Id.* (citing *Assoc. Fisheries of Maine*, 127 F.3d at 116). Given the identification of the false and incorrect analysis relied upon by the Secretary, the burden for the Secretary to show a reasonable effort likely will be increased without a reanalysis by MSHA.

Exhibits

1. John D. Meyer, et al., "Prevalence of Small Lung Opacities in Populations Unexposed to Dusts: A Literature Analysis," *Chest* 111 (1997): 404-410.
2. "Centers for Disease Control Coal Workers Pneumoconiosis Prevalence" (Data retrieved from the Centers for Disease Control website <http://www.cdc.gov/niosh/topics/surveillance/ords/ECWHSPUG.HTML>, accessed April 21, 2011, compiled for use by the National Mining Association).
3. E. Suarhana, et. al., "Coal workers pneumoconiosis in the United States: regional difference after implementation of the 1969 Federal Coal Mine Health and Safety Act," *Occupational and Environmental Medicine* (2011).
4. A. Scott Laney, et al., "Pneumoconiosis among underground bituminous coal miners in the United States: is silicosis becoming more frequent?" *Occupational & Environmental Medicine* 67 (2010): 652-656, doi: 10.1136/oem.2009.047126.
5. Mine Safety and Health Administration, Public Hearing regarding Proposed Rule "Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors"; testimony of Dr. Robert Glenn and Dr. John Gamble, February 2011.
6. David Rosenberg, "An Evidence Based Review of the Literature Supporting the Mine Safety & Health Administration Proposed Coal Mine Dust Rule" (written for use by the National Mining Association, April 2011).
7. National Mining Association, Comments on "A Review of Information Published Since 1995 on Coal Mine Dust Exposures and Associated Health Outcomes," September 2010.
8. Antao, et. al, Advanced Cases of Coal Workers Pneumoconiosis – Two Counties, Virginia, 2006, *MMWR Weekly* 55(33); 909-913 (2006) (a critical review of the data used to support the articles findings)
9. Mine Safety and Health Administration, Public Hearing regarding Proposed Rule "Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors"; Evaluation of MSHA Proposed Rule, testimony of Mark Watson, et al., February 15, 2011.
10. Robert Glenn. "A Critical Review of MSHA's Proposal for Control Measures to be Employed in Lowering Miners' Exposure to Respirable Coal Mine Dust; Comments on Requirements for Designated Area Sampling and for Personal

Sampling Devices to Remain with the Occupation or Designated Area being Sampled" (written for use by the National Mining Association, May 2011)

11. Mine Safety and Health Administration, Public Hearing regarding Proposed Rule "Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors"; Comment on one provision of the proposed rules for "Lowering Miners' Exposure to Respirable Coal Mine Dust...", testimony of Gary M. Hartsog, submitted electronically February 15, 2011, <http://www.msha.gov/REGS/Comments/2010-25249/hearings.asp>.

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