

Fontaine, Roslyn B - MSHA

From: Green, Edward [EGreen@crowell.com]
Sent: Monday, June 20, 2011 11:59 AM
To: Fontaine, Roslyn B - MSHA; zzMSHA-Standards - Comments to Fed Reg Group
Subject: RIN 1219--AB64; Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors; Proposed Rule
Attachments: 6-20-11 Ltr to R.Fontain_001.pdf; CV - J.Gamble_001.pdf; CV - R.Reger_001.pdf; CV - R.Glenn_001.pdf; Epub Suarthana oem 2010 063594 full.pdf; 15398220_1.pdf; Petition for Rulemaking_001.pdf; 15387085_1.pdf

Re: RIN 1219--AB64; Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Personal Dust Monitors; Proposed Rule

Dear Ms. Fontaine:

Attached please find comments on the subject proposed rulemaking from Alliance Coal, Alpha Natural Resources, Arch Coal, BHP Billiton New Mexico Coal, Murray Energy Corporation, and Peabody Energy. We thank you for the opportunity to comment on the proposal.

Sincerely yours,

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June 20, 2011

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Regulatory Development Division
Office of Standards, Regulations, and Variances
Mine Safety and Health Administration
U.S. Department of Labor
1100 Wilson Boulevard, Room 2350
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Re: Comments of Alliance Coal, Alpha Natural Resources, Arch Coal, BHP Billiton New Mexico Coal, Murray Energy Corporation, and Peabody Energy on MSHA's Proposed Rule on Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors: RIN 1219-AB64

Dear Ms. Fontaine:

Introduction

Please find herein and attached the comments of Alliance Coal, Alpha Natural Resources, Arch Coal, BHP Billiton New Mexico Coal, Murray Energy Corporation, and Peabody Energy (hereinafter "the Companies") on MSHA's Proposed Rule on Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors (30 C.F.R. Parts 70, 71, 72, 75, and 90), published in the Federal Register for October 19, 2010. 75 Fed. Reg. 14,412 (hereinafter the "NPR"). In addition to these comments, the Companies hereby endorse the written comments of the National Mining Association ("NMA") on this Proposed Rule, as well as the testimony that the NMA panel presented at the February 15, 2011 MSHA public hearing on this NPR held in Arlington, VA. We incorporate those written comments and that testimony by reference as though fully set forth herein.¹

By way of introduction of the Companies, the independent operating subsidiaries of Alliance Coal, LLC ("Alliance") operate ten underground coal mining complexes throughout Kentucky, Illinois, Indiana, and West Virginia. These mines produce approximately 30 million

¹ All of the Companies are NMA members.

tons of coal annually and employ around 3,000 miners. Mines within the Alliance family strive to be recognized as industry leaders in all metrics of miner safety and health. To accomplish this objective, Alliance empowers its miners to champion the safety process. Achievement is rewarded and miners are encouraged to actively participate in Alliance's continuous efforts to prevent accidents in the work environment. Alliance is also a leader in the advancement and utilization of safety and health technology in its mines, providing its miners with safety and health equipment that goes beyond requirements of existing laws.

Alpha Natural Resources ("Alpha") is the third-largest coal producer in the United States, with production capacity, through its subsidiaries, of nearly 100 million tons of steam and metallurgical coal annually from more than 60 mines throughout Virginia, West Virginia, Kentucky, Pennsylvania, and Wyoming. Alpha's subsidiaries employ approximately 14,000 miners. At Alpha, safety comes first, and the Company believes that all injuries are preventable. Safety is integrated into every activity; and if a task cannot be completed safely, it will not be performed. Every miner has responsibility, not only for his or her own safety, but also for the safety of miners around him or her. In this regard, each and every of our miners is trained to be a safety leader; taught not only to recognize hazardous situations and activities, but also empowered to take immediate corrective action. Because Alpha believes there is nothing more important than the safety and health of its miners, the Company continually invests in the latest equipment and technology, and utilizes the safest mining practices.

Arch Coal ("Arch"), based in St. Louis, Missouri, is the second largest coal company in the United States and the fourth largest in the world. In the United States, Arch's subsidiaries operate eleven coal mining complexes, in Wyoming, Utah, Colorado, West Virginia, Kentucky, and Virginia. Those subsidiaries sold almost 163 million tons of coal in 2010, 15% of the United States' coal supply, serving 195 power plants and other end users in 39 states. Arch's mines employ about 4,700 miners. Arch is an industry leader with regard to the safety and health of its miners, continuing to set the bar higher each year. In 2010, Arch set a new record for safety. This accomplishment is a testament to Arch's deep-rooted culture of safety and the strong participation of Arch's miners in that culture. In short, achieving success in the core value of safety is absolutely critical to Arch.

BHP Billiton ("BHP") is the world's largest diversified natural resources company, with more than 100 operations in approximately 25 countries throughout North and South America, Africa, Asia, and Australia. In the United States, BHP's New Mexico Coal Operations, located in the Four Corners area of Northwestern New Mexico, are comprised of two coal mines: (1) the Navajo Mine, a large surface coal mine located within the boundaries of the Navajo Reservation; and (2) the San Juan Mine, an underground longwall operation. About 65% of the salaried and hourly workforce of 1,000 employees of BHP New Mexico Coal is comprised of Native Americans. The two mines produce about 15 million tons of coal annually and are the sole suppliers of coal for the Four Corners and San Juan Generating Stations, which furnish electricity to New Mexico, Colorado, Utah, Arizona, and California. BHP's approach to miners' safety and health is grounded on compliance with the requirements of federal and state law and a systematic risk-based program comprised of detailed safety process components and a safety process matrix to address identified risks.

Murray Energy Corporation (“MEC”) is the largest privately-owned coal company in America, producing approximately 30 million tons of bituminous coal annually that provides affordable energy to households and businesses across the country. MEC’s subsidiaries operate eight underground and surface mining operations in Southern Illinois and Southern Ohio, Western Kentucky, and Utah, plus 40 subsidiary and support companies. Transporting coal via truck, rail, and waterways, MEC operates the second-largest fleet of longwall mining units in the country. With a support team of 2,800 hard-working, dedicated, and talented employees, MEC’s affordable high-quality coal is mined safely and efficiently, and is supplied to leading producers of electricity, both domestically and abroad. MEC’s committed management team and workforce are dedicated to maintaining a safe work environment,

Headquartered in St. Louis, Missouri, Peabody Energy (“Peabody”) is the world’s largest private-sector coal company. Peabody’s operations are geographically diverse within the United States and around the world, with locations on five continents. In the United States, Peabody operates 17 coal mining complexes, employing more than 8,200 miners, and is the leading coal producer in the Powder River Basin, the Southwest, the Illinois Basin, and Colorado, with U.S. coal production of 189 million tons, fueling 10% of U.S. electricity generation. Peabody’s employees are the company’s most highly-valued resource and their safety and health is a core value that is integrated into all areas of Peabody’s business.

Background

The Mine Safety and Health Administration (“MSHA”) published in the Federal Register on October 19, 2010, its proposed rule for “Lowering Miners’ Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors” (the “NPR”). 75 Fed. Reg. 64,412-64,506. The NPR would regulate miners’ exposure to respirable coal mine dust by revising the Agency’s existing standards. The NPR is excessively complex and overly detailed, but its major provisions would: (1) lower the existing exposure limits for respirable coal mine dust from 2.0 milligrams per cubic meter (mg/m^3) to 1.0 mg/m^3 ; (2) provide for the use of a single full-shift sample to determine compliance under the mine operator’s and MSHA’s inspector sampling programs; (3) require the use of a new technology, the Continuous Personal Dust Monitor (“CPDM”) for exposure monitoring; (4) expand requirements for medical surveillance; and (5) dramatically change ventilation plan processes and operating parameters in ventilation plans, including having the effect of prohibiting the use of supersection system of mining.

To start, all of the Companies believe the current rules of MSHA and the National Institute for Occupational Safety and Health (“NIOSH”), designed to prevent coal workers’ pneumoconiosis (“CWP”) are in need of reform. This belief is grounded in experience gained from the implementation of the Federal Mine Safety and Health Act of 1977, as amended, 30 U.S.C. §§ 801, et seq., (the “Mine Act”) and other health and safety laws. However, while the Companies support such reform, careful review and consideration of the NPR makes clear that the NPR is not the answer to problems that exist under current rules and regulations. The Companies, therefore, reject this NPR, and urge MSHA to withdraw the NPR entirely and start afresh. To the extent the record has remained open on the earlier proposals on this issue published during the Administrations of Presidents Bill Clinton and George W. Bush, the

Companies urge that those earlier proposed rulemakings should also be withdrawn. The time has come to turn a new page on this failed NPR and the two previous ones.

In short, for the reasons set forth below and in the attachments to this letter, the Companies believe MSHA has failed to satisfy its procedural obligations and substantive duties under the Mine Act, other laws, and executive branch policies. Moreover, those failings render this NPR incapable of being sustained. With particular regard to the Mine Act, the NPR is invalid as a direct result of MSHA's failures on at least three provisions: §§ 202(a), 202(f), and 101(a)(6)(A). To that end, if MSHA cannot carry out its most basic, and statutorily required, obligations, then the NPR cannot possibly stand.

- Mine Act § 202(a) requires both the Secretary of Labor and the Secretary of Health and Human Services to prescribe in the Federal Register the methods, locations, intervals, and manner for taking accurate samples of respirable dust in the mine atmosphere to which each miner in the active workings of underground coal mines is exposed. This NPR prescribes the methods, locations, intervals, and manner to take samples of respirable dust, but it is fatally defective because the Secretary of Health and Human Service's involvement in these prescriptions is nowhere to be found. Any rule that MSHA publishes in the Federal Register dealing with these issues *must be both proposed and promulgated jointly* by the Secretary of Labor (through her delegate MSHA, if she so chooses) and the Secretary of Health and Human Services (through her delegate NIOSH, if she so chooses). MSHA simply does not have the statutory authority, under Mine Act § 202(a) or elsewhere, to independently publish proposed or final rules dealing with the above-specified issues. Indeed, even if NIOSH approves of the provisions in the NPR, NIOSH's approval would not correct the fundamental problem of MSHA's failure to follow Mine Act § 202(a)'s specific statutory requirement of *joint* publication in the Federal Register throughout the rulemaking process, from initial proposal to final promulgation.

- Not only is the NPR fatally flawed procedurally—due to MSHA's failure to include the Secretary of Health and Human Services in the development and publication of the NPR—but MSHA also runs afoul of the substantive mandate of Mine Act §202(a) with regard to the accuracy of the samples proposed to be taken. Thus, as the testimony of the NMA witnesses at the MSHA February 15, 2011 public hearing effectively demonstrated, the new continuous personal dust monitor ("CPDM") needs additional development and improvement to provide accurate and consistent results. Under the NPR, however, the CPDM would, after a short period of time be the mandatory sampling device for respirable dust. The Companies also endorse the expert report of Michael Cooper, MPH, CIH, and Sheila McCarthy, MPH, CIH on "Laboratory Testing of Continuous Personal Dust Monitor (CPDM)," prepared for MEC, Alliance, Arch, the Illinois Coal Association, and the Indiana Coal Council. This report will be submitted to the Agency by MEC as part of its separately filed comments. In light of the above noted testimony and expert report, the Companies assert that, while in due course it is possible that the CPDM may be sufficiently perfected to take accurate samples that time has not yet arrived. Rather, for the time being, the CPDM should only be used as a non-compliance administrative control to allow mine operators to monitor the relative exposures of their miners to respirable dust, pending the successful completion of rigorous field trials of the CPDM, pursuant to a protocol developed

by all stakeholders. The CPDM should not be used in its present stage of development as a device to determine compliance with any respirable dust standard.

- On a similar note, Mine Act § 202(f) is extremely clear.

For the purpose of this title, the term "average concentration" means 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.

Thus, the term "average concentration" is defined as a determination accurately representing the mine atmospheric exposure to respirable dust for each miner in the mine's active workings. However, Mine Act §202(f) also provides that an "average concentration" may only be determined in two ways. First, during the eighteen months following the enactment of the Mine Act, "average concentration" was to be measured over a number of continuous production shifts, as determined by the Secretary of Labor and the Secretary of Health and Human Services. Following the eighteen month period, "average concentration" was required to be measured over a single shift, *unless* the Secretary of Labor and the Secretary of Health and Human Services found, in accordance with Mine Act § 101, that such single shift measurement will not, "after applying valid statistical techniques, accurately represent such atmospheric conditions during such shift." The preamble acknowledges that the two Secretaries found in 1972 (and so published their finding in the Federal Register) that single shift measurement of respirable dust would not, after applying valid statistical techniques, accurately represent such atmospheric conditions during such shift.² That joint Secretarial finding remains in effect today. MSHA proposes in this NPR to "rescind the 1972 joint notice of finding."³ However, MSHA lacks any authority to rescind the 1972 joint finding unilaterally. Knowing the limitations of its authority, MSHA falls back on some regulatory legerdemain, claiming that a July 2000 joint MSHA-NIOSH proposal to rescind the 1972 finding is still subject to public comment.⁴ The use of an eleven-year-old proposed joint rescission of the 1972 finding cannot possibly be used as a fundamental basis for the validity of this NPR, particularly when the NPR is such a radical departure from the earlier proposals of the Administrations of Presidents Bill Clinton and George

² See 75 Fed. Reg. 64,413 referencing a joint finding by the Secretaries of the Interior and Health, Education, and Welfare under section 202(f) of the Federal Coal Mine Safety and Health Act of 1969, published on February 23, 1972, at 37 Fed. Reg. 3,833.

³ *Id.* at 64,449.

⁴ *Id.* at 64,415.

W. Bush. Simply put,, the 1972 joint Secretarial finding cannot be rescinded without a *proposed rescission published by both MSHA and NIOSH for comment, followed by a joint final rescission*. In this NPR, no such role for NIOSH or the Secretary of Health and Human Services can be found, and the NPR is thus fatally flawed on that count too.⁵

• Finally, as the “Critical Review of the Scientific Basis for MSHA’s Proposal for Lowering the Coal Mine Dust Standard” (“Critical Review”), described below so powerfully proves, MSHA has not successfully fulfilled its burden, under Mine Act § 101(a)(6)(A), to demonstrate the need for revisions to the respirable dust standards based on the best available evidence. For that reason too, this NPR is fatally flawed. Among the reasons why the Companies reject this NPR, and central to our view that MSHA has not demonstrated that the NPR is based on the best available evidence, is that we vehemently disagree with MSHA that the prevalence of CWP is increasing in the Nation’s coal miner population. To test the validity of what our first hand, yet anecdotal, information seemed to support, the Companies commissioned preparation of the Critical Review, written by three internationally recognized experts in the field of CWP and other occupationally related lung diseases. These three experts (all of whom have long experience as senior NIOSH officials in the early formative years of that Agency’s CWP program) are John F. Gamble, PhD, Robert B. Reger, PhD, and Robert E. Glenn, MPH. A copy of the Critical Review is attached to this letter, as well as the curriculum vitae of these three experts.

The Critical Review is very detailed and comprehensive, and we urge its careful and thorough review by the Agency. Because of its length, and in order to emphasize the fundamental flaws in the NPR, the Companies have extracted below the Executive Summary, the Introduction, and the Overall Summary and Conclusions of the Critical Review.

In addition to this Critical Review, the Companies have learned that a very important new study has been published online by NIOSH scientists on May 19, 2011, entitled “Coal Workers’ Pneumoconiosis in the United States: Regional Differences 40 Years After Implementation of the 1969 Coal Mine Health and Safety Act.”⁶ This new study is quite consistent with and supportive of the of the Critical Review; and the Companies discuss it further below, following our discussion of the Critical Review.

⁵ The Companies note that on April 28, 2011, NIOSH actually filed “comments” on the NPR, sending a letter to the MSHA docket enclosing its current Intelligence Bulletin 64, “Coal Mine Dust Exposures and Associated Health Outcomes, A Review of Information Published Since 1995.” See, letter from Paul A. Schulte, PhD, Director of NIOSH’s education and Information Division (MSHA Docket No. AB64-COMM-41). It would appear that NIOSH itself has forgotten its statutory role under Mine Act §§202(a) and (f).

⁶ Suarathana E., Laney AS, Storey E., et al., *Occup. Environ. Med.*, published online, May 19, 2011.

Executive Summary of the Critical Review

To begin, in order to place the NPR and the Critical Review into context, implementation of a federal coal mine dust (“CMD”) interim standard of 3.0 milligrams per cubic meter (“mg/m³”) began in 1970. The standard was reduced to 2.0 mg/m³ in 1972, and it produced a steady decline in dust levels and prevalence of coal workers pneumoconiosis (“CWP”). Beginning in the mid-1990s, an apparent increase was reported in what was thought to be severe and rapidly progressive CWP and PMF despite stability in CMD levels. These “sentinel health” events led to further investigation and, in part, stimulated the current NPR to lower the current CMD standard from 2.0 mg/m³ to 1.0 mg/m³.

Objectives of the Critical Review, therefore, were to evaluate the epidemiological evidence regarding risk factors associated with these “sentinel health” events and the exposure-response relationships of CMD and CWP. This evaluation included consideration of other risk factors (e.g., quartz, coal rank) plus bias and confounding (e.g., low participation of coal miners in surveillance programs and studies and biased exposure estimates of CMD). The results from this evaluation were then used to assess whether the current CMD standard of 2.0 mg/m³ protects miners from developing disabling CWP and whether the lowering of the standard is scientifically based.

Rapidly progressive pneumoconiosis to category 2+ and PMF is a sentinel health event of low prevalence (less than 0.5%) clustered in the southern Appalachian region (“SAR”). It is a factor stimulating the proposal for setting a new CMD standard but is unsuitable owing to a lack of any evidence whatsoever that such sentinel events are primarily being caused by CMD.

Compelling evidence discussed in the Critical Review indicates that the rapidly progressive cases of pneumoconiosis recently reported are, in reality, silicosis which is based on very high quartz exposures and short latency, both factors clearly being consistent with silicosis and unlike CWP. The higher proportion of r-type opacities in the SAR than in the rest of the US is likewise consistent with a silicosis interpretation. Other factors also related to increased quartz exposures include working in small mines, increased hours worked per day, and smaller coal seams.

Exposure-response studies are necessary to determine a safe level of exposure. US studies of exposure-response are based on the cohort from the National Study of Coal Workers' Pneumoconiosis (“NSCWP”), which, as the Critical Review points out is subject to two primary biases. One is a potential selection bias because of low participation rates in all rounds except the first round.⁷ The direction of this potential bias is speculative as it is not known whether

⁷ NIOSH refers to periods of medical examinations of coal miners, usually in five-year periods, in its nationwide epidemiology studies and nationwide surveillance program as “rounds”. While they are conducted over a period of years they are used to develop cross-sectional prevalence data.

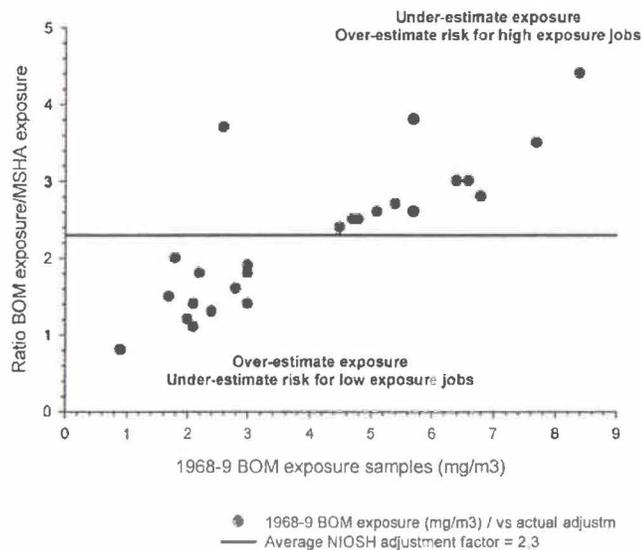
unhealthy miners selectively participate or not. If unhealthy miners do not participate, then the NSCWP artificially lowers CWP rates.

The other potential bias is estimation of pre-1970 exposures which were very high (up to a mean of 8 mg/m³ in high exposure jobs) as reported in a study by the US Bureau of Mines (“BOM”) that began in 1968. NIOSH used these BOM sample results and post-1970 operator sample results for indirect back extrapolations to estimate pre-1970 exposures. The procedure was to calculate mean exposures for specific jobs in both pre- and post-1970 data bases. An adjustment factor for estimating pre-1970 exposures was derived from the ratio of mean exposure (expressed in mg/m³) of BOM job categories divided by the mean exposure for the same job categories from post-1970 compliance data. The mean of all job category adjustment factors was thus calculated (2.3) and used to increase (by multiplication) each BOM mean job exposure. These estimates were then back extrapolated to the pre-1970 work history of the miners. These extrapolations are biased, however, because they are based on an average ratio, which appears to over-estimate risks in high-exposure jobs and under-estimate risks in low-exposure jobs.

The following figure, extrapolated from the Critical Review, shows the bias this procedure produces.

Figure 1

Effect of NIOSH using average adjustment factor for estimating pre-1970 BOM exposure from 1970-2 MSHA mine operator exposure data
Attfield and Moring (1992a)



NIOSH has pointed out the predicted background prevalence of 5% category 1 or greater among non-dust exposed workers. Therefore, Drs. Gamble and Reger and Mr. Glenn used NIOSH's own predicted background prevalence rate in interpreting results from exposure-response studies.

The Critical Review demonstrates that exposure-response analyses of CMD and category 2 CWP show strong associations for high rank coal (coal rank 5 or anthracite and rank 4) with increased prevalence below the current standard. There were no apparent increases in CWP 2 for low rank coals 1-3 at exposures below the current 2.0 mg/m³ standard. When the upward bias in exposure estimation is accounted for, it is probable there are no significant increases in prevalence below the current standard for any rank of coal.

Chronic obstructive pulmonary disease ("COPD"), or reductions in forced expiratory volume in one second ("FEV₁"), are potentially significant response variables for assessing health effects associated with exposure to CMD. FEV₁ performance is obtained from spirometry collected as part of each round of the NSCWP. Consequently, data for assessment of exposure-response trends are readily available in quantities similar to chest radiographs for assessment of CWP. Major confounding exposure variables include age, sex, height, and cigarette smoking that must be adjusted for in attributing risk of CMD exposure. However, bias from these risk factors is reduced as these data are collected as part of spirometry, thus, adjustment for confounding effects is feasible. The greatest potential for bias occurs in studies of US coal miners due to potential misclassification of exposure, spuriously inflating risk, and from low participation rates in the NSCWP, which produces a variable yet unknown effect on results. Reductions in FEV₁ greater than about 300 ml are associated with clinically significant breathlessness and are considered an objective threshold level for determining relatively safe CMD exposure levels for protecting coal miners from COPD.

There are over 20,000 coal miners from four countries (US, UK, South Africa, Sardinia) in nine cross-sectional studies and 13 exposure-response analyses considered relevant for assessing the weight-of-evidence regarding CMD and clinically significant deficits in FEV₁. Associations are weak but consistently show negative trends with increasing CMD exposure. Only two analyses (and one study) show strong associations with deficits of greater than 300 ml (-531 ml and -2750 ml) at exposures below the current standard of 2 mg/m³ for 45-years. That is, 86% of relevant cross-sectional studies show no apparent clinically adverse deficit in FEV₁ attributable to CMD at exposures less than 90 mg/m³-years.

There are over 8,000 individual coal miners from five countries (US, UK, Germany, Sardinia, China) in eight longitudinal or prospective studies and 11 exposure-response analyses. Associations are consistently weak or non-existent. Only one study of Sardinian miners shows a deficit greater than 300 ml (-684 ml) at exposures below the current standard. The remaining 10 analyses show no apparent associations of clinically reduced FEV₁ attributable to CMD at exposures below current standards. Average changes in FEV₁ observed at 90 mg/m³-years ranged from -230 ml to +252 ml with average FEV₁ values greater than the 95% predicted value. There are basically as many positive exposure-response trends as negative trends.

The epidemiological data from these studies show only two studies with steep negative exposure-response trends, and these are considered outliers because results are at such variance from other studies. The bulk of the evidence (~90%) from 21 exposure-response analyses is consistent in showing negligible and positive trends. The weight-of-evidence indicates negligible occurrences of clinically significant deficits in FEV₁ or any increased occurrence of COPD at exposures equivalent to a working lifetime at the current US standard. The epidemiological evidence displayed herein is contrary to and does not support such summary statements from NIOSH as “Epidemiological studies have clearly demonstrated that miners have an elevated risk of developing...deficits in lung function when they are exposed to respirable coal mine dust over a working lifetime at the current MSHA permissible exposure limit (PEL) of 2 mg/m³”.⁸

Exposure-response of CMD and mortality shows a strong association with nonmalignant respiratory diseases (“NMRD”), but no associations with chronic bronchitis, emphysema, lung cancer or stomach cancer. When stratified by rank, the excess NMRD mortality is confined entirely to miners exposed to anthracite. Exposure-response analysis by rank is needed to confirm whether low rank coal poses a threat for increased NMRD mortality in high exposure jobs.

Introduction to the Critical Review

The purpose of this Critical Review was to critically evaluate pertinent scientific information on the subject of respirable coal mine dust (“CMD”) and related diseases, and in particular exposure-response studies, to ascertain if the proposed standard of 1.0 mg/m³ is supported by the epidemiological evidence. Other factors were also evaluated, such as potential roles of quartz and coal rank⁹ with respect to rapidly progressive CWP. Drs. Gamble and Reger and Mr. Glenn believe the studies evaluated in the Critical Review constitute the seminal studies providing the weight of evidence that either support or do not support the portion of the NPR that would lower the exposure limit for CMD from 2.0 mg/m³ to 1.0 mg/m³. These key studies are summarized in the main body of the Critical Review and detailed comments on each are presented.

Prior to 1969, detailed research regarding coal miners’ health in the United States was meager and dispersed. In 1968, a coal mine explosion in Farmington, WV took the lives of 78 miners and was a major impetus for action by Federal and State governments. At the federal

⁸ NIOSH (1995), Criteria for a Recommended Standard – Occupational Exposure to Coal Mine Dust, Public Health Service, CDC, DHHS (NIOSH) Publication No. 95-106.

⁹ Coal rank defines the carbon content with higher ranks having more carbon (and lower rank number). Coal ranks go from 100 to 900 in the UK and 1 to 5 in the US. Number 1 is the highest ranking coal, anthracite with 93-95% carbon, and number 5 is the lowest ranked high volatile Western coal with <85% carbon.

level, the Farmington explosion not only led to a massive revamping of the Nation's coal mine safety laws, but it also resulted in a revolutionary federal program to prevent occupational diseases in US coal miners, especially CWP. This new national, bipartisan consensus led to Congressional passage of the Federal Coal Mine Health and Safety Act of 1969 (the "1969 Mine Act"). Pub. Law 91-173; 83 Stat. 742. Signed into law, by President Richard Nixon on December 31, 1969, the 1969 Mine Act was further strengthened by enactment, in response to other mine disasters, of the Federal Mine Safety and Health Act of 1977 (the "Mine Act"). 30 U.S.C. §§ 801, et seq.

A centerpiece of the coal miner health provisions of the 1969 Mine Act was the establishment of mandatory CMD standards in the Nation's coal mines. Effective in 1970, under the 1969 Mine Act, the average concentration of CMD in underground coal mines was to be maintained at or below 3.0 mg/m³ through 1972, after which the CMD standard was reduced to 2.0 mg/m³. The provisions of the 1969 Mine Act remained largely intact under the 1977 Mine Act.

Major responsibilities under the Mine Act rest with MSHA in the Department of Labor and NIOSH located in the Department of Health and Human Services. Congress mandated that MSHA ensure a safe and healthful work environment be maintained in the nation's coal mines. For NIOSH, the mandate was for health-related research regarding coal workers' ailments and the prospective monitoring of miners' health, primarily CWP. Prior to the passage of the 1969 Mine Act, research in Britain at the Institute of Occupational Medicine was well underway with work which came to be known as the Interim Standards Study. Before publication of the results, consultation between US and UK researchers, and evaluation by various US Congressional Committees and others resulted in portions of the Interim Standards Study results being utilized for setting the above noted CMD standard in the US.

The basis for setting the US CMD from the Interim Standards Study was that a miner exposed at 2.0 mg/m³ over a working lifetime of 35 years would have zero risk of developing Category 2 simple CWP as defined by the International Labor Office ("ILO") Guidelines for the Classification of Radiographs of Pneumoconiosis. This was a logical deduction in that it was known that the likelihood of a miner contracting the more disabling and sometimes fatal condition known as progressive massive fibrosis ("PMF") would be dramatically reduced or eliminated if ILO Category CWP 2 was never reached.

Since the passage of the 1969 Mine Act, measured dust exposures in US coal mines have been reduced to a considerable degree, with a large majority of coal mines being in compliance with the 2.0 mg/m³ dust standard. Likewise, the reported prevalence of CWP in the nation's coal mines has decreased from around 30 % to about 3%.

The source for determining the prevalence of CWP in US coal miners has been the Coal Workers' X-ray Surveillance Program ("CWXS"). The CWXS is administered by NIOSH and participation (with some exception) has been low. Participation rates (by half decades) were 81%, 77%, 38%, 20%, 22%, 29%, and 48% (CDC/NIOSH 2009). Thus, the participants in this

program form a relatively selective group from which inferences to the entire mining population remain questionable, at best.

In addition, NIOSH carries out epidemiological studies under the National Study of Coal Workers' Pneumoconiosis ("NSCWP") program established in 1970. Among other things, this work in the US relates to exposure-response estimates based on health data from US miners and environmental measurements taken in US mines. Thirty-one mines were originally selected for study based on criteria including an expected mine-life of 10-years, work force of 100 or more miners, geographical and geological spread, and accessibility. Rounds 1-3 were conducted at nearly the same mines but with steadily declining participation rates of 90%, 75% and 52% respectively. In addition to periodic examinations, Round 4 included follow-up of participants from the previous three rounds and had 70% participation.

In the past decade, there have been reports of a slight increase in the prevalence of CWP. Moreover, the reported increase is coupled with reports of rapidly progressive CWP in younger miners often exposed for a relatively short time period. New exposure-response estimates for predicting the occurrence of CWP at various cumulative exposure levels have provided estimates greater than previously shown. These three points, (1) increased prevalence, (2) rapid progression, and (3) new exposure-response estimates, are mainly the stimuli for the proposal to lower the current CMD standard to 1.0 mg/m^3 .

Overall Summary and Conclusions of the Critical Review

A large body of literature on CWP was reviewed, with major emphasis on US studies and their relationship to the present MSHA dust standard of 2 mg/m^3 , and the current MSHA proposal to lower the standard to 1 mg/m^3 . The evaluation of other studies (largely from the UK) was used to supplement and/or corroborate a point.

There is a natural progression of thought based in the epidemiological literature that leads to the current situation. Since the 1970s, when an X-ray surveillance program for coal workers in the US began, and CMD standards were initiated, there was a rapid decline in the reported prevalence of CWP from around 30% to 3%, and this decline was coupled with decreasing CMD levels. However, from around 1970 to the 1990s, CMD appeared to stabilize at around 1 mg/m^3 and then decrease slightly. In the 1990s or later, there were reports that CWP prevalence was increasing slightly without concomitant increases in CMD exposure.

In the 2000s, NIOSH reported cases of rapidly progressive CWP. Some miners were described as developing dust-induced disease of high severity over short time periods, and some cases were among relatively young men. While the frequency of these sentinel events was low in absolute numbers, they were nonetheless a serious health concern calling for a determination of their cause and how to prevent their occurrence.

No studies have been conducted to identify specific etiological agents or factors associated with rapidly progressing cases such as a case-control study. The evidence that this reported outbreak of CWP is indeed CWP, and not silicosis, has not been adequately examined.

Aside from the issue of rapidly progressing cases, the current US dust standard is based on data from the UK coal fields; and in 1970, the US standard of 3.0 mg/m^3 became operative, as a transition to 2 mg/m^3 with less than 5% quartz in 1972.

The use of British coal mine data to set a US standard raised concerns about the relevance of that data for US mines. The UK has a similar range of quartz and coal rank as in US coal mines. However, both the reported and estimated CWP prevalence appears to be higher at similar exposure levels in the US than in the UK. Thus, the US exposure-response and other studies of CWP provide a further basis for a possible revised MSHA coal mine dust standard.

Two NIOSH data bases exist but for entirely different purposes; one primarily for research purposes and the other primarily for surveillance of CWP.

The first is the NSCWP which is a major research program of NIOSH to assess the relationship of CMD with CWP and lung function in US coal miners. This research program has produced a variety of studies, including two exposure-response morbidity studies of CMD and radiographic CWP, and one exposure-response mortality study that includes NMRD as a surrogate for CWP.

The NSCWP has two important limitations which make the interpretation of results difficult and questionable. One is the low participation rates which were less than 50% in rounds 2-4. The first round had a 90% participation rate, which is quite acceptable. Like the CWXSP, the magnitude and direction of this bias is not known, and so the effect on risk estimates is not known.

A second limitation is the potential exposure bias produced by limited environmental sampling information available before 1970. Prior to the 1969 Mine Act, CMD levels were quite high as indicated by BOM sampling and 30% or greater prevalence of CWP. Despite these limitations, exposure estimates in critical epidemiological studies were based on back extrapolations from post-1970 sampling results. The methodology employed seriously underestimates exposure for the high exposure jobs and provides over-estimates for the lower exposure jobs. As a result the exposure-response curves are biased upward and risk is over-estimated.

Two of the NIOSH studies are based entirely on pre-1970 exposure data, and miners evaluated in these studies were working in dust levels considerably above the current standard. A proportion of miners in a third NIOSH study worked prior to 1970, and some miners were lost to follow-up because of low participation rates in the later rounds of the NSCWP.

The second NIOSH data base is the NCWXSP which began in 1969 and is considered a secondary disease prevention program that involves periodic medical screening. In addition to benefiting the miner, the radiographic interpretations of x-ray films from this program are used in assessing CWP prevalence in the US and often used in various research efforts. A severe limitation of this program is the very low participation rate of the coal miner work force. As a result, there exists a potential participation bias that could produce misleading research results.

There has been no investigation of non-participants to determine why participation is low and how those choosing to participate might differ from those who do not. Thus, adjustments cannot be made that would allow the results of these studies to be used for inferences regarding CWP to the entire coal miner workforce. In the main, this program is totally inadequate as a prevention tool, and the data from it are plainly unreliable for estimating prevalence of CWP and for most uses in research studies.¹⁰

The Critical Review of this very large body of scientific studies has summarized methods, results, and critiques of both morbidity and mortality exposure-response studies regarding CWP and CMD. Issues relating to “sentinel events” and likely quartz exposure have also been evaluated, as has consideration of rank of coal. The main objective of the Critical Review was to assess the weight of the evidence regarding the proposed change of the CMD standard to 1.0 mg/m³. Overall, this review has led to several overall conclusions regarding CWP and CMD. These are:

Conclusion 1:

Prevalence (%) data from the NCWXSP are potentially biased by low participation. The direction and magnitude of the bias is not known. These data may be useful for assessing trends, but the actual prevalence of CWP in the US is unknown and data from this program remain questionable for use in research studies.

Conclusion 2:

Estimates of pre-1970 CMD exposures are imprecise and biased. The use of an average adjustment factor applied to post-1970 compliance data to estimate pre-1970 data produced biased under-estimates of exposure and over-estimates of risk in high exposure jobs and the reverse in low exposure jobs. The effect is to bias exposure-response trends upward so the curves are inaccurate and produce spuriously low threshold levels of effect.

When adjustments are made for this bias, the associations of excess prevalence at exposures below the standard appear to disappear.

NIOSH should conduct a properly designed analysis of pre-1970 exposures using (to the extent possible) available pre-1970 samples directly. Such an analysis will aid in overcoming the problems that the indirect back extrapolations make the exposure estimates and the exposure-response trends too inaccurate and unreliable for use in setting a new standard base on these results.

¹⁰ In our comments on Proposed section 72.100 of the NPR, the Companies offer our best thoughts on how to reform this NIOSH program.

Conclusion 3:

Sentinel health events such as cases of rapidly progressing disease are unaffected by limitations in participation rates or unreliable exposure estimates. They are events indicating a problem requiring investigation to determine causes and how such events can be prevented.

Our examination of these reports indicates the rapidly progressive cases of pneumoconiosis are more likely to be silicosis being misdiagnosed as CWP. This conclusion is based largely on a number of factors in the SAR region which include: extremely high quartz exposures (two to three times the quartz standard on average); increased mining of low coal seams with high percentages of quartz admixed in the coal; a substantial number of small mines in the region which have demonstrated historically high dust exposures; and longer shifts resulting in higher cumulative exposures of CMD and quartz.

NIOSH should conduct a properly designed case-control study to produce more definitive conclusions as to the etiologic agent and exposure-response relationships.

Conclusion 4:

The prevalence of X-ray readings of category 1 or higher CWP among workers not exposed to dust is considered background prevalence. For there to be excess CWP among coal miners, the prevalence of CWP should be greater than the background prevalence. A background prevalence rate of 5% for category 1 and greater has been suggested by authors of NIOSH studies evaluated in the Critical Review, and this is the background rate Drs. Gamble and Reger and Mr. Glenn adopted to assess excess risk. NIOSH and MSHA need to be cognizant of this fact in evaluating studies as it relates to whether percentage prevalence observed is a true finding.

Conclusion 5:

The NIOSH exposure-response studies show a strong association between CMD and CWP 2+ with higher exposures producing excess pneumoconiosis. Excess CWP 2+ was above background prevalence for coal miners exposed to high rank coal at concentrations below the current standard of 2 mg/m^3 , or $80 \text{ mg/m}^3\text{-years}$. Exposure to low rank coal below the current standard was not associated with an increased risk of CWP 2+. At exposures above the current standards there was some increased risk of CWP 2+ above background prevalence, but not for all coal cohorts.

Note that this conclusion is based on a 5% background prevalence and $80 \text{ mg/m}^3\text{-year}$ as the standard and does not take into account exposure misclassification bias. Adjustments to the biased exposure-response models are suggestive there may be no increased risk of CWP at exposures below the current standard.

Conclusion 6:

The cross-sectional and longitudinal studies of COPD related to CMD exposure show mostly weak and clinically non-significant mean reductions in FEV₁. In the main, these studies suggest that CMD exposure at the current standard is unlikely to be an important cause of COPD or clinically reduced FEV₁ in current coal miners. Increased incidence of COPD potentially attributable to CMD is relatively small and only slightly above measurement error or bias. Background prevalence of COPD in the US is needed for more reliable interpretation of US studies. We conclude that CMD does not appear to cause appreciable reductions in FEV₁ in coal miners at current exposures and less than 45-years tenure underground.

Conclusion 7:

While coal miners have an overall less than expected mortality ratio for death from all causes, CMD exposure is strongly associated with significant excess NMRD mortality among anthracite coal miners. However, this association of increased NMRD mortality is not found among miners of lower rank coals (bituminous and sub-bituminous).

This conclusion is based on only one mortality study and NIOSH should test this observation by analyzing exposure-response trends by coal rank. There are no associations with other diseases including CBE, lung cancer and stomach cancer mortality.

Conclusion 8:

Based on the data reviewed in this report, there is inadequate evidence supporting a reduction in the current standard because of increased risk of CWP; and COPD morbidity or mortality from CMD exposure is not scientifically compelling. The NIOSH exposure data are inaccurate and biased so the risks are over-estimated. Work is required to reduce this bias.

NIOSH should conduct, or fund, further research to provide improved data for more accurately determining safe exposure levels. This research could include, but not be limited to:

- Reanalyzing estimates of pre-1970 exposures of studies where the biased estimates were used for relationships with CWP;
- Conducting case-control studies of post-1970 CWP cases to avoid potential biases from low participation and exposure misclassification; and,
- Conducting case-control studies of rapidly progressive pneumoconiosis to determine etiology (or test the quartz hypothesis) and exposure-response, so needed prevention controls can be instituted where necessary.

The Companies urge MSHA to thoroughly and carefully read the Critical Review prepared by Drs. Gamble and Reger and Mr. Glenn. We believe and, respectfully, hope that MSHA will agree that the Critical Review is an enormously important research work. As such, the Companies intend to encourage Drs. Gamble and Reger and Mr. Glenn to submit it for peer review and publication in an appropriate scientific journal. In any circumstance, however, the

Companies remind MSHA that the Critical Review constitutes a substantive, weighty addition to “the latest available scientific data in the field,” per Mine Act § 101 (a) (6) (A), and thus deserves to be treated as such. Such deference is particularly owed given the qualifications of the authors, including their roles as senior NIOSH officers at the inception of the federal program to reduce concentrations of respirable dust in coal mines and for their longstanding commitment to efforts to eradicate CWP.

In addition to these eight overall conclusions, in its desire to establish a 1.0 mg/m³ respirable dust standard, MSHA is required to take into account the fact this level is substantially lower than all other comparable limits for respirable dust on a world-wide basis, according to no less an authority than the 1995 NIOSH Criteria Document for Occupational Exposure to Respirable Coal Mine Dust (the “Criteria Document”).¹¹ While it is true NIOSH recommended a 1.0 mg/m³ in the Criteria Document, in so doing NIOSH recognized the existing OSHA limit for respirable dust was 2.0 mg/m³, and that the same standard was identified as the Threshold Limit Value (“TLV”) by the American Conference of Governmental Industrial Hygienists (“ACGIH”).¹² In addition, the Criteria Document recognized that virtually every other country in the world had substantially higher limits for respirable coal mine dust than the limits in the United States, including Australia (3.0 mg/m³), Germany (4.0 mg/m³), and the United Kingdom (3.8 mg/m³). Furthermore, the Criteria Document recognized that the United Nations’ World Health Organization (“WHO”) had recommended a tentative health-based exposure limit for respirable coal mine dust ranging from 0.5 to 4.0 mg/m³, and that this limit would be based upon variables including the “risk factors (*i.e.*, coal rank or carbon content, proportion of respirable quartz and other minerals, and particle size distribution of the coal dust) . . . that are determined at each mine”¹³

The Companies believe that Mine Act §101(a)(6)(A), which requires MSHA in this NPR to consider experience gained under health and safety laws other than the Mine Act, includes the laws under which the aforementioned limits were established. Therefore, MSHA must, under Mine Act § 101(a)(6)(A), address this issue head-on by explaining why, in the face of these other legally mandated standards, its proposed new 1.0 mg/m³ is justified.

In short, the above discussion categorically demonstrates MSHA has failed to meet its obligations under the provisions of Mine Act §§ 202(a), 202(f), and 101(a)(6)(A). For these reasons, as well as all of the other reasons identified in the NMA written comments and testimony, this NPR should be withdrawn.

¹¹ NIOSH (1995), Criteria for a Recommended Standard—Occupational Exposure to Coal Mine Dust, Public Health Service, CDC, DHHS (NIOSH) Publication No. 95-106.

¹² Criteria Document at 12.

¹³ *Id.* at 12.

Comments on the New NIOSH Study, “Coal Workers’ Pneumoconiosis in the United States: Regional Differences 40 Years After Implementation of the 1969 Coal Mine Health and Safety Act”

We also wish to bring to your attention a recent study authored by scientists from the National Institute for Occupational Safety and Health (“NIOSH”) that has yet to be published in hard copy in the medical literature but has been published online in the journal *Occupational and Environmental Medicine* entitled, “Coal workers’ pneumoconiosis in the United States: regional differences 40 years after implementation of the 1969 Federal Coal Mine Health and Safety Act.” Please find a copy of the new study attached to this letter, along with a Critical Review of the study, prepared by Robert E. Glenn, MPH, CIH. The Companies believe this new study is a most important contribution to the coal dust literature which examines whether the recently reported increases in the prevalence of (“CWP”) among underground U.S. coal miners is related to (“CMD”) exposures.¹⁴ This important new study found regional differences in the prevalence of CWP that could not be explained by respirable dust measurements taken by MSHA inspectors. In particular, an exposure-response model, previously used in NIOSH epidemiology studies, and MSHA inspector dust data, failed to predict radiographic CWP risks by MSHA District. Specifically, the predicted prevalence from the model for MSHA Districts in southern West Virginia, western Virginia and eastern Kentucky (MSHA Districts 4, 5 and 6, respectively), along with District 7 (Central Kentucky, Tennessee, North and South Carolina) was significantly higher than NIOSH observed from its X-ray surveillance program database from these areas. Conversely, for other MSHA Districts the model under-predicted the radiographic prevalence from the NIOSH X-ray database. It needs to be emphasized that past epidemiological studies of exposure-response relationships for CWP used the same model and similar information, and identified clear trends in prevalence with increasing dust exposures. This adds validity to the findings of the study and points towards factors other than respirable CMD being responsible for the increased prevalence of what has been called CWP.

MSHA Districts 4, 5, 6 and 7 have been identified as “hot spots” for increased prevalence of CWP by NIOSH and MSHA. The new study, however, points toward factors other than respirable CMD being responsible for the increased prevalence of CWP in this region. More specifically, important geological characteristics of the central Appalachian region and patterns in the observed radiological disease strongly indicate that the disease being observed in these miners is not CWP but predominantly silicosis. The geological characteristics of the region include silica-rich rock which commonly surrounds and intrudes into the coal seams in the region. The coal seams themselves are small (thin) requiring mining methods that cut large amounts of silica-containing stone. Small mines (in terms of numbers of employees) working small seams, and in which higher dust exposures are not uncommon, along with very high proportions of quartz contained in the dust, are all major factors contributing to the radiographic disease observed in miners from this region. The etiology of the disease pattern in the region of

¹⁴ Mine Act §101(a)(6)(A) provides, *inter alia*, that, in connection with the NRP, MSHA must consider the “latest available scientific data in the field.” 30 U.S.C. §811(a)(6)(A).

rapidly progressive development of radiographic disease with short latency and the increasing prevalence of r-type opacities are all consistent with the effects of quartz exposure.

These geologic factors and patterns of radiographic disease are highly correlated in the central Appalachian region providing compelling evidence that the explanation for the observed discrepancy in the article of predicted CWP in the central Appalachian region versus the rest of the coal mining regions is that excess quartz exposures are responsible for the increased disease in the region and that the disease endpoint is silicosis and not CWP, or a mixed-dust combination of silicosis and CWP lesions with quartz exposure being the more important contribution to radiographic evidence of disease. Indeed, NIOSH has investigated and confirmed these factors as being important in a number of studies but has failed to single out quartz exposure as the most important cause. The Companies believe this new NIOSH study fully supports and is consistent with the Gamble, Reger, Glenn Critical Review discussed earlier in this letter and attached hereto. The combination of that Review and the Critical Review of the new NIOSH study prepared by Mr. Glenn are so powerful that they make it incumbent upon MSHA, in the opinion of the Companies, to withdraw this NPR and start afresh.

In addition to the comments above, the Companies also wish to comment on:

- the periodic examination provisions of proposed § 72.100;
- MSHA's confusing and inconsistent requirements regarding the use of airstream helmets and other suitable respirators as supplemental controls to protect coal miners from respirable coal mine dust;
- the feasibility of the NPR; and,
- MSHA's failure to adequately consider key Presidential Executive Orders and related materials .

We turn to each of these issues next—and urge the Agency, as it continues its work on this issue, to favorably support and utilize these comments in any new rulemaking published to correct the deficiencies we and others in the industry have identified in the NPR.

Comments on Proposed § 72.100 – Periodic Examinations

In addition to the control of respirable coal mine dust (“CMD”) as coal is mined, medical surveillance and periodic medical examinations of coal miners are an essential component of efforts to prevent CWP. In that respect, the new provisions contained in §72.100 of Subpart B, Medical Surveillance, Periodic Examinations (75 Fed. Reg. 64,497) and the rationale in the Section-by-Section discussion of the Preamble (*id.* at 64,444-64,445) are a step in the right direction. However, many more steps must be taken. We recommend this section be closely

examined by the Agency and coordination with NIOSH be undertaken to ensure that the provisions of 42 C.F.R. Part 37, the long-standing NIOSH regulations setting forth “Specifications for Medical Examinations for Underground Coal Miners,”¹⁵ are revised to make certain they work in a seamless manner with the provisions of § 72.100. Our comments address a number of instances where confusion between Part 37 and § 72.100, as proposed, are almost certain to occur. In addition, we strongly urge that § 72.100 could be greatly improved with the inclusion of fundamental public and occupational health principles regarding occupational medical surveillance. Building these principles into this section will provide coal miners with greater protection from CMD exposure.

We are pleased to see MSHA is extending the periodic examinations to miners at surface coal mines. Some surface miners are potentially overexposed to CMD concentrations and will benefit from inclusion in a medical surveillance program aimed at early detection and intervention for CMD-related diseases. As stated above, however, MSHA also should improve proposed § 72.100 for all coal miners—both surface and underground. We, therefore, urge the Agency to redraft § 72.100 to include the measures discussed below to afford both underground and surface coal miners equally with the protections of the basic occupational health practices used in modern day occupational medical surveillance programs.

The Existing Periodic Examination Program is a Failure

The existing periodic examination program, operated for decades as the NIOSH Coal Workers’ X-ray Surveillance Program (“CWXSP”), under NIOSH’s regulations in 42 C.F.R. Part 37, has been a disappointment and failure as a secondary prevention program, primarily due to poor participation by eligible coal miners and the failure of miners eligible for transfer to a less dusty job to avail themselves of the option to transfer to a less dusty area of the mine.¹⁶

The objective of the secondary prevention feature of the CWXSP is the early detection and transfer of miners with abnormal chest X-ray findings to areas of lower CMD exposure, thereby preventing the progression of coal workers’ pneumoconiosis (“CWP”) to a more serious disease state, Progressive Massive Fibrosis (“PMF”), with associated disabling pulmonary function loss. Both of these flaws can be corrected through redrafting of proposed §72.100 per our recommendations.

¹⁵ 42 C.F.R. Part 37 was promulgated pursuant to the authority of the Secretary of Health and Human Services under § 203 of the Federal Mine Safety and Health Act of 1977, as amended (the “Mine Act”).

¹⁶ By secondary prevention we mean measures that include medical screening for the early detection of diseases and medical intervention, which is aimed at reversing or impeding progression of disease. On the other hand, primary prevention of work-related disease depends on the effective control of worker exposures below occupational exposure limits.

NIOSH has published participation results for the CWXSP over the successive rounds of examinations and the participation rates by eligible miners have steadily declined from a high of 50%, to 44%, 32% and 30% for rounds 1 (1970-73), 2 (1973-78), 3 (1979-81), and 4 (1982-86), respectively.¹⁷ This lack of participation has not only crippled the success of the CWXSP as a secondary prevention program but has also precluded NIOSH from estimating accurate health data on the prevalence and progression of CWP (a problem, we must reiterate, that is a fundamental flaw in the NPR's proposal to lower the standard to 1.0 mg/m³). Critically important for this rulemaking, in particular, is the fact that this flaw in the ability of NIOSH to generate useful data on CWP prevalence and incidence among coal miners undercuts enormously the ability of both NIOSH and MSHA to determine the effectiveness of the primary protection that is afforded by effective control of respirable dust. This substantial problem was recognized by the Department of Labor's Advisory Committee on the Elimination of Pneumoconiosis Among Coal Mine Workers (the "Dust Advisory Committee").¹⁸ The Dust Advisory Committee was established by the Secretary of Labor and was charged with making recommendations for improving the MSHA program to control respirable coal mine dust in underground and surface coal mines in the United States and to examine how to eradicate CWP among coal miners. In its 1995 report to the Secretary, the Advisory Committee expressed concerns with miner participation and the utility of the data for estimating estimates stating:

The CWXSP contains the majority of data available regarding the prevalence of CWP among U.S. underground coal miners who started their underground mining under the current standard. These data, however, are surveillance data based on generally low coal miner participation rates, so it is unclear what sub-population of miners they represent. Consequently, NIOSH has not employed these data to any extent to assess the effect of exposures subsequent to 1972, nor have they used these data to develop risk assessments.

Recently, as the Critical Review prepared by Drs. Gamble and Reger and Mr. Glenn points out, a number of articles have been published by NIOSH researchers expressing concerns regarding increased occurrence in "hot spots" of disease mostly concentrated in the Southern Appalachian coal region ("SAR"). The SAR "hot spots" of disease are mostly concentrated in southern West Virginia, eastern Kentucky, and western Virginia.¹⁹ Further evidence of the failure of the CWXSP to effectively identify early cases of CWP is that these states historically

¹⁷ Criteria Document at 45.

¹⁸ USDOL, MSHA, 1996, Report of the Secretary's Advisory Committee on the Elimination of Pneumoconiosis Among Coal Miners, page 56.

¹⁹ Pollock DE, Potts JO, Joy GJ [2010]. Investigation into dust exposures and mining practices in mines in the southern Appalachian Region. Mining Engineering 62:44-49.

have had some of the lowest participation rates from eligible miners of any of the coal mining states during the period 1996-2002.²⁰

In a recent effort from October 1, 1999–September 30, 2002, NIOSH collaborated with MSHA to increase participation in the program and accepted films from MSHA’s new Miners’ Choice Program (“MCP”) for classification by using CWXSP procedures. The MCP operated independently of coal mine operators because of the supposition that low miner participation was a result of coal operator involvement in the CWXSP program. The MCP ran concurrently with the CWXSP and actively encouraged miners to undergo radiographic examination. The MCP participants included miners from 586 surface coal mines, from which miners are not eligible to participate in the CWXSP, and from 444 underground coal mines from which the miners are eligible. The table below illustrates participation rates for miners from selected states. *See* Pon, et al. for complete participation rates for all coal mining states. We think it notable that, with the exception of Tennessee (not a major coal producing state), the “hot spot” states with a high prevalence and incidence of CWP have the lowest participation rates of underground miners and some of the lowest rates among surface miners. This is stark evidence that under the existing CWXSP program, even when efforts are made to increase participation, rates remain appallingly low and are evidence of a complete failure of the program as a public health prevention strategy.

Table: Participation rates, by selected states – CWXSP and MCP 1996-2002.

State	Underground Miners		Surface Miners	
	No.	(%)	No.	(%)
West Virginia	18,829	16.8	8,939	13.7
Kentucky	19,220	16.0	13,910	9.0
Virginia	6,771	25.8	3,718	20.0
Tennessee	681	15.0	712	7.3
Pennsylvania	6,204	39.8	5,468	14.2
Alabama	3,904	59.1	2,200	23.8

²⁰ Pon MRL, Roper RA, Petsonk EL, Wang ML, Castellan RM, Attfield MD, Wagner GR. Pneumoconiosis Prevalence Among Working Coal Miners Examined in Federal Chest Radiograph Surveillance Programs -- United States, 1996—2002. *MMWR* 2003;52(15): 336-40.

Illinois	4,300	66.6	1,212	14.4
Utah	2,184	72.6	96	50.0
Colorado	1,665	100	712	25.3

Equally disappointing as the operation of the CWXSP has been the lack of any observable benefits from the secondary prevention aspect of transferring miners with early disease detection to less dusty areas in order to prevent development of disabling CWP. As noted previously, the CWXSP is administered by NIOSH and was established under the Federal Coal Mine Health and Safety Act of 1969, a predecessor statute to the Mine Act. Under the current program, underground coal mine operators are required to provide periodic chest X-rays to underground coal miners and workers at surface work areas of underground coal mines. The specifications for giving, interpreting, classifying, and submitting the chest X-rays required for this program are contained in NIOSH rules at 42 C.F.R. Part 37. According to the preamble of this NPR, the MSHA proposal “would extend the opportunity for [radiographic examinations with added periodic spirometry, occupational history, and symptom assessments] to surface miners,” as well as underground miners. 75 Fed. Reg. 64,444. This portion of the NPR is a step in the right direction. We are concerned, however, that because the rules for the CWXSP only allow examinations for underground coal miners, great confusion among miners and operators will ensue unless 42 C.F.R. Part 37 is revised through promulgation of new regulations to ensure that examinations for both underground and surface miners are authorized. The Part 37 rulemaking should be undertaken such that it is finalized at the same time as is § 72.100.²¹

Under the CWXSP, miners who show radiographic evidence of simple CWP category 1 or greater have the option to transfer to another position in the mine where the concentration of respirable dust is either <1.0 mg/m³ (if attainable) or the lowest attainable concentration below 2.0 mg/m³. See 42 C.F.R. §37.7, 30 USC 843(b); and see also 30 C.F.R. Part 90. As we commented previously, CWXSP has also been a failure in this secondary prevention objective because so few miners with early evidence of CWP have availed themselves of the option to transfer.

NIOSH has acknowledged that it is unable to evaluate the effectiveness of medical interventions such as reducing or ceasing exposures to respirable coal dust or respirable crystalline silica.²² Any evaluation of the effectiveness of the transfer program would need to consider possible bias from the low rate of eligible miners choosing to exercise the option to

²¹ The Companies note that this problem could have been avoided had MSHA properly carried out its duties under Mine Act §§ 202(a) and (f) to work and publish jointly with NIOSH on proposed changes to the current regulations.

²² Criteria Document at 107.

transfer. According to Wagner and Speiler (1990), only 23% of eligible coal miners (2,119 of 9,138 miners) elected to participate in the transfer program.²³ The Dust Advisory Committee was critical of the program being able to determine whether or not the transfer program is beneficial in preventing progression of CWP detected through the CWXSP.²⁴

Population studies of secondary prevention efforts (transfer of workers with abnormal chest x-ray findings to lower dust exposures) have not yet been able to demonstrate a significant impact on the progression of CWP in those transferred workers. Therefore, it is not clear that the risk of an individual miner developing PMF once simple CWP is detected can be substantially affected by lowering the dust exposure. However, transfer of workers with chest x-ray abnormalities to lower exposure environments whenever possible is still a prudent practice.

Both of these shortcomings – miner participation and early intervention in disease progression – are readily correctable through strengthening of proposed § 72.100. Under the proposal, medical examinations are mandatory under three circumstances. First, when a miner begins work at a coal mine for the first time an initial examination is to be conducted within the first 30 days of employment. Proposed § 72.100(c)(1). 75 Fed. Reg. 64,497. Second, a follow-up examination is mandatory not later than three years after the initial examination. Proposed § 72.100(c)(2). *Id.* Then, if the three-year mandatory examination shows evidence of pneumoconiosis or evidence of decreased lung function, under proposed § 72.100(c)(3), an additional examination is mandatory no later than two years after the three-year examination. *Id.* After the mandatory examinations the operator is to provide the opportunity for miners to have a voluntary examination at least every five years. *See* proposed § 72.100(b). *Id.*

All Periodic Examinations Should Be Made Mandatory

As noted above, the medical examinations afforded coal miners are authorized in § 203 of the Mine Act (derived from § 203 of the Federal Coal Mine Health and Safety Act of 1969). The current NIOSH mandatory provisions for initial, follow-up and voluntary periodic examinations contained in 43 C.F.R. Part 37 were promulgated pursuant to the authority of Mine Act § 203, most recently in 1978. 43 Fed. Reg. 33,715 (Aug. 1, 1978). Because Mine Act § 203 is an interim mandatory health standard, Mine Act § 201(a) authorizes these regulations to be superseded in whole or in part by improved mandatory health standards promulgated under the

²³ Wagner GR, Spieler EA [1990]. Is the U.S. coal miner chest x-ray surveillance program succeeding in controlling lung disease? In: Proceedings of the VIIth International Pneumoconiosis Conference, August 23-26, 1988, Pittsburgh, PA. Cincinnati, Ohio: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 90-108.

²⁴ Dust Advisory Committee Report at 90.

rulemaking procedures of Mine Act § 101. *After forty years of experience in declining miner participation in the CWXSP, it should be obvious to all involved that voluntary participation is not working.* Even at the outset of the CWXSP the highest participation rate ever obtained was only 50% and it has steadily declined since then.

Under any circumstances, we urge MSHA to work with NIOSH to eliminate any duplication or overlap between § 72.100 and Part 37. *See, e.g., 42 C.F.R. § 37.3, “Chest roentgenograms required for miners.”* Furthermore, and most urgently, to accomplish the objectives of the program it is imperative that the periodic examinations, like the initial and follow-up examination(s), be made mandatory. The final rule should make periodic examinations mandatory for all underground and surface coal miners.

Transfer Should Be Mandatory for Miners with Classifications \geq ILO Category 2

Similarly, the transfer provisions for miners with evidence of CWP under 30 C.F.R. Part 90, like the CWXSP, has been a failure. It should be reformed with the promulgation of new rules. The failure of the early intervention program to persuade miners to avail themselves of the transfer option to a less dusty environment is illustrated in Table 1 below, taken from the NIOSH website.²⁵ As seen in the Table, since 1980, the year in which transfer data began to be electronically tracked, 3,269 miners have received a letter notifying them of their right to exercise the transfer option but only 608 (19%) have exercised their option to transfer. Thus, the intervention strategy to reduce miners' exposure through transfer to areas of lower dust exposure has failed because of miners turning down their option to transfer.

²⁵ www.niosh.gov.

<http://www.cdc.gov/niosh/topics/surveillance/orde/CoalMineHealthSafetyAct35Years.html>.

Time Period[1]	Number of Miners notified of eligibility of transfer[2],[3]	Number of Miners who exercised their transfer rights[4]	Transfer Rate
1980-1984	1606	327	20
1985-1989	506	84	17
1990-1994	397	73	18
1995-1999	200	43	21
2000- Sept 2003	560	81	14

1. Prior to 1980, the transfer data was not electronically tracked.
2. If a miner received more than one letter, they were only included in the time period when the first letter was mailed.
3. Data provided by the NIOSH Underground Coal Mine System
4. Data provided by MSHA Part 90 Mining Tracking System

For the intervention program to be effective in preventing pulmonary function loss, stronger measures must be put in place to increase the participation in the transfer option. As we have discussed earlier in these comments, the current 2.0 mg/m³ coal mine dust standard was derived from British research, which provided the only quantitative exposure-response relationship available at that time. This exposure-response curve predicted that no cases of CWP as severe as category 2 on the ILO classification system would develop among miners who worked for 35 years at 2.0 mg/m³. Similarly at that time, the current information indicated that PMF, the disabling form of CWP, was very unlikely to develop from less severe ILO categories (e.g., category 1 CWP). Therefore, adoption of the 2.0 mg/m³ limit was believed, at that time, to be protective against the risk of disability and premature mortality that accompanies PMF. Thus, if a miner is found to have radiographic changes on a periodic examination consistent with Category 1 (ILO Classification) the miner should be encouraged to exercise the option to transfer. However, because there is a greater probability for miners reaching Category 2 to develop PMF, in the case of miners with a classification ≥ Category 2, transfer to a less dusty job should be mandatory.

The Results of § 72.100 Examinations Should Be Made Available to a Health Professional Designated by the Operator

The NIOSH rules in 42 C.F.R. Part 37 have been interpreted to prevent mine operators, or the operators' health professional designees from having access to miners' X-rays or their results, even though it is the operators who are required to have a plan approved by NIOSH for conducting examinations and to pay for such examinations. We strongly urge that MSHA avoid that outcome in any new rules by affirmatively providing for the results of the § 72.100 examinations to be made available to a health professional designated by the operator.

We say this because:

- First, there is nothing in Mine Act § 203 or its legislative history that supports this exclusory practice;
- Second, Mine Act § 103(h) provides “[e]xcept to the extent otherwise specifically provided by this Act, all records, information, reports, findings, citations, notices, orders, or decisions required or issued pursuant to this Act may be published from time to time, may be released to any interested person, and shall be made available for public inspection”; and,
- Third, important information regarding occupational illness identified by these examinations could be used to provide health counseling and medical management of miners showing evidence of early disease.

To our knowledge, unless this issue is dealt with squarely and affirmatively, the examinations proposed in § 72.100 would be the only occupational medical program mandated by the Department of Labor that prevents the employer from using such information to benefit the worker.

Thus, for example, the Occupational Safety and Health Administration (“OSHA”), MSHA’s sister agency, has promulgated a number of substance-specific standards that mandate provisions for medical surveillance. One such standard that has some similar medical aspects with coal dust is the asbestos standard since both are pneumoconiotic-producing inhalants. The medical surveillance requirements of the asbestos standard are found at 29 C.F.R. § 1910.1001.l. The general requirements are that the employer shall institute a medical surveillance program for all employees who are or will be exposed to airborne concentrations of fibers of asbestos at or above the time-weighted-average (“TWA”) and/or excursion limit. The asbestos standard mandates that the employer shall be informed of the results of the examination that are potentially related to occupational exposure to asbestos, but not to findings or diagnoses not related to asbestos exposure. Specifically, as shown below, the rule at 29 C.F.R. § 1910.1001.l(7) requires the employer to obtain a written opinion from the examining physician.

(7) *Physician’s written opinion.* (i) The employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination and shall include:

(A) The physician’s opinion as to whether the employee has any detected medical conditions that would place the employee at an increased risk of material health impairment from exposure to asbestos;

(B) Any recommended limitations on the employee or upon the use of personal protective equipment such as clothing or respirators;

(C) A statement that the employee has been informed by the physician of the results of the medical examination and of any medical conditions resulting from asbestos exposure that require further explanation or treatment; and

(D) A statement that the employee has been informed by the physician of the increased risk of lung cancer attributable to the combined effect of smoking and asbestos exposure.

(ii) The employer shall instruct the physician not to reveal in the written opinion given to the employer specific findings or diagnoses unrelated to occupational exposure to asbestos.

(iii) The employer shall provide a copy of the physician's written opinion to the affected employee within 30 days from its receipt.

NIOSH, too, has published guidance on guidelines for physicians to provide information to employers regarding occupationally-related medical findings. As recently as 2006, NIOSH published a criteria document for refractory ceramic fibers ("RCFs"), another pneumoconiotic-producing inhalant, which recommends comparable guidance to that of the OSHA asbestos standard for providing written reports of medical findings be provided the employer.²⁶

Following initial and periodic medical examinations, the physician or other qualified health care provider shall also give a written report to the employer containing

- occupationally pertinent results of the medical evaluation,
- a medical opinion about any medical condition that would increase the worker's risk of impairment from exposures to airborne RCFs,
- recommendations for limiting the worker's exposure to RCFs or other agents in the workplace (which may include the use of appropriate PPE or reassignment to another job), and,
- a statement to indicate that the worker has been informed about the results of the medical examination and about any medical condition(s) that should have further evaluation or treatment.

²⁶ Criteria Document at 123.

Findings, test results, or diagnoses that have no bearing on the worker's ability to work with RCFs shall not be included in the report to the employer. Safeguards to protect the confidentiality of the worker's medical records shall be enforced in accordance with all applicable regulations and guidelines.

It is crucial that MSHA conform to the accepted principles of occupational health practice, and the guidance of other federal regulatory and health agencies, by allowing coal mine operators to have access to pertinent occupational health findings for their workforce.²⁷ It is the mine operator who has a duty to prevent the development of occupational illnesses in miners that would impair health or result in premature mortality. We implore MSHA to correct this long overdue disparity in dealing with notification of results of medical examinations as compared to its sister DOL Agency – OSHA.

MSHA Must Take into Account the Effects of Smoking Among Miners as Part of the Periodic Examinations

We are also very concerned that, in proposed § 72.100, MSHA has failed to take into account the effects of smoking among coal miners. It is well known, and even a recognized factor in many of the health studies MSHA cites in its NPR, that the combination of CMD exposure and smoking are additive and increase the prevalence and severity of chronic obstructive pulmonary disease (“COPD”). Silica exposure and smoking seem to have a similar effect on COPD as that of coal mine dust. Yet despite this knowledge and the known toll that smoking takes on the American people, MSHA fails to address this important public health topic in its proposal. MSHA ignores the recommendation of NIOSH that smoking be prohibited in all underground and surface mines and all other work areas associated with coal mining.²⁸ NIOSH is quite specific in its recommendation contained in the Criteria Document regarding prohibition of smoking, stating.

NIOSH recommends that the mine operator prohibit smoking and strictly enforce this policy in all underground and surface coal mines and in all other work areas associated with coal mining. The mine operator or the physician should counsel tobacco-smoking miners about their increased risk of developing lung cancer and COPD; the mine operator or physician should also counsel such miners to participate in a smoking cessation program.

²⁷ As we discussed earlier, Mine Act § 101(a)(6)(A) requires that MSHA consider experience gained under other safety and health laws.

²⁸ Criteria Document at 96.

We further note that MSHA proposes to add occupational history and symptom assessment questionnaires to the medical examinations given coal miners. We agree these questionnaires should be added. However, the proposal does not specifically address adding a smoking history questionnaire to the examination. We further note that NIOSH fails to collect any information regarding smoking in its occupational history questionnaire form for the CWXSP.²⁹ This aberrant omission needs to be corrected in any final rule. A smoking history questionnaire should be mandated.

Further, with regard to the principle that this section and 42 C.F.R. Part 37 should not duplicate or overlap with one another, we are puzzled by the statement in proposed § 72.100(c)(3), that for the purposes of that follow-up examination, if the chest x-ray shows evidence of pneumoconiosis or the spirometry examination indicates evidence of decreased lung function, then “[f]or this purpose, evidential criteria will be defined by NIOSH.” 75 Fed. Reg. 64,497. Nothing in the preamble explains this phrase (*id.* at 64,445). Of course, the existing Part 37 does not include spirometry and, thus, there are no specified criteria for conducting spirometric examinations. Consequently, and again to reconcile Part 37 with proposed § 72.100, MSHA should ask NIOSH to publish, as a proposed rule, the evidential criteria mentioned here so that interested persons will have the opportunity to comment on them. Such NIOSH rulemaking should be carried out pursuant to the rulemaking provisions of the Mine Act, and should be finalized no later than the effective date of § 72.100, whenever it is promulgated.

In addition, MSHA’s proposed § 72.100(d) demanding that operators develop and submit to NIOSH for approval a plan for providing miners with the specified examinations is confusing.

What will be the content of the plan? Is this the same plan as is specified in 42 C.F.R. §§37.3 and 37.4? If so, when finalized, § 72.100(d) should clearly state this to be the case. In any event, since proposed § 72.100 is designated as a mandatory health standard for all coal mines, violations of this provision, including § 72.100(d), will be subject to the full range of Mine Act enforcement and penalty provisions. Mine operators and miners, as well as MSHA’s inspectorate must have a full and clear understanding of what this proposed plan requires.

In summary, this proposed § 72.100 falls unacceptably short of being based on sound occupational health practice and is unclear and confusing in terms of its relationship to the NIOSH rules in 42 C.F.R. Part 37. It is, therefore, doomed to repeat past failures, and will ultimately fail as a secondary prevention program aimed at early detection of disease and intervention to minimize progression to more serious disease outcomes. This is easily corrected by mandating miner participation in initial and periodic medical examinations, by urging miners with evidence of $\geq 1/0$ small opacity profusion to transfer to lower dust, by requiring miners with evidence of $\geq 2/0$ to transfer to lower dust, and by ensuring that this section and Part 37 dovetail effectively with one another.

²⁹ See Criteria Document at 300-301.

Comments on MSHA's Confusing and Inconsistent Requirements Regarding the Use of Airstream Helmets and Other Suitable Respirators as Supplemental Controls to Protect Miners from Respirable Coal Mine Dust

The Companies firmly believe any revision to MSHA's rules for the control of respirable coal mine dust to protect coal miners must clearly allow operators to apply the well-established industrial hygiene precepts, known as the hierarchy of controls, to--

- require the application of all feasible engineering or environmental controls to achieve the applicable coal mine respirable dust standard;
- if such feasible engineering or environmental controls cannot achieve the standard, then apply all feasible administrative controls, including rotation of miners from one working position to another; and,
- finally, if all feasible engineering, environmental, and administrative controls cannot achieve the standard, then suitable respirators, such as airstream helmets or other NIOSH-approved powered-air purifying respirators ("PAPRs"), or other suitably protective NIOSH-approved respirators may be used as a supplement to achieve the standard.³⁰

MSHA's current respirable coal mine dust regulations do not recognize the hierarchy of controls. They defer entirely to the interim mandatory health standard provided for in Mine Act § 202(h) which states, in applicable part, "Use of respirators *shall not be substituted* for environmental control measures in the active workings [of underground coal mines]." (Emphasis added.) That provision of the Mine Act is codified in the current rules at 30 C.F.R. § 70.300. Such a provision is also included in this NPR at proposed § 72.700(a).³¹

The NPR, however, also proposes, in § 70.208(h), to allow, during the initial 24-month effective period of the proposed rules, the "use of supplementary controls" for a period not to exceed six months, if the operator determines that "all feasible engineering or environmental controls are being used" and the operator's request is approved by the MSHA District Manger "through the approval process associated with the mine ventilation plan."³² But this provision does not specify that such supplementary controls can include respirators, nor does the preamble explanation of this provision shed any light on the question of whether or not respirators are considered to be supplementary controls.³³ Furthermore, in proposed §§ 70.207(i) and 70.209 (e), during the time fixed for abatement of a citation of the applicable respirable dust standard,

³⁰ All of these steps in the hierarchy of controls need not be applied all the time. Rather they are to be applied sequentially until compliance with the applicable standard is achieved.

³¹ 75 Fed. Reg. 64,498.

³² *Id.* 64,490.

³³ *Id.* at 64,435.

operators shall “[m]ake approved respiratory equipment available to affected miners in accordance with [proposed] § 72.200.”³⁴

The Companies conclude, therefore, that the NPR does not allow for suitable respirators to be used as a “supplementary control” under proposed § 70.208(h). We conclude further that after a citation is issued for violation of the applicable respirable dust standard, it is only then that *availability (but not necessarily use) of respirators can serve as part of the means of abating the citation.*

The Companies are terribly disappointed with these excessively restrictive proposals. MSHA’s failure to explain why the use of respirators like airstream helmets cannot even be considered to be a temporary supplementary control is, in the opinion of the Companies, a huge step backward from the earlier proposals of the Clinton and Bush Administrations mentioned previously in these comments.

We say this because Mine Act § 202(h) is an *interim* mandatory health standard under the Mine Act which can be revised under the rulemaking provisions of Mine Act § 101.³⁵ The Companies submit that allowing operators to apply the hierarchy of controls, including the use of airstream helmets, other NIOSH-approved PAPRs, or other suitably protective NIOSH-approved respirators does not operate to allow these respirators to be used as “substitutes” for engineering or environmental controls, but only as supplementary controls. *As we understand it, proper application of the hierarchy of controls would demand the sequential use of all feasible controls—engineering, environmental, administrative, and suitable NIOSH-approved respirators—, as and when necessary to achieve compliance with the applicable respirable coal mine dust standard.*

In addition, even under the current provisions of Part 70, according to the preamble of the Clinton Administration’s proposal, “MSHA’s longstanding policy has been that respirators should be used in underground coal mines . . . as an interim method of protection until feasible engineering or environmental controls are available.”³⁶ The Companies also submit that allowing mine operators to properly apply the hierarchy of controls is the best way to fully protect coal miners against respirable coal mine dust, especially in mines operating on a reduced respirable dust standard due to the quartz content of the coal mine dust. MSHA should adopt this approach in any new rule the Agency ultimately promulgates with respect to improved protection of coal miners from respirable dust.

³⁴ *Id.* at 64,489 and 64,490.

³⁵ *See* Mine Act § 201(a).

³⁶ 65 Fed. Reg. 42,134 (Fri. Jul. 7, 2000).

In this regard, the Companies wish to briefly discuss the ways the earlier Clinton and Bush proposals treated this issue, including the Agency's consideration of a 1997 industry Rulemaking Petition on the issue.³⁷ A copy of this Petition (less its voluminous attachments which are in MSHA's possession) is attached to the Companies' comments. Widely supported by the industry, the Companies wish to fully associate themselves with it, and hereby endorse the Petition as their own. The substance of this Petition was favorably addressed in the Clinton and Bush Administration proposals, yet the current NPR effectively rejects the Petition *de facto* without any explanation of the apparent and dramatic reversal of MSHA's position with regard to the Petition's substance. The Companies respectfully insist that MSHA must provide an explanation of this rejection as a part of this current rulemaking, as MSHA is required to do under the Administrative Procedure Act. *See* 5 U.S.C. § 555(e).

In the Clinton Administration's proposal,³⁸ the issues of "Hierarchy of Dust Controls" and "Guidelines for Determining What is a Feasible Dust Control" were discussed at some length in the preamble to the text of those proposed rules themselves.³⁹ Thus, the Rulemaking Petition was discussed in the preamble of that proposal as follows:

In September 1997, Energy West Mining Company (Energy West) petitioned the Secretary of Labor to amend the mandatory health standards for underground coal mines at 30 CFR part 70 to allow Airstream helmets or other types of PAPRs to be used as a supplemental means of complying with the applicable dust standard. The petition for rulemaking proposed that the Secretary issue a standard which would supersede the current interim statutory standard, specified in Section 202(h) of the Mine Act. Energy West contended that PAPRs are necessary as a supplemental means of controlling respirable dust because even the most diligent application of feasible engineering/environmental controls could not always prevent overexposure. MSHA has consistently acknowledged that PAPRs can be effective as an interim method of protecting miners when properly selected, used, and maintained. However, MSHA has never considered that Racal[®] Airstream helmet (or the 3M[™] Airstream[™] Helmet-Mounted PAPR), or any other respiratory protective device approved and labeled as such by the National Institute for

³⁷ *See* "Petition for Rulemaking to Amend 30 C.F.R. Part 70 Mandatory Health Standards—Underground Coal Mines to Allow Use of Airstream Helmets or Other NIOSH-Approved Powered Air-Purifying Respirators as a Supplemental Means of Compliance with Respirable dust Standards," submitted to MSHA by Energy West Mining Company on September 10, 1997.

³⁸ 65 Fed. Reg. 42,122.

³⁹ *Id.* 42,134-42,138.

Occupational Safety and Health (NIOSH), to be an engineering, environmental, or administrative control. Hence, it cannot be used as an environmental control to comply with the respirable dust standard.

In order to provide the greatest possible protection for all miners under typical mining conditions, MSHA is proposing to permit, under certain circumstances, the limited use of either approved loose-fitting PAPRs or verifiable administrative controls for compliance purposes. This would provide . . . the flexibility to select the most appropriate option for supplementing . . . engineering or environmental controls. We believe that permitting longwall mine operators to use loose-fitting PAPRs or verifiable administrative controls for compliance purposes will not reduce the level of protection afforded longwall miners by the existing standard.

This aspect of the proposal is limited to longwall mine operations because technology is available to control respirable dust at or below the applicable standard at MMUs employing continuous and conventional methods of mining. Their use at longwall operations would be permitted, only after MSHA determines that for a specific MMU, excessive dust concentrations cannot be prevented in the environment of miners required to work downwind of the longwall shearer operator (occupation code – 044) by implementing all feasible engineering or environmental controls.

65 Fed. Reg. 42,135-42,136.⁴⁰

In the Bush Administration's proposal,⁴¹ there was even more extensive discussion of the use of PAPRs. For example, the preamble stated:

This proposed rule recognizes that there may be circumstances where, even after implementing all feasible engineering or environmental controls, a mine operator may be unable to maintain concentrations at or below the verification limits. This includes operations that employ longwalls or other mining systems. In

⁴⁰ For other discussion of this issue in the Clinton Administration's proposal, see also 65 Fed. Reg. 42,134, 42,137, 42,138, 42,140, 42,141, 42,146 to 42,148, feasibility statement at 42,164, and proposed regulatory language at 42,180 to 42,181.

⁴¹ The Bush Proposal was published on March 6, 2003, at 68 Fed. Reg. 10,784.

those instances, the proposed rule would allow a mine operator, with the approval of the Administrator of Coal Mine Safety and Health, to use either PAPRs or administrative controls or a combination of both to supplement engineering or environmental controls to reduce the dust exposure of individual miners. Approval to use supplementary control measures would be contingent on the mine operator adopting new engineering and environmental controls when they become available. The proposed rule also recognizes that there may be special situations that occur intermittently and for short periods of time where the approved dust control measures may not protect miners from overexposure. An example would be where the operator is required to mine through a rock parting with high quartz content. In these situations, the district manager may allow the operator to use PAPRs for a period not to exceed 30 calendar days.

This proposed rule would require that the mine operator provide a copy of any request for supplemental controls to the representative of the miners. This would provide an opportunity for miners' input prior to MSHA making any determination.

68 Fed. Reg. 10,785-10,786. No clearer examples exist of how the present NPR is such an inexplicably drastic change from earlier proposals.

To reiterate and reemphasize our concerns about MSHA's confusing and inconsistent pronouncements and provisions in the NPR on the use of PAPRs and other suitable respirators as supplemental controls to protect miners from respirable coal mine dust, MSHA has ignored the issue in spite of earlier laudable efforts by the two previous Administrations to come to grips with it. The Companies submit that sweeping the problem under the rug is the worst way to deal with what the two previous Administrations recognized was a severe problem, especially in mines using longwall technology and or dealing with a reduced respirable dust standard due to the presence of quartz. As we said at the outset of this portion of our comments, the best way for MSHA to come to grips with this issue is to simply permit operators to apply the well-accepted and hierarchy of controls. The time has come for MSHA to emerge from under the shadow of the outmoded interim health standard set out in Mine Act § 202(h) and to join the rest of the international industrial hygiene community.⁴²

⁴² What the Companies find especially troubling about MSHA's treatment about this critically important issue is that MSHA accepts an enclosed cab on a bulldozer or a shuttle car as an engineering control. In this very NPR, MSHA states that engineering controls include "environmentally controlled cabs." 75 Fed. Reg. 64,477. We ask why should not an airstream helmet or other PAPR be treated similarly (*see* enclosed Airstream Helmet Petition at 18)? In addition, the Companies note that in MSHA's limit on exposure of underground metal/nonmetal

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The Companies wish to add that MSHA's failure to do so will result in one more reason (and a major one) demonstrating that compliance with the NPR is not feasible—and it is to that topic that the Companies now turn.

Feasibility of the NPR

When MSHA promulgates standards such as those contained in the NPR, Mine Act § 101(a)(6)(A) requires those standards to be feasible. The importance of feasibility was emphasized in *National Mining Association v. Secretary of Labor*, 153 F.3d 1264 (11th Cir. 1998), which held that “MSHA shall consider feasibility. The language is not discretionary.” *Id.* at 1268. We have read the discussion of feasibility in the preamble of the NPR with care and find ourselves gravely disappointed that the Agency treated the issue in such a cursory fashion.⁴³ The entire discussion of the feasibility issue takes up less than a single page in a preamble that is more than seventy pages long within the Federal Register. Such cursory treatment of both technological *and* economic feasibility utterly fails as a reasonable discharge of MSHA's duty to consider feasibility in its efforts to advance regulatory policy.

As far as economic feasibility is concerned, the Companies strongly endorse the report of Dr. Robin Cantor, “Comments on the MSHA Preliminary Regulatory Economic Analysis for the Coal Mine Dust Rule,” submitted by MEC as a part of its separately filed comments. Dr. Cantor's analysis shows the error of MSHA's conclusion “that compliance with the provisions of the proposed rule would be economically feasible for the industry.”⁴⁴

The Companies will next discuss the points identified by MSHA with regard to technological feasibility and begin by stating that they (and other coal mine operators) have been using all available feasible engineering controls for years to achieve compliance with the current

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miners to diesel particulate matter (“DPM”), at 30 C.F.R. § 57.5060, subsection (d) of that mandatory standard, provides that when feasible engineering and administrative controls do not reduce a miner's exposure to the DPM limit, or controls do not produce significant reductions in DPM exposure, then those controls must be used to reduce the miner's exposure to as low a level as feasible and, then, must be supplemented with suitable respiratory equipment. The Companies urge MSHA to recognize that since the Agency has adopted the application of the hierarchy of controls for the protection of underground metal/nonmetal miners from DPM, then it would not only be consistent, but would also represent sound occupational health policy to allow the use of the hierarchy of controls to protect coal miners from respirable coal mine dust. The “as low as feasible” concept can also be found in the United Kingdom's “Coal Mines (Control of Inhalable Dust) Regulations, 2007,” in which the use of suitable respirators is permitted in addition to engineering or administrative controls. *See* Regulation 5.

⁴³ 75 Fed. Reg. 64,476-64,477.

⁴⁴ *Id.* 64,477.

2.0 mg/m³ standard. No new, miraculous engineering technology exists or can be found in the research cupboard which will allow mine operators to generally comply with the proposed new 1.0 mg/m³ standard. Indeed, as MSHA itself has recognized, in order to reduce respirable dust levels, there are only so many engineering controls available to either reduce dust generation, or suppress, dilute, capture, or divert it.⁴⁵

In its preamble discussion of technological feasibility, the agency proffers three reasons why it believes the proposed rules are technologically feasible. The Companies respond to each of these below.

• (1) *The Agency asserts that both MSHA and mine operator data show that “the majority of miners’ exposures are [already] at or below the [respirable coal mine dust] limits in the proposed rule.”*⁴⁶

The Companies do not agree with MSHA’s claim. Indeed, compelling evidence to the contrary was presented by Alliance engineering representatives, as part of the NMA panel presentation at the February 15, 2011 MSHA public hearing. The vast majority of mines cannot meet the proposed 1.0 mg/m³ limit on a single shift sampling basis at any single mine over any substantial period of time. In other words, mines may be able to meet the proposed limit some of the time, but will not be able to meet the new standard all of the time, which, of course is what the NPR demands.⁴⁷

• (2) *MSHA also has said it has “. . . included a 24-month phase-in period to allow mine operators time [to identify, develop, and implement feasible engineering controls] to come into compliance.”*⁴⁸

A phase-in period, with any proposed rulemaking, makes sense. However, as noted above, the Agency itself has recognized there are only so many engineering controls available to either reduce dust generation (*e.g.*, machine parameters), suppress dust (*e.g.*, water sprays, wetting agents, foams, water infusion, etc.), dilute dust (*e.g.*, ventilation), capture dust (*e.g.*, dust collectors), or divert respirable dust (*e.g.*, shearer clearer, passive barriers, etc.).⁴⁹ The Companies apply all of these engineering controls, as appropriate, at our mines. However, as long as MSHA refuses to permit the full use of the hierarchy of controls (as the Companies urge MSHA to do), then the Agency’s refusal to allow the use of suitable respiratory protection as a

⁴⁵ 65 Fed. Reg. 42,134 (Jul. 7, 2000).

⁴⁶ 75 Fed. Reg. 64,477.

⁴⁷ See testimony of Alliance’s Mark Watson and Heath Lovell at the February 15, 2011 MSHA public hearing.

⁴⁸ *Id.*

⁴⁹ 65 Fed. Reg. 42,134 (Jul. 7, 2000)

supplement to the toolbox of engineering controls will remain a huge impediment to lowering the exposures of miners to respirable coal mine dust.

• (3) *The 24-month phase in period would also allow enough time to produce and deploy a sufficient number of CPDMs for use in measuring for compliance with the new limits on respirable coal mine dust.*

As the Companies commented earlier, in connection with MSHA's failure to meet the substantive requirements of Mine Act §202 (a) with regard to accurate samples, simply put, the CPDM (while showing promise for the future) is not now ready for use as a day-to-day, shift-to-shift compliance tool. Even the manufacturer of the CPDM recognizes that many details of how the device will be used remain to be worked out.⁵⁰

In short, and in no uncertain terms, the NPR is structured such that, if enforced as written, it will throw the industry into such disarray that this consequence, per se, demonstrates the infeasibility of the NPR.

By way of example, at the MSHA public hearing of February 15, Alliance engineers Mark Watson and Heath Lovell (testifying for NMA) stated their calculations showed that, as opposed to less than 200 citations per year for violations of the current 2.0 mg/m³ respirable dust limit, *imposition of a 1.0 mg/m³ limit (based on a single, full-shift measurement) could result in more than 230,000 citations annually.* Because all of these are alleged violations of mandatory health standards, under Mine Act jurisprudence, each of them would be treated in all likelihood as "significant and substantial" unless the operator could show there was absolutely no health effect, a very high bar to cross.

Furthermore, in connection with each citation for an alleged violation of the 1.0 mg/m³ limit, the Companies must assume, if the NPR were to be enforced as written, that revisions to the approved CPDM performance plan, proposed in new §70.206, would be required.⁵¹ The Companies submit MSHA lacks the number of skilled personnel required to deal with the possibility of more than 230,000 revisions to the CPDM performance plan annually. We remind MSHA that if an operator does not have an approved plan, then it is highly likely for the mine in question to be idled pending such approval.

⁵⁰ See Kris Maher, *New Monitor Kicks Up a Dust Storm*, Wall St. J., May 3, 2011 at B6.

⁵¹ 75. Fed. Reg. 64,487-64,488. See especially, proposed §§70.206 (a) and (d) stating that the purpose of the plan is "to ensure that no miner working on an MMU shall be exposed to concentrations of respirable dust in excess of the applicable standard" and that the MSHA district manager may require the plan to be revised if he determines the plan is inadequate for that purpose.

We also must remind MSHA of the centrality of “significant and substantial” violations to the Agency’s proposed rule on “Patterns of Violations.”⁵² If over 230,000 “significant and substantial” violations annually result from this NPR, the Companies are gravely concerned that it will become extraordinarily difficult, if not impossible, to avoid having our mines fall into the pattern of violations enforcement mechanism. Furthermore, once on the pattern of violations, our mines may never emerge from the “pattern” sanctions.

The Companies are very concerned as well that MSHA’s proposed rules on “Examinations of Work Areas in Underground Coal Mines for Violations of Mandatory Health or Safety Standards,”⁵³ will cause further disarray, if promulgated as proposed. This would be true not just for mine operators, but for our key mine examiners. Mine examiners are the first line of defense in identifying hazards during their pre-shift, on-shift, and weekly examinations at mines around the country. Dealing with more than 230,000 additional violations of mandatory health standards annually is obviously a problem in and of itself. However, the additional record-keeping burden upon mine examiners presents a very real likelihood that this NPR—in conjunction with the “Examinations of Work Areas in Underground Coal Mines for Violations of Mandatory Health or Safety Standards”—will result in a multitude of new opportunities for *additional* violations. The results of these two proposed rules being promulgated, as proposed, makes the problems with each proposed rule exponentially greater.

And if MSHA entertains any doubts as to how onerous it will be for mine operators to attempt to comply with this NPR should it be promulgated as written, the Companies call to the Agency’s attention the statement of Dennis O’Dell, Administrator of Occupational Health and Safety for the United Mine Workers of America, presented at MSHA’s public hearing on this NPR in Beckley, WV on December 7, 2010. At this hearing Mr. O’Dell said, “[o]ne significant problem we see with this proposed rule is how complicated it truly is. The explanations are confusing . . . ,”⁵⁴ Mr. O’Dell went on to say that: “As written, parts of the proposed rule is (sic) unintelligible.”⁵⁵ In fact, the Companies also note Mr. O’Dell’s statement regarding the end result of the new respirable dust limit proposed by MSHA. Mr. O’Dell said: “If I have done my math properly, . . . longwall miners and some section miners would be held to a 0.6 mg/m³ or possibly a 0.4 mg/m³ standard. This will be very difficult to meet [W]e strongly believe that current mining practices can be continued without jeopardizing miners’ health. We want to make sure the rule doesn’t make it infeasible for coal miners to work in coal mines.”⁵⁶ The Companies agree with Mr. O’Dell on these limited points.

⁵² 76 Fed. Reg. 5,719 (Feb. 2, 2011).

⁵³ 75 Fed. Reg. 81,165 (Dec. 27, 2010).

⁵⁴ Testimony of Dennis O’Dell at 56.

⁵⁵ *Id.* at 58.

⁵⁶ *Id.* at 56-57.

In sum, for all of the reasons stated above, the Companies are of the firm opinion that this NPR is neither economically or technologically feasible.

The NPR Fails to Adequately Consider Key Presidential Executive Orders on Regulations

Executive Order 12,866

In MSHA's analysis of its compliance with Executive Order 12,866, "Regulatory Planning and Review," among other flawed assertions, MSHA claims that, based on its Preliminary Regulatory Economic Analysis ("PREA"), the NPR "would not have an annual effect of \$100 million or more in terms of compliance costs to the economy and therefore it is not an economically significant regulatory cost action pursuant to section 3(f)" of the Executive Order.⁵⁷ Frankly, this notion of annual effect is so outlandishly low, that it defies any sense of real world impacts. Confounding reality further, the Agency claims that annual "benefit effects of the [NPR] are likely to exceed \$100 million and would be economically significant in terms of benefits."⁵⁸ The Companies have already endorsed the report of Dr. Cantor commenting on the PREA.⁵⁹ Her report shows (by way of brief summary) that MSHA has vastly underestimated the costs and grossly exaggerated the supposed benefits of the NPR. Dr. Cantor states that the *costs of work stoppages alone, were the NPR to be promulgated as proposed and enforced as it is written, would be in the range of \$1.6 billion for underground coal mining alone.* The Companies maintain that amount of money, all by itself (and there are many more costs than the \$1.6 billion identified by Dr. Cantor), easily make this NPR an economically significant cost under the Executive Order, thus mandating much greater scrutiny by the Office of Management and Budget's ("OMB") Office of Information and Regulatory Affairs ("OIRA"). Should a final rule, based on the NPR, be submitted to OIRA for review, the Companies will be fully prepared to inject a dose of economic cost-benefit reality in any future MSHA analysis on the issue by seeking a meeting with OIRA at the appropriate time.

Moreover, even if MSHA's PREA were on target (which it most assuredly is not), this NPR must still be considered to be a "significant regulatory action" under § 3 (f) of the Executive Order, because there can be absolutely no doubt that this NPR would dramatically change MSHA's respirable coal mine dust sampling program from its statutory roots contained in the Federal Coal Mine Health and Safety Act of 1969—one based on averages of gravimetric sampling over a number of shifts now dramatically changed to sampling by the CPDM over a single full shift only. Such a revolutionary change clearly raises the kind of "novel legal or policy issues" contemplated under § 3(f)(4) of the Executive Order.

⁵⁷ 75 Fed. Reg. 64,473.

⁵⁸ *Id.*

⁵⁹ *Supra*, at 34.

Executive Order 13,563

Of course, the NPR was not even reviewed under the new Executive Order 13,563 of January 18, 2011, “Improving Regulation and Regulatory Review,”⁶⁰ since the NPR was published in October 2010. However, should this NPR be developed as a final rule by MSHA, the package will have to be reviewed by OIRA, pursuant to the terms of the new Executive Order, as well Executive Order 12,866. In that regard, and further to our comment about the complex relationships between this NPR and the Patterns of Violations and Examinations of Work Areas proposed rules, the Companies urge MSHA to obey §1(b)(2) of the Executive Order which provides that to the extent permitted by law, MSHA must “tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.”⁶¹

The Companies also urge MSHA to conform to §4 of Executive Order 13,563, “*Flexible Approaches*.”⁶² The Companies strongly believe, for example, that this section, which urges each agency “to reduce burdens and maintain flexibility and freedom of choice for the public,”⁶³ provides MSHA with perfect additional authority to utilize fully the hierarchy of controls, discussed in connection with the use of appropriate respiratory protection for miners.

Furthermore, the Companies note §5 of the new Executive Order dealing with “Scientific Integrity,” and reminding that “each agency shall ensure the objectivity of any scientific and technological information and processes used to support the agency’s regulatory actions.”⁶⁴ Simply put the Critique prepared by Drs. Gamble and Reger, and Mr. Glenn shows that the NPR is in great jeopardy of failing any test for scientific integrity.

Conclusion

To conclude, for all the reasons above, the Companies urge MSHA to withdraw this NPR and start afresh. We agree that the current rules are in need of revision and are prepared to work with the Agency and other stakeholders to modernize them. However, the current respirable dust limit of 2.0 mg/m³ is still solidly based in science and, if properly implemented by MSHA and all stakeholders, it will prevent miners from developing coal miners’ pneumoconiosis. The Companies are also prepared to work with MSHA and other stakeholders to test the CPDM to ascertain its reliability in the rugged conditions of underground coal mining. However, the Companies are not persuaded that use of a single-full shift measurement for compliance purposes

⁶⁰ 76 Fed. Reg. 3,821 (Fri., Jan. 21, 2011)

⁶¹ *Id.* 3,821.

⁶² *Id.* 3,822.

⁶³ *Id.*

⁶⁴ *Id.*

Ms. Roslyn B. Fontaine
June 20, 2011
Page 42

will either be a feasible approach or will accurately represent the atmospheric conditions to which miners are exposed. The Companies also urge MSHA to join the rest of the world's occupational health community by allowing application of the hierarchy of controls such that appropriate respiratory protection can be used as a supplementary control to protect miners from respirable coal mine dust. And finally the Companies urge MSHA to work with NIOSH to make medical monitoring of miners for pneumoconiosis mandatory and to allow the involvement of mine operators in such monitoring as we have suggested in our comments herein.

The Companies appreciate the opportunity to comment on the NPR and look forward to working with MSHA to protect the health of the Nation's coal miners.

Sincerely,



Edward M. Green
Counsel for the Companies

Attachments
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