

Fontaine, Roslyn B - MSHA

From: Dave Moss [dmoss@kentuckycoal.com]
Sent: Monday, June 20, 2011 4:46 PM
To: zzMSHA-Standards - Comments to Fed Reg Group
Cc: 'Bill Bissett'; 'Roberta James'
Subject: Submitting Comments- RIN 1219-AB64
Attachments: RIN 1219-AB64-Lowering Miner's Exposure to Respirable Coal Mine Dust, including Continuous Personal Dust Monitors.pdf

2011 JUN 20 P 4: 46

Please accept these comments on behalf of the Kentucky Coal Association.



Kentucky Coal Association

Leadership for the Coal Industry

June 20, 2011

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

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

Dear Ms. Fontaine:

The Kentucky Coal Association ("KCA") submits the following comments to the Mine Safety and Health Administration ("MSHA") concerning its proposed rule for Lowering Miners' Exposure to Respirable Coal Mine Dust, 75 Fed. Reg. 64,412 (Oct. 19, 2010).

Introduction & Summary

KCA represents the coal mining industry in the Commonwealth of Kentucky. KCA has members in Eastern and Western Kentucky, surface and underground production, and union and non-union operations. KCA's mission is to promote the best interest of the coal mining industry in the Commonwealth of Kentucky and all those engaged therein.

KCA supports efforts to eliminate coal workers pneumoconiosis. There are several measures that could help advance this goal, such as mandatory x-ray surveillance of miners and use of personal engineering controls. Unfortunately, the proposed rule bypasses straightforward approaches to health protection in favor of a fundamentally flawed, unjustified, and sweeping proposal. MSHA's proposal is based upon data that has not been fully revealed and data collected in a manner that is not scientifically sound. Further, MSHA has failed to demonstrate that recent cases of coal workers' pneumoconiosis ("CWP") were actually caused by exposure to coal dust at the current level or that they would have been prevented by the standard set forth in the proposed rule. MSHA has also failed to establish any nationwide rise in CWP. MSHA's failure in this regard does not establish proper justification for the proposed rule and is contradictory to the President's instructions on rulemaking.

KCA is a member of the National Mining Association ("NMA") and, in an effort to minimize repetitive comments; the full comments of NMA are endorsed and incorporated herein. KCA also endorses and incorporates comments submitted by the following group of coal companies, some of which are members of KCA: Alliance Coal,

Alpha Natural Resources, Arch Coal, BHP Billiton New Mexico Coal, Murray Energy Corporation, and Peabody Energy.

I. MSHA's Proposed Rule Lacks Transparency in Violation of the President's Transparency Orders

On January 21, 2009, the President of the United States issued a *Memorandum for the Heads of Executive Departments and Agencies* entitled "Transparency and Open Government."¹ The Memorandum states in part:

My Administration is committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government.

...

My Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use. Executive departments and agencies should harness new technologies to put information about their operations and decisions online and readily available to the public.

The President's memorandum also instructs the Office of Management and Budget to issue an "Open Government Directive" to the Heads of Executive Departments and Agencies.

The Office of Management and Budget ("OMB"), pursuant to the President's instruction, issued an "Open Government Directive" on December 8, 2009. Like the President's Memorandum, the OMB's directive stresses the importance of transparency in Government and states that "the presumption shall favor openness." The directive further states:

- a. Agencies shall respect the presumption of openness by publishing information online (in addition to any other planned or mandated publication methods) and by preserving and maintaining electronic information, consistent with the Federal Records Act and other applicable law and policy. Timely publication of information is an essential component of transparency. Delays should not be viewed as an inevitable and insurmountable consequence of high demand.
- b. To the extent practicable and subject to valid restrictions, agencies should publish information online in an open format that can be retrieved, downloaded, indexed, and searched by commonly used web search applications. An open format is one that is platform independent, machine readable, and made available to the public without restrictions that would impede the re-use of that information.

¹ Available at http://www.whitehouse.gov/the_press_office/TransparencyandOpenGovernment/

- c. To the extent practical and subject to valid restrictions, agencies should proactively use modern technology to disseminate useful information, rather than waiting for specific requests under FOIA.

MSHA has not complied with the spirit or direct instructions of the President's Memorandum or OMB's "Open Government Directive" in advancing its proposed rule.

More specifically, MSHA relies on medical surveillance data collected by the National Institute for Occupational Safety and Health ("NIOSH") in support of the rule and its claim that "the prevalence rate of black lung is increasing." The data was principally collected by NIOSH through its Coal Workers' X-ray Surveillance Program ("CWXSP"). MSHA failed to include NIOSH or the Secretary of Health and Human Services, who oversees NIOSH, in the development and publication of the proposed rule. This is problematic in the context of the President's directive, which orders agencies to disclose information about their decisions online as the agency proposing the decision is not the same agency with the information to disclose.

Further, the comprehensive data collected through the CWXSP has not been disclosed in its entirety, by MSHA or NIOSH.² The data was requested in Freedom of Information Act ("FOIA") requests from the NMA on October 25, 2010 and November 11, 2010. KCA sent MSHA a letter in support of NMA's FOIA requests on April 15, 2011, attached hereto as Exhibit A. MSHA has failed to produce all of the information requested, including the comprehensive CWXSP data.

As a result, the public has not been able to review cases of CWP by year, MSHA district, mine, and worker history in order to fully understand the true nature of observed CWP prevalence and, more importantly, any correlation or lack thereof to dust exposure levels. Comprehensive access to the data is important in further evaluating MSHA's claim that black lung prevalence is "on the rise" and that the current dust standard is to blame, so as to justify MSHA's proposed nationwide rule.

Industry experience with black lung claims, partial data sets that have been released, and qualitative descriptions in studies cited by MSHA and NIOSH all suggest recent CWP cases are largely driven by the results of concentrated screenings in "hot spot" regions rather than an actual rise in nationwide CWP. The partially published data also indicates cases are likely driven by factors other than dust exposure. This makes MSHA's lack of transparency in revealing the comprehensive data even more problematic as the public has not been given the opportunity to thoroughly examine MSHA's fundamental basis for the proposed rule. The public deserves the opportunity to fully review the data upon which this rule is based.

II. The Proposed Rule is Not Supported by Sound Science and MSHA's Process Lacks Scientific Integrity

² The data NIOSH has released contains restrictions impeding thorough re-use of the information by the public. NIOSH has cited privacy concerns for its failure to release the comprehensive data set. Privacy concerns could be addressed through a variety of methods, such as coding, which would still allow the public to access the information while protecting privacy. The piecemeal offering by NIOSH and MSHA falls short of the "open format" demanded by OMB and thwarts the type of public participation called for by the President.

On March 9, 2009, the President issued a *Memorandum for the Heads of Executive Departments and Agencies* entitled "Scientific Integrity."³ The Memorandum specifically directed the executive branch as follows:

(c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect information in complying with and applying relevant statutory standards;

MSHA has not met this directive. First, support for the rule is grounded in data that is not representative of the entire mining population and unfit to serve as the basis for the proposed rule. Second, MSHA does not fairly present the data to support a nationwide change to the current dust standard. Third, MSHA has not demonstrated that exposures at the current dust standard caused cited cases of CWP or that the proposed reduction would have prevented such cases. These failures are in direct contradiction with the President's directive calling for sound scientific processes to support policy decisions of agencies within the executive branch.

A. The CWP Data Collection Methods Are Inadequate

As mentioned above, MSHA relies on data from NIOSH's CWXSP to establish the prevalence of CWP. The CWXSP is a voluntary program. This allows for selection bias as the number of miners examined and the location of the miners varies significantly year to year and is not necessarily representative of the overall mining population.

The CWXSP also suffers from an extremely low participation rate. For example, the total number of examinations over the past five year period (2005-2009) represents approximately 40% of the active underground workforce. This makes the data a poor representation of the overall mining population and makes the data unfit to serve as the basis for the proposed rule.⁴

The Advisory Committee acknowledged as much in its 1996 report to the Secretary of Labor:

NIOSH should oversee the provision of confidential periodic medical examination programs for all mine workers including surface miners in order to achieve at least 85% participation rate.

...

According to Dr. Wagner, the voluntary participation rate in the CWXSP was estimated as 20-35% during Round 5. Dr. Wagner

³ Available at http://www.whitehouse.gov/the_press_office/Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-3-9-09/

⁴ There are other flaws with the data serving as the basis for the proposed rule. Examination of retired miners makes the data less reflective of current working conditions. The fact that X-ray readers are not the same each year adds inconsistency to reported results. And important external factors, such as smoking, are not considered in reported results.

indicated that this rate of participation is unsatisfactory and efforts (e.g. direct mailings to miners= homes) were underway to improve the rate.

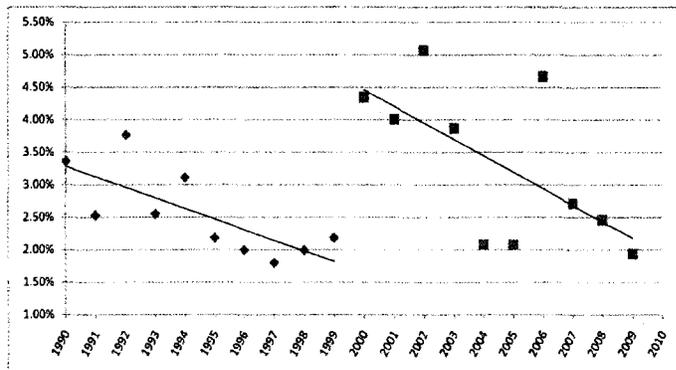
...
 The CWXSP contains the majority of data available regarding the prevalence of CWP among U.S. underground coal miners who started their underground mining under the current standard. These data, however, are surveillance data based on generally low coal miner participation rates, so it is unclear 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.

(Report of the Secretary of Labor’s Advisory Committee on the Elimination of Pneumoconiosis Among Coal Mine Workers at 8, 30, and 56.) Unfortunately, NIOSH and MSHA have not meaningfully improved the screening program and have not achieved anywhere near the targeted participation rate of 85% since 1995. For the same reasons NIOSH refused to use the data with such low participation rates to serve as the basis for a risk assessment in 1996, MSHA should abandon its current rule proposal and risk assessment based on the same flawed data collection practices.

Further, NIOSH and MSHA have, at times, mandated a focus on a particular region, increased the number of screenings, and altered screening methodologies. For example, from October 1999 through September 2002, MSHA operated a special x-ray examination program called Miners’ Choice Program (“MCP”). The MCP involved enhanced publicity, incentives, and other activities focused on motivating miners to obtain screenings. The MCP created a self-selection bias and skewed CWP prevalence results.

NIOSH also engaged in special screenings through the Enhanced Coal Workers’ Health Surveillance Program (“ECWHSP”). The ECWHSP focused on different regions from year to year. Due to NIOSH and MSHA’s changed screening methodologies, 6,291 miners were examined in the year 2000, which was 47% more than in any other year since 1990. The altered screening methodologies altered the CWP data starting in 2000.

Percentage of Examined Miners with CWP (category 1/0+) Annually (1990-2009)



Further in 2006, the NIOSH ECWHSP focused on "hot spot" regions. CWP levels in Districts 5, 6 and 7 were disproportionately higher than the rest of the country and skewed the nationwide results compared to previous and later years.

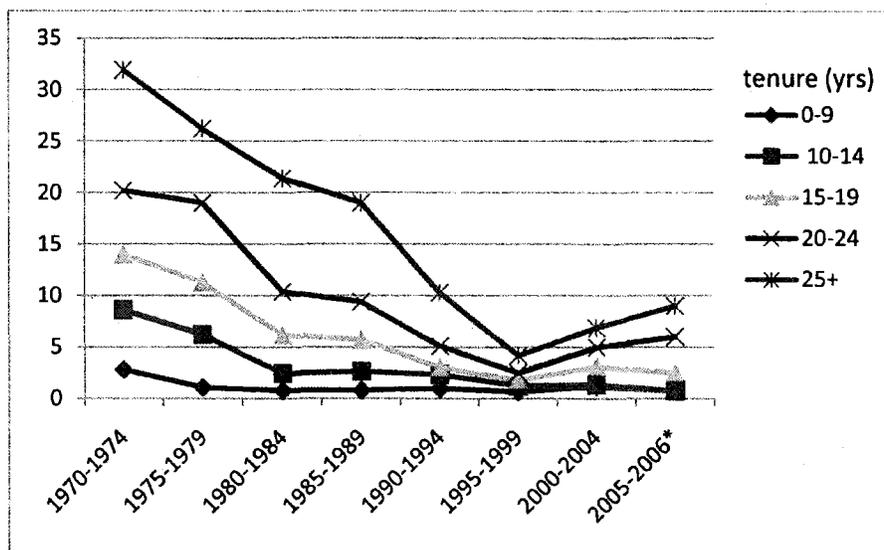
Such alterations in how miners were targeted for screening, changes in regional concentrations of screenings, and variances in the number of annual examinations year to year and region to region influenced the reported results. Taking these factors into account, it is difficult to understand how MSHA claims that "the prevalence rate of black lung is increasing." To the contrary, it appears that after MSHA and NIOSH's changes in data collection practices in 2000, the prevalence rate continues to decrease just as it did leading up to 2000.

MSHA and NIOSH's data collection program is fundamentally flawed with poor participation rates, inconsistency in screening, changes in methodologies, and ascertainment bias, and is unfit to serve as a reliable indicator of CWP prevalence, trends in CWP prevalence, or the basis of the proposed rule. MSHA should employ representative or mandatory screenings based on sound scientific techniques in order to evaluate the prevalence and trends in CWP. The screening programs, including the CWXSP, MCP, and ECWHSP, while useful to promote health among the mining population, do not amount to well-established scientific processes for data collection and are inconsistent with the President's memorandum on Scientific Integrity.

B. MSHA Claim that the "Prevalence of Black Lung is Increasing" is Based on Selective Presentation of Data

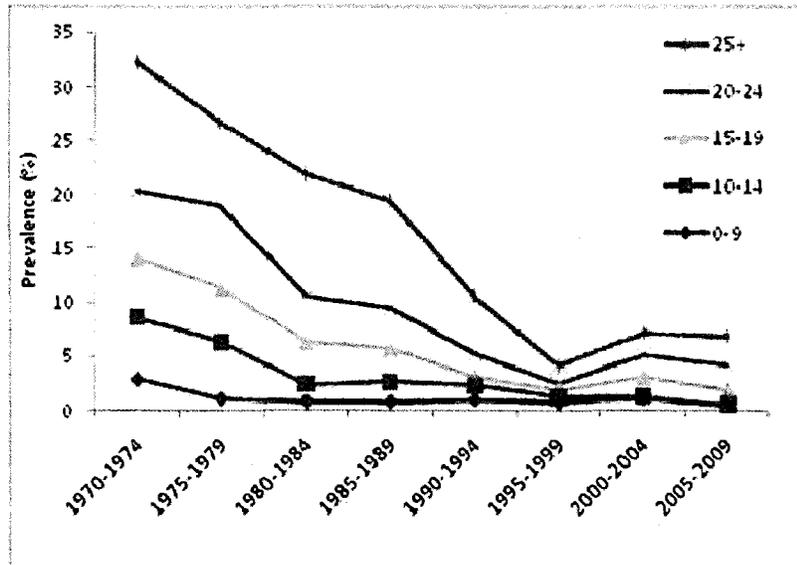
MSHA's rule is also flawed because it fails to present CWP data in a fair and reasonable way. MSHA claims CWP rates were on the rise by relying on multi-year trends in CWP data. More specifically, at the time of proposing its rule, MSHA relied on the following chart in NIOSH's 2007 Work-Related Lung Disease (WoRLD) Surveillance Report in claiming that CWP prevalence was on the rise:

**Percentage of Examined Miners with CWP
(category 1/0+) by Tenure in Mining, (1970-2006)**



The data is presented in groups of years, rather than individual years, which makes it appear that CWP rates are steadily increasing. However, as shown in the graph on page 6 above, there was a shift in the year 2000 when MSHA and NIOSH began enhanced surveillance efforts. The jump in 2000 was followed by a decline in prevalence rates. Despite repeated requests, MSHA and NIOSH did not release yearly information, demonstrating the reduction in CWP prevalence, until mid-April 2011 after all of the public hearings and well into the comment period.⁵

Further, MSHA proposed its rule on October 19, 2010. Yet the graph from the NIOSH's 2007 Work-Related Lung Disease (WoRLD) Surveillance Report stops with the partial period 2005-2006. First, the graph overweights 2006, which, as mentioned above, was influenced by disproportionate CWP prevalence rates in "hot spot" regions focused upon by the NIOSH ECWHSP. Second, the graph omits the data from 2007 through 2009, which shows dropping rates of CWP prevalence. In April, MSHA and NIOSH adjusted the chart to include the 2007 through 2009 data:



Still, the data is presented in groups of years, which suggests there was an alleged increase in 2000-2004. In reality, there was a dramatic jump in 2000 followed by decreasing rates thereafter. Further, the most recent reported rates are within prevalence rates of lung disease within the general population.

MSHA should not base its rule on selective presentation. MSHA claims that black lung rates are increasing. The fact is that they are on the decline and have been since 2000 when MSHA and NIOSH employed enhanced surveillance methods. Because MSHA's claimed justification for the rule – that "black lung rates are on the rise" – proves to be false, MSHA should not proceed with its proposed rule.

C. MSHA Does Not Justify its Proposed Change to Dust Exposure Levels

⁵ As mentioned in section I supra, MSHA and NIOSH still have not released the comprehensive CWP dataset.

MSHA does not show a correlation between specific cases of CWP and specific levels of dust exposure. Instead, MSHA generally (1) relies on the "Criteria Document," which is over 15 years old, in an attempt to establish a connection between dust exposure and CWP rates, (2) claims "the prevalence rate of black lung is increasing" citing health studies that tend to focus on "hot spot" regions, and (3) calls for a 50% reduction in dust exposure levels. This approach begs the question as to why MSHA has not performed a more current and thorough study of miners with CWP to determine their specific levels of dust exposure.

The fact is, according to the most recent study by Dr. Eva Suarathana et al., dust exposure is a poor predictor of CWP incidence. (See Suarathana et. al., "Coal workers' pneumoconiosis in the United States; regional differences 40 years after the implementation of the 1969 Federal Coal Mine Health and Safety Act" (May 19, 2011); see also NIOSH, "Coal Mine Dust Exposures and Associated Health Outcomes" at 14, Figure 9). As the "What this paper adds" section explains:

Regional differences in the prevalence of coal workers' pneumoconiosis (CWP) were observed that could not be explained by respirable dust concentrations derived from compliance measurements.

(Suarathana et al. at 1.) MSHA and NIOSH acknowledge that factors such as coal rank, seam size, and mine size all appear to influence rates of CWP. (NIOSH, "Coal Mine Dust Exposures and Associated Health Outcomes" at 15). If this is the case, it is puzzling why MSHA proposes a nationwide rule on dust exposure levels, particularly without having demonstrated that recent cases of CWP were actually caused by exposure to coal dust at current levels or would have been prevented by the standard set forth in the proposed rule.

MSHA's lack of study into specific causes of recent reported cases of CWP and failure to demonstrate current dust exposure levels actually caused recent cases of CWP leaves MSHA's proposed rule without foundation. MSHA has not met the President's call for use of sound science in rulemaking and has ignored the latest and best scientific evidence, which suggests factors other than dust exposure at current levels are influencing CWP prevalence. MSHA should collect data from a representative or mandatory surveillance program and study the data in a scientifically sound manner to better understand incidence of CWP.

Conclusion

KCA urges MSHA to withdraw the proposed rule. MSHA has not met the President's directives regarding transparency and use of sound science. MSHA's claimed basis for the rule – that CWP rates are on the rise – is incorrect. MSHA has not demonstrated that the current dust standard caused recent cases of CWP or that the proposed standard would have prevented cases of CWP. In sum, MSHA has not met its burden in order to justify the proposed rule.

Sincerely,



Bill Bissett
President, Kentucky Coal Association