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*Subject: MINE SAFETY: Reports and Key Studies Support the Scientific Conclusions Underlying the Proposed Exposure Limit for Respirable Coal Mine Dust*

Coal mine dust is one of the most serious occupational hazards in the coal mining industry, and overexposure can cause coal workers' pneumoconiosis (CWP) and a number of other lung diseases, collectively referred to as black lung disease.<sup>1</sup> CWP has been the underlying or contributing cause of death for more than 75,000 coal miners since 1968, according to the Department of Health and Human Services' (HHS) National Institute for Occupational Safety and Health (NIOSH), the federal agency responsible for conducting research on work-related diseases and injuries and recommending occupational safety and health standards. Since 1970, the Department of Labor (Labor) has paid over \$44 billion in benefits to miners totally disabled by respiratory diseases (or their survivors), including CWP, through the Black Lung Benefits Program.

In October 2010, Labor's Mine Safety and Health Administration (MSHA)—the federal agency responsible for setting and enforcing mine safety and health standards—proposed revising the existing standard for coal mine dust to lower the permissible exposure limit (PEL)<sup>2</sup> from 2.0 milligrams of dust per cubic meter of air ( $\text{mg}/\text{m}^3$ ) to  $1.0 \text{ mg}/\text{m}^3$ .<sup>3</sup> Several coal mining companies and others have questioned the evidence and analytical methods used to support the proposed PEL. In the Consolidated Appropriations Act, 2012, Congress required that GAO review and report on the data collection, sampling methods, and analyses MSHA used to support its proposal.<sup>4</sup> Although MSHA's proposed rule includes other provisions, this review focuses on MSHA's proposal to lower the PEL for coal mine dust from  $2.0 \text{ mg}/\text{m}^3$  to  $1.0 \text{ mg}/\text{m}^3$ . To respond to this requirement, we addressed the following question: What are

<sup>1</sup>In this report, we use the term coal mine dust to refer to respirable coal mine dust. Black lung is a term that includes CWP and other chronic respiratory or pulmonary impairments resulting from coal mine employment.

<sup>2</sup>In this report, the term PEL refers to the respirable coal mine dust standard.

<sup>3</sup>Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors, 75 Fed. Reg. 64,412 (Oct. 19, 2010) (to be codified at 30 C.F.R. pts. 70, 71, 72, 75, and 90). As of August 13, 2012, MSHA had not finalized this regulation.

<sup>4</sup>The Act provided that "[n]one of the funds made available by this Act may be used to implement or enforce [MSHA's] proposed rule" until GAO "issues, at a minimum, an interim report...and...not later than 240 days after enactment of this Act, submits the report ...to the Committees on Appropriations of the House of Representatives and the Senate," or until that deadline has passed. Pub. L. No. 112-74, div. F, tit. I, § 112, 125 Stat. 786, 1064 (2011).

the strengths and limitations of the data and analytical methods MSHA used to support its proposal to lower the PEL for coal mine dust?

To conduct our work, we reviewed relevant federal laws and regulations, MSHA's proposed standard to lower the PEL for coal mine dust, the reports and key scientific studies cited in them that MSHA used to support its proposed standard, and the comments MSHA received on its proposal after it was published in the *Federal Register*. MSHA primarily relied on two reports and the studies cited in them to develop its proposed standard: NIOSH's 1995 *Criteria for a Recommended Standard – Occupational Exposure to Respirable Coal Mine Dust* (Criteria Document) and MSHA's 2010 *Quantitative Risk Assessment in Support of the Proposed Respirable Coal Mine Dust Rule* (Quantitative Risk Assessment). MSHA also relied on the 1996 *Report of the Secretary of Labor's Advisory Committee* (consisting of labor, industry and government representatives) *on the Elimination of Pneumoconiosis Among Coal Mine Workers*.<sup>5</sup> Enclosure I lists and provides a detailed discussion of the reports and key scientific studies we reviewed. The focus of our work was primarily limited to determining whether the scientific studies MSHA used generally support its conclusion that lowering the exposure to coal mine dust would lower miners' risk of disease over their working lives.<sup>6</sup> We assessed the adequacy of the data and measures employed, the reasonableness and rigor of the statistical techniques used to analyze them, and the validity of the conclusions drawn from the analyses. Our work was not designed to determine the optimal PEL for coal mine dust; analyze the costs and benefits of the proposed standard; or determine whether the proposed standard would meet MSHA's legal requirements under the Federal Mine Safety and Health Act of 1977 (Mine Act) or other federal laws that govern the rulemaking process, such as the Administrative Procedure Act.<sup>7</sup>

In addition to reviewing the reports and key scientific studies cited in them that MSHA used to support its proposed standard, we conducted a literature search to identify other studies that examined the relationship between exposure to coal mine dust and its associated health effects. These included an April 2011 NIOSH report on a review of information since 1995 on coal mine dust exposures and associated health outcomes.

Finally, we interviewed MSHA and NIOSH officials and representatives from the mining industry and mine workers. We also reviewed related reports by GAO, Labor's Office of Inspector General, and others on the health effects of exposure to coal mine dust. We visited MSHA and NIOSH offices in Pittsburgh, Pennsylvania and Morgantown, West Virginia, which informed our understanding of the data and the analytical methods used to support MSHA's proposal for lowering the PEL for coal mine dust. A further discussion of our scope and methodology is provided in Enclosure I.

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<sup>5</sup>This report was included in our overall review of relevant materials, but we did not include it in our final analysis of the two reports and the key studies cited in them on which MSHA relied to develop its proposed standard because it did not contain new information or analyses of the relationship between coal mine dust exposure and its associated health effects.

<sup>6</sup>For purposes of this proposed rule, MSHA defines a miner's working life to be 45 years.

<sup>7</sup>Various federal statutes and executive orders require federal agencies to follow a number of procedural and analytic requirements when developing and issuing rules. For example, the Administrative Procedure Act generally requires agencies to publish proposed rules for public comment prior to issuing a final rule. 5 U.S.C. § 553. In addition, section 101(a) of the Mine Act establishes certain procedural and analytic rulemaking requirements for MSHA standards. For example, before issuing a standard on toxic materials, MSHA must determine, based on research and other considerations, that the toxins pose a material impairment to miners' health or functional capacity. 30 U.S.C. § 811(a)(6)(A).

We conducted this performance audit from February 2012 through August 2012 in accordance with generally accepted government auditing standards. These standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## Results In Brief

Our evaluation of the reports MSHA used to support its proposal and the key scientific studies on which the reports were based shows that they support the conclusion that lowering the PEL from 2.0 mg/m<sup>3</sup> to 1.0 mg/m<sup>3</sup> would reduce miners' risk of disease. The reports and key studies concluded that miners' cumulative exposure to coal mine dust at the current PEL over their working lives places them at an increased risk of developing CWP, progressive massive fibrosis, and decreased lung function, among other adverse health outcomes. To mitigate the limitations and biases in the data, the researchers took reasonable steps, such as using multiple x-ray specialists to reduce the risk of misclassifying disease and making adjustments to coal mine dust samples where bias was suspected. In addition to addressing the limitations and biases in the data, researchers used appropriate analytical methods to conclude that lowering the existing PEL would decrease miners' risk of developing black lung disease. For example, in addition to taking steps to precisely estimate a miner's cumulative exposure, the researchers accounted for several factors in their analyses—such as the age of the miners, the carbon content of the coal (coal rank), and other factors known to be associated with the disease—to better estimate the effect of cumulative exposure to coal mine dust.<sup>8</sup> Further, the other studies we identified generally supported the conclusion that reducing the PEL would reduce miners' risk of disease.

## Background

### CWP in the United States

The passage of the Federal Coal Mine Health and Safety Act of 1969 (Coal Act)<sup>9</sup> established the first comprehensive respirable dust standard for coal mines, setting the exposure limit at 2.0 mg/m<sup>3</sup>.<sup>10</sup> Following the passage of the Coal Act, the prevalence of CWP among underground coal miners examined in NIOSH's Coal Workers' X-ray

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<sup>8</sup>Coal rank is a classification of the amount of carbon in the coal. Coal is typically ranked as "high," "medium" or "low," where coal with a high rank has high carbon content. According to NIOSH, several factors are associated with a higher risk of developing CWP, including miners' exposure to coal mine dust with high carbon content.

<sup>9</sup>Pub. L. No. 91-173, 83 Stat. 742.

<sup>10</sup>The Coal Act set an interim standard of 3.0 mg/m<sup>3</sup> that went into effect in 1970, 6 months after the date of enactment and continued until 1972, when the standard of 2.0 mg/m<sup>3</sup> then took effect. In 1977, the Mine Act was passed, which amended and renamed the Coal Act and established MSHA. Pub. L. No. 95-164, 91 Stat. 1290 (1977). The Mine Act maintained the standard at 2.0 mg/m<sup>3</sup>, to be in effect until superseded by improved standards issued by MSHA. The Mine Act also authorized MSHA to issue improved standards, and prohibited it from issuing standards that would reduce the protection provided by existing standards. In 1980, via the rulemaking process, MSHA issued the current standard, keeping the PEL at 2.0 mg/m<sup>3</sup>. 45 Fed. Reg. 23,990 (Apr. 8, 1980), codified at 30 C.F.R. §§ 70.100, 71.100.

Surveillance Program generally decreased about 80 percent from 1970 to 2009.<sup>11</sup> But, according to NIOSH, despite this overall decrease, the observed prevalence of CWP has risen in recent years.<sup>12</sup> NIOSH based this finding on data collected from its Coal Workers' X-ray Surveillance Program and, as a result, it may not be representative of the total population of coal miners since participation in the program is primarily voluntary.

In 2012, coal mine companies employed a total of 86,195 miners in 26 states.<sup>13</sup> While miners across the country are at risk of developing CWP, CWP-related deaths are clustered in the Appalachian region, and, according to NIOSH, clusters of rapidly progressing CWP have been recently observed in Kentucky, Virginia, and West Virginia.<sup>14</sup>

### Types of Lung Disease Resulting from Exposure to Coal Mine Dust

Inhaling excessive amounts of coal mine dust can cause CWP and other debilitating lung diseases, including chronic obstructive pulmonary disease, which encompasses chronic bronchitis and emphysema. According to NIOSH, it usually takes about 10 to 15 years of exposure to coal mine dust to develop CWP, although cases involving fewer years of exposure have been observed. Once contracted, CWP cannot be cured, making it critical to prevent the development of this disease by limiting miners' exposure to coal mine dust. Clinical diagnosis of CWP in an individual patient is generally based on the presence of typical chest radiological findings, history of working in coal mines, and exclusion of alternative diagnoses. Although CWP in its early stages may not be associated with impaired lung function or increased mortality, it can increase a miner's risk of developing the advanced stage of the disease, known as progressive massive fibrosis, which can significantly decrease lung function and result in death. According to NIOSH, several factors are associated with a higher risk of developing CWP, including miners' level of exposure to coal mine dust, coal rank, their length of employment in mining (especially years worked underground), their age, and their occupations in the mines.<sup>15</sup>

### Role of MSHA

MSHA is responsible for protecting miners by enforcing the provisions of the Mine Act, as amended by the Mine Improvement and New Emergency Response Act of 2006.<sup>16</sup> Under these laws, MSHA has a number of responsibilities, including setting new safety and health standards and revising existing standards, approving training programs for mine workers, and developing regulations regarding training requirements for rescue teams, among other

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<sup>11</sup> NIOSH's Coal Workers' X-ray Surveillance Program is a primarily voluntary medical monitoring and surveillance program. NIOSH reports prevalence data as averages of 5-year intervals. The overall decrease since 1970 reported here is based on the oldest and most recent intervals: 1970 to 1974 and 2005 to 2009.

<sup>12</sup> According to NIOSH, the prevalence of CWP appears to have stopped declining around the 1995 to 1999 interval and has been on the rise since that time.

<sup>13</sup> According to the Department of Energy's Office of Oil, Gas, and Coal Supply Statistics, Wyoming mines the most coal, followed by West Virginia, Kentucky, and Pennsylvania.

<sup>14</sup> Appalachia includes Alabama, Ohio, Kentucky, Pennsylvania, Tennessee, Virginia, and West Virginia.

<sup>15</sup> Miners work in different occupations and locations within the mine and, as a result, are exposed to different levels of coal mine dust.

<sup>16</sup> Pub. L. No. 109-236, 120 Stat. 493, codified as amended at 30 U.S.C. §§ 801-965.

things. MSHA also conducts periodic mine inspections and, along with coal mine operators, periodically collects samples of coal mine dust to determine compliance with the PEL. According to MSHA, approximately 750,000 coal mine dust samples have been collected by inspectors and about 4.6 million dust samples have been collected by mine operators since 1970.<sup>17</sup>

MSHA inspectors and mine operators measure the concentration of coal mine dust over an entire production shift, or at a maximum, an 8-hour period, to determine compliance with the current dust standard. MSHA generally determines compliance with the PEL based on the average of coal mine dust concentration samples taken by the mine operator during five consecutive normal production shifts or five normal production shifts worked on consecutive days.<sup>18</sup> Determinations of compliance are also based on an average of multiple measurements taken by an MSHA inspector.

When MSHA sets standards for toxic materials such as coal mine dust, the Mine Act requires the agency to set standards “which most adequately assure on the basis of the best available evidence that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards...for the period of his working life.”<sup>19</sup> In developing a standard, the Mine Act also requires MSHA to consider, among other factors, the feasibility of the standard, and MSHA conducts analyses to determine whether a proposed standard is both economically and technologically feasible.<sup>20</sup> Specific to coal mine dust, the Mine Act further specifies that one of its purposes is to “provide, to the greatest extent possible, that the working conditions in each underground coal mine are sufficiently free of respirable dust concentrations...to permit each miner the opportunity to work underground during the period of his entire adult working life without incurring any disability from...[an] occupation-related disease during or at the end of such period.”<sup>21</sup>

### Role of NIOSH

NIOSH shares some responsibility with MSHA for improving mine safety and protecting miners’ health. It conducts research on the causes of work-related diseases and injuries; researches, develops, and tests new technologies and equipment designed to improve mine safety; and recommends occupational safety and health standards, such as the PEL for coal mine dust. NIOSH recommends safety and health standards to MSHA and other regulatory agencies through its guidance documents (e.g., criteria documents), which provide the scientific basis for its recommended standards and a critical review of the scientific and technical information available on the prevalence of hazards, among other information.

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<sup>17</sup>These figures include only samples for underground mines.

<sup>18</sup>See 30 C.F.R. §§ 70.201(b), 70.207, 70.208 (for underground coal mines). Similar sampling procedures apply to surface mines. 30 C.F.R. §§ 71.201(b), 71.208.

<sup>19</sup>30 U.S.C. § 811(a)(6)(A).

<sup>20</sup>See *Nat’l Mining Ass’n v. Sec’y of Labor*, 153 F.3d 1264, 1269 (11th Cir. 1998).

<sup>21</sup>30 U.S.C. § 841(b).

NIOSH also administers the Coal Workers' X-ray Surveillance Program, a medical monitoring and surveillance program to detect and prevent lung disease.<sup>22</sup> This program requires mine operators to provide up to three initial chest x-rays for coal miners within specified time frames after their employment begins, followed by voluntary periodic chest x-rays approximately every 5 years thereafter. NIOSH uses this program for disease surveillance, which includes tracking trends, setting prevention and intervention priorities, and assessing prevention and intervention efforts. Miners' chest x-rays are read and classified by at least two x-ray specialists who must meet certain qualifications.<sup>23</sup>

To estimate the prevalence of lung disease among underground coal miners and to study the relationship between miners' lung disease and their level of exposure to coal mine dust, NIOSH developed the National Study of Coal Workers' Pneumoconiosis (NSCWP). Through the NSCWP, NIOSH analyzed epidemiological data for a sample of mines and miners across all major coalfields. The data included miners' chest x-ray findings, lung function test results, and occupational and smoking histories, as well as available results of coal mine dust sampling.<sup>24</sup> According to NIOSH, epidemiological studies examining the relationship between coal mine dust and disease must contain a sufficiently large body of data over a time period that is adequate to derive reliable findings. (CWP generally takes at least 10 years from first exposure, and usually longer, to become clinically apparent).

### **Reports and Key Scientific Studies MSHA Used to Support Its Proposal Showed That Lowering the PEL Would Reduce Disease Risk**

The two primary reports MSHA used to support its proposed standard—NIOSH's Criteria Document and MSHA's Quantitative Risk Assessment—and the six key scientific studies on which those reports were based each concluded that lowering the PEL from 2.0 mg/m<sup>3</sup> to 1.0 mg/m<sup>3</sup> would reduce coal miners' risk of developing disease.<sup>25</sup> Furthermore, these studies concluded that cumulative exposure to coal mine dust over a working life at the current PEL is associated with adverse health outcomes. These outcomes include CWP, progressive massive fibrosis, emphysema, decreased lung function, and mortality. A statistical model used in both NIOSH's Criteria Document and MSHA's Quantitative Risk Assessment showed that reducing exposure to coal mine dust from 2.0 mg/m<sup>3</sup> to 1.0 mg/m<sup>3</sup> over a miner's working life would decrease the risk of developing CWP from 34 percent to 12 percent for miners working in mines with high coal rank (high carbon content), and from 17 percent to 6 percent for miners working in mines with medium- and low-rank coal (lower carbon content).<sup>26</sup> Key scientific studies also showed that reducing miners' cumulative exposure to coal mine dust over their working lives would decrease their risk of developing other respiratory diseases. For example, another model NIOSH used in its Criteria

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<sup>22</sup>This program is part of NIOSH's Coal Workers' Health Surveillance Program, carried out pursuant to requirements in the Mine Act and NIOSH regulations. 30 U.S.C. § 843; 42 C.F.R. §§ 37.1 - 37.80.

<sup>23</sup>Through NIOSH's B Reader program—a training and testing program that began in 1974—a pool of qualified readers is established, using initial and periodic examinations to verify the competence of physician-readers in assessing and classifying pneumoconiosis.

<sup>24</sup>NIOSH's NSCWP was conducted in four rounds of medical surveys. This NSCWP differs from NIOSH's Coal Workers' X-ray Surveillance Program in that the NSCWP achieved higher participation rates and collected more detailed medical information for each miner than the Coal Workers X-ray Surveillance Program.

<sup>25</sup>See Enclosure I for additional information on these reports and studies.

<sup>26</sup>These estimates are for a hypothetical population of 65-year-old miners who have been exposed to coal mine dust over a 45-year working life.

Document showed that the same reduction in exposure to coal mine dust would reduce the risk of a miner developing a dust-caused reduction in lung function by roughly half, and this would be the case for miners across different regions of the United States. However, the studies also concluded that, even if coal mine dust concentrations were successfully reduced to the proposed PEL of 1.0 mg/m<sup>3</sup>, miners would still be at some risk of developing disease.<sup>27</sup>

#### Reasonable Steps Were Taken to Mitigate the Limitations and Biases in the Data MSHA Relied on to Estimate the Health Effects of Exposure to Coal Mine Dust

Researchers who prepared the reports and key scientific studies on which they were based took reasonable steps to mitigate the limitations and biases in the data MSHA relied on to support its proposal to lower the PEL. These steps included:

- *Using a sufficiently large number of coal mine dust samples.* An accurate examination of the association between exposure to coal mine dust and disease depends, in part, on the reliability of the coal mine dust samples. Precisely measuring coal mine dust is difficult, partly because of the large degree of variation in the levels of coal mine dust in a particular area. However, the reports and the key scientific studies on which they were based relied on a sufficiently large number of coal mine dust samples, which helped mitigate the effect of random variation between individual samples and ensure more accurate measurements of coal mine dust overall.<sup>28</sup>
- *Adjusting coal mine dust samples where bias was suspected.* To improve the accuracy of coal mine dust samples, researchers developed specific procedures to adjust the samples where bias was suspected. For example, according to MSHA, coal mine dust samples collected by mine operators have historically been systematically lower than coal mine dust samples collected by MSHA inspectors at the same mines. Because of this downward bias, according to NIOSH, samples taken by operators likely underestimated miners' exposure to coal mine dust. To address this bias, researchers of some of the key scientific studies systematically adjusted coal mine dust samples upward to complete their analyses.
- *Addressing potential limitations where there were lower participation rates.* Researchers also addressed potential limitations in the data resulting from lower participation rates of miners in medical examinations. Although participation of coal miners in some rounds of the medical examinations was lower than in other rounds, researchers conducted additional analyses to check whether those who participated were systematically different from those who did not participate, which could bias the

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<sup>27</sup>According to NIOSH, the goal of its recommendation to lower the PEL is to minimize, to the greatest extent possible, the health risks associated with a miner's exposure to coal mine dust. In making this recommendation, NIOSH took into account an evaluation of health effects data as well as the feasibility of collecting and analyzing dust samples. NIOSH also considered the technological feasibility of controlling exposures. Specifically, NIOSH determined that the recommended PEL of 1.0 mg/m<sup>3</sup> would have clear beneficial health effects for all miners. At the time the Criteria Document was published, however, a PEL lower than 1.0 mg/m<sup>3</sup> was not considered to be technologically feasible. According to NIOSH, if improvements in the technological feasibility of dust controls become available in the future, the agency would consider recommending a lower PEL.

<sup>28</sup>To develop the statistical model of CWP used by NIOSH in its Criteria Document and by MSHA in its Quantitative Risk Assessment, researchers drew on 293,292 coal mine dust samples in order to estimate a personal cumulative coal mine dust exposure for each of 3,194 miners.

data. For example, chest x-rays used to identify and classify the presence of CWP were obtained from medical surveys from NIOSH's NSCWP, which was conducted in multiple rounds over roughly two decades.<sup>29</sup> The participation rates for these four rounds of surveys ranged from as low as 52 percent to as high as 90 percent.<sup>30</sup> Low participation in the medical surveys could have introduced bias into the analysis if the characteristics of the miners who did not participate—such as their age, the number of years they had worked in the mines, or other factors associated with the development of disease—differed substantially from those who did participate in the surveys. To mitigate this possible bias, researchers conducted additional analyses of the NSCWP data and found that those who participated in these surveys were similar to those who did not participate in terms of age, years working in underground mines, and presence of CWP in a prior round of the NSCWP.<sup>31</sup> These analyses lend greater confidence to the conclusion that lower participation rates did not influence the results of the studies.

- *Limiting the risk of misclassifying disease.* To further improve the reliability of the medical data used in the key scientific studies, some researchers took steps to limit the risk of misclassifying disease by using x-ray data that were read and classified by multiple x-ray specialists using a standardized process. MSHA largely relied on two key scientific studies to examine the relationship between exposure to coal mine dust and CWP. In one of these studies, researchers used x-ray data classified by one specialist, and in the other study, researchers used x-ray data independently classified by three specialists. Using x-ray data classified by multiple independent specialists limits the possible error that can be introduced when relying on classifications by one specialist. Although one of the two studies used only one x-ray specialist to classify disease, the findings of that specialist were similar to those in the study that used three x-ray specialists to classify disease.<sup>32</sup> In addition, these three x-ray specialists used the same standardized classification system for determining the presence and severity of CWP, consistent with standard practices for epidemiological research.<sup>33</sup> Furthermore, since classifications of disease have been known to vary among multiple x-ray specialists interpreting the same x-ray, researchers mitigated this concern by using selected specialists who were known,

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<sup>29</sup>Medical surveys from the NSCWP included a chest x-ray, test of lung function, and a questionnaire on current symptoms, demographics, smoking and work history. Examinations in Round 1 were conducted from 1969 to 1971, Round 2 from 1972 to 1975, Round 3 from 1977 to 1981, and Round 4 from 1985 to 1988.

<sup>30</sup>Participation rates of eligible participants were 90, 75, 52, and 70 percent for Rounds 1 through 4, respectively.

<sup>31</sup>In Round 4 of the NSCWP—which was the basis for one of the key exposure-response models relating dust exposure and risk of CWP—miners who participated in the study and those who did not were very similar with regard to age. Non-participants, however, had worked underground for a slightly longer period of time. Despite this, the non-participants had a slightly lower prevalence of CWP in an earlier round of the study. None of the key scientific studies we reviewed included data collected from Round 3—the Round with the lowest participation rate (52 percent).

<sup>32</sup>The study that used only one x-ray specialist originally included classifications from three specialists who classified disease, but the classifications of two of them were excluded because one specialist did not apply the correct system of classification and the other specialist's readings were found to show unusually high levels of disease.

<sup>33</sup>These x-ray specialists used the International Labour Organization classification system, an internationally-accepted means for assessing the severity and types of abnormality arising from inhalation of mineral dusts. A summary classification of CWP was used for each participant by taking the median category of disease when three x-ray readings were available. The three specialists classified similar overall prevalences of CWP (7 percent, 7 percent, and 9 percent, respectively).

based on historical data, to assign CWP classifications at rates close to the median of multiple readers.

The statistical models in the key scientific studies generally included samples of coal mine dust collected from 1968 to 1987, and the researchers used these data to estimate the relationship between exposure to coal mine dust and risk of disease. We find it reasonable that NIOSH and MSHA used these models to estimate risk of disease due to exposure to coal mine dust in present mining conditions. It is possible, however, that changes in the composition of coal mine dust or characteristics of the coal mine workforce since 1987 have altered the relationship between exposure to coal mine dust and risk of disease. For example, the research we reviewed showed that the quartz (silica) component of coal mine dust, which is known to increase the risk of disease, may have increased in certain states in the years since key scientific studies were conducted.<sup>34</sup> It follows that the health risks of a given level of exposure to coal mine dust may be even greater today than estimated in the models. Therefore, we concluded that an increase in silica levels would not undermine the proposal to lower the exposure limit, and that it was reasonable to rely on the coal mine dust samples used in the key scientific studies to estimate disease risk in support of the proposal.<sup>35</sup>

#### Appropriate Analytical Methods Were Used in the Key Scientific Studies MSHA Relied on to Develop its Proposed Standard

The researchers for the reports and six key scientific studies that supported MSHA's proposed standard used appropriate analytical methods to conclude that lowering miners' exposure to coal mine dust over their working lives reduces their risk of developing black lung disease. For example, they accounted for known factors associated with black lung disease and precisely estimated miners' cumulative exposure to coal mine dust. Previous research established that the development of black lung disease is affected by certain factors other than cumulative exposure to coal mine dust, such as coal rank and a miner's age. By taking these factors into account, the researchers were able to better isolate the effect of cumulative exposure to coal mine dust and provide greater confidence in their assessment of the relationship between exposure to coal mine dust and the development of disease. For example, one key scientific study that examined the association between lung function and exposure to coal mine dust accounted for each miner's age, height, cigarette smoking, ethnicity, mining status (current or ex-miner), and years worked in non-mining yet dusty occupations. In all of the key scientific studies, coal mine dust was found to be a statistically significant predictor of health risk, even when taking other known factors into

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<sup>34</sup>Some mining involves cutting and extracting rock containing silica overlying or underlying the coal seam. Inhaling silica can cause silicosis, a form of pneumoconiosis. Currently, when the respirable coal mine dust contains more than 5 percent quartz (silica), the PEL is determined based on a formula that reduces the PEL commensurate with the proportion of the dust that is silica. 30 C.F.R. §§ 70.101, 71.101. NIOSH has recommended a separate PEL for silica of 0.05 mg/m<sup>3</sup> and MSHA is planning to establish a separate standard for silica.

<sup>35</sup>Other factors that may have changed since 1987 and could affect the relationship between exposure to coal mine dust and disease risk include the prevalence of smoking among coal miners and the age composition of the mining workforce. Although smoking has its own health effects, it does not appear to alter the risk of CWP due to exposure to coal mine dust, according to researchers. We did not identify any other research on how age affects the relationship between exposure to coal mine dust and disease.

account.<sup>36</sup> Furthermore, some key scientific studies tested several different combinations of factors that may contribute to disease to further assess the effect of each factor and better determine the relationship between exposure to coal mine dust and development of disease.<sup>37</sup> While many known factors were taken into account, none of the key scientific studies accounted for exposure to silica dust because, according to NIOSH, reliable information on silica exposure was not available at the time these studies were conducted.

In addition to accounting for known factors associated with disease to better isolate the effect of exposure to coal mine dust on health outcomes, researchers took steps to increase the precision of a miner's estimated cumulative exposure to help ensure greater reliability in their predictions of health outcomes. The key scientific studies estimated each miner's cumulative exposure to coal mine dust from the beginning of his or her employment as a miner to the time of his or her medical examination. Estimating the cumulative exposure to coal mine dust over many years is important because, according to NIOSH, black lung disease generally develops slowly over time. Steps were taken to collect coal mine dust measurements in specific mines and include specific occupations for each year of the study so that precise estimates of a coal miner's exposure could be calculated based on the miner's actual occupation and tenure in that occupation.<sup>38</sup> Some key scientific studies included miners who began mining prior to the establishment of the first PEL in 1970 and MSHA's systematic sampling of coal mine dust concentrations.<sup>39</sup> For these miners, the researchers took reasonable steps to estimate miners' exposure to coal mine dust in years prior to 1970, despite having limited data for those years. Furthermore, to ensure that the conclusions did not depend on the exact method used to estimate coal mine dust exposure prior to 1970, the researchers used various alternatives to estimate a miner's exposure to coal mine dust. Using these alternative methods, the researchers found similar results, lending greater confidence in the accuracy of the estimates of disease risk.

While the analytical methods researchers used in the six key scientific studies supported the conclusion that lowering coal mine dust exposure would reduce the risk of disease for miners over their working lives, the actual estimates of disease risk for miners at the end of their working lives may lack precision. The Mine Act requires MSHA to set standards to protect miners even if they are exposed to hazards for their full working lives. Therefore, predicting the risk of disease at the end of a miner's career (for example, miners age 65 with 45 years of employment) is important when considering a new PEL. However, in most of the key scientific studies, few miners actually had 45 or more years work experience in a mine, and few were 65 or older. Because the key scientific studies predicted disease risk at the end of a miner's career, the estimated levels of risk may not be as precise as if there had been more data on miners at the end of their careers. This limitation, however, does not

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<sup>36</sup>Specifically, coefficients for coal mine dust exposure were statistically significant in all of the key models used by MSHA and NIOSH. A coefficient is considered statistically significant if the probability of observing a value as large as it is, due to chance alone, is less than a specified probability—often 5 percent. In this case, statistical significance means that the observed association between coal mine dust exposure and disease risk, after accounting for other factors such as age and coal rank, is unlikely to be due to chance alone.

<sup>37</sup>The model fit, or how well the model's predictions of disease prevalence matched observed prevalence, was generally good for the key scientific studies. For example, NIOSH evaluated how well model predictions matched actual observations and found that the model-predicted prevalence of early stages of CWP fit the observed prevalence closely within the range of cumulative dust exposure corresponding to the current and proposed PEL.

<sup>38</sup>Information on a miners' work history, including the dates of starting and stopping work in each occupation in each mine, was obtained from interviews of each participant of the NSCWP.

<sup>39</sup>Prior to 1970, coal mine dust concentrations often exceeded the current PEL of 2.0 mg/m<sup>3</sup>, according to NIOSH. There is evidence indicating that dust concentrations were as high as 6.0 mg/m<sup>3</sup> for certain occupations within mines prior to 1970.

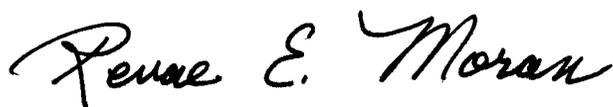
undermine the studies' overall conclusion that a reduction in exposure to coal mine dust is associated with a reduction in the risk of disease.

In addition to our evaluation of the reports MSHA used to support its proposal and the key scientific studies on which the reports were based, we identified and reviewed several other scientific studies that examined the association between exposure to coal mine dust and respiratory disease. See Enclosure I for additional information on these other studies. These other studies generally supported the conclusion that lowering miners' exposure to coal mine dust would reduce their risk of developing CWP and other dust-induced respiratory diseases. We also found no evidence of other findings or other methodological approaches that would call into question the underlying conclusions in the key scientific studies on which MSHA based its proposal.

### **Agency Comments and Our Evaluation**

We provided a draft of this report to Labor and HHS to obtain their comments. In its written comments, which are reproduced in enclosure II, Labor agreed with our findings. HHS also agreed with our findings, but did not provide formal written comments. Labor and HHS both provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees and the Secretaries of Labor and Health and Human Services. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>. Should you or your staff have questions concerning this report, please contact me at (202) 512-7215 or [moranr@gao.gov](mailto:moranr@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in enclosure III.



Revae Moran  
Director  
Education, Workforce, and Income Security Issues

Enclosures - 3

***List of Committees***

The Honorable Tom Harkin  
Chairman  
The Honorable Richard C. Shelby  
Ranking Member  
Subcommittee on Labor, Health and Human  
Services, Education, and Related Agencies  
Committee on Appropriations  
United States Senate

The Honorable Denny Rehberg  
Chairman  
The Honorable Rosa L. DeLauro  
Ranking Member  
Subcommittee on Labor, Health and Human  
Services, Education, and Related Agencies  
Committee on Appropriations  
House of Representatives

## Enclosure I: Scope and Methodology

In the Consolidated Appropriations Act, 2012, Congress required that GAO review and report on the data collection, sampling methods, and analyses the Department of Labor's (Labor) Mine Safety and Health Administration (MSHA) used to support its recent proposal to lower the permissible exposure limit (PEL) for respirable coal mine dust<sup>40</sup> from 2.0 milligrams of dust per cubic meter of air (mg/m<sup>3</sup>) to 1.0 mg/m<sup>3</sup>.<sup>41</sup> Although MSHA's proposal includes other provisions,<sup>42</sup> our review focused on MSHA's proposal to lower the PEL. To respond to this requirement, we answered the following question: What are the strengths and limitations of the data and analytical methods MSHA used to support its proposal to lower the permissible exposure limit for coal mine dust?

To conduct our work, we reviewed relevant federal laws and regulations, MSHA's proposed standard for exposure to coal mine dust, the comments MSHA received in response to the proposed rule, and the reports and the key scientific studies MSHA used to support its proposed standard. We also reviewed additional scientific studies as well as related reports by GAO, Labor's Office of Inspector General, and others on the health effects of exposure to coal mine dust. We interviewed officials with MSHA and the Department of Health and Human Services' National Institute for Occupational Safety and Health (NIOSH), representatives from the mining industry and mine workers. We also conducted site visits to MSHA and NIOSH offices in Pittsburgh, Pennsylvania and Morgantown, West Virginia, which informed our understanding of the data and analytical methods used to support MSHA's proposal to lower the PEL for coal mine dust.

We conducted this performance audit from February 2012 through August 2012 in accordance with generally accepted government auditing standards. These standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

### Analysis of Reports Used by MSHA and the Key Scientific Studies on Which They Were Based

To determine the strengths and limitations of the data and analytical methods MSHA used to support its proposal to lower the PEL for coal mine dust, we identified and reviewed the reports and key scientific studies cited in them that MSHA relied on to support its proposed standard. MSHA primarily relied on two reports and the studies cited in them to develop its proposed standard: NIOSH's 1995 *Criteria for a Recommended Standard – Occupational Exposure to Respirable Coal Mine Dust* (Criteria Document) and MSHA's 2010 *Quantitative Risk Assessment in Support of the Proposed Respirable Coal Mine Dust Rule* (Quantitative

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<sup>40</sup>In this report, we use the term coal mine dust to refer to respirable coal mine dust.

<sup>41</sup>Pub. L. No. 112-74, div. F, tit. I, § 112, 125 Stat. 786, 1064 (2011). MSHA's proposed rule was published in October 2010. Lowering Miners' Exposure to Respirable Coal Mine Dust, Including Continuous Personal Dust Monitors, 75 Fed. Reg. 64,412 (Oct. 19, 2010) (to be codified at 30 C.F.R. pts. 70, 71, 72, 75, and 90). As of August 13, 2012, MSHA had not finalized this regulation.

<sup>42</sup>For example, the proposed rule also contained provisions that would change dust sampling procedures—including requirements for the use of continuous personal dust monitors—and expand medical surveillance.

Risk Assessment). Table 1 lists the reports and the key scientific studies. We selected these reports because they were used by MSHA to develop or support the proposed rule.<sup>43</sup> In addition, we reviewed MSHA's policies and procedures for its coal mine dust sampling program and NIOSH's processes for administering the Coal Workers' X-ray Surveillance Program.<sup>44</sup> The focus of our work was limited to determining whether the scientific studies MSHA used generally supported its conclusion that lowering the PEL from 2.0 mg/m<sup>3</sup> to 1.0 mg/m<sup>3</sup> would lower the risk of disease over a miner's working life.<sup>45</sup> We assessed the adequacy of the data and measures employed, the reasonableness and rigor of the statistical techniques used to analyze them, and the validity of the conclusions drawn from the analyses. Our work was not designed to determine the optimal limit for coal mine dust exposure; assess the cost-benefit analysis MSHA conducted in support of its proposed standard; or determine whether MSHA's proposed rule complied with any legal requirements imposed by the Federal Mine Safety and Health Act of 1977 (Mine Act), the Administrative Procedure Act, or other applicable federal laws or executive orders that govern the rulemaking process.<sup>46</sup>

Through interviews with NIOSH officials, we identified four key scientific studies in its Criteria Document that served as the primary basis for its recommendation to lower the PEL from 2.0 mg/m<sup>3</sup> to 1.0 mg/m<sup>3</sup>. During our review of the Criteria Document, we identified and reviewed an additional five studies that contained important details necessary for evaluating NIOSH's report.<sup>47</sup> In addition, through an interview with the principal author of the Quantitative Risk Assessment and MSHA officials, we identified three key scientific studies used in that report to quantify the relationship between coal mine dust exposure and disease risk. Two GAO specialists with expertise in social science methods, statistics, or

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<sup>43</sup>These reports are referenced in the proposed rule, 75 Fed. Reg. 64,412, 64,414, 64,469 (Oct. 19, 2010). We also confirmed with MSHA officials that the agency used these reports to develop and support its proposal to lower the PEL.

<sup>44</sup>The Coal Workers' X-ray Surveillance Program is a component of NIOSH's Coal Workers' Health Surveillance Program, a medical monitoring and surveillance program carried out pursuant to requirements in the Mine Act and NIOSH regulations. 30 U.S.C. § 843, 42 C.F.R. §§ 37.1-37.80.

<sup>45</sup>For purposes of this proposed rule, MSHA defines a miner's working life to be 45 years.

<sup>46</sup>Various federal statutes and executive orders require federal agencies to follow a number of procedural and analytic requirements when developing and issuing rules. For example, the Administrative Procedure Act generally requires agencies to publish proposed rules for public comment prior to issuing a final rule. 5 U.S.C. § 553. In addition, section 101(a) of the Mine Act establishes certain procedural and analytic rulemaking requirements for MSHA standards. For example, before issuing a standard on toxic materials, MSHA must determine, based on research and other considerations, that the toxins pose a material impairment to miners' health or functional capacity. 30 U.S.C. § 811(a)(6)(A).

<sup>47</sup>The five additional studies reviewed contained more detailed information on the derivation of dust exposure estimates, the cohort of miners examined, the sampling design, and the overall analysis methods. The five studies include (1) Attfield, M. D., & Moring, K. "The derivation of estimated dust exposures for U.S. coal miners working before 1970," *American Industrial Hygiene Association*, vol. 53, no. 4 (1992); (2) Seixas, N. S., Moulton, L. H., Robins, T. G., Rice, C. H., Attfield, M. D., & Zellers, E. T. "Estimation of cumulative exposures for the National Study of Coal Workers' Pneumoconiosis," *Applied Occupational and Environmental Hygiene*, vol. 6, no. 12 (1991); (3) Seixas, N. S., Robins, T.G., Attfield, M. D., & Moulton, L. H. "Exposure-response relationships for coal mine dust and obstructive lung disease following enactment of the Federal Coal Mine Health and Safety Act of 1969," *American Journal of Industrial Medicine*, vol. 21, no. 5 (1992); (4) Morgan, W. K. C., Burgess, D. B., Jacobson, G., O'Brien, R. J., & Pendergrass, E. P., Reger, R. B., & Shoub, E. P. "The prevalence of coal workers' pneumoconiosis in US coal miners," *Archives of Environmental Health*, vol. 27, no. 4 (1973); and (5) Kuempel, E. D., Smith, R. J., Attfield, M. D., & Stayner, L. T. "Risks of occupational respiratory diseases among U.S. coal miners," *Applied Occupational and Environmental Hygiene*, vol. 12, no. 12 (1997).

epidemiology and public health examined each study to assess the adequacy of the samples and measures employed, the reasonableness and rigor of the statistical techniques used to analyze them, and the validity of the conclusions drawn from the analyses. For selected studies, we contacted the researchers directly as necessary for clarification or additional information.

**Table 1: Reports and Key Scientific Studies MSHA Used to Support Its Proposed Standard**

Report	Key Studies Cited in the Report	Description of Study
NIOSH's 1995 Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust	Attfield, M.D. and K. Moring, "An Investigation into the Relationship Between Coal Workers' Pneumoconiosis and Dust Exposure in U.S. Coal Miners" (1992)	Provides an estimate of the relationship between the cumulative coal mine dust miners are exposed to over their working lives and disease prevalence in U.S. coal miners.
	Attfield, M.D. and N.S. Seixas, "Prevalence of Pneumoconiosis and its Relationship to Dust Exposure in a Cohort of U.S. Bituminous Coal Miners and Ex-Miners" (1995)	Provides an estimate of the relationship between the cumulative coal mine dust miners are exposed to over their working lives and disease prevalence among current and former miners.
	Attfield M.D. and T.K. Hodous, "Pulmonary Function of U.S. Coal Miners Related to Dust Exposure Estimates" (1992)	Provides an estimate of the effects of coal mine dust exposure on lung function in U.S. coal miners.
	Seixas N.S., T.G. Robins, M.D. Attfield, L.H. Moulton, "Longitudinal and Cross Sectional Analyses of Exposure to Coal Mine Dust and Pulmonary Function in New Miners" (1993)	Provides an estimate of the effects of coal mine dust exposure on lung function in U.S. coal miners.
MSHA's 2010 Quantitative Risk Assessment	Attfield, M.D. and N.S. Seixas, "Prevalence of Pneumoconiosis and its Relationship to Dust Exposure in a Cohort of U.S. Bituminous Coal Miners and Ex-Miners" (1995) <sup>a</sup>	Provides an estimate of the relationship between the cumulative coal mine dust miners are exposed to over their working lives and disease prevalence among current and former miners.
	Kuempel et al., "Emphysema and Pulmonary Impairment in Coal Miners: Quantitative Relationship with Dust Exposure and Cigarette Smoking" (2009)	Provides predictions of the relationship between the cumulative coal mine dust miners are exposed to and their risk of developing emphysema.
	Attfield, M.D. and E.D. Kuempel, "Mortality Among U.S. Underground Coal Miners: A 23-Year Follow-Up" (2008)	Examines the contributing and underlying causes of death in U.S. coal miners.

Source: GAO review of reports.

<sup>a</sup>Attfield, M.D., and N.S. Seixas (1995) is a key study that was used in both the NIOSH Criteria Document and the MSHA Quantitative Risk Assessment.

NIOSH's Criteria Document included a review of all available information through 1995 and estimated the adverse health effects associated with exposure to coal mine dust over a miner's working life to provide the scientific basis for NIOSH's recommendation for a reduced PEL. In this report, NIOSH concluded that epidemiological studies demonstrated that miners have an elevated risk of developing black lung disease, which includes coal workers pneumoconiosis (CWP) and other respiratory or pulmonary impairments, when they are exposed over their working lives to coal mine dust at the current PEL of 2.0 mg/m<sup>3</sup>. This conclusion represents a change in the understanding of disease risk since the time the 2.0 mg/m<sup>3</sup> PEL was initially established.<sup>48</sup> Further, based on its evaluation of health effects data, the feasibility of collecting and analyzing coal mine dust samples, and technological

<sup>48</sup>According to NIOSH, the current PEL of 2.0 mg/m<sup>3</sup> for coal mine dust exposure was based primarily on estimates of earlier studies of coal miners in the United Kingdom, where the probability of disease progression was thought to be zero for miners' exposure to coal mine dust at an average concentration of 2.0 mg/m<sup>3</sup> over a 35-year working life.

feasibility of controlling exposures, NIOSH recommended that the PEL be reduced to 1.0 mg/m<sup>3</sup> as a time-weighted average concentration for up to 10 hours per day during a 40-hour work week. NIOSH concluded, however, that even at an exposure level of 1.0 mg/m<sup>3</sup>—the lowest PEL NIOSH considered feasible—miners exposed at this concentration over a working life still have a risk of developing black lung disease.

In response to NIOSH's Criteria Document in support of its recommendation to lower the PEL, MSHA completed a Quantitative Risk Assessment in September 2010 to determine whether current conditions involving exposure to coal mine dust place miners at risk for developing black lung and whether the proposed rule will substantially reduce those risks. The report addressed three questions related to MSHA's proposed rule: whether (1) the potential health effects associated with current exposure levels constitute material impairments to a miner's health or functional capacity; (2) current conditions place miners at a significant risk of incurring any of these material impairments; and (3) the proposed rule will substantially reduce those risks.<sup>49</sup> MSHA's report concluded that the current exposure level of 2.0 mg/m<sup>3</sup> placed miners at a significant risk of incurring each of the material impairments considered and that the proposed rule would substantially reduce the risks of CWP, severe emphysema, and mortality attributable to coal mine dust exposure.<sup>50</sup>

We also reviewed NIOSH's April 2011 report, *Coal Mine Dust Exposures and Associated Health Outcomes: A Review of Information Published Since 1995*.<sup>51</sup> This report provides a summary of information on exposure to coal mine dust and its associated health effects since 1995. NIOSH's intent was to determine whether its recommendations in 1995 to lower the PEL to 1.0 mg/m<sup>3</sup> remained valid in light of new findings. We reviewed the sections of the report most relevant to respiratory disease outcomes. We also reviewed two studies that were referred to in this report that were especially relevant to our research objective, as they contained additional information about the relationship between exposure to coal mine dust and risk of disease in British coal miners.<sup>52</sup>

### Additional Scientific Studies Reviewed

We also conducted a search for studies that explored the relationship between exposure to coal mine dust and respiratory disease. This search drew on several sources:

- an extensive literature search for such studies;

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<sup>49</sup>The Mine Act establishes the criteria for MSHA's Quantitative Risk Assessment, 30 U.S.C. § 811(a)(6)(A). According to MSHA, these three questions are based on court interpretations of similar statutory language in the Occupational Safety and Health Act of 1970.

<sup>50</sup>We did not assess whether MSHA met applicable statutory requirements in issuing this proposed rule. Specifically, we did not evaluate whether the risk posed by coal mine dust at current conditions constitutes a "material impairment" to a miner's health, whether the current conditions create a "significant risk" of impairment, or whether the proposed rule will "substantially reduce" those risks, as those terms are used in the statute and related court decisions. 30 U.S.C. § 811(a)(6)(A); see, for example, *Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 639 (1980).

<sup>51</sup>This report had not been issued at the time MSHA published its proposed rule in October 2010. Our review of studies in this report was limited to those published before October 2010.

<sup>52</sup>These studies included Hurley J.F., and W.M. Maclaren, "Dust-related risks of radiological changes in coalminers over a 40-year working life: Report on work commissioned by NIOSH," *Institute of Occupational Medicine*. (1987) and Soutar C.A., J.F. Hurley, B.G. Miller, H.A. Cowie, D. Buchanan, "Dust concentrations and respiratory risks in coalminers: key risk estimates from the British pneumoconiosis field research." *Occupational and Environmental Medicine*. 61 (2004).

- a review of materials submitted to MSHA in response to its proposed rule during the public comment period; and,
- interviews with MSHA and NIOSH officials, mining company representatives, and representatives of mine workers.

The initial search netted hundreds of research studies. We applied the following criteria in order to limit our review to include only studies with the potential to shed new light on the scientific support for the proposal to lower the PEL:

(1) studies not cited in the two reports MSHA used to develop its proposed rule, or any of the key scientific studies on which they were based;<sup>53</sup>

(2) studies published in the last 50 years and before October 19, 2010, the publication date of MSHA's proposed rule; and,

(3) studies containing original analysis (as opposed to those that used or relied on research already conducted).

This effort yielded 10 research studies that met our criteria (see table 2).

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<sup>53</sup>In addition to MSHA's proposed rule published in 2010, we reviewed two prior proposed rules related to coal mine dust published on July 7, 2000, and March 6, 2003, to further identify any additional epidemiological studies examining the relationship between exposure to coal mine dust and respiratory disease. 65 Fed. Reg. 42,122 (July 7, 2000), 68 Fed. Reg. 10,784 (March 6, 2003).

**Table 2. Additional Studies That Met Our Criteria**

(1) Leigh, J., Todorovic, M., & Driscoll, T., "Histological Changes in Hilar Lymph Glands in Relation to Coal Workers' Progressive Massive Fibrosis and Lung Coal and Quartz Contents," <i>The Annals of Occupational Hygiene</i> , Vol.41, (1997)
(2) Wang, X.R. and D. Christiani, "Respiratory Symptoms and Functional Status in Workers Exposed to Silica, Asbestos, and Coal Mine Dusts," <i>Journal of Occupational and Environmental Medicine</i> , Vol.42, No.11, (2000)
(3) Noble, R.B., Bailer, A.J., & Park, R., "Model-Averaged Benchmark Concentration Estimates for Continuous Response Data Arising from Epidemiological Studies," <i>Risk Analysis</i> , Vol.29, No.4, (2009)
(4) Liu, H., Tang, Z., Yang, Y., Weng, D., Sun, G., Duan, Z., & Chen, J., "Identification and Classification of High Risk Groups for Coal Workers' Pneumoconiosis Using an Artificial Neural Network Based on Occupational Histories: A retrospective Cohort Study," <i>BMC Public Health</i> , Vol.9, No.366, (2009)
(5) Liu, H., Tang, Z., Weng, D., Yang, Y., Tian, L., Duan, Z., & Chen, J., "Prevalence Characteristics and Prediction of Coal Workers' Pneumoconiosis in the Tiefa Colliery in China," <i>Industrial Health</i> , Vol.47, (2009)
(6) Ashford, J.R., Fay, J.W.J., & Smith, C.S., "The Correlation of Dust Exposure with Progression of Radiological Pneumoconiosis in British Coal Miners," <i>American Industrial Hygiene Association Journal</i> , Vol.26, No.4, (1965)
(7) Mamuya, S. HD., Bratveit, M., Mashalla, Y., & Moen, B., "High Prevalence of respiratory Symptoms Among Workers in the Development Section of a Manually Operated Coal Mine in a Developing Country: A Cross Sectional Study," <i>BMC Public Health</i> , Vol.7, No.17, (2007)
(8) Atlin, R., Savranlar, A., Kart, L., Mahmutyazicioglu, K., Ozdemir, H., Akdag, B., & Gundogdu, S., "Presence and HRCT Quantification of Bronchiectasis in Coal Workers," <i>European Journal of Radiology</i> , Vol.52, (2004)
(9) Morefeld, P., Ambrosy, J., Bengtsson, U., Bicker, H., Kalkowsky, B., Kusters, A., Lenaerts, H., Ruther, M., Vautrin, H.J., & Piekarski, C., "The Risk of Developing Coal Workers' Pneumoconiosis in German Coal Mining Under Modern Mining Conditions," <i>The Annals of Occupational Hygiene</i> , Vol.46, (2002)
(10) Attfield, M.D., Kuempel, E., & Wagner, G., "Exposure Response for Coal Workers' Pneumoconiosis in Underground Coal Miners: A Discussion of Issues and Findings," <i>The Annals of Occupational Hygiene</i> , Vol.41, (1997)

Source: GAO review of additional studies.

Each of these studies was then reviewed by a GAO specialist with expertise in social science methods, statistics, or epidemiology and public health. Each specialist made an initial determination of whether the study's results were inconsistent with, or revealed limitations in the work used to support the proposal to lower the PEL. If a study met this criterion, then an additional GAO specialist conducted a further review to assess the adequacy of the samples and measures employed, the reasonableness and rigor of the statistical techniques used to analyze them, and the validity of the conclusions drawn from the analyses.

We based our findings primarily on the results of the models used in the key scientific studies, which are based on data for U.S. miners only. While our methodology included a review of other studies, we found only one different type of model employed by others that attempted to estimate disease risk based on dust exposure.<sup>54</sup> This model used data on British coal miners only. We did not evaluate whether the predicted estimates of disease risk in the key scientific studies of U.S. coal miners would be similar if they were generated from the models presented in other studies. The key scientific studies were used to determine the predicted risk of disease due to exposure to coal mine dust, according to NIOSH, because they are more relevant to mining conditions in the United States. The results from other studies generally showed lower risk of CWP and progressive massive fibrosis compared

<sup>54</sup>This model was included in Hurley J.F., and W.M. Maclaren, "Dust-related risks of radiological changes in coalminers over a 40-year working life: Report on work commissioned by NIOSH," *Institute of Occupational Medicine*. (1987).

with the predicted risk of disease in the key scientific studies. These differences in predicted risk, however, may be due to a number of factors, including differences in the models and the underlying assumptions used. While these differences may exist, they do not indicate that the relationship between coal mine dust exposure and disease risk is different in different countries. For example, all of the studies we reviewed indicate that a reduction in exposure to coal dust is associated with a reduction in risk of developing disease.

### Interviews with MSHA, NIOSH, and Other Groups

To further inform our review of the evidence used to develop the proposed rule, we interviewed MSHA and NIOSH officials as well as representatives from the mining industry and mine workers. At MSHA, we spoke with officials in the Office of Standards, Regulations, and Variances, the Safety and Health Technology Center, and its District 2 field office in Prosperity, Pennsylvania. At NIOSH, we spoke with officials in its Office of Mine Safety and Health Research in Pittsburgh, Pennsylvania; its Division of Respiratory Disease Studies in Morgantown, West Virginia; its Education and Information Division in Cincinnati, Ohio; and its Office of the Director in Washington, D.C. We also spoke with several representatives from the mining industry and mine workers, including officials from the National Mining Association, the Bituminous Coal Operators' Association, the United Mine Workers of America, Murray Energy, Alliance Coal Company, and Consol Energy.

### Site Visits

To obtain information on the research on improved dust control technologies and sampling methods used to measure the level of coal mine dust to which miners are exposed, we visited NIOSH's Office of Mine Safety and Health Research in Pittsburgh, Pennsylvania. To obtain information about epidemiological studies used to support NIOSH's recommendation to lower the existing PEL for coal mine dust, we also visited NIOSH's Division of Respiratory Disease Studies, in Morgantown, West Virginia. Officials from NIOSH's Education and Information Division, in Cincinnati, Ohio, and NIOSH's Office of the Director, in Washington, D.C. also participated in these discussions. In addition, we visited MSHA's Safety and Health Technology Center at the Bruceton Laboratory in Pittsburgh, Pennsylvania to obtain information on how samples containing coal mine dust, including silica, are processed and analyzed. To observe the conditions under which underground coal miners work, we also visited the Bailey Coal Mine in Wind Ridge, Pennsylvania.

## Enclosure II: Comments from the Department of Labor

U.S. Department of Labor

Mine Safety and Health Administration  
1100 Wilson Boulevard  
Arlington, Virginia 22209-3939



AUG -9 2012

Revae Moran, Director  
Education, Workforce, and  
Income Security  
U.S. Government Accountability Office  
441 G Street, NW  
Washington, D.C. 20548

Dear Ms. Moran,

The Mine Safety and Health Administration (MSHA) appreciates the opportunity to review the GAO Report entitled, Mine Safety: Reports and Key Studies Support The Scientific Conclusions Underlying the Proposed Exposure Limit for Coal Mine Dust. MSHA concurs with the draft report.

If you need further information, please do not hesitate to contact me at: [main.joseph@dol.gov](mailto:main.joseph@dol.gov) or (202) 693-9414.

Sincerely yours,

A handwritten signature in blue ink that reads "Joseph A. Main". The signature is written in a cursive style.

Joseph A. Main  
Assistant Secretary of Labor for  
Mine Safety and Health

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## **Enclosure III: GAO Contact and Staff Acknowledgments**

### **GAO Contact**

Revae Moran, (202) 512-7215 or [moranr@gao.gov](mailto:moranr@gao.gov)

### **Staff Acknowledgments**

In addition to the individual named above, Mary Crenshaw, Assistant Director, and Claudine Pauselli, Analyst in Charge, managed all aspects of this assignment and Russell Burnett, Sarah Cornetto, Kathleen van Gelder, Brian Schwartz, Sushil Sharma, Shana Wallace, and Monique Williams made significant contributions to this report.

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Chuck Young, Managing Director, [youngc1@gao.gov](mailto:youngc1@gao.gov), (202) 512-4800  
U.S. Government Accountability Office, 441 G Street NW, Room 7149  
Washington, DC 20548

