Quantitative Risk Assessment in Support of Proposed Respirable Coal Mine Dust Rule

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Statistical Methods and Analysis

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Summary

This quantitative risk assessment (QRA) addresses three questions related to MSHA's proposed respirable coal mine dust rule: (1) whether potential health effects associated with current exposure conditions constitute material impairments to a miner's health or functional capacity; (2) whether current exposure conditions place miners at a significant risk of incurring any of these material impairments; and (3) whether the proposed rule will substantially reduce those risks.

After summarizing respirable coal mine dust (RCMD) measurements for miners in various occupational categories, Part 1 of the QRA shows that **exposures at current levels are associated with coal workers pneumoconiosis (CWP), chronic obstructive pulmonary disease (COPD) including severe emphysema, and death due to non-malignant respiratory disease (NMRD). All of these outcomes constitute material impairments to a miner's health or functional capacity.** Furthermore, a body of scientific research has been published relating specific exposure levels to the increased risk of incurring these material impairments attributable to an occupational lifetime of exposure. Estimates of current average exposure levels are respectively shown in Figures 8 and 9 for underground and surface coal mining occupations. Graphs expressing the relationship between occupational exposure level and attributable risk are displayed in Figures 10 and 11 for CWP, Figure 12 for death due to CWP, Figure 14 for severe emphysema, and Figure 15 for death due to COPD.

Part 2 of the QRA analyzes and quantifies the excess risk of miners' incurring CWP or COPD, or dying due to NMRD, after 45 years of full-shift occupational exposure at levels currently observed in various exposure categories. Miners having different occupations and working at different locations face significantly different levels of RCMD exposure, as shown in Table 12. Average dust concentrations range from 0.02 mg/m^3 to 2.94 mg/m^3 across these exposure categories. Because of curvature in the exposure response relationships, average risks currently confronting miners exceed risks calculated at the average exposure level. Therefore, risks of material impairment attributable to current exposure levels are calculated separately for the various exposure categories. These risks are shown in Tables 13–15 for CWP, Table 16 for severe emphysema, and Tables 17–18 for NMRD mortality. **In every exposure category, including clusters of occupational environments showing the lowest average dust concentrations, current exposure conditions place miners at a significant risk of incurring each of the material impairments considered.** For example, the attributable risk of severe emphysema by age 73 ranges from six excess cases per thousand racially "white" crane or dragline operators at those surface work locations currently presenting the lowest risk to 193 excess cases per thousand "non-white" mechanics and their helpers at those surface work locations currently presenting the highest risk (see Table 16).

Part 3 of the QRA projects the risk of material impairments after the proposed final exposure limit is applied to each shift. Table 20 shows the average RCMD concentrations projected for the various exposure categories under successful implementation of the proposed rule. Table 20 may be directly compared with Table 12 to see the projected impact of the proposed rule on the average RCMD concentration for each category. Residual health risks associated with an occupational lifetime of exposure to the projected dust concentrations of Table 12 are shown in Tables 21–23 for CWP, Table 24 for severe emphysema, and Tables 25–26 for NMRD mortality. **Although significant risks would remain in every exposure category, the proposed rule would substantially reduce the risks of CWP, severe emphysema, and NMRD mortality attributable to RCMD exposures.** Table 28 contains the projected reduction in these risks for each occupational category. For progressive massive fibrosis (PMF, the most severe stage of CWP considered), projected improvements for underground workers at age 73 range from a reduction of four excess cases per thousand loading machine operators to a reduction of 75 excess cases per thousand cutting machine operators. For severe emphysema at age 73, the range of projected improvements for underground workers runs from a reduction of three cases per thousand white loading machine operators to a reduction of 50 cases per thousand non-white cutting machine operators. Again for underground workers, the range of projected improvements in the risk of death due to NMRD by age 85 is projected to run from one excess case per thousand loading machine operators to 15 excess cases per thousand cutting machine operators. For surface workers, reductions are projected of up to three excess cases of PMF per thousand cleaning plant operators and utility men, eight excess cases of severe emphysema per thousand non-white cleaning plant operators and utility men, and three excess cases of NMRD mortality by age 85 per thousand laborers.

In its calculations, the QRA assumes that miners are occupationally exposed to RCMD for a total of 86,400 hours over a 45-year occupational lifetime (e.g., either 48 weeks per year at 40 hours per week, 32 weeks per year at 60 hours per week, or any other work pattern that amounts to an average of 1920 exposure hours per year). Current health risks are greater than those shown in the QRA for miners working more than 1920 hours per year. Since the proposed rule would adjust dust concentration limits downward to compensate for exposure hours in excess of eight hours per shift, improvements for such miners would be greater than those shown in Table 28.

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Introduction

In Section IV of the NPRM, MSHA has reviewed the available scientific literature on adverse health effects associated with exposure to respirable coal mine dust (RCMD). Under current regulations and enforcement policies, such exposure is limited to 2.0 mg/m^3 as measured by either (a) the average dust concentration to which the Designated Occupation (DO) is exposed over the course of five shifts (operator samples); (b) the average dust concentration to which five occupations (including but not limited to the DO) are exposed on a single shift (MSHA inspector samples); or (c) the 5-shift average dust concentration at other key areas and work positions. In addition, dust concentrations are currently further limited to 1.0 mg/m^3 for Part-90 miners[1] and for the fresh air being delivered to an active area of an underground coal mine (i.e., intake air).[2] In this quantitative risk assessment (QRA), MSHA compares the risks of developing coal workers' pneumoconiosis (CWP) and chronic obstructive pulmonary disease (COPD) under current exposure conditions to the risks expected after limiting RCMD concentrations, wherever miners normally work or travel, to the equivalent of 1.0 mg/m^3 on each 8-hour shift (0.5 mg/m^3 for intake air and Part-90 miners). Thus, the QRA compares current health risks to health risks expected under successful implementation of two aspects of the proposed rule: (1) the final exposure limit (FEL) and (2) enforcement of the FEL on every shift.

The criteria for this QRA are established by §101(a)(6)(A) of the Mine Act, which states that:

> The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall 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 dealt with by such standard for the period of his working life. [30 U.S.C. 811(a)(6)(A)]

Based on Supreme Court interpretations of similar language under the Occupational Safety and Health Act, there are three questions that must be addressed: (1) whether potential health effects associated with current exposure conditions constitute material impairments to a miner's health or functional capacity; (2) whether current exposure conditions place miners at a significant risk of incurring any of these material impairments; and (3) whether the proposed rule will substantially reduce those risks.

Accordingly, the QRA is divided into three major parts respectively addressing these three questions. Part 1 describes current RCMD conditions and shows that exposures at these levels have been associated with health effects constituting material impairments to a miner's health or functional capacity. These material impairments include not only CWP and COPD, as respectively manifested by progressive massive fibrosis (PMF) and severe pulmonary impairment, but also death from non-malignant respiratory disease (NMRD) attributable to the occupational ex-

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[1] A miner covered under § 203(b) of the Mine Act.

[2] Both of the current respirable coal mine dust exposure limits (1.0 mg/m^3 for intake air (30CFR §70.100(b)) and Part-90 miners (30CFR §90.100); 2.0 mg/m^3 everywhere else (30CFR §70.100(a) and §71.100)) are reduced when the dust contains more than five percent quartz. The impact of these reduced limits will be reflected by current exposure conditions as described below.

posure. Part 2 evaluates the excess risk of miners' incurring CWP or COPD, or dying due to NMRD, after 45 years of full-shift occupational exposure at current levels.[3] The conclusion drawn from Part 2 is that current occupational exposures place miners at an unacceptably high risk of material impairment. Part 3 of the QRA evaluates miners' projected risk of material impairments after the proposed FEL is applied to each shift. This evaluation shows that compliance with the proposed rule would not entirely eliminate the health risks attributable to occupational exposures. However, compliance would result in substantial risk reductions, as compared to risks presented at current levels.

The criteria for this QRA are further guided by Sections 201(b), 101(a), and 101(a)(9) of the Mine Act. Section 201(b), which relates to MSHA's current RCMD standard, states that:

> Among other things, it is the purpose of this title to provide, to the greatest extent possible, that the working conditions in each underground coal mine are sufficiently free of respirable dust concentrations in the mine atmosphere to permit ***each miner*** the opportunity to work underground during the period of his ***entire adult working life*** without incurring any disability from pneumoconiosis or any other occupation-related disease during or at the end of such period. [emphasis added] [30 U.S.C. 841(b)]

Section 101(a) authorizes the Secretary of Labor to "…develop, promulgate, and revise as may be appropriate***, improved*** mandatory health or safety standards [emphasis added]…" [30 U.S.C. 811(a)]. Section 101(a)(9) states that "No mandatory health or safety standard promulgated under this title shall reduce the protection afforded miners by an existing mandatory health or safety standard." [30 U.S.C. 811(a)(9)] Together, these sections of the Mine Act call for conservative (i.e., assuredly protective) measures of risk, including the assumption of a full 45-year occupational lifetime for all exposed miners.

It is also important to note that the statutory criteria for evaluating health effects evidence do not require absolute certainty. Under § 101(a)(6)(A) of the Mine Act, MSHA is required to proceed according to the "best available evidence" (30 U.S.C. 811(a)(6)(A)). Furthermore, the need to evaluate risk does not mean that an agency is placed into a "mathematical straightjacket." In *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, otherwise known as the "Benzene" decision, the Court ruled that

> …so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data... risking error on the side of overprotection rather than underprotection. [448 U.S. 607, 100 S.Ct 2844 (1980) at 656]

For its analysis of current RCMD exposure levels, and its projections of exposure under implementation of the proposed rule, the QRA utilizes both MSHA inspector and mine operator sampling data collected during the 5-year period 2004–2008. These data are being placed in the record for public comment in connection with the proposed rule.[4]

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[3] MSHA and OSHA have both stipulated 45-year occupational lifetimes in their past quantitative risk assessments of occupational hazards. For example, MSHA used a 45-year lifetime in its risk assessment for diesel particulate (66 FR 5526 and 66 FR 5706). Similarly, OSHA used a working life of 45 years in its QRAs to support health standards for Benzene (52 FR 34460), Bloodborne Pathogens (56 FR 64004), Methylene Chloride (62 FR 1494), and 1,3-Butadiene, (61 FR 56746)).

[4]The MSHA inspector and operator data are available as ASCII text files: InspSamp.txt and OpSamp.txt, respectively. Coding information for key fields in these data files is provided in Appendix A.

Peer reviews of this QRA were provided by the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA).[5] The NIOSH review characterized the QRA as "very thorough and detailed," relying on "sophisticated methods" and "exposure-response…information [that] is interpreted correctly as well as employed properly." Further, the NIOSH review concluded that "the QRA indicates that the proposed …[rule] would have the effect of substantially reducing the number of occupational respiratory disease cases." Similarly, the OSHA review characterized the QRA as generally "well supported" and "scientifically reasonable." The OSHA review concluded that "MSHA has satisfied its statutory obligation to show that current exposures lead to significant risk of material impairment and that the proposed rule will substantially reduce the risk." Specific suggestions and comments from both peer reviews are incorporated and/or addressed where applicable throughout the text. An index of responses to these reviews is provided on p. 156.

1. Material Impairments Associated with Current Coal Mine Dust Conditions

In this part of the QRA, MSHA first describes RCMD exposure distributions for miners in various occupational categories. MSHA then shows that exposures at current levels can lead to material impairments of a miner's health or functional capacity. The material impairments involved include coal workers pneumoconiosis (CWP), chronic obstructive pulmonary disease (COPD), and death due to non-malignant respiratory disease (NMRD). CWP has long been recognized as a progressive disease, and miners progressing to the PMF stage qualify as totally disabled due to pneumoconiosis under the Department of Labor's criteria set forth at (20 CFR 718.304(a)). COPD, including emphysema, is characterized by a significant loss of respiratory function and therefore qualifies as a material impairment under the Mine Act. Clearly, death due to NMRD constitutes a material impairment.[6]

(a) Available Exposure Data

Both the data available from the Mine Operators' Sampling Program (OpSamp.txt) and the MSHA inspector data (InspSamp.txt) were collected for enforcement purposes rather than for exposure assessment. A sampling strategy designed for enforcement does not generally provide data that are optimally representative of exposure conditions. As will be further explained below, neither available dataset is ideally suited to estimating typical exposure levels, and each may slant exposure estimates. For example, sampling requirements for the operators' program target those occupations and areas in a mine that MSHA considers most likely to experience the highest dust concentrations on a given shift.[7] This sampling strategy is intended to protect all workers by monitoring the most highly exposed. The MSHA inspectors' sampling data, on the other hand, include dust concentration measurements for a broader assortment of occupations

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[5] These reviews are being placed into the public record. See p. 139 for OSHA review and p. 152 for NIOSH review.

[6] In its review of this QRA, OSHA noted that "the QRA does not provide an evaluation of the scientific evidence that would lead to a conclusion that mining exposure to RCMD is causally related to CWP, COPD, or other serious adverse health effects." OSHA was correct in suspecting that "this important risk assessment component is probably contained in a separate MSHA review of the scientific [health effects] literature." This review appears in the health effects section, Section IV of the NPRM. Moreover, the causal relationship between RCMD exposure and CWP is not at issue here, since it is recognized in §201(b) and §203(b) of the Mine Act.

[7] i.e., mine operators routinely collect *designated occupation* (DO) and *designated area* (DA) underground samples, and *designated work position* (DWP) surface samples.

and areas than the operators' data but do so at the expense of less frequent sampling and of potential alterations of work practices in the presence of an inspector.

MSHA's inspector data has at least two major advantages over the operators' data with respect to obtaining representative estimates of exposure levels. First, with the MSHA data there is less likelihood of distortion due to selection bias entering through choice of the sampling days. Whereas some operators may avoid sampling shifts on which relatively high dust concentrations are anticipated,[8] MSHA inspections are unannounced and independently scheduled. Second, as already mentioned, the MSHA inspector samples cover a far greater diversity of occupations and areas than do the operators' samples. Therefore, the inspector data can be used to estimate exposure levels experienced by miners in many specific occupational categories.

The inspector data also have some disadvantages, stemming from their origin as enforcement rather than representational samples. These include statistical bias due to re-visitation of work locations exhibiting excessively high dust concentrations, fewer routine samples (as compared to the operators' data) for designated high-risk occupations and areas, and possible distortions induced by modification of work practices in the presence of an MSHA inspector. However, these problems can be addressed by screening out certain inspector samples and supplementing the remainder with information from the operators' sampling program when appropriate. Correcting for the potential biases and lack of occupational coverage in the operators' data would be far more difficult.

For these reasons, the exposure information utilized in this QRA is drawn primarily from MSHA's inspector samples. However, as will be explained later, information obtained from operators' samples will be used to supplement and adjust inspector-based exposure estimates in some cases.

During the five-year period from 2004 through 2008, MSHA collected and processed nearly 200,000 RCMD samples. Approximately 18,000 of these samples were voided for various reasons, leaving 181,767 valid samples.[9] Appendix B provides details on an additional 20,833 samples excluded from this QRA either because they could not be linked to an occupational exposure or because they were collected within 21 days of samples collected on a prior MSHA dust inspection day. The later samples were excluded because they were generally collected in response to excessively high dust concentration measurements on the first day of an inspection.[10] Appendix C contains a statistical analysis of these samples and explains why retaining them would bias the occupational exposure estimates. The remaining 146,917 valid occupational "Day-1" samples are broken down by year and mine type in Tables 1 and 2 and by year and occupation in Tables 3, 4 and 5.

Table 1 contains the number and percentage of these samples collected at underground mines, surface mines, and surface processing facilities. For underground mines, the sample count is further broken down by mining method or area. The percentage of samples at surface mines increased each year, while the corresponding percentage of samples at underground mines

[8] Biased selection of sampling days under the Operators' Sampling Program was repeatedly noted in oral testimony by miners during public hearings on proposed coal mine dust regulations held in August, 2000 and May, 2003.

[9] Table 30 in Appendix A defines the various reasons for voiding samples and displays the void code used in the sampling data files to identify samples voided for these reasons. Table 33 in Appendix B shows the number of samples voided for each reason.

[10] Samples collected more than 21 days apart may be considered to come from independent inspections.

declined. Similarly, within the underground mines, the percentage of samples at surface areas increased each year.[11] Table 1 also contains a separate breakdown of the samples according to whether they were collected at anthracite or non-anthracite coal operations.

A *work location* (WL) groups together miners of the same job category working in the same general area of a given mine or processing facility.[12] For mine types broken out in the same ways as in Table 1, Table 2 displays the number of distinct work locations at which the Day-1 samples were collected. As mining progresses, a particular WL is frequently replaced by another. Many WLs persisted for more than one year but less than the entire 5-year period. Therefore, the number of distinct WLs shown for 2004–2008 is greater than the number sampled in any given year but less than the sum of distinct WLs shown in the five individual years.

MSHA inspectors collected more than one dust sample for most work locations. Table 2 also displays, for each mine type, the average number of samples collected per WL. This average is simply the number of samples shown in Table 1, divided by the corresponding number of distinct WLs. It is important to note that within each category shown in Table 2, the number of samples collected for individual WLs may vary considerably. For example, the number of samples collected at underground continuous mining work locations in 2008 ranged from 1 to 21, with 10 percent of the WLs represented by more than 8 dust samples. Although the 2008 average number of samples per WL was almost identical in continuous and "other" underground production areas (i.e., 3.84), and the maximum number of samples at a WL falling into the "other" category was only 11, a somewhat higher percentage of the "other" WLs was represented by more than 8 samples (viz. 12.5% as compared to 10% of the "continuous" WLs).

[11] Both increases are statistically significant at a confidence level exceeding 99 percent.

[12] Occupational dust samples associated with the same WL within a mine or processing facility are identified by their sharing the same middle two digits of the 4-digit entity code, along with the same mine identification number and job classification, in the dust sampling data files. Samples from different mines or processing facilities, and samples associated with different job-categories within the same mining operation, are always counted as representing different work locations. For example, a total of 4,743 distinct work locations were counted for underground continuous mining operations in 2008. A specific underground mine may contain more than one continuous mining production area, and each occupational category associated with a particular continuous mining production area is counted as a separate WL within the total of 4,743.

Table 1. — Number of valid "Day-1" respirable coal mine dust concentration samples collected by MSHA inspectors, by mine type and year. Intake air samples, samples not associated with an occupation, and samples collected within 21 days after "Day 1" of an MSHA dust inspection are excluded.

Mine Type		2004	2005	2006	2007	2008	2004-2008
UG Mining Method	Surface at UG	849	1,005	871	865	1,072	4,662
	Longwall	1,947	1,456	1,437	1,468	1,174	7,482
	Continuous	20,414	20,562	15,521	14,974	18,223	89,694
	Conventional or SOS*	851	882	613	509	451	3,306
	Other UG mining methods	121	122	131	123	123	620
	Non-producing UG areas	84	69	63	47	119	382
Total at Underground Mines		24,266	24,096	18,636	17,986	21,162	106,146
Percentage†		*75.2*	*74.9*	*72.2*	*69.5*	*68.8*	*72.3*
Surface Mines		5,250	5,356	4,880	5,201	6,546	27,233
Percentage†		*16.3*	*16.6*	*18.9*	*20.1*	*21.3*	*18.5*
Surface Processing Facilities		2,751	2,723	2,298	2,693	3,073	13,538
Percentage†		*8.5*	*8.5*	*8.8*	*10.4*	*10.0*	*9.2*
TOTAL, all coal mines and surface facilities		**32,267**	**32,175**	**25,814**	**25,880**	**30,781**	**146,917**
		100.0	***100.0***	***100.0***	***100.0***	***100.0***	***100.0***
All coal operations except anthracite		31,488	31,335	24,888	24,820	29,723	142,254
All anthracite operations		779	840	926	1,060	1,058	4,663

* SOS refers to "shoot on solid" mining method.
† Percentages may not add to 100 due to rounding.

It should also be noted that inspector presence, as measured by the average number of dust samples per WL, seems to have been lower at anthracite mines than at other coal mines. This is not immediately apparent from Table 2, since underground and surface operations are lumped together within the anthracite and non-anthracite categories. However, the number of MSHA dust samples per WL has generally been lower for anthracite mines even when underground and surface mines are examined separately.[13] Since (as will be shown later in the QRA) exposure to anthracite dust poses significantly greater health risks than equivalent bituminous dust exposures, this observation may have important implications for optimizing MSHA's allocation of dust inspection resources.

[13] The same relationship does *not* hold for processing facilities. For anthracite, the average numbers of MSHA dust samples per WL in 2008 were 3.15, 1.54, and 2.01 for underground mines, surface mines, and processing facilities, respectively. The corresponding averages for coal other than anthracite were 3.57, 1.81, and 1.71.

Table 2. — Number of distinct occupational work locations (WLs) sampled by MSHA inspectors, by year and mine type. Bottom number in each cell is the average number of valid, "Day-1" samples collected at each work location.

Mine Type		2004	2005	2006	2007	2008	2004-2008†
Underground Mining Method	Surface at UG	539 *1.58*	616 *1.63*	527 *1.65*	492 *1.76*	638 *1.68*	1,653 *2.82*
	Longwall	391 *4.98*	330 *4.41*	315 *4.56*	311 *4.72*	286 *4.10*	640 *11.69*
	Continuous	4,409 *4.63*	4,579 *4.49*	4,356 *3.56*	4,210 *3.56*	4,743 *3.84*	9541 *9.40*
	Conventional or SOS*	214 *3.98*	205 *4.30*	188 *3.26*	175 *2.91*	148 *3.05*	475 *6.96*
	Other UG mining methods	40 *3.03*	25 *4.88*	35 *3.74*	39 *3.15*	32 *3.84*	65 *9.54*
	Non-producing UG areas	50 *1.68*	49 *1.41*	45 *1.40*	39 *1.21*	82 *1.45*	260 *1.47*
Total at Underground Mines		5,643 *4.30*	5,804 *4.15*	5,466 *3.41*	5,266 *3.42*	5,929 *3.57*	12,634 *8.40*
Surface Mines		3,056 *1.72*	3,161 *1.69*	2,921 *1.67*	2,927 *1.78*	3,639 *1.80*	7,811 *3.49*
Surface Processing Facilities		1,642 *1.68*	1,637 *1.66*	1,406 *1.63*	1,486 *1.81*	1,751 *1.75*	3,585 *3.78*
TOTAL, all mines and surface facilities		**10,341** ***3.12***	**10,602** ***3.03***	**9,793** ***2.64***	**9,679** ***2.67***	**11,319** ***2.72***	**24,030** ***6.11***
All coal operations except anthracite		9,904 *3.18*	10,162 *3.08*	9,311 *2.67*	9,169 *2.71*	10,789 *2.75*	22,994 *6.19*
All anthracite operations		437 *1.78*	440 *1.91*	482 *1.92*	510 *2.08*	530 *2.00*	1,036 *4.50*

† Because WLs may not persist over the entire 5-year period, the number of distinct WLs shown for 2004–2008 is less than the sum of distinct WLs shown in the individual years.

* SOS refers to "shoot on solid" mining method.

Repeated dust concentration measurements at the same WL are useful for purposes of risk assessment in that they reflect variability in the dust concentration to which miners working at that location are exposed on different shifts. The average of such measurements provides an estimate of long-term mean exposure in a particular working environment, and the statistical reliability of this estimate improves as the number of available measurements (and the time-span they cover) increases. However, disparities in the number of samples collected at different WLs engender disparities in the degree to which the various WLs are represented statistically within the aggregated data: aggregated results are distorted, or statistically *biased* toward those WLs represented by relatively large numbers of available samples. Therefore, as explained later, individual samples will be appropriately weighted to compensate for this type of bias when aggregated estimates of dust exposure levels are calculated in Part 2 of this QRA.

The risk assessment submitted in support of MSHA and NIOSH's 2003 joint coal mine dust proposed rulemaking notice was restricted to underground mines and based on aggregating dust exposure estimates within such mines according to just three categories: designated occupation (DO), non-designated occupation (NDO), and roof-bolter designated area (RB-DA).[14] Doing so was (a) predicated on the premise that reducing exposures for the DO would, *a fortiori,* reduce exposures for the associated NDO occupations by a commensurate amount and (b) sensitive to the fact that RB-DA exposures are often subject to a different exposure limit than nearby workers in other occupational categories. However, subsequent to publication of the 2003 risk assessment, MSHA carried out a statistical analysis of the relationship between DO exposures and exposures for other occupations on the same shift. (Kogut, 2003.) This analysis showed, among other findings, that at least one NDO exposure exceeded the associated DO exposure on more than 50 percent of MSHA's "1st-Day" dust sampling inspections during 2000-2002. The 2004-2008 MSHA inspection data confirm this finding, with the dust concentration for at least one NDO exceeding the corresponding DO exposure on 55% of the "Day-1" shifts sampled. Consequently, in the present risk assessment, dust exposure estimates are not aggregated according to the DO, NDO, and RB-DA trichotomy. Instead, aggregated exposure estimates are formed within 33 mutually exclusive and exhaustive occupational categories defined in Appendix A, with the addition of a special category for Part-90 miners.[15] In addition to avoiding a special status for DO samples that may not be fully warranted, the occupational approach used here has several advantages:

- it is easier to extend beyond underground mines to surface mines and processing facilities;
- there is no need to handle roof-bolters differently from any other occupation, since the occupational exposure estimates are formed independently of any current exposure limit;
- the dust exposure breakdown by occupational category is conceptually simpler than one based on a distinction between DO and NDO categories.

Table 3 breaks down MSHA's 146,917 valid occupational "Day-1" samples by job category or Part-90 status. The number of distinct WLs at which these samples were collected is shown in Table 4, and the average number of usable samples for each WL is presented in Table 5 for each occupation. It is evident from Table 5 that WLs involving longwall jack setters, longwall headgate operators, mobile bridge operators, shuttle car operators, and roofbolters tend to be represented by significantly greater numbers of dust samples than are WLs for other occupations. WLs for surface occupations are generally represented by fewer samples than are WLs for underground occupations. In 2008, for example, the average number of samples per WL for "laborer" was 1.60 at surface mines and 2.34 underground.

[14] U.S. Dept. of Labor and U.S. Dept. of Health and Human Services, 2003, pp 10942-10946.

[15] In this QRA, Part-90 miners are excluded, from all of the occupational categories.

Table 3. — Number of valid "Day-1" dust concentration samples collected by MSHA inspectors, by occupation and year. Intake air samples, samples not associated with an occupation, and samples collected within 21 days after "Day 1" of an MSHA dust inspection are excluded. Part-90 miners are excluded from job categories.

	Occupation	2004	2005	2006	2007	2008	2004-2008
Underground Workers	Auger Op	39	31	17	19	12	118
	Continuous Miner Op	3824	3889	2945	2860	3547	17,065
	Cutting Mach Op	139	149	109	92	80	569
	Drill Op	158	176	124	101	83	642
	Electrician & helper	604	532	387	386	447	2,356
	Laborer	180	130	137	109	124	680
	Loading Mach Op	161	136	80	95	129	601
	LW Headgate Op	467	377	389	404	307	1,944
	LW Jacksetter	516	363	405	411	313	2,008
	LW Tailgate Op	232	206	210	221	167	1,036
	Mechanic & helper	238	199	134	156	165	892
	Mobile Bridge Op	750	835	619	581	621	3,406
	Roof Bolter	6029	6281	4690	4702	5829	27,531
	Shuttle Car Op	6114	6046	4691	4501	5429	26,781
	Section Foreman	376	257	190	155	174	1,152
	Scoop Car Op	2055	2044	1579	1420	1595	8,693
	Tractor Op	229	207	136	112	139	823
	Utility Man	456	492	375	314	353	1,990
	Other UG workers*	828	719	527	464	560	3,098
Part-90 Miners		176	189	204	197	182	948
Surface Workers	Auger Op	132	123	122	137	168	682
	Backhoe Op	297	287	315	373	480	1,752
	Bull Dozer Op	1683	1612	1368	1526	1977	8,166
	Crane/Dragline Op	116	109	83	88	79	475
	Cleaning plant Op	371	325	292	300	393	1,681
	Drill Op	585	562	514	556	628	2,845
	Electrician & helper	125	128	114	135	177	679
	Highlift Op/FEL	1843	1970	1636	1782	2128	9,359
	Laborer	245	249	222	219	251	1,186
	Mechanic & helper	320	345	326	326	376	1,693
	Tipple Op	165	158	113	153	159	748
	Truck Driver	1116	1195	1089	1174	1543	6,117
	Utility Man	427	500	382	409	500	2,218
	Other Surf. Workers	1271	1354	1290	1402	1666	6,983

*Includes 301 samples at 51 WLs involving area samples on the return side of a longlwall face (occupation codes 60 or 61).

Table 4. — Number of distinct work locations sampled by MSHA inspectors, by year and occupation. Part-90 miners are excluded from job categories.

	Occupation	2004	2005	2006	2007	2008	2004-2008
Underground Workers	Auger Op	9	11	6	8	5	19
	Continuous Miner Op	917	976	963	956	1052	1782
	Cutting Mach Op	38	38	38	38	32	90
	Drill Op	47	48	43	43	34	110
	Electrician & helper	260	260	236	238	274	653
	Laborer	90	55	52	51	53	207
	Loading Mach Op	57	54	45	52	59	110
	LW Headgate Op	53	56	55	53	52	90
	LW Jacksetter	54	56	55	54	52	88
	LW Tailgate Op	55	56	55	56	54	97
	Mechanic & helper	119	110	89	94	103	342
	Mobile Bridge Op	93	114	104	102	95	194
	Roof Bolter	961	1021	1006	997	1091	1904
	Shuttle Car Op	831	858	857	851	952	1663
	Section Foreman	223	164	138	117	136	514
	Scoop Car Op	635	669	639	594	667	1424
	Tractor Op	40	46	42	31	35	112
	Utility Man	278	283	239	210	239	741
	Other UG workers*	333	303	267	223	296	811
Part-90 Miners		51	51	49	46	59	110
Surface Workers	Auger Op	89	90	90	98	120	260
	Backhoe Op	228	227	236	255	329	763
	Bull Dozer Op	982	967	820	854	1060	2169
	Crane/Dragline Op	74	71	57	54	52	139
	Cleaning plant Op	230	215	197	191	229	489
	Drill Op	337	340	317	313	355	848
	Electrician & helper	96	99	90	96	123	273
	Highlift Op/FEL	1035	1081	952	942	1128	2310
	Laborer	182	162	154	128	157	481
	Mechanic & helper	212	229	208	213	254	668
	Tipple Op	116	114	87	108	120	288
	Truck Driver	605	643	600	606	775	1480
	Utility Man	300	350	288	284	366	916
	Other Surf. Workers	711	785	719	723	911	1885

*Includes 51 WLs involving area samples on the return side of a longwall face (occupation codes 60 or 61)

Table 5. — Average number of valid, "Day-1" samples collected per work location, by year and occupation (obtained by dividing number of samples in Table 3 by corresponding number of work locations in Table 4). Part-90 miners are excluded from job categories.

	Occupation	2004	2005	2006	2007	2008	2004-2008
Underground Workers	Auger Op	4.33	2.82	2.83	2.38	2.40	6.21
	Continuous Miner Op	4.17	3.98	3.06	2.99	3.37	9.58
	Cutting Mach Op	3.66	3.92	2.87	2.42	2.50	6.32
	Drill Op	3.36	3.67	2.88	2.35	2.44	5.84
	Electrician & helper	2.32	2.05	1.64	1.62	1.63	3.61
	Laborer	2.00	2.36	2.63	2.14	2.34	3.29
	Loading Mach Op	2.82	2.52	1.78	1.83	2.19	5.46
	LW Headgate Op	8.81	6.73	7.07	7.62	5.90	21.60
	LW Jacksetter	9.56	6.48	7.36	7.61	6.02	22.82
	LW Tailgate Op	4.22	3.68	3.82	3.95	3.09	10.68
	Mechanic & helper	2.00	1.81	1.51	1.66	1.60	2.61
	Mobile Bridge Op	8.06	7.32	5.95	5.70	6.54	17.56
	Roof Bolter	6.27	6.15	4.66	4.72	5.34	14.46
	Shuttle Car Op	7.36	7.05	5.47	5.29	5.70	16.10
	Section Foreman	1.69	1.57	1.38	1.32	1.28	2.24
	Scoop Car Op	3.24	3.06	2.47	2.39	2.39	6.10
	Tractor Op	5.73	4.50	3.24	3.61	3.97	7.35
	Utility Man	1.64	1.74	1.57	1.50	1.48	2.69
	Other UG workers*	2.49	2.37	1.97	2.08	1.89	3.82
Part-90 Miners		3.45	3.71	4.16	4.28	3.08	3.70
Surface Workers	Auger Op	1.48	1.37	1.36	1.40	1.40	2.62
	Backhoe Op	1.30	1.26	1.33	1.46	1.46	2.30
	Bull Dozer Op	1.71	1.67	1.67	1.79	1.87	3.76
	Crane/Dragline Op	1.57	1.54	1.46	1.63	1.52	3.42
	Cleaning plant Op	1.61	1.51	1.48	1.57	1.72	3.44
	Drill Op	1.74	1.65	1.62	1.78	1.77	3.35
	Electrician & helper	1.30	1.29	1.27	1.41	1.44	2.49
	Highlift Op/FEL	1.78	1.82	1.72	1.89	1.89	4.05
	Laborer	1.35	1.54	1.44	1.71	1.60	2.47
	Mechanic & helper	1.51	1.51	1.57	1.53	1.48	2.53
	Tipple Op	1.42	1.39	1.30	1.42	1.33	2.60
	Truck Driver	1.84	1.86	1.82	1.94	1.99	4.13
	Utility Man	1.42	1.43	1.33	1.44	1.37	2.42
	Other Surf. Workers	1.79	1.72	1.79	1.94	1.83	3.70

*Includes 301 samples at 51 WLs involving area samples on the return side of a longwall face (occupation codes 60 or 61).

As before, summarizing the number of samples per WL with a single statistic, such as the average, can mask important differences in the numbers of samples drawn from individual WLs. Nearly 10 percent (64 out of 680) of all the samples for underground laborers in 2004-2008 come from a single WL, while 99 distinct WLs for underground laborers (drawn from 91 different mines) are represented by only a single sample. Similarly, 59 of the 621 samples for mobile bridge operators in 2008 represent a single WL. Therefore, aggregated dust exposures for these categories should be interpreted cautiously, avoiding bias toward those WLs represented by disproportionately high sample counts.

(b) Observed Single-Shift Dust Concentrations, by Occupation

Figures 1 and 2 respectively summarize MSHA's underground and surface single-shift respirable dust concentration measurements in 2004-2008, broken out according to the occupational categories shown in Table 3. (Dust concentrations observed for Part-90 miners are shown in either Figure 1 or Figure 2, depending on occupation.) With the exception of 6 job categories (underground auger operators, continuous miner operators, cutting machine operators, and the three longwall categories), the upper quartile of the dust concentrations (i.e., the 75^{th} percentile) for each occupation fell below the proposed final exposure limit (FEL) of 1.0 mg/m^3 (or 0.5 mg/m^3 for Part-90 miners). Furthermore, only in the case of longwall tailgate operators was this threshold exceeded on a majority of sampled shifts. On the other hand, dust concentrations exceeded 1.0 mg/m^3 on at least 10 percent of the sampled shifts for nearly all of the underground job categories and also for the surface category of cleaning plant operators. Nineteen percent of the measurements for Part-90 miners exceeded 0.5 mg/m^3.

Figure 3 plots the dust concentration distribution as a histogram for the most frequently sampled occupation: continuous miner operators. Figure 4 contains the corresponding histogram for longwall tailgate operators, the occupation showing greatest percentage of measurements in excess of 1.0 mg/m^3. Distributions of the dust concentration measurements for the other occupational categories are shown in Appendix D(a). Appendix D(b) addresses the distribution of dust concentrations observed using MSHA's intake air samples.

Figure 5 contains the cumulative distribution of dust concentration measurements for selected underground occupations exhibiting a relatively high proportion of dust concentration measurements greater than the proposed FEL. For any exposure level specified along the horizontal axis, the proportion of measurements observed at or below that level is shown by the corresponding value along the vertical axis. From Figure 5, it is evident that about 80% of the roof bolter measurements and 40% of the measurements for longwall tailgate operators fell at or below 1.0 mg/m^3. Consequently, it may be inferred that longwall tailgate measurements exceeded 1.0 mg/m^3 at three times the rate observed for roofbolters — i.e., at a rate of 60 per 100 measurements versus 20 per 100 for roofbolters. For comparison purposes, Figure 6 shows the cumulative distributions for three surface job categories and for Part-90 miners. Approximately 20 percent of the measurements on Part-90 miners exceeded 0.5 mg/m^3.

Table 6 provides descriptive statistics on MSHA's dust concentration measurements for each occupation. The number of WLs shown comprises the total over the entire 5-year period, which exceeds the number in operation at any given time. The mean, median, and coefficient of variation[16] are calculated across all samples, so that WLs represented by a greater number of samples are given more weight in these summary statistics than WLs represented by fewer samples. Likewise, the percentages shown of measurements exceeding 0.5 mg/m^3, 1.0 mg/m^3, and 2.0 mg/m^3 are unadjusted and derive from equal weights being placed on all of the measurements falling within an occupational category.

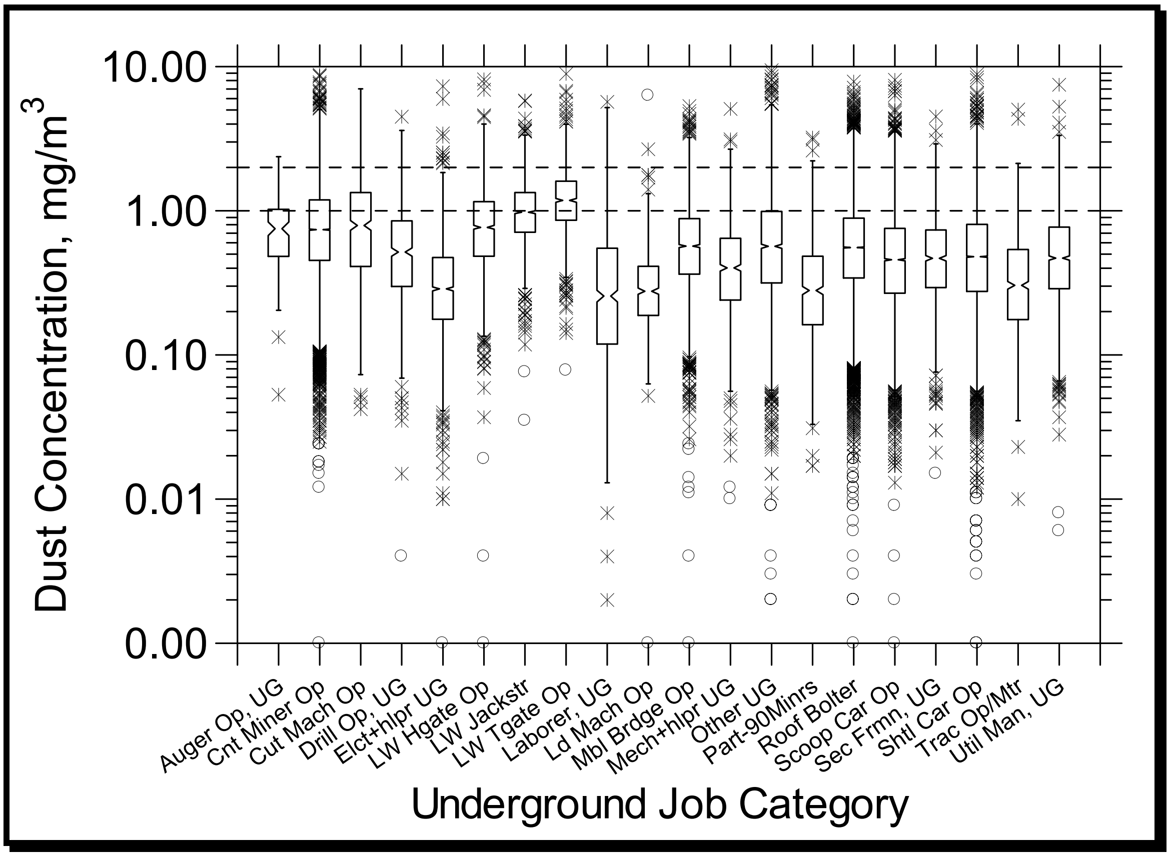

Figure 1. — Box Plots (Tukey, 1977) for coal mine dust concentrations measured by MSHA inspectors, 2004-2008, on selected underground occupations. Top and bottom of each box represent upper and lower quartiles, respectively. Notch within each box represents 95-percent confidence interval for the median. Vertical lines span most measurements. Isolated points (either ○ or ∗) are outliers, representing unusually low or high observations compared to other measurements for the same job category. Horizontal dashed lines are plotted at proposed and existing dust concentration limits.

[16] Since simultaneous measurements at the same work location are unavailable, analytical measurement error is confounded with shift-to-shift variability. MSHA assumes that variability due to analytical measurement error is negligible compared to variability of dust concentrations on different shifts.

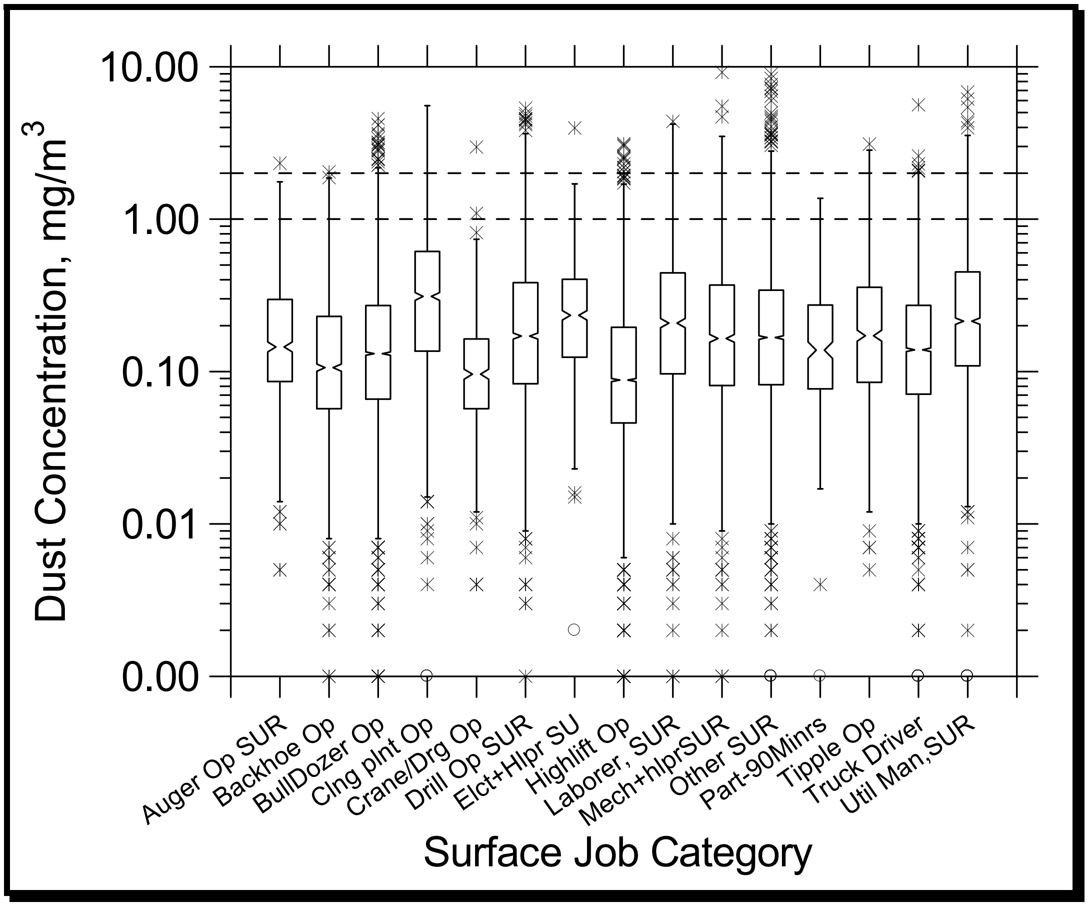

Figure 2. — Box Plots (Tukey, 1977) for coal mine dust concentrations measured by MSHA inspectors, 2004-2008, on selected surface occupations. Top and bottom of each box represent upper and lower quartiles, respectively. Notch within each box represents 95-percent confidence interval for the median. Vertical lines span most measurements. Isolated points (either ○ or ∗) are outliers, representing unusually low or high observations compared to other measurements for the same job category. Horizontal dashed lines are plotted at proposed and existing dust concentration limits.

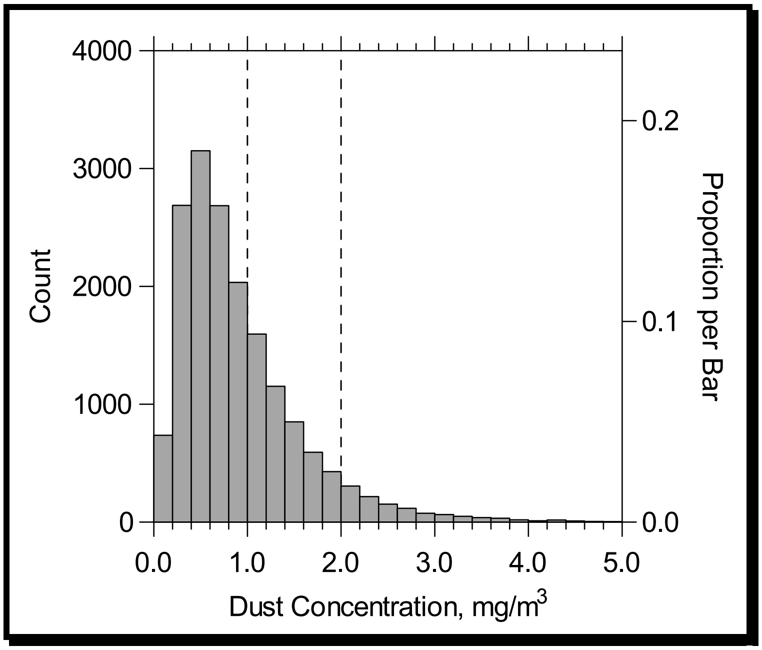

Figure 3. — Respirable coal mine dust concentration distribution for continuous miner operators, based on 17,065 MSHA inspector samples collected from 2004-2008. 33 measurements exceeding 5.0 mg/m^3 are excluded. Vertical dashed lines are plotted at proposed and existing dust concentration limits.

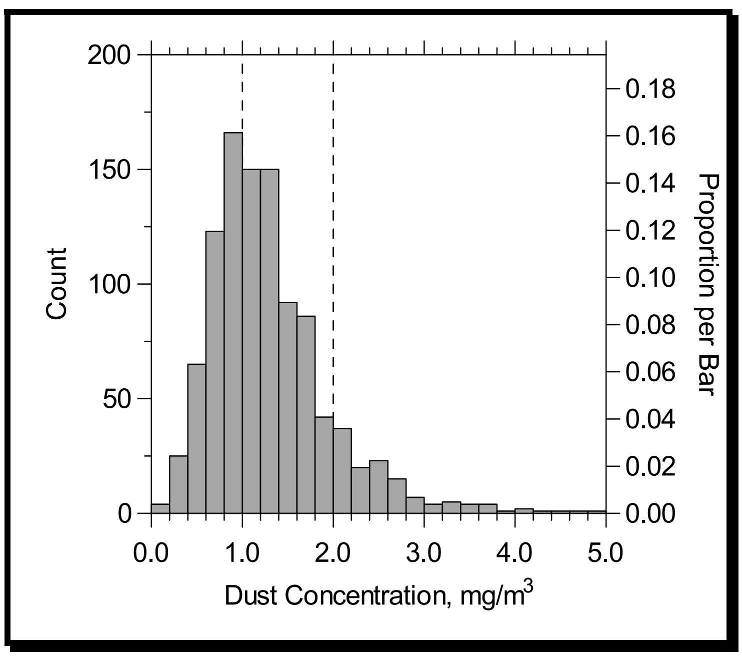

Figure 4. — Respirable coal mine dust concentration distribution for longwall tailgate operators, based on 1,036 MSHA inspector samples collected from 2004-2008. 7 measurements exceeding 5.0 mg/m^3 are excluded. Vertical dashed lines are plotted at proposed and existing dust concentration limits.

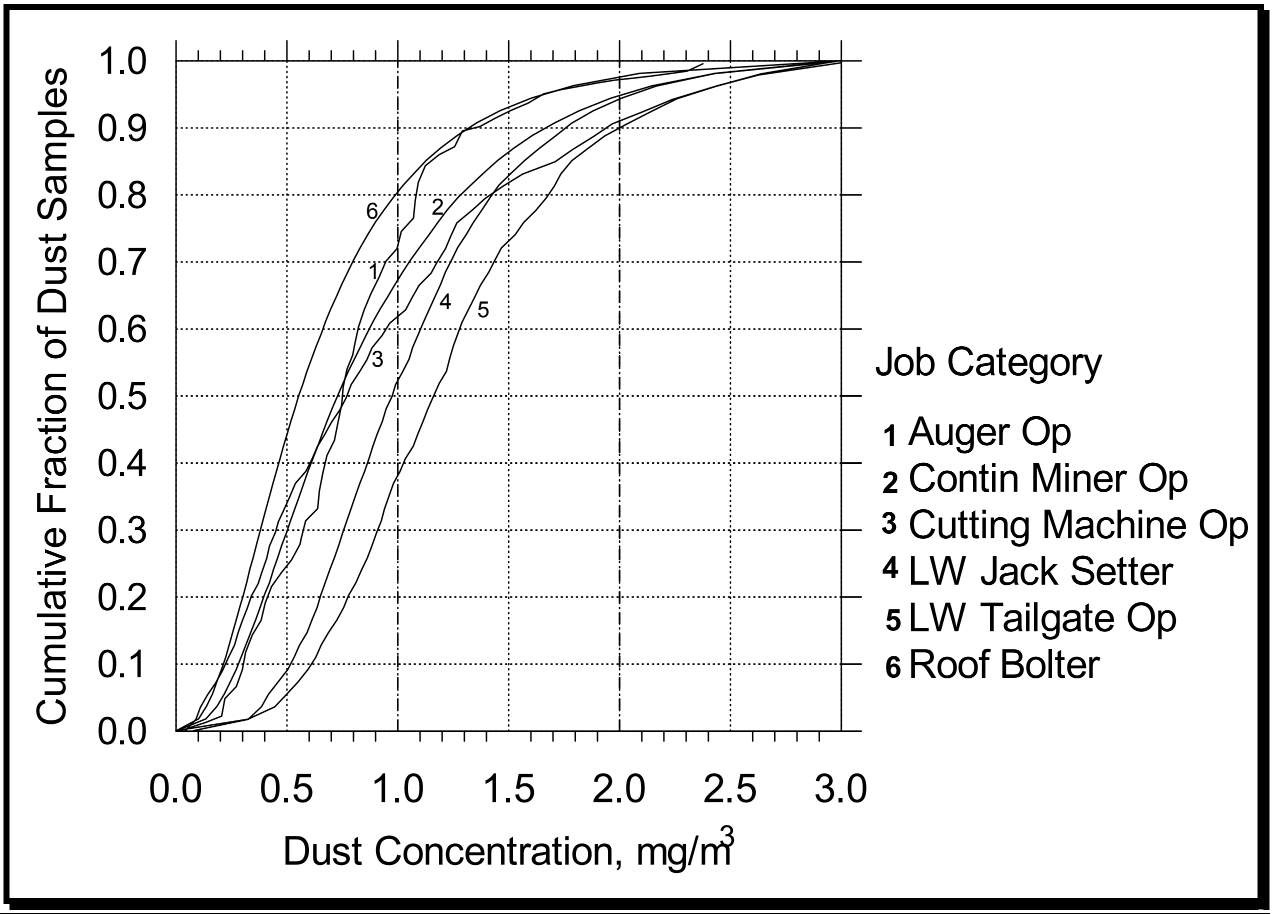

Figure 5. — Cumulative distribution of MSHA inspector coal mine dust measurements, 2004-2008, for selected underground occupations. Of 48,327 measurements for the listed occupations, 514 were excluded because they exceeded 3.0 mg/m^3. Vertical dashed lines are plotted at proposed and existing dust concentration limits.

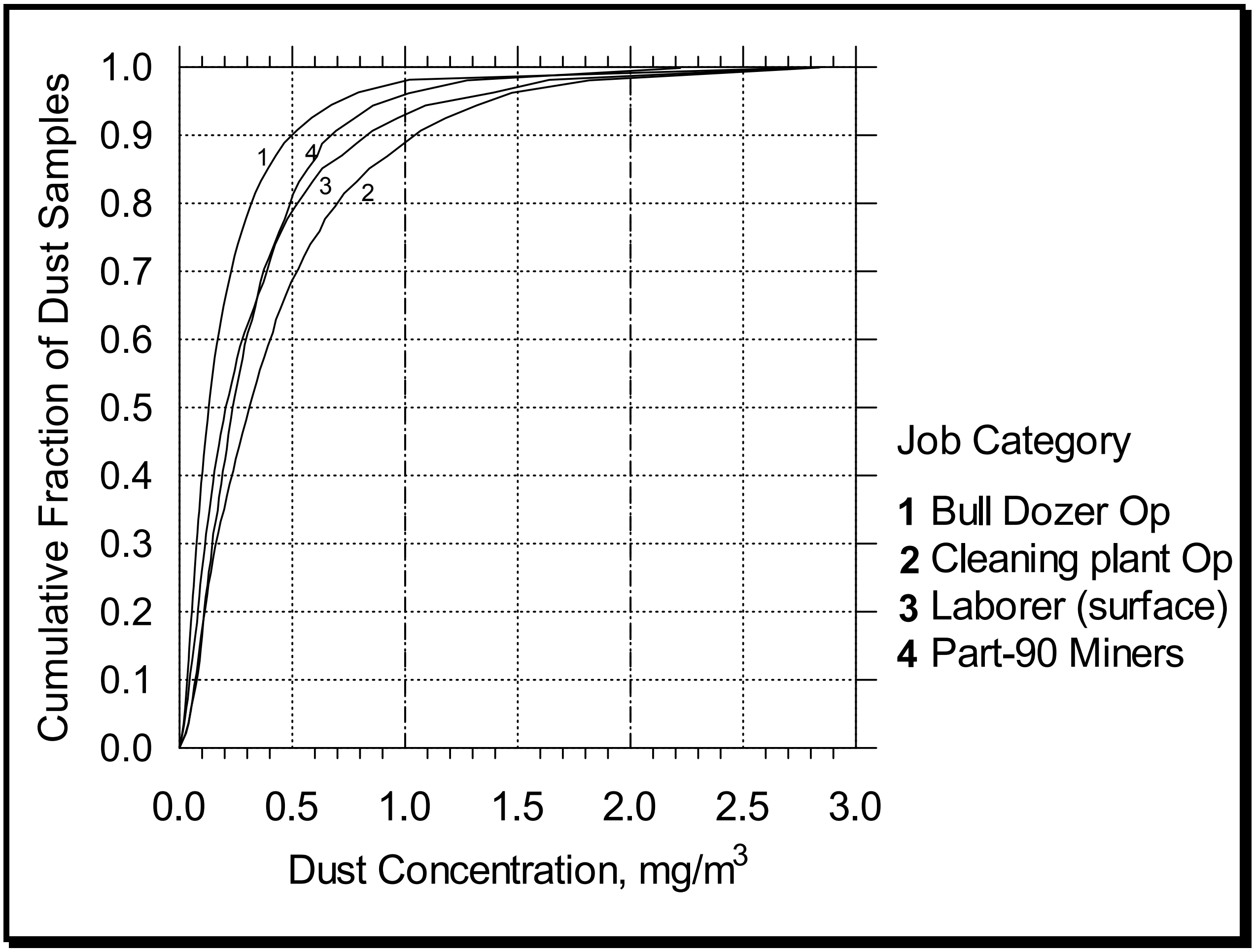

Figure 6. — Cumulative distribution of MSHA inspector coal mine dust measurements, 2004-2008, for Part-90 Miners and selected surface occupations. Of 11,981 measurements for the listed categories, 25 were excluded because they exceeded 3.0 mg/m^3. Vertical dashed lines are plotted at proposed and existing dust concentration limits.

Table 6. — Coal mine respirable dust measurements by occupation, based on 2004-2008 MSHA inspector samples. Part-90 miners are excluded from job categories.

	Occupation	Num. of Samples	Num. of WLs†	Mean (mg/m^3)	Coef. of Var. (%)	Median (mg/m^3)	Pct > 0.5 mg/m^3	Pct > 1.0 mg/m^3	Pct > 2.0 mg/m^3	Trend‡ (% per yr)
Underground Workers	Auger Op	118	19	0.81	54.9	0.75	74.6	26.3	2.5	—
	Continuous Miner Op	17,065	1,782	0.92	76.0	0.74	70.7	33.8	6.8	—
	Cutting Mach Op	569	90	1.05	88.1	0.79	67.3	40.1	12.5	—
	Drill Op	642	110	0.67	84.0	0.52	52.0	19.2	3.4	—
	Electrician & helper	2,356	653	0.38	96.1	0.29	22.8	4.6	0.5	—
	Laborer	680	207	0.43	130.3	0.26	27.9	8.4	2.1	−10.2
	Loading Mach Op	601	110	0.36	98.6	0.28	17.0	2.8	0.3	—
	LW Headgate Op	1,944	90	0.91	70.6	0.77	73.3	33.4	5.1	—
	LW Jacksetter	2,008	88	1.09	51.5	0.98	91.0	48.0	6.4	—
	LW Tailgate Op	1,036	97	1.33	62.0	1.18	94.6	62.8	12.8	—
	Mechanic & helper	892	342	0.52	86.6	0.40	36.5	10.3	1.8	—
	Mobile Bridge Op	3,406	194	0.70	74.8	0.57	57.5	19.1	2.6	—
	Roof Bolter	27,531	1,904	0.70	76.8	0.56	55.9	20.0	2.9	−0.8
	Shuttle Car Op	26,781	1,663	0.61	80.5	0.48	47.9	16.0	1.8	—
	Section Foreman	1,152	514	0.58	77.4	0.47	45.4	12.0	1.6	—
	Scoop Car Op	8,693	1,424	0.60	110.2	0.46	45.5	14.7	2.1	+2.4
	Tractor/Motor Op	823	112	0.43	95.9	0.30	27.9	7.7	0.6	+4.5
	Utility Man	1,990	741	0.60	81.8	0.47	46.9	14.3	1.6	—
	Other UG workers*	3,098	811	0.82	113.1	0.57	56.6	24.3	7.1	−4.3
Part-90 Miners		948	110	0.34	101.4	0.24	19.0	4.2	0.9	—
Surface Workers	Auger Op	682	260	0.24	109.7	0.14	11.0	2.3	0.1	—
	Backhoe Op	1,752	763	0.19	121.1	0.10	9.4	1.2	0.1	—
	Bull Dozer Op	8,166	2,169	0.22	129.3	0.13	10.0	2.1	0.3	−4.4
	Crane/Dragline Op	475	139	0.13	132.1	0.10	1.7	0.4	0.2	—
	Cleaning plant Op	1,681	489	0.46	108.5	0.31	31.4	11.5	1.6	—
	Drill Op	2,845	848	0.33	146.5	0.17	17.7	5.8	1.5	−3.4
	Electrician & helper	681	273	0.31	95.7	0.23	16.4	3.2	0.1	−5.6
	Highlift Op/FEL	9,359	2,310	0.16	136.8	0.09	0.0	0.0	0.0	−2.8
	Laborer	1,186	481	0.36	125.8	0.21	21.4	7.74	1.4	—
	Mechanic & helper	1,693	668	0.31	151.1	0.16	16.8	5.5	1.2	—
	Tipple Op	748	288	0.29	118.6	0.17	16.6	4.4	0.5	—
	Truck Driver	6,117	1,480	0.22	114.7	0.14	8.8	1.7	0.1	−4.2
	Utility Man	2,218	916	0.37	128.9	0.21	21.9	6.7	1.2	—
	Other Surf. Workers	6,983	1,885	0.30	165.6	0.16	15.2	4.9	0.9	−2.4

†Number of distinct work locations sampled, based on mine I.D. combined with middle two digits of MSHA's entity code. Because samples spanned 5 years, this number may exceed the number of distinct work locations at any given time.

‡ Estimated annual percentage change in median dust concentration during 5-year study period, based on Bayes regression analysis with diffuse prior. Estimates are presented only if probability of an underlying change exceeds 98 percent

*Includes 301 samples at 51 WLs involving area samples on the return side of a longwall face (occupation codes 60 or 61).

Trends over time in MSHA's dust concentration measurements were also analyzed.[17] For those occupations showing a statistically significant upward or downward trend, the last column of Table 6 provides an estimate for the rate of change. A negative value indicates a decline (i.e., *improvement*) in median dust concentration. Measurements on underground laborers, for example, improved significantly over the 5-year period, at an annual rate averaging about 10 percent.

(c) Estimated Exposure Levels, by Occupation

In this subsection of the QRA, MSHA identifies potential biases in the RCMD measurement data and forms estimates of current exposure levels that adjust for such biases. Occupational exposures based on two different estimation methods are presented and compared.

(i) Bias corrections: ANCOVA estimates

Figures 1 and 2, along with Table 6, corroborate the common knowledge that substantial differences exist in the average dust concentrations experienced by workers belonging to different occupational groups. However, as shown in Table 5, occupational categories also differ widely with respect to the average number of samples collected per work location. If MSHA tended to collect more samples at the more hazardous WLs, then the observed differences in average dust concentration may be exaggerated. Furthermore, there may be other, less apparent biases induced by imbalances in the numbers of samples collected at different WLs. Any exposure estimates based on MSHA's inspector samples that are used to assess health risks should account for these imbalances. This QRA addresses imbalances in the number of available samples by developing separate exposure estimates for each WL. Results are then aggregated by occupational category, assigning equal weight to the mean dust concentration observed at each WL.

First, MSHA supports this approach by establishing that there is, in fact, a correlation between average dust concentration and the number of Day-1 samples at specific WLs. For this purpose, Pearson correlation coefficients were calculated both across and within occupational categories. To avoid potential confounding, the analysis was restricted to WLs subject to an unreduced dust standard of 2.0 mg/m^3 — i.e., a standard not reduced due to quartz.[18]

Results of the correlation analysis are presented in Table 7. A statistically significant, positive correlation is evident in the overall data and within the occupational categories listed. The correlation ($\hat{\rho}$) across all jobs (i.e., ignoring the occupational category) is 0.32, which is statistically significant at a high confidence level ($p = 10^{-15}$) and indicates substantial upward bias in the uncorrected aggregated exposure data.

Recognizing that differences in the applicable standard, mine effects, and sampling date could similarly bias the data if left uncorrected, an analysis of covariance (ANCOVA) was per-

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[17] Trend probabilities were evaluated by Bayesian regression on the logarithm of dust concentration, with a diffuse prior probability distribution assumed for the coefficient of sequential sampling day. Because trends were examined for a multiplicity of occupational categories, the criterion for statistical significance was placed at 98 percent, rather than the conventional 95-percent confidence level. An estimate for rate of change is presented only if the 98-percent posterior probability interval for the rate of change excludes zero.

[18] A relatively large number of the WLs subject to an unreduced dust standard of 2.0 mg/m^3 (12,835 out of 19,784) are associated with fewer than five Day-1 samples, while the number of samples associated with the remaining 6,936 WLs ranges from 5 to 99. To avoid over-influencing the results by WLs with sample counts falling into a narrow range, the correlation analysis was further restricted to the 6,936 WLs associated with at least five Day-1 samples. This restriction should have no bearing on conclusions drawn from the analysis.

formed to obtain unbiased estimates of the mean dust concentration associated with each occupation on shifts sampled by MSHA.[19] The nested ANCOVA model used adjusts not only for variability in the sample count at different WLs, but also for mine-to-mine effects and variability in sampling dates and the applicable dust standard. All of these factors turned out to be statistically significant. Figure 7 displays the resulting point estimates, along with approximate 95-percent confidence intervals, for underground occupations.[20] A detailed description of the ANCOVA for both underground and surface occupations is provided in Appendix D(c). Table 40 and Table 42 in Appendix D(c) contain the ANCOVA estimates for underground and surface occupations, respectively.

Table 7. — Correlations between dust concentration and number of MSHA Day-1 dust samples at 6,936 work locations subject to an unreduced exposure limit† of 2.0 mg/m³ and sampled at least 5 times during 2004–2008.

Occupation	Number of Work Locations	Correlation ($\hat{\rho}$)	p-value
Continuous Miner Operator	817	0.258	< 0.001
UG Drill Operator	49	0.286	0.047
UG Mechanic or Helper	38	0.321	0.050
Roof Bolter	895	0.136	< 0.001
Shuttle Car Operator	849	0.246	< 0.001
UG Section Foreman	29	0.234	< 0.001
Misc. UG Workers	155	0.271	0.001
Surface Utility Man	110	0.454	< 0.001
All Occupations Combined	**6,936**	**0.321**	**< 0.001**

† i.e., an exposure limit not reduced due to quartz.

As expected on account of the correlations discussed above, the adjusted mean dust concentrations from the ANCOVA are generally lower than the uncorrected means listed in Table 6. (See Table 40 and Table 42.) The only exceptions are for Crane/Dragline Op., Loading Machine Op., Tractor/Motor Op., and Laborer (underground). For the latter two of these categories, the observed correlation between sample count and average dust concentration was *negative*, unlike the general pattern, though not statistically significant.

It is important to recognize that each confidence interval plotted in Figure 7 applies to the mean dust concentration across all WLs associated with a given occupational category and not to the mean dust concentration experienced at any specific WL. None of the adjusted occupational means exceeds the proposed FEL. However, there are individual mines in which the average

[19] Since conditions on shifts sampled by MSHA inspectors may not be fully representative of conditions on other shifts, MSHA presumes only that these estimates are unbiased with respect to the observed shifts.
[20] Please note that the estimates of MSHA's mean RCMD concentration measurements shown in Figure 7 are presented only for preliminary, comparative purposes and do not represent the final estimates of current exposure used in this QRA to quantify health risks. The estimates actually used are developed later in this section of the QRA and are presented in Figure 8 and Figure 9.

dust concentration for an occupation is far greater at some WLs than the industry-wide norm.[21] Table 8 lists a few specific examples; and Table 9 shows, within each occupational category, the percentage of WLs at which the average dust concentration exceeded the proposed FEL. Abnormally hazardous environments such the one involving cutting machine operators at Mine 1518659 may go unnoticed when averages are aggregated across too many disparate locations. The proposed rule is intended to eliminate these sorts of hazards.

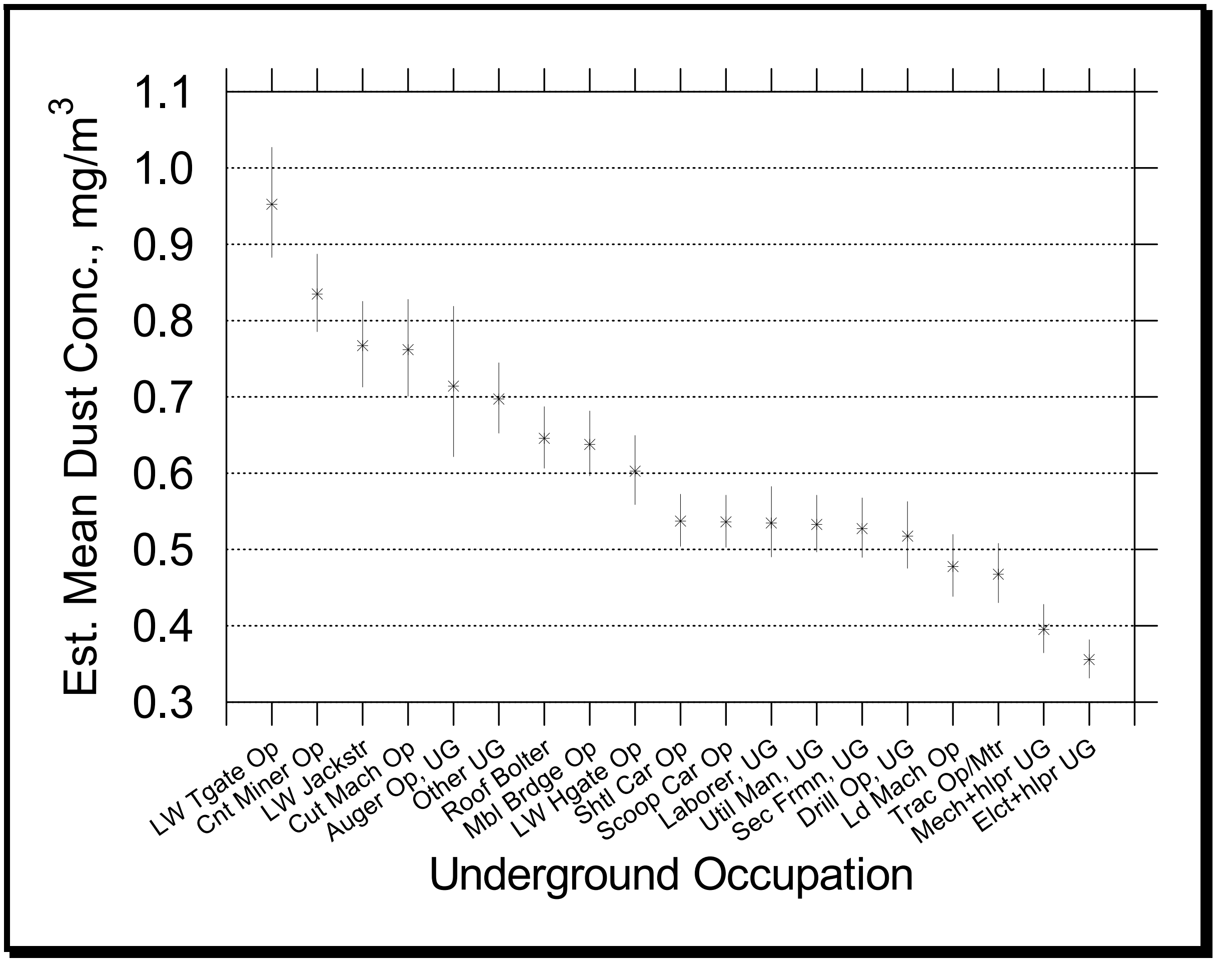

Figure 7. — Estimated mean respirable coal mine dust concentration for underground occupations on shifts sampled by MSHA from 2004–2008. Estimates are adjusted to correct for unbalanced factors at different sampling locations. Vertical line approximates 95-percent confidence interval for the estimated mean.

[21] The ANCOVA in Appendix D(c) identifies statistically significant systematic differences between mines in addition to the differences between work locations.

Table 8. — Examples of work locations showing significantly higher than normal average dust concentrations, based on MSHA samples collected from 2004–2008.

Occupation	Work Location	Number of Samples	Average Dust Concentration (mg/m^3)
Cleaning plant Op	3609210–01	5	1.86
Continuous Miner Op	1518233–03	12	1.99
Cutting Mach Op	1518659–01	9	2.14
Longwall Tailgate Op	1102752–57	10	2.07
Roof Bolter	4609129–02	6	1.84

Table 9. — Percentage of work locations whose average respirable dust concentration exceeded proposed FEL (0.5 mg/m³ for Part-90 Miners, 1.0 mg/m³ for all other occupational categories) on shifts sampled by MSHA inspectors, 2004–2008.

	Occupation	Number of Work Locations	Pct. of WLs with Avg. > FEL	Std. Error of Estimated Pct.	95% LCL	95% UCL
Underground Workers	Auger Op	19	26.3	10.38	4.5	48.1
	Continuous Miner Op	1,782	33.5	1.12	31.3	35.7
	Cutting Mach Op	90	42.2	5.24	31.8	52.6
	Drill Op	110	13.6	3.29	7.1	20.2
	Electrician & helper	653	2.9	0.66	1.6	4.2
	Laborer	207	10.6	2.15	6.4	14.9
	Loading Mach Op	110	0.9	0.91	0.0	2.7
	LW Headgate Op	90	32.2	4.95	22.4	42.1
	LW Jacksetter	88	57.3	5.27	46.8	67.8
	LW Tailgate Op	97	72.2	4.57	63.1	81.2
	Mechanic & helper	342	6.4	1.33	3.8	9.0
	Mobile Bridge Op	194	10.3	2.19	6.0	14.6
	Roof Bolter	1,904	12.9	0.77	11.4	14.4
	Shuttle Car Op	1,663	9.8	0.73	8.4	11.2
	Section Foreman	514	11.1	1.39	8.4	13.8
	Scoop Car Op	1,424	11.2	0.84	9.6	12.9
	Tractor/Motor Op	112	5.4	2.14	1.1	9.6
	Utility Man	741	11.7	1.18	9.4	14.1
	Other UG workers*	811	19.2	1.39	16.5	22.0
Part-90 Miners		110	23.6	4.07	15.6	31.7
Surface Workers	Auger Op	260	2.3	0.93	0.5	4.1
	Backhoe Op	763	0.8	0.32	0.2	1.4
	Bull Dozer Op	2,169	1.0	0.22	0.6	1.4
	Crane/Dragline Op	139	0.7	0.72	0.0	2.1
	Cleaning plant Op	489	5.9	1.07	3.8	8.0
	Drill Op	848	5.8	0.80	4.2	7.4
	Electrician & helper	273	2.9	1.02	0.9	4.9
	Highlift Op/FEL	2,310	0.6	0.17	0.3	1.0
	Laborer	481	2.9	0.77	1.4	4.4
	Mechanic & helper	668	3.9	0.75	2.4	5.4
	Tipple Op	288	3.1	1.03	1.1	5.1
	Truck Driver	1,480	0.7	0.22	0.3	1.2
	Utility Man	916	3.6	0.62	2.4	4.8
	Other Surf. Workers	1,885	2.9	0.38	2.1	3.6

*Includes 51 WLs involving area samples on the return side of a longwall face (occupation codes 60 or 61).

Table 9 shows that under current regulations and enforcement policies, average dust concentration measurements exceed the proposed FEL at a number of work locations in every occupational category. The percentage of WLs in which this occurs ranges from less than one percent for a few surface occupations to more than 70 percent for longwall tailgate operators.[22] Although these percentages are generally greater for underground occupations than for surface, a substantial and statistically significant percentage of even the surface work locations (most notably those associated with cleaning plant operators and surface drill operators) appear to experience average dust concentrations in excess of the proposed FEL. For Part-90 Miners, the measurement average exceeded 0.5 mg/m^3 at more than 20 percent of the work locations.

(ii) Bias corrections: adjusted, supplemented (AS) estimates

As suggested earlier, the exposure estimates used to quantify health risks in this QRA will address one kind of bias evident in the unadjusted MSHA inspector data by assigning equal weights to the mean dust concentration observed at each WL. However, two other known sources of potential bias remain. Although improvements in average dust concentration over the period 2004–2008 were evident for several occupational categories, the rates of improvement differed significantly; and statistically significant increases were even observed for some occupations.[23] Therefore, undue influence of measurements in earlier years constitutes one source of potential bias with respect to estimates of current exposure conditions. Second, there is evidence suggesting that dust concentrations are lower than average on shifts sampled by MSHA inspectors.[24] Therefore, the ANCOVA estimates shown in Figure 7 and Appendix D(c) may exhibit a systematic downward bias.

One way to address these potential biases is to restrict the analysis to 2008 data and to use the mine operators' data to adjust estimates upward when a downward bias in the inspector data is indicated. Furthermore, many WLs were sampled by MSHA only once or twice during 2008, and it is advisable to supplement estimated mean dust concentrations with operator data if available for these WLs. Adjusted, supplemented (AS) estimates, based on adjusted 2008 MSHA data supplemented by 2008 operators' data in some cases, are described below.

Any use of the operators' sampling data to adjust and/or supplement exposure estimates should be exercised with caution. The operators' data contains measurements collected for three distinctly different purposes: *periodic* (bimonthly) measurements routinely collected to monitor exposure levels; *support* measurements, collected after an initial single sample is found to exceed the exposure limit in a designated area or work position; and *abatement* measurements collected to demonstrate compliance with the applicable standard after noncompliance has been cited.[25] A statistical analysis presented in Appendix E shows that, within WLs, abatement measurement

[22] For several occupational categories (e.g., Part-90 miners, longwall tailgate operators, and underground laborers), the percentage of WLs whose average measurement exceeded the proposed FEL (shown in Table 9) is greater than the percentage of individual measurements that exceeded it (shown in Table 6). This happens because most of the measurement distributions within WLs are skewed, so that the mean in a WL may exceed the FEL even when a majority of measurements within that WL do not. Measurement distributions within WLs are discussed in Appendix G.

[23] Much, if not all, of these changes are attributable to flux in the WL population, rather than change within WLs.

[24] See MSHA, 1993. Also, anecdotal evidence was presented in oral testimony at the public hearings on proposed coal mine dust regulations held in August, 2000 and May, 2003.

[25] The datafile codes corresponding to these categories are laid out in Table 31 of Appendix A.

averages are significantly lower than the corresponding averages of periodic and support measurements. Accordingly, abatement measurements will not be used in forming the AS estimates.

Appendix E also shows that, for both continuous miner operators and roof bolters (the job categories most commonly sampled by mine operators), even the periodic operator samples yielded lower average concentration measurements (within WLs) than the corresponding MSHA samples.[26] To make efficient use of the operator data without introducing additional biases, AS estimates of current average exposure conditions at each WL are constructed according to the following procedure:

- The AS estimates utilize 2008 samples exclusively.
- Each sample is weighted so that every sampled WL receives the same weight, regardless of how many samples were collected at that WL. As explained earlier, this is necessary in order to avoid bias due to MSHA's collecting disproportionately more samples at dustier locations. Weighting the samples in this manner is equivalent to calculating, for each job-category, the mean dust concentration observed within each WL and then averaging the WL means to obtain a "grand mean" for the job-category under consideration.
- Within each WL and job-category, if there are fewer than two MSHA samples, or the MSHA measurement average is less than the operator average, then the combination of MSHA and operator samples is used for that WL and job category. Otherwise, only MSHA's samples are used. The intention is to obtain a reasonably unbiased estimate of the mean RCMD concentration across *all* shifts and not just those on which work practices may have been modified in the presence of an MSHA inspector.
- Within each WL and job-category, if the average of those dust concentration measurements exceeding the proposed FEL is greater for operator samples alone than for the combination of operator and MSHA samples, then the estimate of current average exposure for that WL and job category is increased to reflect this difference. This adjustment is motivated by the evidence, mentioned earlier, suggesting that, at some WLs, excessive RCMD concentrations are temporarily reduced in the presence of an MSHA inspector.

Appendix F contains a more mathematically precise formulation of the foregoing procedure. The emphasis on upward adjustments (in the third and fourth bullets) is intended to compensate for a downward bias in operator measurements as documented in Appendix E, MSHA (1996), and miners' testimony at public hearings on proposed coal mine dust regulations held in August, 2000 and May, 2003. MSHA's current policy of enforcing the applicable standard based on an operator's average of five consecutive production shifts, rather than the dust concentration measured by the operator on any individual shift, enables operators to dilute the average with abnormally low measurements.[27]

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[26] For longwall jacksetters, the analysis in Appendix E found the operators' average measurements within WLs to be slightly higher than the corresponding MSHA averages. This agrees with the finding in MSHA (1993) that, at longwall face areas, the average dust concentration experienced by the designated occupation on shifts sampled by mine operators tends to exceed the corresponding average on shifts sampled by MSHA. The MSHA (1993) report also found that, at longwall face areas, production on shifts sampled by MSHA tends to fall below production on shifts sampled by mine operators.

[27] The effects of varying production (raw tonnage) on dust concentrations within WLs was investigated using the mine operators' 2008 data for continuous miner operators and longwall tailgate operators. For both occupations, the

(iii) Comparison of ANCOVA and AS occupational exposure estimates

Figure 8 and Figure 9 compare the underground and surface AS exposure estimates with the 2004–2008 ANCOVA estimates shown in Table 40 and Table 42. The AS estimates are lower for a few occupations, but this can be attributed to improvements in 2008 as compared to previous years. In its peer review of this QRA, OSHA suggested that, for several reasons, it would be preferable to rely more heavily on the five-year MSHA inspector data, as reflected by the ANCOVA estimates, than on the AS estimates. [28] This suggestion, however, ignores indications from the operator data that inspector measurements have been biased downwards at some WLs — i.e., WLs at which RCMD concentrations on shifts sampled by an MSHA inspector tend to be lower than on non-abatement shifts sampled by the mine operator. On balance, MSHA believes that it is more prudent to utilize the most recent inspector data and to adjust and/or supplement that data with operator measurements in such cases. Therefore, in the second part of this QRA, MSHA will evaluate health risks based on the generally higher AS estimates of current RCMD exposures. Also, as Part 2 will explain, the occupational averages will be broken down into narrower groups of WLs. This will help avoid glossing over those WLs that present the highest risk, such as those identified in Table 8 and Table 9.

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statistical analysis showed a small but statistically significant effect of production on respirable coal mine dust concentrations. Details of the two ANCOVAs used in this analysis are provided in Appendix G(a).

[28] The OSHA review recommended that, instead of adjusting and supplementing inspector data with operator data, "the QRA rely, as much as possible, on the five year MSHA inspector samples to determine the job-specific exposure estimates for risk characterization." The main reasons given for this recommendation were (1) that for most occupations (22 of 33) there was no statistically significant change in RCMD concentrations measured by MSHA over the five-year period and therefore no need to restrict the estimation procedure to only the most recent year; (2) that the AS estimates are overly complex and are therefore not amenable to the calculation of confidence intervals; and (3) that the introduction of operator samples in the AS estimates may introduce unintended biases.

First, although Table 6 shows a statistically significant time trend (probability greater than 98 percent) for only 11 of 33 occupational categories, the ANCOVA documented in Appendix D(c) detected a statistically significant time trend cutting across all occupations. (See the entry for "Sampling Date" (D_l in the ANCOVA model) in Table 39 and Table 41.) Within most of the individual occupational categories, the effect is not sufficiently pronounced to meet the criterion for statistical significance used in Table 6. However, a high level of statistical significance ($p<0.001$) is apparent when all occupations are considered simultaneously. Furthermore, an insufficient number of MSHA samples in 2008 is not the only factor motivating the use of operator samples to adjust and/or supplement MSHA's measurements. As shown above in the third and fourth bullets outlining the AS estimation procedure, operator samples are used to identify and modify likely under-estimates of normal exposure at specific WLs.

Second, it is true that calculating confidence intervals is far simpler for the ANCOVA estimates than for the AS estimates (see Figure 7). However, MSHA believes that its inspector measurements systematically underestimate normal exposure at some WLs and that the AS estimation procedure works toward correcting this bias. If MSHA is correct in this belief, then OSHA's emphasis on confidence intervals is misplaced. For purposes of providing the best available estimates of current exposure levels, it is better to rely on an unbiased estimate whose uncertainty is left un-quantified than on a biased estimate whose calculated confidence interval is biased by an equal amount. Although reasonable confidence intervals for the AS estimates could theoretically be calculated using an elaborate bootstrap method, MSHA believes that the marginal benefit of quantifying uncertainty in the AS estimates would not justify the required cost in time and resources.

Third, MSHA recognizes that the AS estimates may be biased relative to mean exposure levels measured on those shifts sampled by MSHA inspectors. Indeed, this is reflected by the generally higher values shown for the AS estimates, as compared to the ANCOVA estimates, in Figure 8 and Figure 9. However, the objective is to obtain the best possible estimate of mean exposure across *all* shifts, and not just those that are sampled by an MSHA inspector. Accordingly, MSHA believes that its use of operator data in the AS estimation procedure as applied to specific WLs serves, on balance, to reduce rather than increase the potential for overall bias.

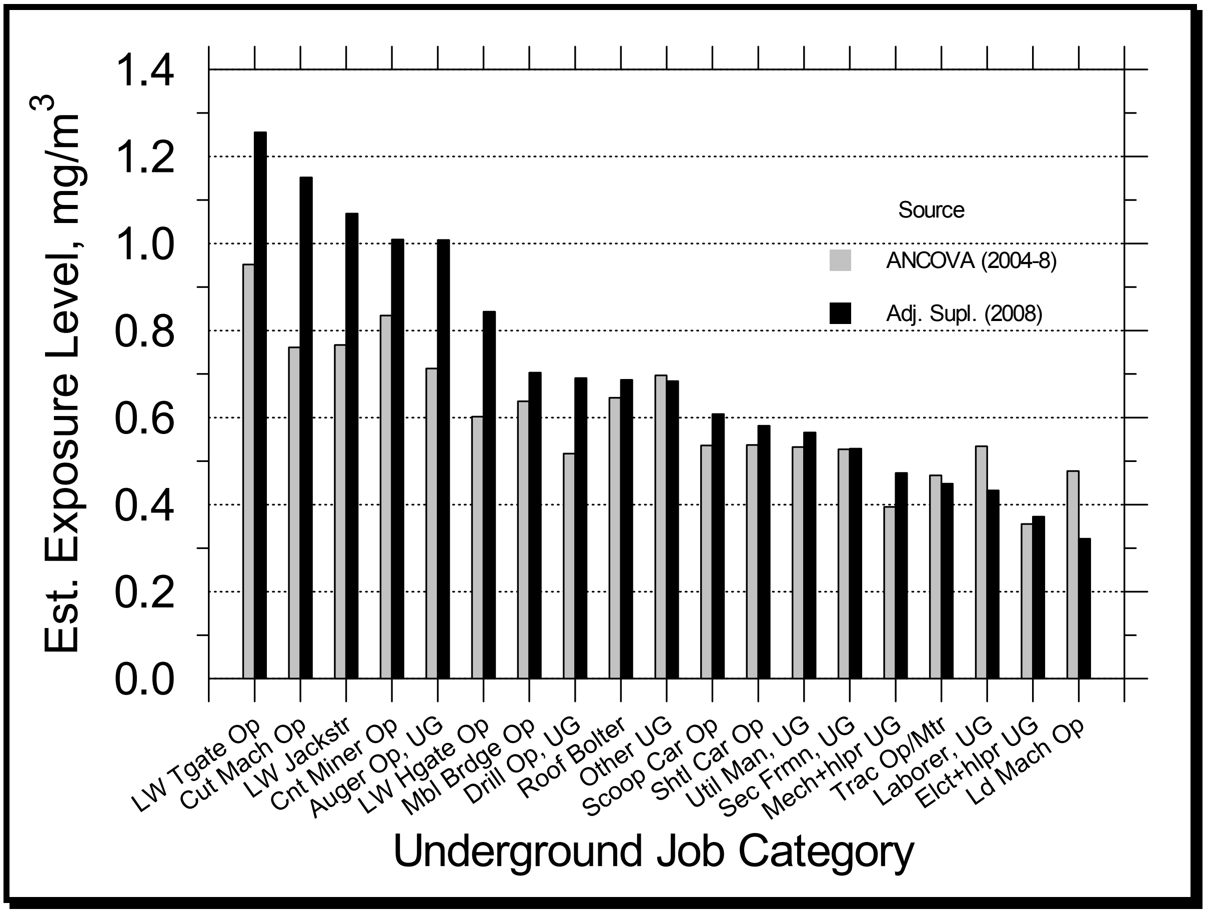

Figure 8. — Underground respirable dust exposure levels aggregated by occupation, as estimated from ANCOVA (2004–2008 MSHA inspector data) or from Adjusted and Supplemented (AS) estimation procedure (2008 MSHA inspector data supplemented by 2008 mine operator data). Health risks in this QRA are evaluated based on the AS estimates.

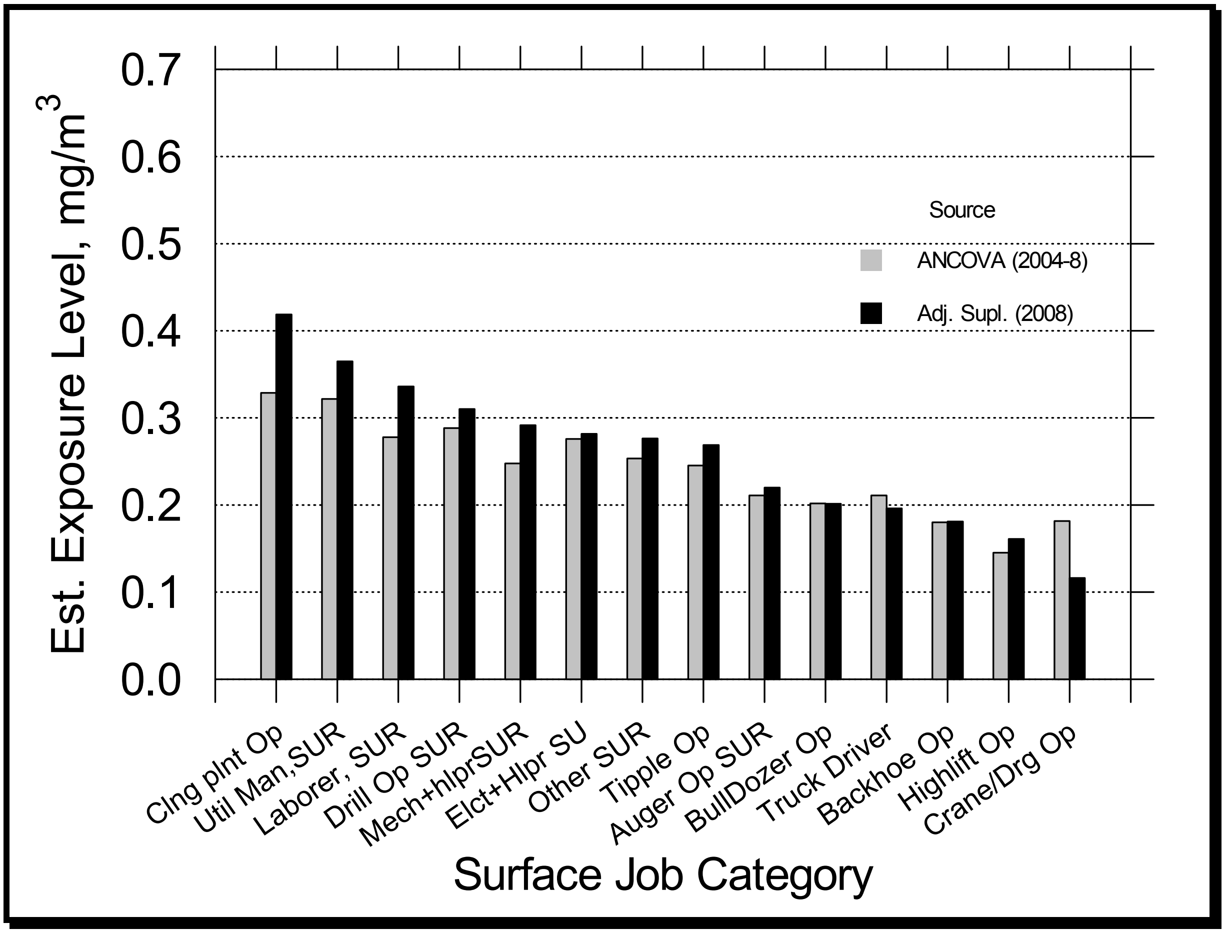

Figure 9. — Surface respirable dust exposure levels aggregated by occupation, as estimated from ANCOVA (2004–2008 MSHA inspector data) or from Adjusted and Supplemented (AS) estimation procedure (2008 MSHA inspector data supplemented by 2008 mine operator data). Health risks in this QRA are evaluated based on the AS estimates.

(d) Health Effects and Material Impairments under Current Conditions

In 1995, NIOSH issued a Criteria Document (NCD) for a recommended coal mine dust standard. After reviewing the relevant epidemiologic literature available at that time, the NCD presented the following conclusion:

> Exposure-response studies of coal miners in the United States … indicate that miners exposed to respirable coal mine dust for a working lifetime at the current U.S. standard of 2 mg/m^3 have a substantial risk of developing simple CWP and PMF … PMF has been associated with impaired lung function, disability, and early death… [M]iners may also develop severe decrements in lung function as a result of their exposures to respirable coal mine dust — whether or not pneumoconiosis is present. [(NIOSH, 1995, p. 110]

Section IV of the NPRM contains a comprehensive review of the scientific literature involving health effects associated with RCMD exposures, including literature that does not specifically pertain to exposure-response relationships. The objective in this portion of the QRA is to assess risks associated with actual current exposure levels. Figure 8 and Figure 9 suggest that, on average, miners in every occupational category are currently exposed to RCMD at levels falling well below the existing 2.0 mg/m^3 standard. Therefore, this subsection of the QRA summarizes the quantitative evidence that an occupational lifetime of exposure at the average levels displayed in Figure 8 and Figure 9 can lead to material impairments of a miner's health or functional capacity. Part 2 of the QRA quantifies the risks currently presented to miners in greater detail.

In accordance with the NCD, this QRA accepts the assumption implicit in published exposure-response relationships that health risks associated with RCMD exposures are a function purely of cumulative exposure, regardless of any peaks and valleys in the intensity of dust concentrations that have been experienced over time. In the absence of data differentiating the inhalation rates of individual miners, cumulative exposure is expressed in units of $mg \cdot yr/m^3$. As stated in the NCD:

> … the exposure-related risk of a given disease is assumed to be equal among miners exposed to 2 mg/m^3 for 20 years (i.e., 40 $mg \cdot yr/m^3$) and for miners exposed to 1 mg/m^3 for 40 years (also 40 $mg \cdot yr/m^3$). Evidence suggests that this is a reasonable assumption provided the duration of exposure has been sufficient… — usually considered to be 10 or more years… [NCD, p 127]

It follows from this assumption that the *mean*, rather than *median*, of dust concentrations experienced by a miner is the appropriate measure of exposure intensity to be used in calculating cumulative exposure. Total cumulative exposure is the product of exposure duration and mean exposure intensity, not typical, or median, intensity.[29]

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[29] The distributional forms of MSHA's RCMD measurements are shown (on a logarithmic scale) in Appendix D(a), and the shape of dust concentration distributions within WLs is addressed in Appendix G(b). A pair of respondents to MSHA's July 7, 2000 NPRM argued that the distribution of dust concentrations is likely to be skewed and would, therefore, be better represented by its median than by its mean. Likewise, in its peer review of the QRA, OSHA stated that the focus on the arithmetic mean, as opposed to the "median or geometric mean as the appropriate measure of central tendency …should be further explained in the context of the expected distribution in exposure measurements." Although Appendix D(a) and Appendix G(b) confirm that the exposure distributions are generally skewed, the most appropriate measure of central tendency is not what is at issue here. The lifetime accumulated RCMD dose, which is the predictor variable used in all published exposure-response models involving RCMD exposures, is *always* the product of exposure duration and *mean* exposure duration, irrespective of the expected distribution in exposure measurements.

i) Pneumoconiosis (CWP, including PMF)

For the risk of pneumoconiosis, the QRA relies on the most recent exposure-response analyses cited in the NCD. This study (Attfield and Seixas, 1995) still provides the best available estimates of CWP risks as they relate to RCMD conditions experienced by U.S. coal miners. The study is based on radiographs and exposure histories obtained for 3,194 bituminous miners and ex-miners who were no older than 58 years in 1985. Cumulative RCMD exposures utilized in the study "…ranged from 0 to 211 mg-yr/m^3, with 75% lying between 13 and 41 mg-yr/m^3, the mean and [standard deviation] being 34 and 32 mg-yr/m^3." (op. cit., p. 142) Under the assumption of a 45-year occupational lifetime with an average number of hours worked per year equal to that for miners in the study, the stated mean corresponds to an average RCMD concentration of 0.76 mg/m^3, the 75% range corresponds to RCMD concentrations falling between 0.29 and 0.91 mg/m^3, and the stated maximum corresponds to an average lifetime RCMD exposure level of 4.69 mg/m^3.

Attfield and Seixas used the median category assigned by three specially selected B readers to identify the profusion of opacities based on the ILO classification scheme and applied logistic regression models to estimate risk for three outcome categories.[30] The most inclusive category used in their report is CWP 1+, which includes all cases of simple CWP (ILO categories 1, 2, and 3) as well as PMF. The second category, CWP 2+, consists of CWP1+ without the ILO category 1 cases. The third category is PMF, denoting all cases of large opacities (ILO categories A, B, or C). The logistic regressions model the risk of CWP 1+, CWP 2+, or PMF as a function of a miner's age, accumulated coal mine dust exposure, and the "rank" of coal to which the miner was exposed.[31] Since the models show risk increasing with age, that portion of the risk attributable to the accumulated exposure is obtained by calculating the difference in risk calculated with and without the exposure. The attributable risk can be expressed as ***e****xcess* **c**ases of disease **p**er **t**housand exposed miners (ECPT). Appendix I contains a technical description of the Attfield-Seixas models and an explanation of how they were applied to obtain estimates of CWP risk attributable to coal mine dust exposure at a specified level.

Figure 10 and Figure 11 depict the Attfield-Seixas exposure-response relationships at average dust concentrations below the current limit of 2.0 mg/m^3. Figure 10 shows the estimated excess risks of CWP 1+, CWP 2+, and PMF presented to miners of age 65 or 73 years, after 45 years of occupational exposure at low or medium rank bituminous coal mines. Figure 11 pro-

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[30] For 162 of the 3,194 miners, one of the three readers said the radiograph was unreadable, and the higher of the two remaining assignments was used as the summary determination.

[31] Coal rank is a measure of the coal's carbon content. In the Attfield-Seixas study, geographic location was used as a proxy measure of coal rank. Therefore, some part of the effect attributed to coal rank may, in fact, be due to other regional differences, such as diet and ambient air pollution.

In its review of this QRA, OSHA noted that "the Attfield-Seixas regression model does not appear to account for the effects of cigarette smoking" and recommended that the reasons for this be explained. Attfield and Seixas did, in fact, investigate and reject the hypothesis of a smoking effect. In their report, Attfield and Seixas noted that "smoking has not [previously] been found to modify the effect of dust in relation to CWP incidence" but acknowledged "the possibility that it may be a confounding variable…" They further noted that "[t]his might mean that the age effect … is really due, in part or totally, to smoking." To test this possibility, they compared their results with the results of a logistic regression in which age was replaced by lifetime accumulated cigarette pack-years (based on a personal questionnaire). According to the authors, "[t]he results showed that pack-years contributed substantially less to the model than age …, a result that does not support a link with smoking in these data." (Attfield and Seixas, 1995, p. 148) vides the same information for miners exposed to high rank bituminous coal. Since occupational exposures are assumed to cease at age 65, the significantly higher risk shown for all CWP categories at age 73 may reflect a latent effect of coal particle deposition in the lungs.[32]

As suggested by the difference in vertical scale for Figures 10 and 11, Attfield and Seixas found the effect of exposure to be significantly elevated at high rank coal mines. For example, given a 45-year average concentration of 1.5 mg/m^3, high rank bituminous coal is, at age 73 years, associated with approximately four times the excess risk of PMF as low rank coal (200 ECPT as compared to 50 ECPT). The Attfield and Seixas study did not include miners exposed to anthracite, which is of higher rank than bituminous coal, or to lignite, which is of lower rank.

The Attfield-Seixas exposure–response models predict significant excess risk of both simple CWP and PMF at current exposure levels. For 45-year exposures to low or medium rank dust concentrations between 0.5 mg/m^3 and 1.2 mg/m^3 (a span that covers nearly all occupational estimates shown in Figure 8), the expected excess prevalence of CWP2+ at age 73 ranges from at least 20 ECPT to about 70 ECPT. For high rank coal, the corresponding excess risk runs from about 50 to 190 ECPT. Moreover, increased exposures may result in disproportionately high increases in excess risk. For example, a fifty-percent increase in average high rank RCMD concentration, from 1.0 mg/m^3 to 1.5 mg/m^3, doubles the excess risk of PMF at age 73 — from about 100 ECPT to about 200 ECPT. This is important since, as discussed earlier in connection with Table 9, average dust concentrations at many individual WLs exceed the proposed FEL, even though occupational averages (aggregated across all WLs) may not.

[32] Some support is given to this interpretation by evidence of a significant 15-year lagged exposure effect in CWP mortality (Miller et al, 2007), discussed below. However, as Attfield and Seixas point out, "[t]he significant age term in the models has various interpretations, and may be the combined manifestation of several effects." (See Attfield and Seixas, 1995, pp 147-8.)

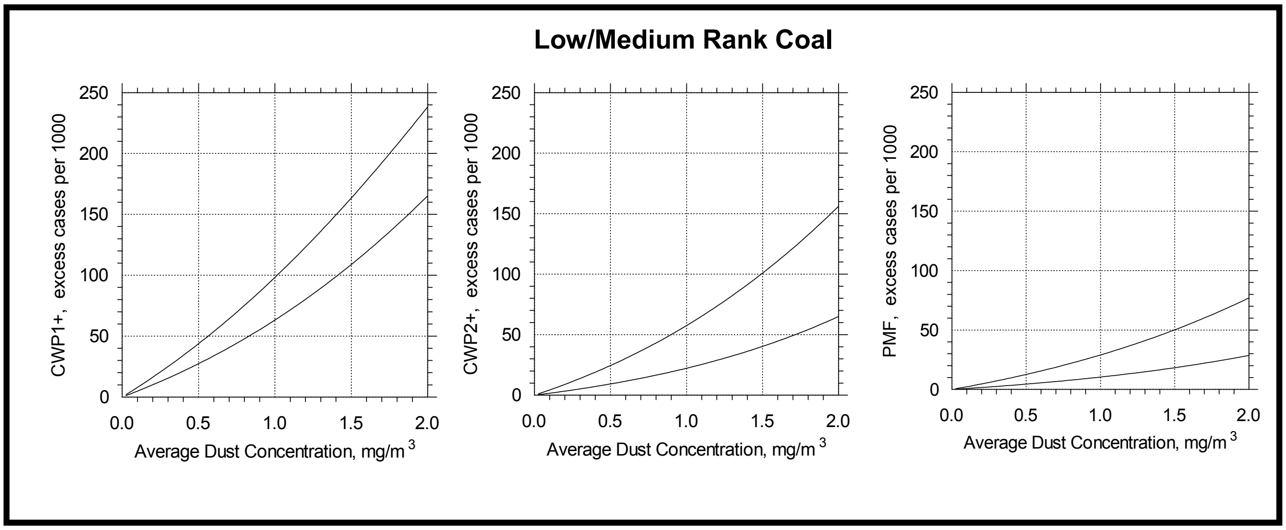

Figure 10. — Estimated relationship between average respirable coal mine dust concentration experienced over a 45-year working lifetime and excess risk of CWP1+, CWP2+, and PMF for workers at low and medium rank U.S. bituminous coal mines. Upper and lower curves are for 73 and 65 year-old miners, respectively.

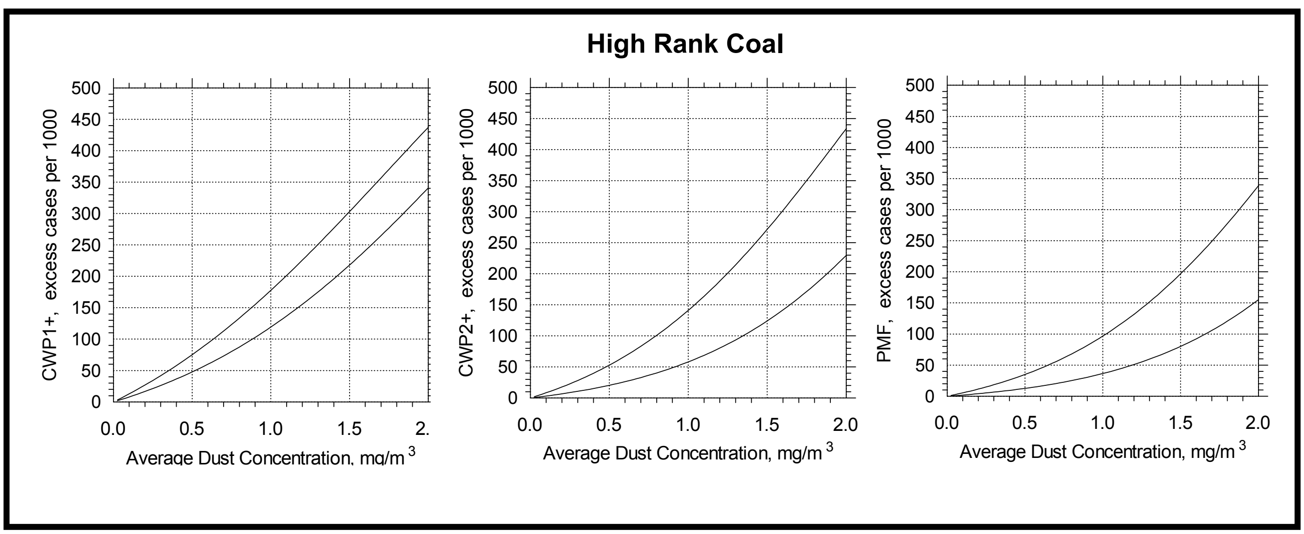

Figure 11. — Estimated relationship between average respirable coal mine dust concentration experienced over a 45-year working lifetime and excess risk of CWP1+, CWP2+, and PMF for workers at high rank U.S. bituminous coal mines. Upper and lower curves are for 73 and 65 year-old miners, respectively.

CWP has long been recognized as a progressive disease, and miners progressing to the PMF stage qualify as totally disabled due to pneumoconiosis under the Department of Labor's criteria set forth at (20 CFR 718.304(a)). Simple CWP is "…an important risk factor for the development of PMF… and risk increases with increasing [ILO] category of small opacity profusion on the radiograph." (Attfield et al., 2007). Furthermore, there is evidence that the progression may continue even after exposure ceases:

> Bates [Bates et al., 1985] noted that x-rays taken at retirement and then again 10 years later showed fewer normal readings and an increase over time of simple and complicated pneumoconiosis. These data show that, unlike the inflammatory process caused by tobacco smoke, the effects of mineral dust retained in the lungs may continue even after the worker is removed from exposure. [Cohen et al., 2008]

Therefore, the development of simple CWP, as detected on radiographs, poses a significant risk to miners of eventually contracting complicated CWP or PMF.

Two earlier investigations of the relationship between coal mine dust exposure and death from pneumoconiosis have recently been updated to include extended follow-up periods for the original cohorts. Miller et al. (2007) analyzed cause-specific mortality for a cohort of 17,820 British miners drawn from 10 collieries, whose exposures occurred between 1950 and the early 1980s, with a 56-year follow-up period. There were 10,917 deaths in this cohort by the end of follow-up in 2006. Among 15,049 miners for whom RCMD exposures were obtained, the mean cumulative RCMD exposure was 131.4 g-hr/m^3 (Std. Dev. = 118.9) with the central 50 percent (inter-quartile range) of cumulative exposures falling between 33.2 and 200.1 g-hr/m^3 (Op. Cit., Table 4.9) Assuming a 45-year occupational lifetime at an average of 1,920 exposed hours per year, the reported mean exposure corresponds to an average RCMD concentration of 1.5 mg/m^3, and the inter-quartile range corresponds to RCMD concentrations ranging from 0.4 mg/m^3 to 2.3 mg/m^3. Likewise, Attfield and Kuempel (2008) analyzed cause-specific mortality in a cohort of 8,899 coal miners who participated in medical examinations at 31 widely distributed U.S. mines, with follow-up extended to an average of 23 years. The mean cumulative RCMD exposure reported for this cohort was 64.4 mg-yr/m^3 (Std. Dev. = 46.4), and the mean tenure as a miner was 20.7 years. (Op.Cit., Table II. The range of exposures experienced by miners in the cohort was not reported.) Under the assumption of a 45-year occupational lifetime with an average number of hours worked per year equal to that for miners in the study, the reported mean exposure corresponds to an average RCMD concentration of 1.4 mg/m^3. 3,213 members of the U.S. cohort had died by the end of follow-up in 1993.

Both of these studies applied Cox proportional hazard multiple regression models to estimate the relationship between cumulative coal mine dust exposures and the relative risk of death due to pneumoconiosis, after adjustment for other factors such as age and smoking habits. In both studies, a statistically significant relationship was found between cumulative coal mine dust exposure and the relative risk (RR) of death due to pneumoconiosis. Figure 12 displays these relationships as a function of average dust concentration experienced over a miner's 45-year working history.[33] In the British exposure-response model (denoted P/11), the effect of accumulated

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[33] The graphs in Figure 12 are based on information from Table X in Attfield and Kuempel (2008) and Table 5.9 in Miller et al. (2007). Table X of Attfield and Kuempel, 2008, shows RR = $\exp(0.0087 \times CDE_0)$, where CDE_0 is unlagged cumulative dust exposure. In this QRA, the P/11 model was selected from among the 12 alternatives in Tables 5.8 and 5.9 of the Miller report because it appears to best fit the data, as indicated by the log-likelihood listed for each alternative. (The very slight improvement in log-likelihood for Model P/12 does not appear to justify utilization of an additional explanatory variable.) To convert exposure units used in the British analysis (g-hr/m^3) to mg-

exposure is lagged by 15 years, so that the RR continues to increase for 15 years after occupational exposure ceases at the assumed retirement age of 65 years. Therefore, Figure 12 contains separate P/11 exposure-response charts for RR at ages 65, 73, and 80. The Attfield/Kuempel chart, which depends on un-lagged cumulative exposure, is most similar to the P/11 model at age 73.

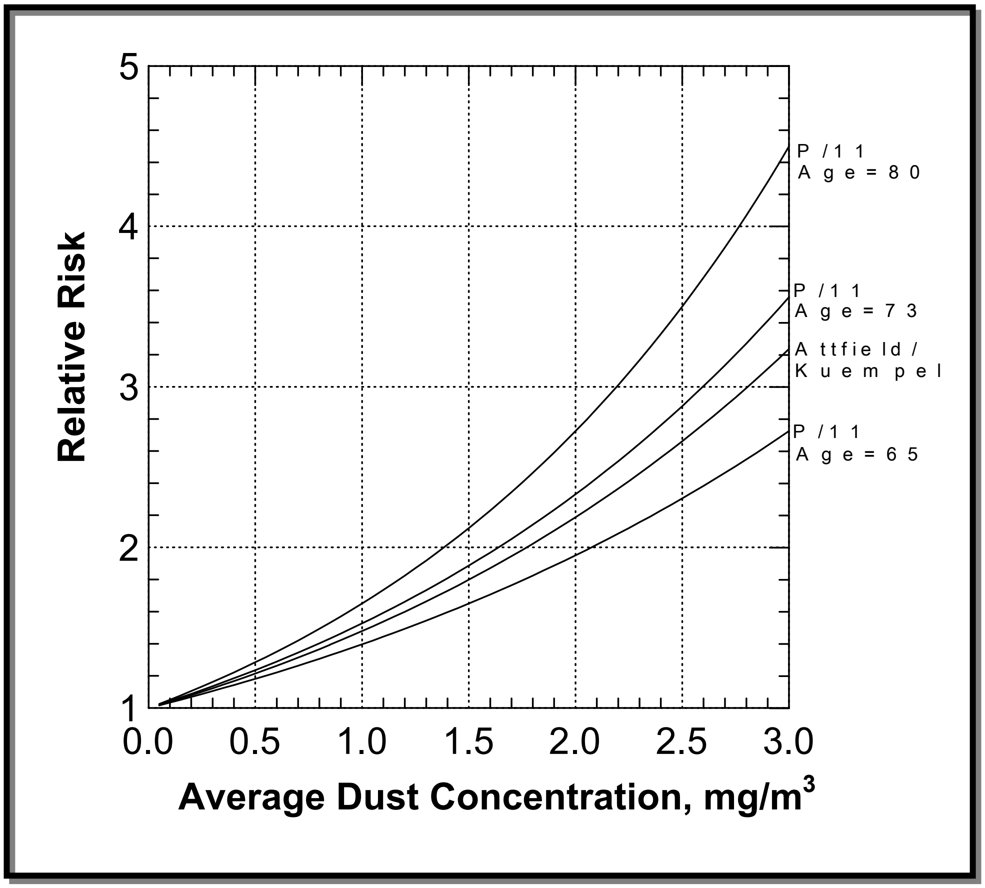

Figure 12. — Estimated relationship between average coal mine dust concentration experienced over a 45-year working lifetime and Relative Risk for death due to pneumoconiosis. Attfield/Kuempel model is based on cohort mortality among U.S. coal miners and relates to un-lagged cumulative dust exposure. P/11 model is based on cohort mortality among British coal miners and relates to cumulative dust exposure lagged by 15 years.

For dust concentrations spanning current underground occupational averages (roughly 0.5 mg/m^3 to 1.2 mg/m^3), Figure 12 shows relative pneumoconiosis mortality risks ranging from at least 1.2 to about 1.6 or 1.7, using the Attfield-Kuempel or P/11 (at age 73) models. These rela-

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yr/m^3, the coefficient was divided by 1000 mg/g and it was assumed that U.S. miners are exposed for an average of 1920 hours per year. Using this conversion, Model P/11 shows $RR = \exp(0.0058 \times 1.920 \times CDE_{15})$, where CDE_{15} is cumulative dust exposure ($mg \cdot yr/m^3$) lagged by 15 years.

tive risks represent an expected 20 to 70-percent increase in pneumoconiosis mortality, attributable to the exposure.

ii) Reduced Lung Function and Chronic Obstructive Pulmonary Disease (COPD)

The NCD identified FEV_1 less than 80 percent of the predicted normal value as representing a clinically important deficit, and FEV_1 less than 65 percent of the predicted normal value as indicating the presence of severe respiratory disease. Using these thresholds to define dichotomous outcomes, Table 7-3 of the NCD contains estimates of the excess prevalence of reduced lung function at 45-year average dust concentrations of 0.5 mg/m^3, 1.0 mg/m^3, and 2.0 mg/m^3. The NCD points out that "…even at a mean concentration of 0.5 mg/m^3, miners have a [greater than] 1/1,000 risk of developing these conditions" and notes that a 1/1000 risk "was defined as significant by the U.S. Supreme Court in the 1980 benzene decision."

In a review of evidence of a causal link between coal mining and COPD, Coggan and Taylor (1998) summarized the quantitative relationships between cumulative coal mine dust exposure and reductions in FEV_1 reported in epidemiologic studies available at that time. They expressed these relationships in terms of the expected volume (ml) of air lost per g·hr/m^3 of exposure. Their summary is reproduced here as Table 10.[34]

Table 10. — Estimated reductions in FEV_1 per gh/m^3 of accumulated exposure to coal mine dust. (Reproduced from Table 1 of Coggan and Taylor, 1998.)

Study	*Type of analysis*	*Notes*	*Reductions in FEV_1 (ml per ghm^{-3})*
Rogan *et al* (1973)[7]	Cross-sectional	Current miners	0.6
Love and Miller (1982)[8]	Longitudinal	Extra loss over 11 years in relation to previous dust exposure	0.36
Attfield (1985)[14]	Longitudinal	Extra loss over 11 years in relation to concurrent dust exposure	*1.6
Soutar and Hurley (1986)[9]	Cross-sectional	Current and ex-miners	0.76
Attfield and Hodous (1992)[15]	Cross-sectional	White males aged 25+ years	0.69
Seixas *et al* (1992)[16]	Cross-sectional	Miners who started work in or after 1970	*3.4
Seixas *et al* (1993)[17]	Longitudinal	Miners who started work in or after 1970. Extra loss over 11 years in relation to previous dust exposure	*−4.8
		Miners who started work in or after 1970. Extra loss over 11 years in relation to concurrent dust exposure	*−1.8
Soutar *et al* (1993)[11]	Cross-sectional	South Wales	1.04
		Yorkshire	0.08
		NE England	−0.28
Henneberger and Attfield (1996)[18]	Longitudinal	Miners who worked before 1970. Extra loss over 11 years in relation to previous dust exposure	*0.48
		Miners who worked before1970. Extra loss over 11 years in relation to concurrent dust exposure	*−1.3
Carta *et al* (1996)[20]	Longitudinal	Extra loss over 11 years in relation to previous dust exposure	*−9.6
		Extra loss over 11 years in relation to concurrent dust exposure	*4.8

*Calculated by us from the published results with the assumption that a miner works for 1600 hours per year.

The authors noted that

> …the steepness of the decline in FEV_1 with a given exposure has varied between studies. …One reason for this variation is likely to be differences in the impact of biases, such as from inaccurate exposure assessment, but other factors may also contribute… On theoretical grounds, the study by Soutar and Hurley is probably the most reliable of the cross-sectional analyses. It uses the best da-

[34] To convert the coefficients of accumulated exposure shown in Table 10 for use with exposures expressed in units of mg·yr/m^3, they should be multiplied by 1920 hr/yr and divided by 1000 mg/g.

> ta on exposure and includes both current and ex-miners… …the results of the longitudinal studies are … generally compatible with Soutar and Hurley's estimate… In the absence of further empirical data, it seems reasonable Soutar and Hurley's figure of 0.76 ml per g·hr/m^3 [i.e., 1.5 ml per mg·yr/m^3, assuming 1920 exposure hours per year] as a best estimate of the average loss of FEV from dust exposure in coal miners. [Coggan and Taylor, 1998]

Relative to the general lack of agreement, the Soutar/Hurley estimate does not differ much from that of Attfield and Hodous.

Figure 13 expresses the Soutar/Hurley estimate as the slope of a line showing the expected reduction in FEV_1 as a function of the average dust concentration experienced over the course of a 45-year occupational history. [35] One disadvantage of summarizing research findings in this way is that the *average* reduction in FEV_1 fails to reveal the risk of reductions that exceed the average by a clinically significant amount. Dust exposure at a given level may affect susceptible individuals to a far greater extent than what is suggested by the average effect. This issue is directly addressed when, as in the NCD, findings are expressed in terms of the prevalence of clinically significant outcomes. Similarly, averaging exposure over an occupational lifetime can mask important aspects of the health effect. For example, as noted by Cohen et al. (2008), "The decline in lung function associated with coal mine dust exposure is not linear. Studies of U.S. and Italian miners [3 citations provided] showed abrupt dust-associated declines in lung function early in the worker's mining tenure." Also, their remark, cited above in connection with CWP, that "…the effects of mineral dust retained in the lungs may continue even after the worker is removed from exposure" refers not only to CWP but also to progressive lung function impairment.

[35] As explained in Footnote 34, the reduction in FEV_1 is plotted as $0.76 \times 1920 \times 45 \times$ (Avg. Dust Conc.)/1000.

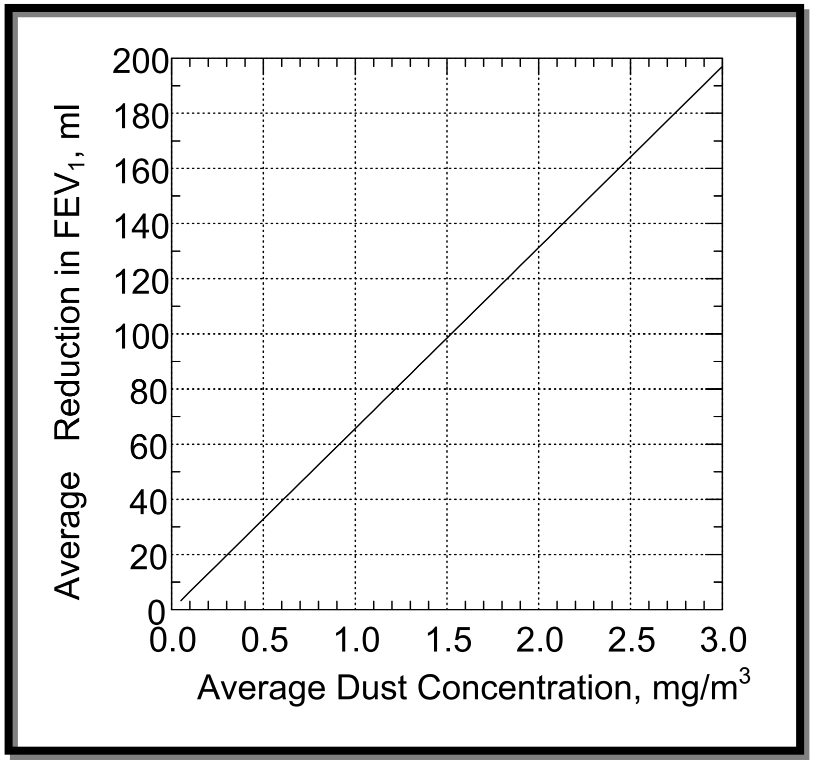

Figure 13. — Estimated relationship between average coal mine dust concentration experienced over a 45-year working lifetime and predicted average reduction in FEV_1 according to Soutar/Hurley (1986) analysis

The weight of evidence from studies published subsequent to the NCD supports the theory that coal mine dust exposure can cause a decrement in lung function that is independent of any CWP. Citing Cowie et al.(1999), Soutar et al. (2004) concluded that [t]he lung function of miners can be affected adversely by dust exposure, irrespective of the presence of pneumoconiosis." Naidoo et al. (2004) reported a statistically significant average decrement of 0.03 percent of the predicted normal FEV_1 value per mg·yr/m^3 among 667 current miners with no radiological evidence of CWP. The authors stated that their results also support earlier research showing significant relationships between coal mine dust exposure and decline in lung function "among those with CWP in the absence of PMF." (Naidoo et al., 2004, p. 479)

Kuempel et al. (2009(a)) explored the relationship between reduced lung function and cumulative coal mine dust exposure in a group of 616 deceased coal miners and 106 deceased non-miners who died during 1957-1978. Among the coal miners, the mean cumulative RCMD exposure was 103 mg-yr/m^3 (Std. Dev. = 40.6), the mean tenure as a miner was 34.3 years (Std. Dev. = 10), and the mean age at death was 66.2 years (Std. Dev. = 10.2). (Kuempel et al., 2009(b), Table 1. The range of RCMD exposures was not reported.) Under the assumption of a 45-year occupational lifetime with an average number of hours worked per year equal to that for miners in the study, the reported mean exposure corresponds to an average RCMD concentration of 2.3 mg/m^3. All group members were autopsied and assigned a standardized index of emphysema severity based on pathologists' examinations of lung sections. FEV_1 measurements made prior to death were available for 116 members of the group, and these were used to establish a relationship between FEV_1 and the emphysema severity index. Other factors considered included cigarette smoking history, age at death, and race.

Based on a regression analysis (n=116), the investigators established values of the emphysema severity index corresponding, on average, to FEV_1 = 80% and FEV_1 = 65% of predicted normal values. As in the NCD, these two thresholds were specified as marking clinically important pulmonary impairment (at FEV_1 < 80%) and severe respiratory disease (FEV_1 < 65%). Using the corresponding threshold values of the emphysema index as proxies,[36] the investigators then applied logistic regression models to estimate the risks of these two outcomes as a function of the various factors considered. (Kuempel et al., 2009(a)) Accumulated coal mine dust exposure, accumulated cigarette smoking (packs/day × years), age at death, and race were all found to be statistically significant predictors of either risk. As with the logistic models used for CWP, that portion of the risk attributable to a specified level of dust exposure may be estimated by subtracting the predicted risk without any exposure from the predicted risk with the exposure. Appendix J contains a technical description of the Kuempel pulmonary impairment exposure-response model and an explanation of how it was applied to estimate the excess risk of severe respiratory disease attributable to coal mine dust exposure at a specified level.

To simplify terminology, the remainder of this QRA sometimes refers to emphysema severity corresponding to FEV_1 < 65% of predicted normal values as *severe emphysema*. Figure 14 plots the risk of severe emphysema attributable to dust exposure (excess cases per thousand exposed miners) against average coal mine dust concentration experienced over a 45-year occupational lifetime. For simplicity, the exposure-response curves shown are restricted to "whites" with no history of cigarette smoking.[37]

According to this model, the effect of dust exposure increases with age. After a 45-year exposure averaging 1.0 mg/m^3, the excess risk of severe emphysema is predicted to be 50 excess cases per thousand (ECPT) for 65-year-old miners and 72 ECPT for 80-year-olds.[38] At higher exposure levels, the effects of age differences are even more pronounced.

Figure 14 shows higher exposure levels giving rise to disproportionate increases in excess risk. Doubling the average dust concentration, for example from 0.6 mg/m^3 to 1.2 mg/m^3, more than doubles the predicted excess risk for 73-year-olds: it increases from about 34 ECPT to about 76 ECPT. For 45-year average dust concentrations spanning 0.5 mg/m^3 to 1.2 mg/m^3, the excess risk of severe emphysema ranges from about 23 ECPT for 65-year-old miners at 0.5 mg/m^3 to about 88 ECPT for 80-year-olds at 1.2 mg/m^3.

[36] The threshold values of the emphysema severity index were 285 and 392, respectively for FEV_1=80% and FEV_1=65% of predicted normal values. These are the expected values of emphysema severity predicted by the regression model at the corresponding thresholds of pulmonary impairment.

[37] According to the logistic regression results, both "non-white" race and cigarette smoking elevate the risk of severe emphysema. The risks for non-whites, as well as whites, will be evaluated later in this QRA.

[38] Since the model does not lag exposure, it does not differentiate between exposure accumulated all the way up to the specified age and exposure accumulated earlier in a miner's work history. The graphs for ages 73 and 80 may be interpreted as representing excess risks for former miners who retired at age 65 after 45 years of exposure.

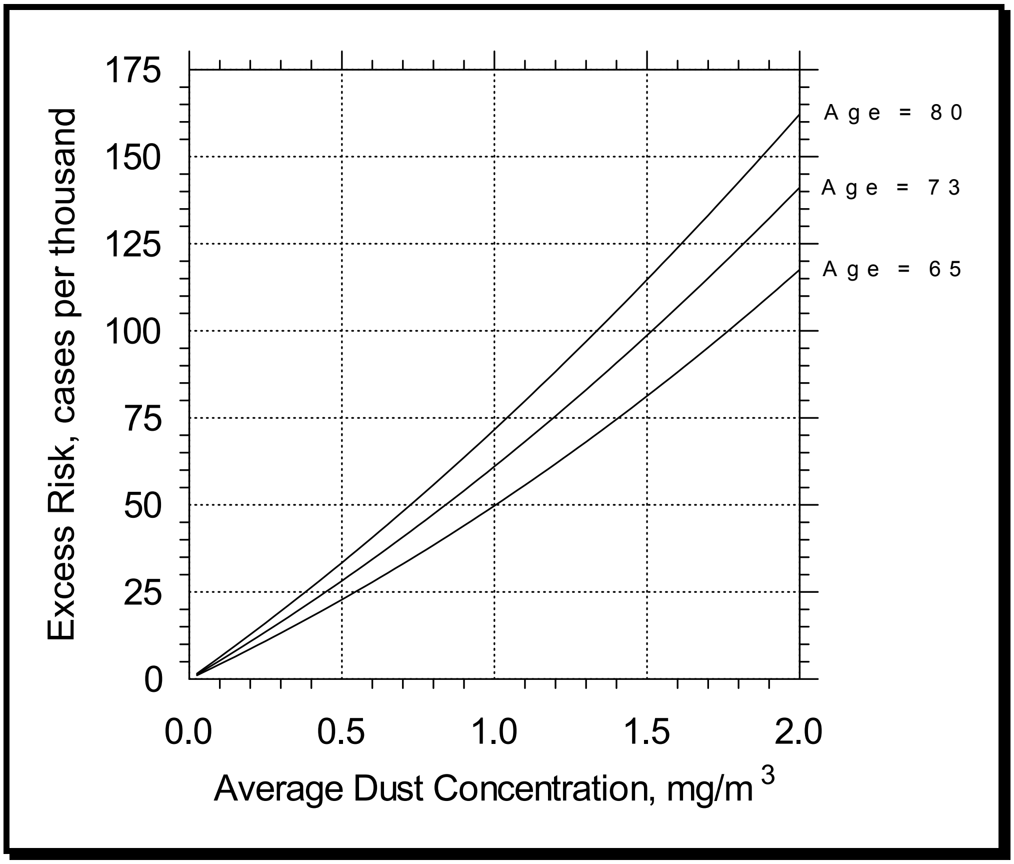

Figure 14. — Estimated relationship between average coal mine dust concentration experienced over a 45-year working lifetime and excess risk of developing emphysema severity corresponding to FEV_1 < 65% of predicted normal value, for white, never-smoking U.S. coal miners at ages 65, 73, and 80 years.

The two mortality studies cited earlier with respect to death from pneumoconiosis also covered deaths from COPD. Miller et al. (2007) and Attfield and Kuempel (2008) both applied Cox proportional hazard multiple regression models to estimate the relationship between cumulative coal mine dust exposures and the relative risk of death due to COPD, after adjustment for age and smoking habits. As in the case of CWP mortality, the Attfield/Kuempel model used un-lagged exposure while the selected Miller model (COPD/17) used cumulative exposure lagged by 15 years. Both studies reported a statistically significant exposure-response relationship, and Figure 15 plots the resulting relative risk associated with 45-year average dust concentrations according to the two studies.[39] Separate COPD/17 charts are shown for RR at ages 65, 73, and 80 years since exposure in the COPD/17 model is lagged by 15 years.

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[39] The graphs in Figure 15 are based on information from p. 238 of Attfield and Kuempel (2008) and Table 5.18 in Miller et al. (2007). The Attfield/Kuempel model for COPD mortality shows $RR = \exp(0.0065 \times CDE_0)$, where CDE_0 is un-lagged cumulative dust exposure. In this QRA, Model COPD/17 was selected from among the 18 alternatives shown in Tables 5.16–5.18 of the Miller report because it appears to best fit the data, as indicated by the log-likelihood listed for each alternative. (The addition of quartz exposure as an explanatory variable in Model

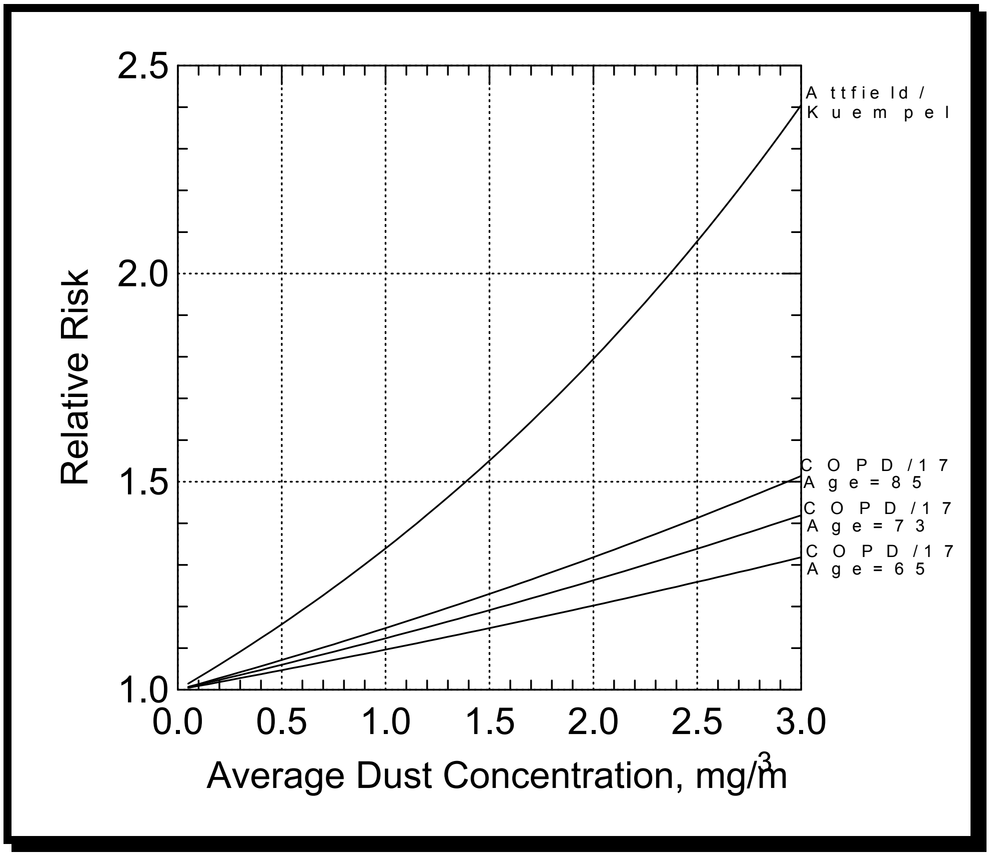

Figure 15. — Estimated relationship between average coal mine dust concentration experienced over a 45-year working lifetime and Relative Risk for death due to COPD. Attfield/Kuempel model is based on cohort mortality among U.S. coalminers and relates to un-lagged cumulative dust exposure. COPD/17 model is based on cohort mortality among British coalminers and relates to cumulative dust exposure lagged by 15 years.

Unlike the corresponding results for CWP, the U.S. (Attfield/Kuempel) data for COPD mortality indicate a much greater dust exposure effect than the British (Miller et al.) data. However, even the lower estimate shows a significant increase in COPD mortality attributable to the dust exposure. The COPD/17 model predicts a 15% increase (RR=1.15) in the risk of death from COPD for 80-year old former miners who have been exposed for 45 years at an average 1.0 mg/m^3. For the same exposure, the Attfield/Kuempel model predicts a 34% increase in risk.

This part of the QRA has shown that coal mine dust exposure at currently experienced occupational averages poses significant risks of material impairment in nearly all occupational categories. As noted by Cohen et al. (2008), "…there are subgroups of highly susceptible miners in

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COPD/18 was not statistically significant.) To convert $g{\cdot}hr/m^3$ used in Model COPD/17 to $mg{\cdot}yr/m^3$, the coefficient was divided by 1000 mg/g and multiplied by 1920 hr/yr. Using this conversion, Model COPD/17 yields

$$RR = \exp(0.0016\times 1.920\times CDE_{15}),$$

where CDE_{15} is cumulative dust exposure ($mg{\cdot}yr/m^3$) lagged by 15 years.

the United States who are developing rapidly progressive pneumoconiosis under the current dust standards." (Cohen et al., 2008) Coggon and Taylor (1998) conclude that "[t]he balance of evidence points overwhelmingly to impairment of lung function from exposure to coal mine dust, and this is consistent with the increased mortality from COPD that has been observed in miners." COPD, including emphysema, is characterized by a significant loss of respiratory function and therefore clearly qualifies as a material impairment under the Mine Act. Similarly, deaths due to either pneumoconiosis or COPD comprise clear instances of material impairment. Part 2 of the QRA will show that these risks are significantly greater at some mines and work locations than others and will estimate risks for miners who work at dustier-than-average work locations.

2. ***Analysis of Risk under Current Conditions***

In this part of the QRA, MSHA first refines the AS estimates of average occupational exposure developed earlier to cover narrower groups, or clusters, of WLs presenting roughly similar risks to exposed miners. Exposure-response models for CWP, severe emphysema, and NMRD mortality are then applied to the average exposure level associated with each cluster to obtain risk estimates for miners working under similar conditions. Part 2 of the QRA ends with a discussion of the major assumptions underlying these estimates and the implications of these assumptions with regard to MSHA's quantitative assessment of risk under current conditions.

Applying an exposure-response model to an occupational average exposure level fails to account for risks in more specific environments where the exposure is above the occupational average. Moreover, risk calculated at an average exposure level is not necessarily the same as the average of risk calculations at the constituent exposure levels. Indeed, when exposure-response relationships are curved upwards as those shown above, evaluating risk at the average exposure level will always underestimate average risk.

To see this, suppose that the dust concentration averages 0.75 mg/m^3 (high rank coal) in one work location and 1.75 mg/m^3 (also high rank coal) in another WL for the same occupation. The average dust concentration across these two WLs is 1.25 mg/m^3, and the attributable risk of PMF at that level is 142 excess cases per thousand for 73-year old former miners. (See upper curve in rightmost portion of Figure 11.) None of the miners working at these two WLs, however, are actually exposed to an average concentration of 1.25 mg/m^3. Instead, some are exposed to an average of 0.75 mg/m^3 and others to an average of 1.75 mg/m^3. The corresponding risks are 62 ECPT at the first WL and 263 ECPT at the second. Therefore, the average risk of PMF at age 73 attributable to dust exposure at these WLs is (62 + 263)/2 = 162 ECPT. This exceeds risk calculated at the 1.25 mg/m^3 average by 20 ECPT. But it is even more important to notice that some miners (i.e., those working at the second WL) face a risk that is twice the average.

It is evident from Figures 8 and 9 that occupational categories differ substantially with respect to their current average dust concentrations, and this is confirmed by the ANCOVA described in Appendix D(c). The same ANCOVA, however, also establishes that dust conditions at different mines, and different production areas within mines, may vary substantially in ways that cut across all occupations sampled within a given production area. Table 11 illustrates this point by showing MSHA's dust concentration measurements for all four occupations sampled at two different production areas in different mines. Although the same occupations were sampled, the measurements indicate strikingly different exposure environments, even after allowing for normal shift-to-shift variability.

Table 11. — Dust concentrations measured by MSHA inspectors for the same occupations in two different production areas.

Occupation	Mine A, area 01 (mg/m^3)	Mine B, area 01 (mg/m^3)
Continuous Miner Operator	1.73 2.51	0.09 0.14
Shuttle Car Operator	1.29 2.04 1.73 2.66 3.75	0.25 0.08 0.13 0.10
Scoop Car Operator	2.42	0.10
Roof Bolter	2.56 1.15	0.12 0.12

Therefore, in this part of the QRA, exposure-response models for CWP, severe emphysema, and NMRD mortality are applied to dust concentration averages for clusters of WLs whose dust conditions pose similar risks. The clusters will be defined by occupational category, coal rank, and record of excessive dust concentrations. Average exposure for each cluster will be estimated by combining the AS estimates of current average dust concentration for those WLs included within the cluster. (The AS estimation procedure is described in §1(c) and Appendix F.)

MSHA recognizes that many miners work extended (i.e., > 8-hour) shifts, and that this may affect estimated cumulative exposure as used in all of the exposure–response models considered. However, in the absence of data differentiating annual exposure time for miners working normal shifts from that of miners working extended shifts, the QRA assumes that all miners are exposed for an average of 1,920 hours/year. More precisely, all of the risk calculations assume that miners are occupationally exposed to RCMD for a total of 86,400 hours over a 45-year occupational lifetime (e.g., either 48 weeks per year at 40 hours per week, 32 weeks per year at 60 hours per week, or any other work pattern that amounts to an average of 1920 exposure hours per year). Therefore, the QRA underestimates health risks for miners working more than 1920 hours per year for 45 years under current conditions.

(a) Clusters of WLs presenting similar risks

The clustering of WLs presenting similar risks is based on three factors. The first of these is occupational category and has already been adequately described. The second factor, coal rank, was previously mentioned as entering into the Attfield/Seixas exposure–response relationships for CWP. With the addition of anthracite, coal rank also enters into the Attfield–Kuempel (2008) exposure–response model for NMRD mortality risk. Therefore, MSHA classified each WL as belonging to one of three coal rank categories — anthracite, high-rank bituminous, or low/medium rank.[40] At most work locations in U.S. underground coal mines, exposures are to high rank RCMD. Except for District 1 (all anthracite), it was assumed that exposures at surface

[40] In making these determinations, MSHA followed a definition of "high rank" as "coals containing less than 4% of moisture in the air-dried coal or more than 84% of carbon in dry ash-free coal." All underground and surface coal operations in MSHA's District 1 were classified as anthracite and were counted as "high rank" when applying the Attfield/Seixas CWP risk models. Except in District 1, all surface coal mines and processing facilities were classified as low/medium rank. Using the US Coal Quality Database from the USGS National Coal Resources Data System, MSHA was able to determine high vs. low/medium coal rank for approximately 70 percent of all underground mines outside District 1. In the QRA, coal in all indeterminate underground mines was classified as low/medium rank unless the mine was in a county with at least 2 known high-rank, and no low/medium rank, underground coal mines. In such counties, all of the underground coal mines were classified as high rank. Surface areas of underground mines were always assigned the same coal rank as the associated underground mine.

mines and facilities are to low/medium rank coal mine dust. The third factor used in clustering WLs extends the concept of "recurrent overexposures" introduced in support of the joint MSHA/NIOSH 2003 proposed rulemaking (68 FR10942, March 6, 2003)..

In the 2003 QRA, analysis was restricted to underground WLs exhibiting a "pattern of recurrent overexposures." In these WLs, at least two MSHA or operator dust concentration measurements for the designated occupation or roof-bolter designated area exceeded the applicable standard during a given year. It had been determined that "[WLs] exhibiting such a pattern are highly likely to have experienced excessive exposures on at least six shifts during the year under consideration." The present QRA defines three mutually exclusive "recurrency" classes, based on the combination of valid MSHA and periodic operator dust concentration measurements in 2008, and assigns each WL to one of these classes.[41] Unlike the 2003 QRA, the present QRA analyzes overexposure recurrency for all occupations (surface as well as underground) and evaluates risks presented not only by WLs exhibiting a pattern of recurrent overexposures, but also by WLs falling into the other two recurrency classes. The three recurrency classes — denoted {R1−}, {R(1–2)}, and {R2+} — are defined as follows:

- {R2+} consists of all WLs with at least two valid MSHA or periodic operator measurements greater than 2.0 mg/m^3 (or 1.0 mg/m^3 for Part-90 miners) for the same job-category in 2008. Since the applicable standard is sometimes less but never more than 2.0 mg/m^3, this category sets a higher threshold for inclusion than the criterion used in the earlier QRA. However, it is more inclusive in the sense of being open to other occupations besides the designated occupation or roof bolters sampled as designated areas. Among the 5,336 underground WLs sampled in 2008, 9 percent were classified as R2+. In contrast, less than 0.5 percent of the 6,081 surface WLs were so classified.
- {R(1–2)} consists of all WLs that are not members of {R2+} in which at least two valid MSHA or periodic operator measurements for the same job-category exceeded the proposed FEL in 2008. 21 percent of the underground WLs and slightly more than 1 percent of the surface WLs were classified as R(1–2).
- {R1−} consists of all WLs in which no more than one valid MSHA or periodic operator measurement for the same job-category exceeded the proposed FEL in 2008. About 70 percent of the underground WLs and 99 percent of the surface WLs fell into the {R1−} recurrency class.

Figure 16 shows, by underground occupation, how many WLs fall into each recurrency class. Figure 17 does the same for Part-90 miners and surface occupations. For some job categories, such as surface highlift operator and underground electrician or helper, nearly all WLs fall into {R1-}. For others , such as longwall jacksetters, WLs are more or less evenly distributed. A plurality of WLs for continuous miner operators (44 percent) are classified as R(1-2), but 33 percent are classified as R2+ and 27 percent as R1−. The occupation with the highest percentage of R2+ WLs is underground auger operators (40%), and this was also the only occupation with no WLs classified as R1−. Although more than half (59%) of all sampled WLs for Part-90 miners fell into the lowest recurrency class, 32 percent were classified as R(1–2) and 9 percent as R2+.

[41]Each WL involves a specific job-category but not necessarily a specific job. For example, two separate WLs are defined for a continuous miner operator and a shuttle-car operator working in the same production area of a mine. However, a single WL covers all shuttle car operators working in that production area.

(b) Current RCMD exposure levels for clusters of related WLs

Together, the job-category, recurrency class, and coal rank define clusters of work environments presenting similar health risks to miners. Table 12 presents the average dust concentration estimated for each of these clusters based on the AS estimation procedure. [42] (A blank indicates that no WLs were sampled for a particular combination of job-category, recurrency class, and coal rank.) The estimates range from 0.02 mg/m^3 for surface "Utility Man" in two {R1−} anthracite WLs to 2.94 mg/m^3 for "Other UG workers" in four {R2+} WLs exposed to high rank bituminous coal dust. The latter four WLs all involve samples collected on the return side of longwall face areas (occupation code 61).

[42] In its review of this QRA, OSHA recommended, as an alternative to the breakdown by recurrency classes in Table 12, "showing the percentage of measurements of WL-job title that exceed 0.5, 1.0, and 2.0 mg/m^3" and/or the "exposure estimate of the 10th, 50th , 90th or 95th percentile of working locations for any given job title." Note that Table 6 already contains the exceedance percentages aggregated across WLs. Since there were 11,319 distinct WLs in 2008, with an average of only 2.7 valid, Day-1 MSHA samples per WL (see Table 20), a table showing the three exceedance percentages for each WL would require 33,957 entries and, since the percentages would nearly always be based on a very small number of WLs, would contain little usable information. Similarly, MSHA believes that the marginal benefit of adding percentiles and their confidence limits to the averages presented in Table 12 would not justify the additional size and complexity of the resultant table.

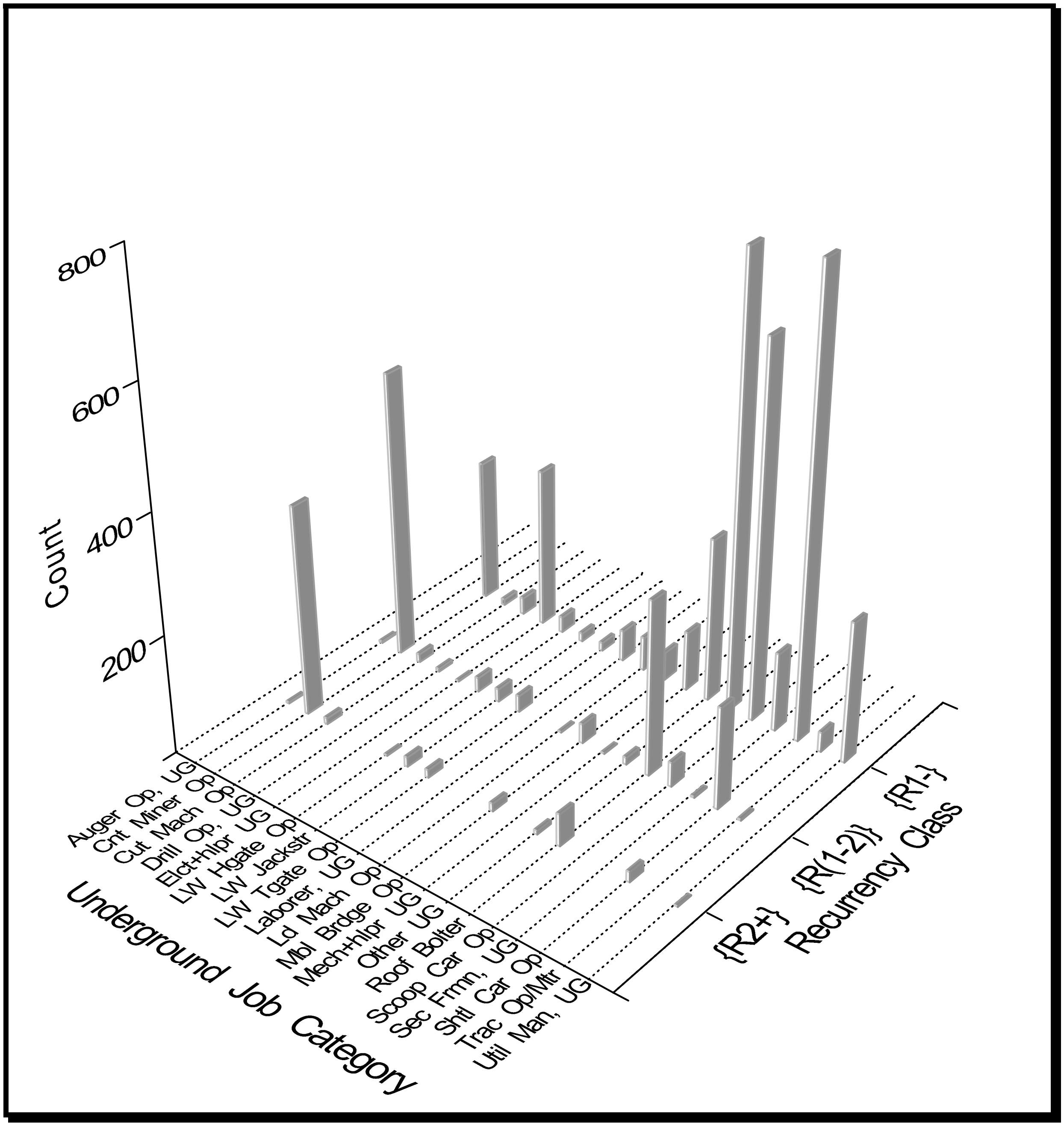

Figure 16. — Number of underground work locations sampled in 2008, by job-category and recurrency class. Note that the height of the bars depicts a count of WLs falling into each cell and not the number of samples collected.

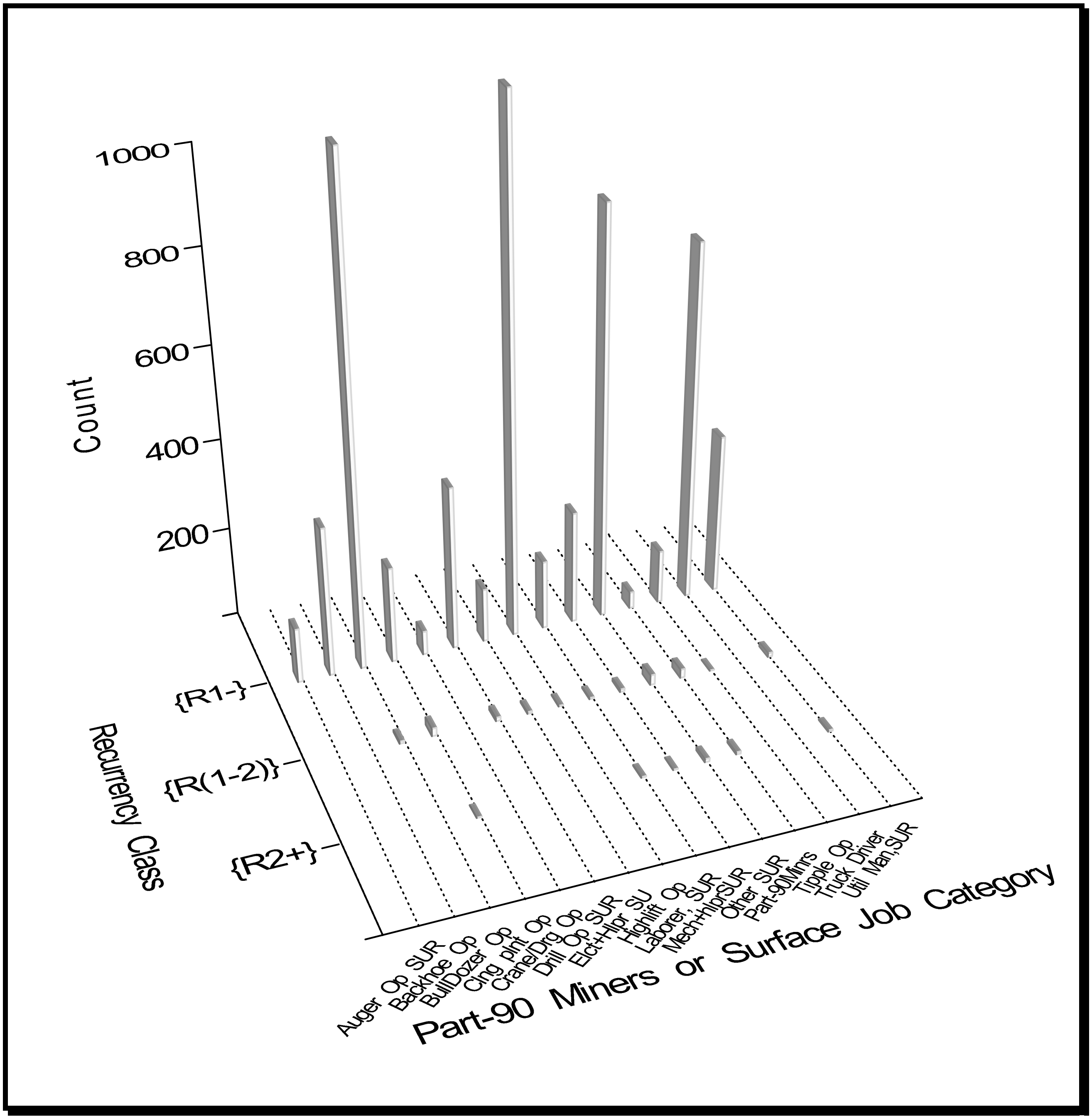

Figure 17. — Number of Part-90 miner and surface work locations sampled in 2008, by job-category and recurrency class. Note that the height of the bars depicts a count of WLs falling into each cell and not the number of samples collected.

Table 12. — Estimated current average dust concentrations (mg/m^3) for Part-90 miners and selected job categories, by coal rank and recurrency class. Part-90 miners are excluded from job categories.

Occupation		Recurrency Class {R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				0.80	1.19		1.22	1.03	
	Cont Miner Op	0.65	0.63		0.99	0.90	1.00	1.38	1.36	1.32
	Cutting Mach Op	0.49	0.49		1.51	1.20		1.13	1.75	
	Drill Op	0.57	0.66			1.03				
	Electrician & helper	0.37	0.37	0.53	0.91					
	Laborer	0.57	0.47	0.25						
	Loading Mach Op	0.18	0.33			0.88				
	LW Headgate Op	0.65	0.73		1.05	0.96		1.26		
	LW Jacksetter	0.76	0.74		1.19	1.00		1.40	1.34	
	LW Tailgate Op	0.74	1.00		1.36	1.27		1.36	1.67	
	Mechanic & helper	0.55	0.42	0.33		1.25				
	Mobile Bridge Op	0.42	0.53	0.33	0.96	0.86		1.04	0.98	
	Roof Bolter	0.54	0.54	0.54	1.00	0.91		1.39	1.19	
	Shuttle Car Op	0.51	0.45	0.38	0.98	0.97	1.00	1.48	1.51	
	Scoop Car Op	0.58	0.56		1.28	1.14				
	Section Foreman	0.54	0.52	0.32		1.44	0.85			
	Tractor Op	0.32	0.48	0.27		0.77				
	Utility Man	0.60	0.52						2.23	
	Other UG workers*	0.67	0.61	0.27	1.48	1.21	1.15	2.92	2.94	
Part-90 Miners		0.39	0.28		0.47	0.46		0.59	1.45	
Surface Workers	Auger Op	0.22								
	Backhoe Op	0.19	0.08	0.14						
	Bull Dozer Op	0.20	0.10	0.22	0.71					
	Crane/Dragline Op	0.11		0.12						
	Cleaning plant Op	0.39	0.35	0.28	0.98		1.01			1.30
	Drill Op	0.29		0.27	1.00					
	Electrician & helper	0.26	0.21	0.34	1.01					
	Highlift Op/FEL	0.16	0.15	0.16	1.11					
	Laborer	0.28	0.31	0.35			0.92	1.74		
	Mechanic & helper	0.26	0.31	0.11	1.38		1.23	1.92		
	Tipple Op	0.27	0.17		0.64					
	Truck Driver	0.20	0.09	0.18						
	Utility Man	0.36	0.24	0.02	1.37			1.21		2.27
	Other Surf. Workers	0.25	0.19	0.25	0.97	0.78	0.96	2.01		1.11

†Includes locations where MSHA has not determined the coal rank.

*13 of the 296 WLs associated with this job-category, including all six in recurrency class {R2+}, involve samples collected on the return sides of longwall face areas (occupation code 61).

Although relatively few surface WLs belong to {R(1–2)} or {R2+}, there are some notable cases of surface work locations with unusually high average dust concentrations compared to others for the same occupation. Seventeen WLs for "Cleaning Plant Operators" fall into {R(1–2)}, including one at an anthracite facility. The estimated current average exposure for these workers is approximately 1.0 mg/m^3. This is nearly three times the exposure estimated for the same occupation at 211 WLs classified as being in {R1-}. The one remaining WL for a cleaning plant operator is classified as R2+ and has an estimated average exposure level of 1.3 mg/m^3. Since this WL is at an anthracite facility, it poses an inordinately high excess risk of CWP and death due to NMRD as will be shown below.

Similarly, all but 12 of the 366 WLs for surface "Utility Man" belong to {R1−}. The average exposure level estimated at these "normal" locations is 0.4 mg/m^3. However, at the nine WLs in {R(1–2)}, the estimated average exposure is about 1.4 mg/m^3; and at the three in {R2+}, the exposure level is about 1.6 mg/m^3. Again, the unusually high average exposure shown for "Utility Man" at an R2+ surface anthracite WL (approximately 2.3 mg/m^3) poses inordinately high health risks. The remaining surface WLs falling into the {R2+} category include two involving "Laborer," one involving "Mechanic and helper," and seven involving "Other" surface workers. Although surface WLs are far less likely to be classified R(1–2) or R2+ than are underground WLs, the surface miners at such locations face dust exposures commensurate with those of their underground counterparts. In contrast, current exposures are significantly lower at surface WLs classified as R1− than at underground WLs falling into the same category.

Among underground work locations, those associated with "Laborer" and "Auger Operator" are, respectively, most and least likely to be in the {R1−} recurrency class. Of the 296 WLs for "Other" underground workers, all six falling into the {R2+} category represent exposures on the return side of longwall face areas (occupation code 61). The average exposure estimated for workers at such locations is 2.9 mg/m^3. Average dust levels are also unusually high at Class {R2+} WLs for underground "Utility Man" (1 WL at 2.2 mg/m^3), "Cutting Machine Operator" (10 WLs averaging 1.7 mg/m^3), "Longwall Tailgate Operator" (13 WLs averaging 1.6 mg/m^3), and "Shuttle Car Operator" (17 WLs averaging 1.5 mg/m^3).

As stated earlier, the recurrency classes for Part-90 miners were based on thresholds of 0.5 mg/m^3 and 1.0 mg/m^3 instead of the 1.0 mg/m^3 and 2.0 mg/m^3 used for all other job-categories. Six WLs for Part-90 miners fall into the {R2+} recurrency class, and the estimated average exposure for this group is 1.3 mg/m^3. Five of these six, with an estimated average exposure of 1.45 mg/m^3, occur at high rank bituminous coal mines. The exposure level faced by Part-90 miners at these five work locations appears to be greater, on average, than the exposure for continuous miner operators, longwall jacksetters, and roof bolters in the corresponding recurrency and coal rank categories.

Within each occupational category, the proportion of miners exposed to the average dust level estimated for a given recurrency class and coal rank is roughly equal to the proportion of WLs represented by the corresponding cell of Table 12. These proportions are provided in Table 27. However, because of occupational disparities in the number of workers covered by each WL, it is not valid to estimate the proportion of miners belonging to each occupational category in this way.

In Table 13, Table 14, and Table 15, the Attfield–Seixas exposure–response models for CWP1+, CWP2+, and PMF are applied to the estimates of current exposure shown in Table 12 to yield estimates of excess risk under current conditions. Similarly, Table 16 provides excess risk estimates for severe emphysema using the Kuempel pulmonary impairment model, and Table 17 and Table 18 do the same for NMRD mortality as predicted by the Attfield–Kuempel model. All risks are calculated for miners 73 years of age, who have previously accumulated 45 years of occupational coal mine dust exposure. Technical details are provided in Appendix I for the Attfield–Seixas models, Appendix J for the Kuempel pulmonary impairment model, and Appendix K for the Attfield–Kuempel NMRD mortality model.

(c) Pneumoconiosis

Although the Attfield–Seixas CWP models were developed from data restricted to bituminous coal regions, this QRA applies the "additional effect of exposure for high rank [coal]" to exposures in anthracite work locations, as well as to those in high rank bituminous mines. Similarly, the QRA extrapolates the Attfield-Seixas model for low/medium rank bituminous coal to exposures at lignite WLs.

For surface WLs under current conditions, both the lowest and highest estimated excess risks of pneumoconiosis are associated with workers classified as "Utility Man". The lowest risks apparently occur at two anthracite WLs of recurrency class {R1−}, and the highest at a single anthracite WL of class {R2+}. At the latter work location, a 73-year old surface "Utility Man" exposed for 45 years under current conditions would face a 51-percent chance of CWP1+ attributable to occupational exposure and a 43-percent chance of PMF (i.e., 507 per thousand and 428 per thousand, shown in Table 13 and Table 15 respectively). The excess risk of PMF estimated for cleaning plant operators ranges from 0.9 percent (9 per thousand) at 166 WLs of class {R1−} in Low/Med. rank coal to 15 percent (152 per thousand) at the single anthracite WL of class {R2+}.

The additional impact of exposure to high rank coal is illustrated by the CWP excess risk estimates for class {R2+} WLs associated with continuous miner operators. As shown in Table 12, current exposure levels for these WLs are roughly the same in low/medium rank and high rank coal mines. The estimated excess risks due to exposure, however, are markedly greater in high rank coal mines — especially in the case of PMF. Under current conditions, the risk of PMF attributable to 45 years of exposure as a continuous miner operator in a high rank coal mine is, on average, more than three times the risk in a low/medium rank coal mine, assuming comparable WLs of recurrency class {R2+}. (See Table 15.) In 2008, there were 197 class {R2+} WLs for continuous miner operators at high rank coal mines (including anthracite). At age 73, after working for 45 years at such WLs, a continuous miner operator would face a 16-percent risk of PMF attributable to the occupational exposure.

Excluding the six WLs for "Other UG workers" in class {R2+}, all of which represent dust levels on the return side of longwall face areas, the greatest excess risks of pneumoconiosis are for workers classified as "Utility Man" in the only work location of a high rank bituminous coal mine that falls into recurrency class {R2+}. A utility man at that WL would face a 41-percent excess risk of PMF at age 73. This is 2½ times the excess risk estimated for continuous miner operators at WLs of the same coal rank and recurrency class. Other WLs in class {R2+} that present unusually high excess risks of pneumoconiosis (i.e., excess risk of PMF ≥ 20 percent at age 73) involve cutting machine operators, longwall tailgate operators, and shuttle car operators exposed to high rank bituminous coal. As indicated above, a total of 40 WLs fall into these categories.

Table 13. — Estimated Excess Risk of CWP 1+ by age 73 after 45 years of occupational exposure at current exposure levels (cases attributable to occupational exposure per 1000 exposed workers).

	Occupation	Recurrency Class {R1−} Low/Med. Rank†	{R1−} High Rank Bituminous	{R1−} Anthracite	{R(1–2)} Low/Med Rank†	{R(1–2)} High Rank Bituminous	{R(1–2)} Anthracite	{R2+} Low/Med Rank†	{R2+} High Rank Bituminous	{R2+} Anthracite
Underground Workers	Auger Op				75	224		125	185	
	Cont Miner Op	59	98		97	156	178	147	266	255
	Cutting Mach Op	43	73		165	225		114	369	
	Drill Op	51	106			184				
	Electrician & helper	31	54	80	88					
	Laborer	51	70	34						
	Loading Mach Op	14	46			151				
	LW Headgate Op	59	118		105	168		131		
	LW Jacksetter	71	121		122	178		149	262	
	LW Tailgate Op	68	179		144	243		145	350	
	Mechanic & helper	49	61	47		238				
	Mobile Bridge Op	36	80	47	94	146		103	174	
	Roof Bolter	48	82	82	98	156		148	222	
	Shuttle Car Op	45	66	55	96	170	178	161	304	
	Scoop Car Op	51	85		133	211				
	Section Foreman	48	79	45		287	144			
	Tractor Op	27	72	38		128				
	Utility Man	54	79						497	
	Other UG workers*	61	95	37	161	229	214	391	652	
Part-90 Miners		33	38		41	69		52	290	
Surface Workers	Auger Op	18								
	Backhoe Op	16	10	19						
	Bull Dozer Op	16	13	30	65					
	Crane/Dragline Op	9		16						
	Cleaning plant Op	33	50	39	96		180			252
	Drill Op	25		38	99					
	Electrician & helper	22	29	48	99					
	Highlift Op/FEL	13	20	21	111					
	Laborer	23	44	50			160	198		
	Mechanic & helper	22	44	15	147		232	225		
	Tipple Op	23	23		58					
	Truck Driver	16	12	25						
	Utility Man	31	32	2	145			124		507
	Other Surf. Workers	20	25	35	95	128	168	240		205

†Includes locations where MSHA has not determined the coal rank.

*13 of the 296 WLs associated with this job-category, including all six in recurrency class {R2+}, involve samples collected on the return sides of longwall face areas (occupation code 61).

Table 14. — Estimated Excess Risk of CWP 2+ at age 73 after 45 years of occupational exposure at current exposure levels (cases attributable to occupational exposure per 1000 exposed workers).

	Occupation	Recurrency Class {R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				43	187		75	148	
	Cont Miner Op	34	71		56	121	141	90	231	219
	Cutting Mach Op	24	51		102	188		67	349	
	Drill Op	28	77			147				
	Electrician & helper	17	37	57	51					
	Laborer	29	49	23						
	Loading Mach Op	8	31			116				
	LW Headgate Op	34	88		62	132		78		
	LW Jacksetter	40	90		73	141		91	226	
	LW Tailgate Op	39	142		87	206		88	325	
	Mechanic & helper	28	42	31		201				
	Mobile Bridge Op	20	57	31	55	112		61	137	
	Roof Bolter	27	58	58	57	121		90	185	
	Shuttle Car Op	25	46	37	56	134	141	99	273	
	Scoop Car Op	29	61		80	173				
	Section Foreman	27	56	31		253	110			
	Tractor Op	15	50	25		96				
	Utility Man	30	56						510	
	Other UG workers*	34	69	25	99	192	176	289	715	
Part-90 Miners		18	26		23	48		29	257	
Surface Workers	Auger Op	10								
	Backhoe Op	9	6	12						
	Bull Dozer Op	9	9	20	37					
	Crane/Dragline Op	5		10						
	Cleaning plant Op	18	34	26	56		143			215
	Drill Op	14		25	58					
	Electrician & helper	12	19	33	58					
	Highlift Op/FEL	7	13	14	66					
	Laborer	13	29	34			124	125		
	Mechanic & helper	12	29	9	89		195	146		
	Tipple Op	12	15		33					
	Truck Driver	9	8	16						
	Utility Man	17	21	1	88			74		525
	Other Surf. Workers	11	17	23	55	96	132	157		167

†Includes locations where MSHA has not determined the coal rank.

*13 of the 296 WLs associated with this job-category, including all six in recurrency class {R2+}, involve samples collected on the return sides of longwall face areas (occupation code 61).

Table 15. — Estimated Excess Risk of PMF at age 73 after 45 years of occupational exposure at current exposure levels (cases attributable to occupational exposure per 1000 exposed workers).

	Occupation	Recurrency Class								
		{R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				22	130		38	102	
	Cont Miner Op	17	47		29	82	97	45	165	155
	Cutting Mach Op	12	34		51	132		34	262	
	Drill Op	15	52			101				
	Electrician & helper	9	24	38	26					
	Laborer	15	32	15						
	Loading Mach Op	4	21			79				
	LW Headgate Op	17	59		31	90		39		
	LW Jacksetter	21	60		36	97		45	161	
	LW Tailgate Op	20	97		44	145		44	242	
	Mechanic & helper	14	28	21		142				
	Mobile Bridge Op	10	38	21	28	76		31	94	
	Roof Bolter	14	39	39	29	83		45	129	
	Shuttle Car Op	13	30	25	28	92	97	49	198	
	Scoop Car Op	15	40		40	120				
	Section Foreman	14	37	20		182	75			
	Tractor Op	8	33	16		65				
	Utility Man	16	37						413	
	Other UG workers*	18	46	16	49	134	123	145	643	
Part-90 Miners		10	17		12	32		15	185	
Surface Workers	Auger Op	5								
	Backhoe Op	4	4	8						
	Bull Dozer Op	5	6	13	19					
	Crane/Dragline Op	2		7						
	Cleaning plant Op	9	22	17	28		98			152
	Drill Op	7		17	29					
	Electrician & helper	6	12	21	29					
	Highlift Op/FEL	4	9	9	33					
	Laborer	7	19	22			85	62		
	Mechanic & helper	6	19	6	45		137	72		
	Tipple Op	6	10		17					
	Truck Driver	5	5	11						
	Utility Man	9	14	1	44			37		428
	Other Surf. Workers	6	11	15	28	65	90	78		116

†Includes locations where MSHA has not determined the coal rank.

*13 of the 296 WLs associated with this job-category, including all six in recurrency class {R2+}, involve samples collected on the return sides of longwall face areas (occupation code 61).

Of the 136 WLs sampled for "Section Foreman," all but two fall into {R1−}. However, the single "Section Foreman" WL falling into both recurrency class {R1–2} and high rank bituminous coal stands out as presenting an unusually high excess risk of pneumoconiosis. Under current conditions, the excess risk of PMF at age 73 after 45 years of exposure at this WL is estimated to be 18 percent. This exceeds the risk shown for average dust conditions at WLs associated with nearly every other underground job category, regardless of coal rank or recurrency class. The only exceptions all occur in high rank bituminous coal at WLs of class {R2+}. Besides the 41 WLs identified above as presenting excess risk of PMF ≥ 20 percent by age 73, the exceptions include four WLs for "Other UG workers" that represent dust levels on the return side of longwall face areas.

(d) Severe Emphysema

Table 16 provides excess risk estimates for severe emphysema (i.e., emphysema severity corresponding to $FEV_1 < 65\%$ of predicted normal value) using the Kuempel pulmonary impairment model as described in Appendix J. Since coal rank is not a factor in this model, work locations are clustered only according to job category and recurrency class. The model does, however, include a statistically significant upward adjustment of the risk for "non-white" workers. Consequently, Table 16 shows separate risk estimates for whites and non-whites. For the sake of simplicity and clarity, the risks shown assume no history of tobacco smoking. For miners who have smoked, the excess risk of emphysema predicted by the Kuempel pulmonary impairment model would be higher.[43]

A total of 96 surface WLs fall into recurrency classes {R(1–2)} and {R2+}. Although these WLs represent less than two percent of all surface exposures, they present a risk of severe emphysema that exceeds the risk in most underground WLs. More specifically, there are six WLs in class {R(1–2)} and one in class {R2+} for surface "Mechanic and helper"; and there are 9 WLs in class {R(1–2)} and three in class {R2+} for surface "Utility Man." For these two job-categories, the four surface WLs in class {R2+} present an excess risk of severe emphysema (13% and 10%, respectively, for "whites"; 19% and 15% for "non-whites") that exceeds the predicted excess at more than 99 percent of all underground WLs. Apparently, even the 15 class R(1–2) WLs for these two surface job-categories are more hazardous, with respect to emphysema, than 92 percent of all underground WLs.

Apart from WLs associated with "Other UG workers," class R2+ underground work locations currently presenting the greatest excess risk of severe emphysema include 10 WLs for cutting machine operators, 13 WLs for longwall tailgate operators, and 17 WLs for shuttle car operators. The probability that a never-smoking worker will, at age 73, have developed severe emphysema after 45 years of exposure in such WLs is estimated to be about 10–11% for "whites" and 15–17% for "non-whites." For the single WL involving a "Utility Man," the risk appears to be substantially greater: 16% for whites and 23% for "non-whites."

[43] Although cigarette smoking and coal mine dust exposure appear as independent factors in the model, curvature in the joint exposure-response relationship amplifies the predicted response to RCMD exposure for smokers. (This is an inherent characteristic of the logistic model employed.) Furthermore, the portion of emphysema risk attributable to dust exposure is greater for smokers than for non-smokers, by an amount that increases with the intensity and duration of smoking. See Appendix J for an example.

Table 16. —Estimated excess risk of developing severe emphysema† by age 73, for racially "white" and "non-white" never-smokers occupationally exposed to coal mine dust at current levels over a 45-year working lifetime (cases attributable to occupational exposure per 1000 exposed workers).

	Occupation	Recurrency Class {R1−}		{R(1–2)}		{R2+}	
		White	Non-White	White	Non-White	White	Non-White
Underground Workers	Auger Op			56	87	70	107
	Cont Miner Op	37	58	57	88	88	133
	Cutting Mach Op	28	44	82	124	114	167
	Drill Op	37	58	63	97		
	Electrician & helper	20	33	55	85		
	Laborer	24	39				
	Loading Mach Op	17	27	53	82		
	LW Headgate Op	41	64	60	93	80	121
	LW Jacksetter	44	69	65	100	89	133
	LW Tailgate Op	53	83	83	126	103	153
	Mechanic & helper	26	42	79	120		
	Mobile Bridge Op	28	45	54	83	61	94
	Roof Bolter	31	49	58	89	80	121
	Shuttle Car Op	26	42	59	92	98	146
	Section Foreman	29	47	71	109		
	Scoop Car Op	32	51	77	117		
	Tractor Op	24	38	46	72		
	Utility Man	32	51			162	228
	Other UG workers*	35	56	79	121	232	306
Part-90 Miners		17	28	26	42	84	126
Surface Workers	Auger Op	12	19				
	Backhoe Op	10	16				
	Bull Dozer Op	10	17	41	65		
	Crane/Dragline Op	6	10				
	Cleaning plant Op	20	33	60	93	83	126
	Drill Op	16	26	61	95		
	Electrician & helper	14	23	62	95		
	Highlift Op/FEL	8	14	69	105		
	Laborer	17	27	56	86	118	173
	Mechanic & helper	14	23	87	131	134	193
	Tipple Op	15	24	37	58		
	Truck Driver	10	17				
	Utility Man	18	29	88	133	104	154
	Other Surf. Workers	13	21	58	90	131	189

† Emphysema severity corresponding to FEV_1 < 65% of predicted normal value.

*13 of the 296 WLs associated with this job-category, including all six in recurrency class {R2+}, involve samples collected on the return sides of longwall face areas (occupation code 61).

Even for average WLs of recurrency class {R1−}, the excess risk of severe emphysema predicted by the Kuempel pulmonary impairment model is substantial for all job-categories under current conditions. For "whites" at these WLs, the predicted excess ranges from six cases per thousand exposed crane or dragline operators to 53 cases per thousand exposed longwall tailgate operators. For "non-whites," the corresponding range runs from 10 to 83 cases per thousand exposed workers.

(e) NMRD Mortality

Mortality due to non-malignant respiratory disease (NMRD) includes deaths ascribed to either pneumoconiosis or any of the various chronic obstructive pulmonary diseases (COPD) including emphysema, bronchitis, and chronic airways obstruction. In addition to the exposure-response relationship for COPD mortality discussed earlier, Attfield and Kuempel (2008) reported a relationship for the more inclusive category of NMRD mortality based on the same type of proportional hazards model. In this QRA, the Attfield–Kuempel NMRD model is used to compare current and projected mortality risks for two reasons: (1) it is the most inclusive of the available models for respiratory disease mortality; and (2) it enables estimation of increased mortality risks associated with exposure to anthracite and high rank bituminous coal.[44]

Table 17 shows the predicted excess risks of NMRD mortality by age 73 corresponding to current exposure levels as categorized in Table 12. Table 18 shows the substantially greater excess risks of NMRD mortality by age 85, based on the same occupational exposures.[45] These estimates of excess risk were derived from the Attfield–Kuempel NMRD mortality model in two steps. First, as described in Appendix K, the coefficients of coal rank and accumulated coal mine dust exposure reported in Attfield and Kuempel (2008) were used to calculate relative risks. Table 56 (in Appendix K) provides the relative risk for each exposure category after 45 years of occupational exposure under current conditions. Second, excess risk estimates were formed by comparing the relative risk during each year of a 45-year occupational history to the NMRD mortality rate in an appropriate reference population.[46]

The increased effect of exposure to high rank coal, and especially anthracite, on excess NMRD mortality risk is readily apparent by age 73 (Table 17) and even more pronounced by age 85 (Table 18). The risks shown for continuous miner operators illustrate the general point. Although current exposure levels for continuous miner operators are roughly the same at class R2+

[44] For excess risks estimated using the Attfield–Kuempel NMRD mortality model, coal rank enters indirectly by geographic region. This QRA identifies the Attfield–Kuempel "anthracite" category with all WLs (surface as well as underground) in MSHA's District 1, and the model's "East Appalachia" category with high rank bituminous coal. All of the remaining geographic categories ("West Appalachia," "Mid-west," and "West") are identified with low/medium rank coal.

[45] NIOSH's review of this QRA expressed concern over setting 85 years of age as an outcome endpoint. The reviewer stated that "extrapolating the epidemiologic findings well beyond the age range of the participants stretches credibility." However, in making this comment, the reviewer was apparently referring to age ranges for participants in the various CMRD morbidity studies, rather than the recent mortality studies with extended follow-up periods (i.e., Attfield and Kuempel, 2008; Miller et al., 2007). For morbidity outcomes, risks in this QRA are estimated only at age 73, as recommended by the NIOSH reviewer.

[46] At MSHA's request, Randall Smith of NIOSH's Education and Information Division computed the excess NMRD mortality risk estimates in Table 17 and Table 18 from relative risk estimates produced by the Attfield–Kuempel model. The estimates were formed using a competing risk life-table analysis, based on a method published in the BEIR VI report (NRC, 1988). The estimates are for exposures starting at age 20 and continuing for up to 45 years.

Table 17. — Estimated Excess Risk of NMRD mortality by age 73 after 45 years of occupational exposure at current exposure levels (deaths per 1000 exposed workers).

	Occupation	Recurrency Class {R1−} Low/Med. Rank†	{R1−} High Rank Bituminous	{R1−} Anthracite	{R(1–2)} Low/Med Rank†	{R(1–2)} High Rank Bituminous	{R(1–2)} Anthracite	{R2+} Low/Med Rank†	{R2+} High Rank Bituminous	{R2+} Anthracite
Underground Workers	Auger Op				6	18		10	16	
	Cont Miner Op	5	12		8	15	110	12	20	122
	Cutting Mach Op	4	10		14	18		10	26	
	Drill Op	4	12			16				
	Electrician & helper	3	9	94	7					
	Laborer	4	10	85						
	Loading Mach Op	1	9			15				
	LW Headgate Op	5	13		9	16		11		
	LW Jacksetter	6	13		10	16		12	20	
	LW Tailgate Op	6	16		12	19		12	25	
	Mechanic & helper	4	10	87		19				
	Mobile Bridge Op	3	11	87	8	14		9	16	
	Roof Bolter	4	11	94	8	15		12	18	
	Shuttle Car Op	4	10	89	8	16	110	13	22	
	Scoop Car Op	4	11		11	18				
	Section Foreman	4	11	87		22	105			
	Tractor Op	2	10	86		13				
	Utility Man	5	11						33	
	Other UG workers*	5	12	86	13	19	116	33	46	
Part-90 Miners		3	8		4	10		5	22	
Surface Workers	Auger Op	2								
	Backhoe Op	1	7	82						
	Bull Dozer Op	1	7	84	6					
	Crane/Dragline Op	1		81						
	Cleaning plant Op	3	9	86	8		110			121
	Drill Op	2		86	8					
	Electrician & helper	2	8	88	8					
	Highlift Op/FEL	1	7	82	9					
	Laborer	2	9	88			107	16		
	Mechanic & helper	2	9	81	12		118	18		
	Tipple Op	2	7		5					
	Truck Driver	1	7	83						
	Utility Man	3	8	78	12			10		164
	Other Surf. Workers	2	8	85	8	13	108	19		114

†Includes locations where MSHA has not determined the coal rank.

*13 of the 296 WLs associated with this job-category, including all six in recurrency class {R2+}, involve samples collected on the return sides of longwall face areas (occupation code 61).

Table 18. — Estimated Excess Risk of NMRD mortality by age 85 after 45 years of occupational exposure at current exposure levels (deaths per 1000 exposed workers).

	Occupation	{R1−} Low/Med. Rank[†]	{R1−} High Rank Bituminous	{R1−} Anthracite	{R(1–2)} Low/Med Rank[†]	{R(1–2)} High Rank	{R(1–2)} Anthracite	{R2+} Low/Med Rank[†]	{R2+} High Rank Bituminous	{R2+} Anthracite
Underground Workers	Auger Op				17	48		28	43	
	Cont Miner Op	14	31		22	39	243	32	53	266
	Cutting Mach Op	10	27		36	48		26	67	
	Drill Op	12	32			43				
	Electrician & helper	7	24	212	20					
	Laborer	12	27	194						
	Loading Mach Op	4	23			38				
	LW Headgate Op	14	34		24	41		29		
	LW Jacksetter	16	34		27	42		33	53	
	LW Tailgate Op	16	42		32	50		32	64	
	Mechanic & helper	12	25	199		50				
	Mobile Bridge Op	9	28	199	21	38		23	41	
	Roof Bolter	11	29	212	22	39		33	48	
	Shuttle Car Op	11	26	202	22	41	243	35	58	
	Scoop Car Op	12	29		30	46				
	Section Foreman	11	28	198		56	233			
	Tractor Op	7	27	195		35				
	Utility Man	13	28						86	
	Other UG workers*	14	31	195	35	49	254	86	117	
Part-90 Miners		8	22		10	27		12	56	
Surface Workers	Auger Op	4								
	Backhoe Op	4	17	187						
	Bull Dozer Op	4	17	192	15					
	Crane/Dragline Op	2		186						
	Cleaning plant Op	8	24	196	22		244			265
	Drill Op	6		195	22					
	Electrician & helper	5	20	199	22					
	Highlift Op/FEL	3	19	188	25					
	Laborer	6	23	200			238	43		
	Mechanic & helper	5	23	185	32		259	49		
	Tipple Op	5	19		13					
	Truck Driver	4	17	190						
	Utility Man	7	21	179	32			28		337
	Other Surf. Workers	5	20	194	21	35	240	52		251

[†]Includes locations where MSHA has not determined the coal rank

*13 of the 296 WLs associated with this job-category, including all six in recurrency class {R2+}, involve samples collected on the return sides of longwall face areas (occupation code 61).

WLs in low/medium rank, high rank bituminous, and anthracite coal (see Table 12), the predicted rate of NMRD mortality by age 73 due to occupational exposure at anthracite WLs exceeds the predicted rate at low/medium rank WLs by 110 cases per thousand exposed workers. For mortality by age 85, the gap widens to 234 excess cases per thousand. Coal rank appears to far outweigh occupation and recurrency class in determining excess NMRD mortality.

(f) Major assumptions and their implications for QRA under current conditions

Estimated excess risks under MSHA's current regulations and enforcement policies are shown in Tables 13–15 for CWP, Table 16 for severe emphysema, and Tables 17–18 for NMRD mortality. These tables imply that in every exposure category, including clusters of occupational environments showing the lowest average dust concentrations, current exposure conditions place miners at a significant risk of incurring each of the material impairments considered. The analysis underlying this conclusion depends on the following major assumptions:

- *Sufficient homogeneity within WL clusters* — that occupational category, coal rank, and recurrency class define clusters of WL's presenting sufficiently similar health risks to exposed miners. "Sufficiently similar" means that variability of exposure levels at different WLs within each cluster is small enough that the exposure-response models are approximately linear within the range of exposures represented by the cluster. With approximate linearity, the exposure-response model can validly be applied to each cluster's mean exposure as provided in Table 12.[47]
- *Adequacy of bias adjustments* — that the AS procedure produces realistic estimates of the mean exposure level for each cluster of related WLs. Although the AS procedure is intended to compensate for such biases, the mean exposure estimates in Table 12 may still underestimate actual mean exposures due to lower-than-average production on sampled shifts or other modifications of normal work practices in the presence of an MSHA inspector. (See Appendix G(a) for significance and estimated impact of the production effect.) However, since similar biases are likely to have been present in the exposure data used to establish the exposure-response relationships, it not clear that such biases (if they exist) would have any significant net effect on the risk estimates.
- *Duration of exposure* — that miners are exposed for 45 years at an average of 1,920 hours/year. More precisely, all of the risk calculations assume that miners are occupationally exposed to RCMD for a total of 86,400 hours over a 45-year occupational lifetime (e.g., either 48 weeks per year at 40 hours per week, 32 weeks per year at 60 hours per week, or any other work pattern that amounts to an average of 1920 exposure hours per year). The QRA underestimates health risks for miners who expect to work more than 86,400 hours during their occupational lifetime and overestimates risks for miners whose lifetime total comes to less than 86,400 hours.
- *Strictly cumulative exposure effects* — that the risks of the specific adverse health effects under consideration depend only on cumulative exposure (the product of duration and *average*

[47] For most occupations, average exposure varies substantially at different WL's in the {R2+} category. Because of curvature in the exposure-response relationships, subdividing the {R2+} category would have led to slightly higher estimates of current risk. However, the subdivided categories would, in general, have been represented by very few WLs. Therefore, the risk estimates associated with these subdivided categories would have been subject to significantly increased uncertainty.

RCMD concentration) and are independent of any short-term peaks in RCMD exposure. Such peaks might, for example, overload the respiratory system's clearance mechanisms. This assumption also pertains to risks presented to workers on extended shifts: if it is not valid, then working five 8-hour shifts per week would not necessarily present the same health risks as working four 10-hour shifts. None of the published exposure-response models, however, take any account of exposure patterns. Therefore, this QRA has made no attempt to quantify their effects.

- *Validity of extrapolating published exposure-response models to all U.S. miners* — that the models are applicable to miners and mining environments beyond the populations and geographic areas studied. The work locations studied were not randomly drawn from or otherwise designed to be statistically representative of the population of mines currently operating. Therefore, there may be significant differences in factors, such as RCMD particle size distribution, distinguishing the study population from current WLs. Also, the QRA extends the published models to sub-bituminous and surface coal miners. These miners might not respond to RCMD in exactly the same way as the study populations. Furthermore, the QRA assumes that all surface coal mines (outside of MSHA's District 1) are low/medium rank coal.[48] All other factors held equal, the pneumoconiosis and NMRD mortality models predict greater risk from exposures to high rank than to low/medium rank RCMD. Therefore, to the extent there are high rank bituminous surface coal mines, the QRA underestimates risks presented to surface coal miners.

3. Risk under Implementation of Proposed Rule

The objective in this part of the QRA is to project health risks under successful implementation of the proposed rule and to compare those projected risks with risks under current exposure conditions. There are five sections in this part. The first (a) provides background and explains why this QRA does not utilize the same method used by NIOSH in its 1995 Criteria Document to project exposures under the proposed rule. The second (b) presents and explains the procedure by which projections are made in this QRA. The third (c) applies the various exposure response models to the exposures projected for clusters of WLs previously identified as presenting similar risks under current conditions. For each of the adverse health outcomes considered, this yields MSHA's projected risk estimates for the clusters of related WLs. The fourth section (d) discusses the major assumptions underlying these estimates and the implications of these assumptions with regard to MSHA's quantitative assessment of risk under successful implementation of the proposed rule. The fifth section (e) summarizes the comparison of health risks under current conditions to risks projected under successful implementation of the proposed rule.

(a) Background

This analysis takes a different approach than NIOSH used in the NIOSH Criteria Document (NCD, 1995, *op. cit.*). NIOSH projected that successfully implementing its recommended exposure limit (REL)[49] of 1.0 mg/m^3 would result in average RCMD levels less than 0.5 mg/m^3. The basis for this projection was a finding that dust concentration variability within occupations, as quantified by the geometric standard deviation (GSD) was, "fairly uniform." Based on

[48] This assumption is *not* made for non-extractive surface facilities or surface areas of underground mines.

[49] The NIOSH REL was a time-weighted average respirable coal mine dust concentration for up to ten hours per day during a 40-hour workweek.

ANOVA–adjusted GSD values, along with an assumption that dust concentrations within occupational categories are Lognormally distributed (used to generate NCD Figure 7-9), NIOSH concluded that the long-term average exposure would be approximately one-half of the REL.

Appendix G examines exposure distributions at individual work locations and tests the assumption that they are Lognormally distributed. Based on this analysis, MSHA concludes that individual WLs currently exhibit a wide variety of distributional forms and that the diversity of these forms cannot adequately be approximated by a lognormal model. Consequently, it appears more appropriate to use distribution-free ("nonparametric") methods to predict the impact on long-term average exposures of compliance with the proposed rule (i.e., compliance with the proposed FEL on every shift).

Fortunately, the available dust sampling data do contain some information on the effects of reducing the exposure limit from 2.0 mg/m^3 to 1.0 mg/m^3, albeit under existing enforcement policies. Currently, the coal mine dust exposure limit at a WL is reduced below 2.0 mg/m^3 whenever silica content is determined to exceed 5 percent of the RCMD. Consequently, MSHA collected 2,600 valid occupational Day-1 samples in 2004–2008 from WLs with a 1.0 mg/m^3 exposure limit. These samples may be compared with 114,585 valid occupational Day-1 samples MSHA collected during the same period at WLs with an exposure limit of 2.0 mg/m^3. [50] (As will be explained below, WLs with reduced exposure limits also provide a means for estimating the impact of the proposed rule on Part-90 miners.) Appendix H(a) provides a comparison of dust concentrations at WLs operating under the current and proposed exposure limits.

MSHA's current enforcement policy permits individual shift excursions above the exposure limit. The proposed rule would not only reduce exposure limits but also change MSHA's enforcement policy so as to prohibit such excursions. Therefore, simply comparing dust concentrations at WLs subject to the two exposure limits would likely underestimate impacts of the proposed changes. Instead, the QRA utilizes a distribution-free simulation procedure that reflects both aspects of the proposal. For each WL, this procedure is applied to the AS estimate of current average exposure (see Appendix F). The result is a separate projection of what average exposure at each WL would be after successful implementation of the proposed rule. For comparison with risks under existing regulations and enforcement policies, these projections are then aggregated by occupational category, coal mine rank, and the same recurrency class used in evaluating current risks.[51]

(b) Simulation procedure for projecting exposure levels under proposed rule

There are two parts to the simulation procedure, corresponding to the proposed reduction in exposure limit and the proposed change in enforcement policy. The AS estimate of current exposure for any given WL can be divided into two components: one representing shifts already in compliance with the proposed FEL and another representing shifts on which the proposed FEL is currently exceeded. In one part of the simulation, the first component is reduced by an amount derived from the comparison of WLs operating under 2.0 mg/m^3 and 1.0 mg/m^3 exposure limits. This expected reduction factor (ERF) depends on the occupational category and applies only to

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[50] MSHA collected an additional 29,732 samples at WLs with reduced dust standards not equal to 1.0 mg/m^3. The total (146,917 = 2,600 + 114,585 + 29,732) is shown in Table 1.

[51] Under successful implementation of the proposed rule, there should be no recurrence since the exposure limit would apply to each sampling location on each shift. Comparisons between current and projected risks will be made within recurrency classes established under current conditions, as determined in Part 2 of this QRA.

shifts already in compliance with the proposed FEL. In the other part, the component representing shifts on which the proposed FEL has been exceeded is reduced so as to bring projected exposure on all such shifts down exactly to the proposed FEL. Thus, the simulation assumes that single-shift exposures currently exceeding the proposed FEL would be brought down no further than what is necessary for compliance on every shift.

The derivation of occupational ERFs is based on an ANCOVA, described in Appendix H(b), that simultaneously estimates effects of the exposure limit on each occupation while accounting for extraneous job-specific trends over time. This ANCOVA yields an estimate of the general effect of reducing the exposure limit, which must then be combined with estimated modifications for the various job-categories to form the occupational estimates. On a logarithmic scale, the estimated general effect, or norm, is −0.151, which translates to an ERF of exp(−0.151) = 0.86 (i.e., a 14–percent reduction).[52] For eight occupations, such as auger operators (both surface and underground) and cleaning plant operators, the available data contain no instances of an exposure limit equal to 1.0 mg/m^3. Therefore, for these occupations, the ERF is simply set equal to the unmodified norm of 0.86. To better understand how the ERFs for other occupations are constructed, it is helpful to work through a few examples. The logarithmically scaled modifications and the resultant ERFs specific to each occupation are presented in Table 19.

For continuous miner operators, the occupational modification obtained from the ANCOVA in Appendix H(b) is −0.092, with a standard error of 0.083. The *score* shown in Table 19 is the modification divided by its standard error. If, as in the case of continuous miner operators, the score's absolute value exceeds 1.0, then the occupational modification is added to the general effect to yield, on a logarithmic scale, the estimated total effect for the occupation.[53] For continuous miner operators, this is (−0.151) + (−0.092) = −0.243. The ERF is the antilog of this quantity: exp(−0.243) = 0.784. So, for each WL associated with continuous miner operators, that part of estimated current exposure representing shifts already in compliance with the proposed FEL will be multiplied by 0.784, or reduced by 21.6 percent.

If the score shown in Table 19 for an occupation does *not* exceed 1.0 in absolute value, then the estimated occupational modification is considered statistically insignificant, and the ERF for the occupation is set equal to the 0.86 norm. This occurs for 11 job-categories including longwall jacksetters and tailgate operators. For these occupations, the reduction expected on shifts already in compliance with the proposed FEL is slightly smaller than for continuous miner operators.

For bull dozer operators, the estimated modification is +0.460, with a standard error of 0.136 and a score of 3.38. Since the score exceeds 1.0, the modification is added to the estimated

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[52] In its review of this QRA, OSHA stated that it is "not clear on what basis the applicable standard for a particular WL was determined, and whether the general 14% difference based on the ANCOVA can be attributed to efforts made to comply with an effective limit of 1.0 mg/m^3, or whether these measurements can be considered truly representative of conditions likely to occur under the proposed standard." Within each WL, the applicable standard associated with each RCMD measurement is the standard actually in effect on the date of the measurement. These are included in the two data files, InspSamp.txt and OpSamp.txt, that are being placed into the public record in connection with the proposed rule. Although measurements obtained under a current standard reduced to 1.0 mg/m^3 due to quartz content are not necessarily "truly representative of conditions likely to occur under the proposed standard," they provide the best available evidence of what the effects of implementing the proposed FEL would be.

[53] The inclusion criterion for occupation-specific effects in the ERFs relies on the 1-tailed Chebyshev inequality, which holds regardless of the underlying probability distribution. Occupation-specific effects are included when they are more likely than not to reflect a genuine deviation from the overall norm.

norm. The total, however, is greater than zero — indicating that on shifts with dust concentration measurements ≤ 1.0 mg/m^3, average dust concentrations at WLs for bull dozer operators were actually greater when the exposure limit was 1.0 mg/m^3 than when it was 2.0 mg/m^3. Assuming that this is nothing more than a statistical anomaly, the total effect is capped at 0.0 (on a logarithmic scale), corresponding to an ERF of 1.0 or a zero-percent reduction. This also occurs for three other surface (but no underground) job-categories.

Table 19. — Estimated effects of reducing exposure limit from current PEL to proposed FEL on shift exposures currently falling at or below the FEL. Estimated total effect is obtained by adding estimated modification to a norm of −0.151.

	Occupation	Estimated modification	Standard Error	Score	Estimated Total Effect	Expected Reduction Factor (ERF)	Expected Reduction (Pct)
Surface Workers	Auger Op†	.	.	.	-0.151	0.860	14.0
	Backhoe Op	0.886	0.330	2.68	0.000	1.000	0.0
	Bull Dozer Op	0.460	0.136	3.38	0.000	1.000	0.0
	Crane/Dragline Op	0.002	0.799	0.003	-0.151	0.860	14.0
	Cleaning plant Op†	.	.	.	-0.151	0.860	14.0
	Drill Op	0.353	0.179	1.97	0.000	1.000	0.0
	Electrician & helper†	.	.	.	-0.151	0.860	14.0
	Highlift Op/FEL	0.083	0.287	0.29	-0.151	0.860	14.0
	Laborer†	.	.	.	-0.151	0.860	14.0
	Mechanic & helper	0.176	0.564	0.31	-0.151	0.860	14.0
	Tipple Op†	.	.	.	-0.151	0.860	14.0
	Truck Driver	0.236	0.172	1.37	0.000	1.000	0.0
	Utility Man	-0.161	0.577	-0.28	-0.151	0.860	14.0
	Other Surf. Workers	-0.063	0.164	-0.38	-0.151	0.860	14.0
Underground Workers	Auger Op†	.	.	.	-0.151	0.860	14.0
	Cont Miner Op	-0.092	0.083	-1.11	-0.243	0.784	21.6
	Cutting Mach Op†	.	.	.	-0.151	0.860	14.0
	Drill Op†	.	.	.	-0.151	0.860	14.0
	Electrician & helper	-0.302	0.132	-2.29	-0.453	0.636	36.4
	Laborer	-0.640	0.172	-3.72	-0.791	0.453	54.7
	Loading Mach Op	-0.176	0.566	-0.31	-0.151	0.860	14.0
	LW Headgate Op	-0.350	0.287	-1.22	-0.501	0.606	39.4
	LW Jacksetter	0.009	0.208	0.043	-0.151	0.860	14.0
	LW Tailgate Op	-0.142	0.569	-0.25	-0.151	0.860	14.0
	Mechanic & helper	-0.352	0.273	-1.29	-0.503	0.605	39.5
	Mobile Bridge Op	-0.130	0.144	-0.90	-0.151	0.860	14.0
	Roof Bolter	-0.156	0.070	-2.23	-0.307	0.736	26.4
	Shuttle Car Op	-0.152	0.072	-2.11	-0.303	0.739	26.1
	Section Foreman	0.074	0.202	0.37	-0.151	0.860	14.0
	Scoop Car Op	-0.125	0.094	-1.32	-0.276	0.759	24.1
	Tractor Op	-0.123	0.222	-0.55	-0.151	0.860	14.0
	Utility Man	-0.260	0.165	-1.57	-0.411	0.663	33.7
	Other UG workers	-0.304	0.129	-2.36	-0.455	0.634	36.6

†For this occupation, there were no instances of an exposure limit equal to 1.0 mg/m^3, so a specific occupational effect could not be determined. Therefore, the total effect for this occupation is set equal to the general effect.

As shown in Table 19, occupational ERFs range from 0.453 to 1.0. Equivalently, the expected occupational reductions, on shifts already complying with the proposed FEL, range from 54.7 percent to 0.0 percent. For 19 job categories (8 lacking data plus 11 with scores indicating statistically insignificant deviations from the norm), the ERF is 0.86. A more mathematically precise formulation of the algorithm by which occupational ERFs are calculated and applied to AS estimates of current exposure is provided in Appendix H.

The ERF for Part-90 miners was established by a different method. During the period 2004–2008, 933 valid MSHA Day-1 inspector samples were collected on Part-90 miners subject to an exposure limit of 1.0 mg/m^3. Among these, 755 exhibited dust concentrations no greater than the Part-90 proposed FEL of 0.5 mg/m^3. Only 15 samples are available for Part-90 miners subject to an exposure limit below 1.0 mg/m^3, and 14 of these are from WLs with a limit of 0.8 mg/m^3. Since there were no Part-90 miners subject to the proposed limit of 0.5 mg/m^3 during this period, it was necessary to draw the comparison using the reduced dust standard of 0.8 mg/m^3 and to extrapolate the observed effect to 0.5 mg/m^3. Twelve of the 14 dust concentration measurements obtained from WLs subject to a 0.8 mg/m^3 limit did not exceed 0.5 mg/m^3. Notwithstanding uncertainty due to the small number of samples, the available data suggest that reducing the exposure limit from 1.0 mg/m^3 to 0.5 mg/m^3 for Part-90 miners could cut average shift exposures currently less than or equal to 0.5 mg/m^3 by about 50 percent.[54]

As stated earlier, applying the appropriate ERF to reduce a WL's AS exposure estimate constitutes just one part of the simulation procedure for projecting average exposure at each WL after successful implementation of the proposed rule. The other part consists of replacing all dust measurements currently exceeding the proposed FEL with measurements exactly equal to it. The object of doing this is to simulate the proposed limitation of exposure on each individual shift.[55] MSHA recognizes that under successful implementation of the proposed rule, average dust concentrations on those shifts corresponding to the portion currently exceeding the FEL would almost certainly fall somewhere below the FEL. However, MSHA knows of no valid theoretical or empirical basis for estimating the degree by which "single-sample single-shift" enforcement would reduce exposures on these shifts below the FEL. Therefore, it seems prudent to assume that exposures on shifts corresponding to those on which the FEL is currently exceeded will be

[54] MSHA recognizes that the small number of available MSHA inspector samples on Part-90 miners working under an exposure limit less than 1.0 mg/m^3 renders this finding somewhat questionable. Nevertheless, 0.5 falls within the range of occupational ERFs shown in Table 19 and is MSHA's best estimate of the ERF for Part-90 miners based on the currently available data. Details from the simple regression analysis on which this estimate is based are presented in Appendix H(b).

[55] In its review of this QRA, OSHA mischaracterized the two parts of the simulation as applying ERFs to "jobs already below the proposed limit [i.e., FEL]" and reductions of "average exposure levels …[to the FEL], and no further" to "WL-jobs in which the current levels exceed the proposed limit [i.e., FEL]…" Each part of the simulation procedure was, in fact, applied separately within each WL to just those measurements in or out of compliance with the proposed FEL as appropriate. Therefore, contrary to OSHA's interpretation, the simulation procedure does not involve an assumption that for "WL-jobs in which the current levels exceed the [FEL]…, compliance would be achieved if the *average* exposure levels are reduced to [the FEL], and no further" [emphasis added]. Nor were the projections calculated, as the OSHA review states, "based on the ERFs for WLs below 1.0 mg/m^3 and a projected exposure of 1.0 mg/m^3 for WL[s] above the proposed standard…" In the simulation procedure as actually applied to each WL, the average of just those measurements currently falling at or below the FEL is reduced by the ERF, and just those individual measurements that are above the FEL are brought down to the FEL and no further. Therefore, at any WL currently showing at least one measurement below the proposed FEL, the simulation procedure projects that the average concentration will fall *below* the FEL under the proposed rule. This holds even if the WL's measurement average currently exceeds the FEL.

brought down only so far as necessary for compliance. This assumption will promote a conservative assessment of the proposed rule's overall impact. Appendix H(c) contains a more precise description of how projected average dust concentrations are calculated using both parts of the simulation procedure combined.

Table 20 contains average dust concentrations projected under the proposed rule, categorized by occupation, coal rank, and current recurrency class. Since compliance with the proposed rule is being assumed, the average dust concentration shown for each category has been brought down to a value no higher than the FEL. Moreover, because the simulation was separately applied to each WL, there are no individual WLs at which projected average exposure exceeds the FEL. Although the assumption of compliance implies that all WLs will fall into class {R1-}, WLs are broken out by current recurrency class to facilitate comparison with the current exposure levels shown in Table 12.

Table 20 . — Average dust concentrations (mg/m^3) projected under successful implementation of the proposed rule for Part-90 Miners and selected job categories, by coal rank and current recurrency class. Part-90 miners are excluded from job categories.

Occupation		Current Recurrency Class‡ {R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				0.64	0.89		0.89	0.64	
	Cont Miner Op	0.43	0.45		0.65	0.62	0.72	0.74	0.68	0.69
	Cutting Mach Op	0.44	0.42		0.83	0.71		0.84	0.82	
	Drill Op	0.45	0.51			0.78				
	Electrician & helper	0.24	0.24	0.34	0.71					
	Laborer	0.30	0.23	0.12						
	Loading Mach Op	0.15	0.28			0.76				
	LW Headgate Op	0.42	0.45		0.66	0.64		0.70		
	LW Jacksetter	0.65	0.61		0.81	0.77		0.85	0.83	
	LW Tailgate Op	0.56	0.78		0.90	0.89		0.81	0.95	
	Mechanic & helper	0.37	0.25	0.22		0.79				
	Mobile Bridge Op	0.36	0.45	0.28	0.72	0.66		0.71	0.62	
	Roof Bolter	0.40	0.39	0.40	0.70	0.63		0.75	0.61	
	Shuttle Car Op	0.38	0.32	0.28	0.72	0.65	0.71	0.80	0.72	
	Scoop Car Op	0.44	0.40		0.83	0.76				
	Section Foreman	0.45	0.43	0.26		0.85	0.61			
	Tractor Op	0.28	0.39	0.23		0.66				
	Utility Man	0.41	0.36						1.00	
	Other UG workers	0.43	0.38	0.17	0.86	0.85	0.56	1.00	0.97	
Part-90 Miners		0.14	0.16		0.28	0.29		0.28	0.47	
Surface Workers	Auger Op	0.19								
	Backhoe Op	0.19	0.08	0.14						
	Bull Dozer Op	0.19	0.10	0.22	0.58					
	Crane/Dragline Op	0.09		0.10						
	Cleaning plant Op	0.31	0.30	0.23	0.73		0.68			0.87
	Drill Op	0.26		0.27	0.61					
	Electrician & helper	0.23	0.18	0.29	0.77					
	Highlift Op/FEL	0.14	0.13	0.13	0.78					
	Laborer	0.24	0.26	0.27			0.72	0.88		
	Mechanic & helper	0.21	0.26	0.10	0.74		0.54	0.64		
	Tipple Op	0.22	0.15		0.52					
	Truck Driver	0.19	0.09	0.18						
	Utility Man	0.28	0.20	0.01	0.80			0.73		1.00
	Other Surf. Workers	0.21	0.16	0.21	0.68	0.58	0.79	0.65		0.62

†Includes locations where MSHA has not determined the coal rank.

‡Under the successful implementation of the proposed rule, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

A graphic comparison of current and projected exposure levels is provided in Figure 18 for underground job-categories and in Figure 19 for Part-90 miners and surface job-categories. Expected reductions are substantial for all underground occupations in all three recurrency classes. Average dust concentrations for continuous miner operators are projected to fall by nearly one-half at WLs currently in recurrency class {R2+} and by nearly one-third in recurrency classes {R1−} and {R(1–2)}. These relationships are approximately the same for all three coal rank categories. For longwall tailgate operators, the projected reductions are approximately 40% at WLs currently in class {R2+}, 30% at WLs in class{R(1–2)}, and slightly under 25% at WLs in class{R1−}. (Somewhat larger percentage reductions are projected for longwall headgate operators.) Among surface occupations, substantial reductions in average dust concentration are generally expected only at WLs currently in recurrency classes {R(1–2)} and {R2+} — except for cleaning plant operators, mechanics/helpers, laborers, and "utility man." Substantial improvements are, however, projected for *all* surface occupations at the 96 WLs currently in classes {R(1–2)} and {R2+}. At most WLs, Part-90 miners are projected to experience a reduction in average dust concentration of about 40 percent. However, at the five high rank coal WLs for Part-90 miners currently in recurrency class {R2+}, the average dust concentration is projected to decline from 1.45 mg/m^3 (Table 12) to 0.47 mg/m^3 (Table 20) — a reduction of 68 percent. This projected improvement is attributable primarily to MSHA's proposed application of the new exposure limit to every individual shift.[56]

Despite the large percentage reductions in average dust concentrations projected for WLs in classes {R(1–2)} and {R2+}, all occupational averages in these recurrency classes (except Part-90 miners) are projected to remain above the NCD's target of 0.5 mg/m^3. As shown in Table 20, this includes both surface and underground occupations. Aside from "Other UG workers" in recurrency class {R2+},[57] the largest residual dust concentrations are projected for underground "utility man," longwall tailgate operators, and underground auger operators.

[56] At three of the five WLs for Part-90 miners currently in recurrency class {R2+}, single-shift enforcement of the proposed FEL is projected to bring average exposure down to exactly 0.5 mg/m^3 from estimated current values exceeding 1.5 mg/m^3. This is because current exposures on all shifts at these WLs are estimated to exceed 1.0 mg/m^3. At the remaining two WLs in this category, average dust concentration is projected to decline from 0.80 mg/m^3 to 0.40 mg/m^3 and from 0.98 mg/m^3 to 0.44 mg/m^3.

[57] All six of these WLs represent areas on the return sides of longwall faces (occupation code 61).

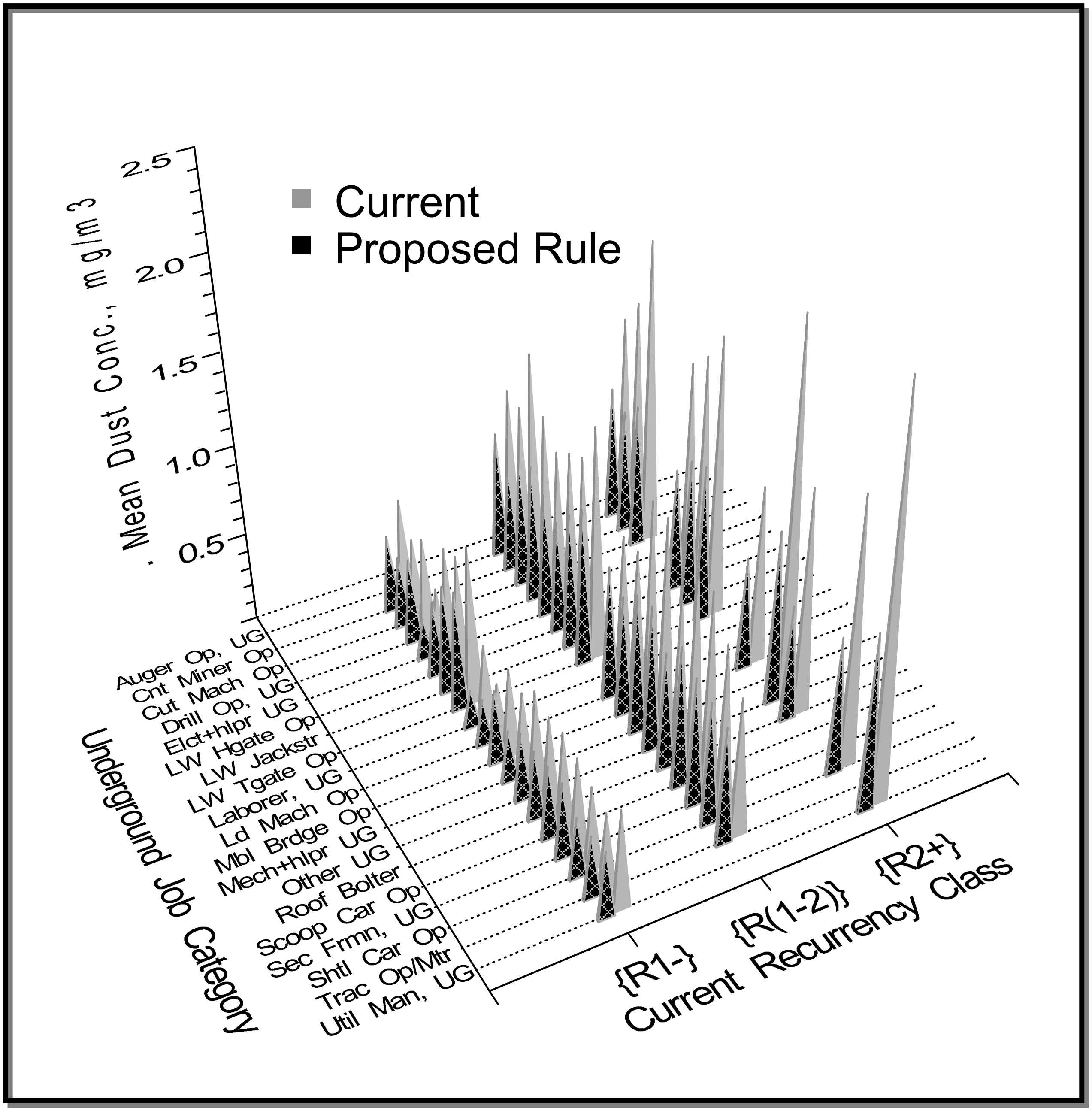

Figure 18. — Comparison of current and projected underground coal mine dust concentrations, by job-category and current recurrency class.

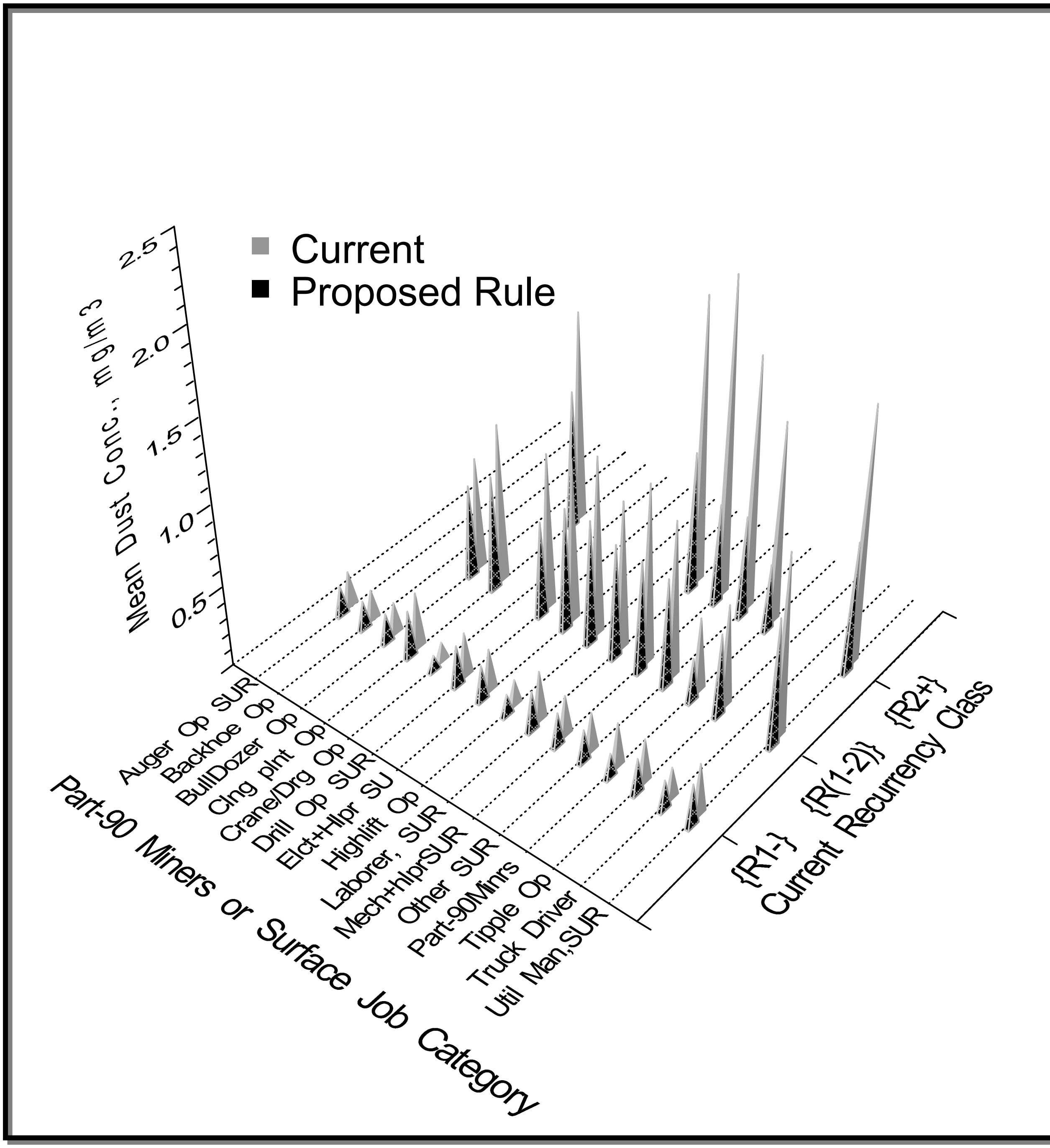

Figure 19. — Comparison of current and projected coal mine dust concentrations for Part-90 miners and surface occupations, by job-category and current recurrency class.

(c) Projected health risks under the proposed rule

(i) Pneumoconiosis

Excess risks of CWP1+, CWP2, and PMF, estimated using the Attfield–Seixas models at the projected exposure levels in Table 20, are respectively shown in Table 21, Table 22, and Table 23. Since these models predict greater risks for exposures to anthracite and high rank bituminous coal than to low/medium rank coal, the projected excess pneumoconiosis risks are not perfectly correlated with projected exposure levels. For example, at WLs in recurrency class {R2+}, the projected average dust concentration for underground auger operators is 0.89 mg/m^3 for those exposed to low/medium rank coal and 0.64 mg/m^3 for those exposed to high rank bituminous coal. Nevertheless, the projected excess risk of PMF is nearly twice as high for the latter group (49 cases per thousand exposed workers versus 25). Similarly, for continuous miner operators in recurrency class {R2+}, projected average exposure is higher in low/medium rank coal than in high rank bituminous or anthracite coal. However, the residual excess risk of PMF in high rank coal is projected to be 54 cases per thousand as compared to 20 in low/medium rank coal.

Table 21. — Estimated Excess Risk of CWP 1+ at age 73 after 45 years of occupational exposure at projected exposure levels under the proposed rule (cases attributable to occupational exposure per 1000 exposed workers).

	Occupation	Current Recurrency Class‡								
		{R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				58	153		85	101	
	Cont Miner Op	37	66		59	96	117	69	110	111
	Cutting Mach Op	38	61		78	115		79	137	
	Drill Op	39	77			130				
	Electrician & helper	19	33	47	66					
	Laborer	25	32	15						
	Loading Mach Op	12	39			124				
	LW Headgate Op	36	66		60	101		65		
	LW Jacksetter	59	95		76	127		81	139	
	LW Tailgate Op	49	129		87	153		77	165	
	Mechanic & helper	31	34	30		131				
	Mobile Bridge Op	31	67	39	66	106		65	97	
	Roof Bolter	34	57	58	65	98		70	95	
	Shuttle Car Op	32	46	39	66	103	114	75	117	
	Scoop Car Op	38	58		79	125				
	Section Foreman	39	64	36		144	95			
	Tractor Op	23	56	32		105				
	Utility Man	35	51						178	
	Other UG workers	37	55	23	82	143	85	98	170	
Part-90 Miners		11	21		23	40		23	70	
Surface Workers	Auger Op	15								
	Backhoe Op	15	10	19						
	Bull Dozer Op	15	13	30	52					
	Crane/Dragline Op	7		14						
	Cleaning plant Op	26	41	32	67		108			149
	Drill Op	21		38	55					
	Electrician & helper	18	24	41	72					
	Highlift Op/FEL	11	17	17	73					
	Laborer	20	35	38			117	84		
	Mechanic & helper	17	36	12	68		82	57		
	Tipple Op	18	19		46					
	Truck Driver	15	12	25						
	Utility Man	24	27	2	75			68		178
	Other Surf. Workers	17	22	28	62	90	131	59		96

†Includes locations where MSHA has not determined the coal rank.

‡ Under the successful implementation of the proposed regulations, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

Table 22. — Estimated Excess Risk of CWP 2+ at age 73 after 45 years of occupational exposure at projected exposure levels under the proposed rule (cases attributable to occupational exposure per 1000 exposed workers).

Occupation		Current Recurrency Class‡								
		{R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				33	118		49	73	
	Cont Miner Op	21	46		33	70	87	39	80	81
	Cutting Mach Op	21	42		45	85		46	104	
	Drill Op	22	54			98				
	Electrician & helper	11	22	32	37					
	Laborer	14	21	10						
	Loading Mach Op	7	26			93				
	LW Headgate Op	20	46		34	73		37		
	LW Jacksetter	33	68		44	95		47	106	
	LW Tailgate Op	28	97		50	118		44	129	
	Mechanic & helper	17	23	20		99				
	Mobile Bridge Op	17	46	26	38	77		37	70	
	Roof Bolter	19	39	40	37	71		40	68	
	Shuttle Car Op	18	31	26	38	75	84	43	87	
	Scoop Car Op	21	40		45	93				
	Section Foreman	21	44	24		110	68			
	Tractor Op	13	38	21		77				
	Utility Man	19	35						141	
	Other UG workers	21	38	15	47	110	61	57	134	
Part-90 Miners		6	14		13	27		13	49	
Surface Workers	Auger Op	8								
	Backhoe Op	8	6	12						
	Bull Dozer Op	8	9	20	29					
	Crane/Dragline Op	4		9						
	Cleaning plant Op	14	28	21	38		79			115
	Drill Op	12		25	31					
	Electrician & helper	10	16	27	41					
	Highlift Op/FEL	6	11	11	42					
	Laborer	11	24	25			86	48		
	Mechanic & helper	10	24	8	39		58	33		
	Tipple Op	10	13		26					
	Truck Driver	8	8	16						
	Utility Man	13	18	1	43			39		141
	Other Surf. Workers	9	14	19	35	65	98	33		70

†Includes locations where MSHA has not determined the coal rank.

‡ Under the successful implementation of the proposed regulations, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

Table 23. — Estimated Excess Risk of PMF at age 73 after 45 years of occupational exposure at projected levels under the proposed rule (cases attributable to occupational exposure per 1000 exposed workers).

	Occupation	Current Recurrency Class‡ {R1−} Low/Med. Rank†	{R1−} High Rank Bituminous	{R1−} Anthracite	{R(1–2)} Low/Med Rank†	{R(1–2)} High Rank Bituminous	{R(1–2)} Anthracite	{R2+} Low/Med Rank†	{R2+} High Rank Bituminous	{R2+} Anthracite
Underground Workers	Auger Op				17	80		25	49	
	Cont Miner Op	11	30		17	46	58	20	54	54
	Cutting Mach Op	11	28		23	57		23	70	
	Drill Op	11	36			66				
	Electrician & helper	6	14	21	19					
	Laborer	7	14	6						
	Loading Mach Op	4	17			63				
	LW Headgate Op	10	30		17	49		19		
	LW Jacksetter	17	45		22	64		24	72	
	LW Tailgate Op	14	65		25	80		22	88	
	Mechanic & helper	9	15	13		67				
	Mobile Bridge Op	9	31	17	19	52		19	47	
	Roof Bolter	10	26	26	19	48		20	46	
	Shuttle Car Op	9	20	17	19	50	57	22	58	
	Scoop Car Op	11	26		23	63				
	Section Foreman	11	29	16		74	46			
	Tractor Op	7	25	14		51				
	Utility Man	10	23						97	
	Other UG workers	11	25	10	24	74	40	29	92	
Part-90 Miners		3	9		7	17		7	32	
Surface Workers	Auger Op	4								
	Backhoe Op	4	4	8						
	Bull Dozer Op	4	6	13	15					
	Crane/Dragline Op	2		6						
	Cleaning plant Op	7	18	14	20		53			78
	Drill Op	6		17	16					
	Electrician & helper	5	10	18	21					
	Highlift Op/FEL	3	7	7	21					
	Laborer	6	15	16			58	25		
	Mechanic & helper	5	16	5	20		39	17		
	Tipple Op	5	8		13					
	Truck Driver	4	5	11						
	Utility Man	7	12	1	22			20		97
	Other Surf. Workers	5	9	12	18	43	66	17		46

†Includes locations where MSHA has not determined the coal rank.

‡Under the successful implementation of the proposed regulations, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

The estimates of residual pneumoconiosis risks in Tables 21–23 were all obtained by applying the Attfield/Seixas pneumoconiosis models (Appendix I) to the projected average dust concentrations shown in Table 20, assuming 45 years of occupational exposure.. They may be compared with the corresponding values in Tables 13–15 to ascertain the proposed rule's projected impact on pneumoconiosis risk within WL categories. Although improvements are projected in every category, the greatest risk reductions are projected to occur at WLs currently in recurrency classes {R(1–2)} and {R2+} with high rank coal. For example, for continuous miner operators in high rank bituminous coal, the excess risk of PMF at class {R1−} WLs is projected to decline from 47 down to 30 cases per thousand exposed workers. The corresponding reduction at class {R(1–2)} WLs is projected to be from 82 to 46; and, at class {R2+} WLs, the improvement is projected to be still greater: 165 excess cases of PMF per thousand continuous miner operators are predicted under current conditions, compared to 54 excess cases under the proposed rule.

There are six occupations with more than five class {R2+} WLs in high rank bituminous or anthracite coal: continuous miner operators (197 WLs), roof bolters (34 WLs), cutting machine operators (9 WLs), mobile bridge operators (9 WLs), longwall tailgate operators (8 WLs), and longwall jacksetters (7 WLs). At these WLs, the projected reduction in PMF risk at age 73 ranges from 47 cases per thousand mobile bridge operators to 192 cases per thousand cutting machine operators. For the same six occupations in high rank bituminous coal, but at WLs currently in recurrency class {R1−}, the range of projected improvements in PMF risk runs from 6 cases per thousand cutting machine operators (6 WLs) to 32 cases per thousand longwall tailgate operators (8 WLs).

(ii) Severe Emphysema

Table 24 contains categorized estimates of the residual excess risks of developing severe emphysema by age 73 under the proposed rule. This table may be compared to Table 16, which presents corresponding risk estimates under current conditions. Both tables assume 45 years of occupational exposure to coal mine dust and a history of never smoking tobacco. The estimates in Table 24 were obtained by applying the Kuempel pulmonary impairment model (Appendix J) to the projected exposure levels shown in Table 20.

Under the proposed rule, projected excess risks of severe emphysema remain systematically greater for "non-whites" than for "whites" and for workers at WLs currently in recurrency classes {R(1–2)} and {R2+} rather than {R1−}. However, these are also the categories in which the largest reduction in risk is expected. For example, the projected risk for "non-white" cutting machine operators at the 10 WLs currently in {R2+} is 76 excess cases of severe emphysema per thousand exposed workers. This risk is 55 percent greater than for "white" workers at the same WLs and 67 percent greater than the risk projected for "non-white" cutting machine operators at WLs currently in {R1−}. Under current conditions, however, the estimated risk for "non-white" cutting machine operators at the {R2+} WLs is 167 excess cases per thousand. The projected improvement of 167 − 76 = 91 excess cases per thousand exceeds the reduction projected for both "white" workers at the same WLs (i.e., 114 − 49 = 65) and "non-white" cutting machine operators in class {R1−} (i.e., 44 − 38 = 6).

Table 24. — Estimated excess risk of developing severe emphysema† by age 73, for "white" and "non-white" never-smokers occupationally exposed to coal mine dust at levels projected under the proposed rule over a 45-year working lifetime (cases attributable to occupational exposure per 1000 exposed workers).

	Occupation	Current Recurrency Class‡ {R1−} White	{R1−} Non-White	{R(1–2)} White	{R(1–2)} Non-White	{R2+} White	{R2+} Non-White
Underground Workers	Auger Op			42	66	45	70
Underground Workers	Cont Miner Op	25	39	36	57	41	65
Underground Workers	Cutting Mach Op	24	38	44	69	49	76
Underground Workers	Drill Op	28	44	46	73		
Underground Workers	Electrician & helper	13	21	42	65		
Underground Workers	Laborer	12	19				
Underground Workers	Loading Mach Op	15	24	44	70		
Underground Workers	LW Headgate Op	24	39	37	59	41	65
Underground Workers	LW Jacksetter	36	57	46	72	50	78
Underground Workers	LW Tailgate Op	40	63	54	84	54	84
Underground Workers	Mechanic & helper	16	26	47	73		
Underground Workers	Mobile Bridge Op	24	38	40	62	37	59
Underground Workers	Roof Bolter	22	35	38	61	38	60
Underground Workers	Shuttle Car Op	19	30	40	64	46	72
Underground Workers	Section Foreman	24	39	43	67		
Underground Workers	Scoop Car Op	23	37	47	74		
Underground Workers	Tractor Op	19	31	38	61		
Underground Workers	Utility Man	21	34			61	94
Underground Workers	Other UG workers	22	35	49	77	60	92
Part-90 Miners		8	13	15	25	24	39
Surface Workers	Auger Op	10	16				
Surface Workers	Backhoe Op	9	15				
Surface Workers	Bull Dozer Op	10	17	33	53		
Surface Workers	Crane/Dragline Op	5	9				
Surface Workers	Cleaning plant Op	16	26	42	67	52	81
Surface Workers	Drill Op	14	23	35	55		
Surface Workers	Electrician & helper	12	20	46	71		
Surface Workers	Highlift Op/FEL	7	12	46	72		
Surface Workers	Laborer	14	22	42	66	52	82
Surface Workers	Mechanic & helper	12	19	41	65	37	58
Surface Workers	Tipple Op	12	19	30	47		
Surface Workers	Truck Driver	10	16				
Surface Workers	Utility Man	14	23	47	74	49	76
Surface Workers	Other Surf. Workers	11	18	40	63	37	59

† Emphysema severity corresponding to $FEV_1 < 65\%$ of predicted normal value.

‡ Under the successful implementation of the proposed regulations, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

Projected reductions in the risk of severe emphysema are similar for surface and underground occupations at WLs currently in recurrency classes {R(1–2)} and {R2+}. Although very few WLs fall into these categories, relatively large improvements are projected for class {R2+} surface mechanics & helpers, surface laborers, and "Other" surface workers. Improvements (and residual risks) are projected to be far smaller for class {R1−} surface occupations, but they are nevertheless significant. The projected improvements for cleaning plant operators and "utility man" at WLs currently in this class are especially noteworthy — four or seven fewer cases of severe emphysema per thousand "white" or "non-white" cleaning pant operators (211 WLs); four or six fewer cases per thousand "white" or "non-white" workers classified as surface "utility man" (358 WLs).

(iii) NMRD Mortality

Assuming 45 years of occupational exposures at the projected levels shown in Table 20, Table 25 and Table 26 contain estimated excess risks of NMRD mortality by ages 73 and 85, respectively, based on a life-table analysis of the relative risks produced by the Attfield–Kuempel model as described in Appendix K.[58] Table 57 (in Appendix K) provides the relative risk of NMRD mortality for each exposure category after 45 years of occupational exposure at the average dust concentrations projected assuming compliance with the proposed rule.

For anthracite WLs, the projected excess NMRD mortality risks are extremely high compared to those for pneumoconiosis and emphysema — especially when the excess risk is accumulated to age 85 as shown in Table 26. For continuous miner operators at anthracite WLs, the residual risk of death due to NMRD by age 85 is projected to remain above 220 deaths per thousand. For other occupations in anthracite (including surface), the projected risk is also very high, even at WLs in recurrency class {R1−}.

Though less apparent, residual risks at high rank bituminous WLs are also relatively high. This becomes clearer if they are compared to the corresponding risks in Tables 17 and 18. For example, despite a projected 31-percent reduction in average dust concentration (from 0.90 mg/m^3 to 0.62 mg/m^3 using Table 12 and Table 20), the excess risk of NMRD mortality by age 85 for continuous miner operators in high rank bituminous WLs of class {R(1–2)} is projected to decline by only 21 percent (from 39 to 31 cases per thousand). In contrast, the excess risk of PMF at WLs in the same category is projected to decline by 46 percent. (See Table 15 and Table 23.)

The high residual risks of NMRD mortality in WLs with anthracite or high rank bituminous coal suggest that some substantial part of the increased NMRD risk associated with coal rank is actually due to geographic factors unrelated to occupational dust exposure. This possibility was duly noted by Attfield and Kuempel in their report:

> It should be noted that any variations in lifestyle, health care, and non-coalmine exposures across geographic regions are also confounded with coal rank in this comparison. [Attfield and Kuempel, 2008, p. 241]

Even with cumulative coal mine dust exposure set at zero, the Attfield–Kuempel exposure–response model produces relative risk estimates of 4.4 and 1.2, respectively, for miners regionally associated with anthracite and high rank bituminous coal. Therefore, all of the excess risks

[58] As before (see footnote 46), Randall Smith of NIOSH's Education and Information Division computed the excess NMRD mortality risks using a competing risk life-table analysis.

shown for NMRD mortality at WLs with high coal rank should be interpreted with extreme caution. This issue is further addressed in Appendix K.[59]

Fortunately, projected *reductions* in NMRD mortality risk are not subject to confounding by extraneous geographic factors. Since exactly the same term representing coal rank appears in the exposure–response model for both current and projected exposures, whatever portion of NMRD mortality risk is not attributable to accumulated occupational exposure should get cancelled out by subtraction.[60] For example, according to Table 18, 266 excess NMRD deaths by age 85 are expected per thousand continuous miner operators working 45 years under current conditions at anthracite WLs in recurrency class {R2+}. Table 26 shows the corresponding risk projected under the proposed rule to be 222 excess deaths per thousand exposed miners. Presumably, geographic factors unrelated to occupational exposure would contribute the same amount to both the 266 and the 222 figures. Therefore, subtracting 222 from 266 should yield a projected improvement — i.e., 44 fewer cases per thousand exposed miners — that is independent of extraneous geographic factors. Notice, however, that essentially the same change in exposure levels is expected to produce a far smaller improvement (32−16 = 16 deaths per thousand) in low/medium rank coal. This difference is consistent with a more potent exposure effect for anthracite.

[59] As pointed out by OSHA in its review of this QRA. the relatively large weight placed on high coal rank by the Attfield-Kuempel exposure-response model for NMRD mortality produces some apparent "inconsistencies between the excess risks of morbidity (e.g., CWP, PMF, emphysema) outcomes and NMRD…mortality" especially "among anthracite workers in some of the low exposure job categories." Specifically, the excess risk of NMRD mortality can exceed the combined excess risks of CWP and severe emphysema for workers at anthracite or high rank bituminous WLs. However, as explained in Appendix K, the extraneous effects giving rise to such anomalies are cancelled out by subtraction when calculating the difference between current and projected NMRD mortality risks.

[60] Because of the concave, exponential structure of the Attfield–Kuempel exposure–response relationship, the effects associated with anthracite or high rank bituminous coal are not purely additive. Although the model contains no explicit interaction term, any change in occupational exposure is modeled as producing a greater effect in the presence of high rank coals than in the presence of low rank coals. Therefore, not all of the increased risk associated with high rank coal is cancelled by subtraction. The portion that is not cancelled is attributable to occupational exposure. This is explained in greater depth in Appendix K.

Table 25. — Estimated Excess Risk of NMRD mortality by age 73 after 45 years of occupational exposure at projected levels under the proposed rule (deaths per 1000 exposed workers).

Occupation		Current Recurrency Class[‡] {R1−} Low/Med. Rank[†]	{R1−} High Rank Bituminous	{R1−} Anthracite	{R(1–2)} Low/Med Rank[†]	{R(1–2)} High Rank Bituminous	{R(1–2)} Anthracite	{R2+} Low/Med Rank[†]	{R2+} High Rank Bituminous	{R2+} Anthracite
Underground Workers	Auger Op				5	15		7	12	
	Cont Miner Op	3	10		5	12	100	6	12	99
	Cutting Mach Op	3	10		7	13		7	14	
	Drill Op	3	11			14				
	Electrician & helper	2	8	88	6					
	Laborer	2	8	81						
	Loading Mach Op	1	8			13				
	LW Headgate Op	3	10		5	12		6		
	LW Jacksetter	5	12		6	13		7	14	
	LW Tailgate Op	4	13		7	15		7	15	
	Mechanic & helper	3	8	84		14				
	Mobile Bridge Op	3	10	86	6	12		6	12	
	Roof Bolter	3	9	89	6	12		6	12	
	Shuttle Car Op	3	9	86	6	12	100	6	13	
	Scoop Car Op	3	10		7	13				
	Section Foreman	3	10	85		14	96			
	Tractor Op	2	9	84		12				
	Utility Man	3	9						16	
	Other UG workers	3	9	83	7	14	95	8	16	
Part-90 Miners		1	7		2	8		2	10	
Surface Workers	Auger Op	1								
	Backhoe Op	1	7	82						
	Bull Dozer Op	1	7	84	5					
	Crane/Dragline Op	1		81						
	Cleaning plant Op	2	9	84	6		99			105
	Drill Op	2		86	5					
	Electrician & helper	2	7	86	6					
	Highlift Op/FEL	1	7	81	6					
	Laborer	2	8	86			100	7		
	Mechanic & helper	2	8	80	6		94	5		
	Tipple Op	2	7		4					
	Truck Driver	1	7	83						
	Utility Man	2	8	78	6			6		110
	Other Surf. Workers	2	7	84	5	11	102	5		96

[†]Includes locations where MSHA has not determined the coal rank.

[‡]Under the successful implementation of the proposed rule, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

Table 26. — Estimated Excess Risk of NMRD mortality by age 85 after 45 years of occupational exposure at projected levels under the proposed rule (deaths per 1000 exposed workers).

	Occupation	Current Recurrency Class[‡] {R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank[†]	High Rank Bituminous	Anthracite	Low/Med Rank[†]	High Rank Bituminous	Anthracite	Low/Med Rank[†]	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				13	39		19	31	
	Cont Miner Op	9	26		14	31	224	16	33	222
	Cutting Mach Op	9	25		18	33		18	36	
	Drill Op	9	28			35				
	Electrician & helper	5	21	199	15					
	Laborer	6	21	186						
	Loading Mach Op	3	22			35				
	LW Headgate Op	9	26		14	31		15		
	LW Jacksetter	14	30		17	35		19	37	
	LW Tailgate Op	12	35		20	39		18	40	
	Mechanic & helper	7	21	192		36				
	Mobile Bridge Op	7	26	196	15	32		15	31	
	Roof Bolter	8	25	203	15	31		16	30	
	Shuttle Car Op	8	23	196	15	32	223	17	34	
	Scoop Car Op	9	25		18	35				
	Section Foreman	9	26	194		37	217			
	Tractor Op	6	25	193		32				
	Utility Man	8	24						42	
	Other UG workers	9	24	189	19	37	213	22	41	
Part-90 Miners		3	19		6	22		6	27	
Surface Workers	Auger Op	4								
	Backhoe Op	4	17	187						
	Bull Dozer Op	4	17	192	12					
	Crane/Dragline Op	2		185						
	Cleaning plant Op	6	22	193	16		221			235
	Drill Op	5		195	13					
	Electrician & helper	4	19	196	17					
	Highlift Op/FEL	3	18	187	17					
	Laborer	5	21	195			224	19		
	Mechanic & helper	4	21	184	16		212	13		
	Tipple Op	4	19		11					
	Truck Driver	4	17	190						
	Utility Man	6	20	179	17			16		243
	Other Surf. Workers	4	19	191	15	30	229	14		217

[†]Includes locations where MSHA has not determined the coal rank.

[‡]Under the successful implementation of the proposed rule, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

(d) Major Assumptions and their Implications for Projected Risks

Residual health risks projected assuming successful implementation of the proposed rule are shown in Tables 21–23 for CWP, Table 24 for severe emphysema, and Tables 25–26 for NMRD mortality. When compared to the corresponding tables for risks under current conditions, these tables imply that the proposed rule would substantially reduce adverse health outcomes attributable to RCMD exposures. In addition to assumptions already discussed in connection with the assessment of risk under current conditions (§2(f)), the analysis underlying this conclusion relies on three more major assumptions:

- *Representative effect of a 1.0 mg/m³ reduced standard* — that the 2,600 valid occupational Day-1 samples obtained by MSHA in 2004–2008 from WLs with a 1.0 mg/m³ RCMD exposure limit due to excessive quartz are representative of the effect that adopting the FEL, apart from enforcement on each shift, would have on RCMD concentrations at all other WLs. (To project the impact, these samples were compared with 114,585 valid occupational Day-1 samples MSHA collected during the same period at WLs with an exposure limit of 2.0 mg/m³.) This assumption applies only to samples representing shifts on which the RCMD concentration is already at or below the FEL.
- *Effect of single-shift, single-sample enforcement* — that exposures representing individual shifts with RCMD concentrations currently above the FEL would be brought down no further than necessary to achieve compliance with the FEL on each and every shift. MSHA recognizes that this assumption is artificial and extremely conservative, in that compliance on every shift would surely entail some reductions to below the FEL. However, the assumption was deliberately designed to avoid overestimating the effect of applying an single-sample exposure limit to every individual shift, in the absence of any data establishing what the effects would actually be.
- *Fully successful implementation* — that implementation and enforcement of the proposed rule will be fully successful in bringing all WLs into compliance with the FEL on each and every shift.

(e) Summary of Expected Reductions in Health Risks

This subsection of the QRA summarizes the reductions in risk expected for each job category from successful implementation of the proposed rule. To do this, the improvements projected for the various WL categories are combined according to the category's relative prevalence. It is important to remember, however, that aggregating estimated impact across widely differing categories will inevitably dilute the estimates for WLs at which the greatest reductions in risk are expected. Quantifying projected effects at "the average WL" masks conditions and projected effects at WLs currently posing the greatest health hazards. Therefore, after presenting the aggregated results for each occupation, the QRA concludes with a description of risk reductions projected for the individual WLs listed in Table 8.

Table 27 contains the estimated percentage of miners, within each occupation, working at WLs in each of the nine categories used in this QRA. (The sum across each row is 100 percent of the WLs for the corresponding occupation.) In the absence of more refined data, these estimates are based directly on the percentage of WLs falling into each category. Hence, the percentage of workers within a category is assumed to equal the percentage of WLs.

It is apparent from Table 27, along with Figures 16 and 17, that the distribution of WLs is highly uneven across recurrency and coal rank categories. To aggregate projected risk reductions for a given occupation, the following formula is used to form the weighted average of changes associated with each WL category associated with that occupation:

$$\mathcal{R}_{\Delta} = \sum_{i=1}^{K} \frac{w_i\left(R_i^c - R_i^p\right)}{100}$$

where the summation (∑) ranges (from i = 1 to K) over the WL categories applicable to a particular adverse health outcome. For severe emphysema, K = 3 recurrency classes; for all other outcomes, K = 9 combinations of recurrency class and coal rank category. For each outcome, R_i^c and R_i^p respectively represent current and projected excess risk for the i^{th} WL category, and the weight (w_i) is the corresponding percentage from Table 27. (Each of the 3 weights used for emphysema is set equal to the sum of the 3 percentages for coal ranks within a recurrency class.)

For each occupation, the aggregated reductions in excess risk projected for the adverse health outcomes considered are shown in Table 28. Clearly significant improvements are projected in every job category, ranging from one fewer case of pneumoconiosis per thousand exposed truck drivers to 105 fewer cases of pneumoconiosis, 50 fewer cases of severe emphysema, and 15 fewer deaths due to NMRD per thousand exposed cutting machine operators. Especially large aggregated improvements are also projected for longwall tailgate operators and continuous miner operators.

For progressive massive fibrosis (PMF, the most severe stage of CWP considered), projected improvements for underground workers at age 73 range from a reduction of four excess cases per thousand loading machine operators to a reduction of 75 excess cases per thousand cutting machine operators. For severe emphysema at age 73, the range of projected improvements for underground workers runs from a reduction of three cases per thousand "white" loading machine operators to a reduction of 50 cases per thousand "non-white" cutting machine operators. Again for underground workers, the range of projected improvements in the risk of death due to NMRD by age 85 is projected to run from one excess case per thousand loading machine operators to 15 excess cases per thousand cutting machine operators. For surface workers, reductions are projected of up to three excess cases of PMF per thousand cleaning plant operators and utility men, eight excess cases of severe emphysema per thousand "non-white" cleaning plant operators and utility men, and three excess cases of NMRD mortality by age 85 per thousand laborers.[61]

Projected risk reductions are, of course, greater for WLs currently in recurrency class {R2+}. For example, the average improvements expected for four such occupations in high rank bituminous coal environments are as follows:

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[61] In its review of this QRA, OSHA stated that "[t]he risk reduction findings would be clearer and more compelling if the risks were reported as projected cases of impairment *within each job category* (i.e., population risk estimate) in addition to the individual risk descriptor per 1000 exposed miners." One advantage of presenting risks and projected risk reductions in terms of cases per thousand exposed miners is that it identifies which miners currently face the greatest likelihood of material health impairments and stand to benefit the most from the proposed rule. Please note that Section **VII.B.** of the NPRM, which addresses projected benefits of the proposed rule, contains MSHA's estimates of the number of miners in each occupational category, as well as the overall projected reductions in the number of adverse health outcomes.

Reduction in Number of Outcomes per Thousand Exposed Workers

Occupation (Recurrency Class {R2+} in high rank bituminous coal)	**PMF** at Age 73	**Severe Emphysema** at Age 73		**NMRD Mortality**	
		White	Non-White	by Age 73	by Age 85
Cutting Mach Op.	192	65	91	12	31
Longwall Tailgate Op.	154	49	69	9	24
Shuttle Car Op.	140	52	74	10	25
Underground Utility Man	316	101	133	17	44

Projected risk reductions in other specific WL categories can be obtained by simply calculating the difference between corresponding entries in the tables presented earlier.

As stated earlier, all of the risk calculations in this QRA assume that miners are occupationally exposed to RCMD for a total of 86,400 hours over a 45-year occupational lifetime. Therefore, the QRA underestimates health risks under current conditions for miners working more than an average of 1920 hours per year for 45 years. Since the proposed rule would adjust dust concentration limits downward to compensate for exposure hours in excess of eight hours per shift, reductions in risk for such miners would be greater than those shown in Table 28.

In its review of this QRA, NIOSH pointed out that

> …the issue of silica exposure … is not dealt with at all in the QRA, which has a focus totally on mixed [coal] mine dust. To a large extent, this focus is reasonable — historically silica exposure has not featured greatly in findings concerning CWP development… and there are no epidemiologic models from the U.S. that include silica exposure as a predictor variable. However, in concentrating on this particular exposure-response relationship with coal mine dust, we must not forget that [coal] miners today are being exposed to excess silica levels, particularly in thinner seam and small mines, and that this situation could well get worse as the thicker seams are mined out. Hence, since silica is more toxic than mixed coal dust, tomorrow's [coal] miners could well be at greater risk, despite a reduction in the mixed coal mine dust standard. It seems appropriate that this fact should be noted in the QRA.

Table 27. — Estimated percentage of miners, within each job category, subject to health risks associated with each current recurrency and coal rank class, based on proportion of WLs in 2008. Part-90 miners are excluded from job categories.

	Occupation	Current Recurrency Class‡ {R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op	0.0	0.0	0.0	40.0	20.0	0.0	20.0	20.0	0.0
	Cont Miner Op	8.5	14.7	0.0	18.5	25.5	0.1	14.7	17.8	0.2
	Cutting Mach Op	14.3	17.1	0.0	11.4	28.6	0.0	2.9	25.7	0.0
	Drill Op	26.5	58.8	0.0	0.0	14.7	0.0	0.0	0.0	0.0
	Electrician & helper	37.7	61.6	0.4	0.4	0.0	0.0	0.0	0.0	0.0
	Laborer	20.8	52.8	26.4	0.0	0.0	0.0	0.0	0.0	0.0
	Loading Mach Op	11.9	86.4	0.0	0.0	1.7	0.0	0.0	0.0	0.0
	LW Headgate Op	21.2	30.8	0.0	15.4	30.8	0.0	1.9	0.0	0.0
	LW Jacksetter	9.6	17.3	0.0	11.5	30.8	0.0	17.3	13.5	0.0
	LW Tailgate Op	10.9	14.5	0.0	18.2	32.7	0.0	9.1	14.5	0.0
	Mechanic & helper	36.5	59.6	2.9	0.0	1.0	0.0	0.0	0.0	0.0
	Mobile Bridge Op	13.7	36.8	1.1	11.6	23.2	0.0	4.2	9.5	0.0
	Roof Bolter	25.8	42.2	0.2	12.8	14.1	0.0	1.8	3.1	0.0
	Shuttle Car Op	30.1	50.0	0.1	11.6	6.3	0.1	1.3	0.5	0.0
	Scoop Car Op	38.5	55.4	0.0	3.4	2.7	0.0	0.0	0.0	0.0
	Section Foreman	48.5	44.9	5.1	0.0	0.7	0.7	0.0	0.0	0.0
	Tractor Op	22.9	65.7	5.7	0.0	5.7	0.0	0.0	0.0	0.0
	Utility Man	48.1	51.5	0.0	0.0	0.0	0.0	0.0	0.4	0.0
	Other UG workers	31.8	56.8	5.4	0.7	3.0	0.3	0.7	1.4	0.0
Part-90 Miners		19.7	39.4	0.0	21.2	10.6	0.0	1.5	7.6	0.0
Surface Workers	Auger Op	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Backhoe Op	84.0	1.5	14.5	0.0	0.0	0.0	0.0	0.0	0.0
	Bull Dozer Op	93.2	1.8	4.6	0.5	0.0	0.0	0.0	0.0	0.0
	Crane/Dragline Op	38.5	0.0	61.5	0.0	0.0	0.0	0.0	0.0	0.0
	Cleaning plant Op	72.5	3.5	16.2	7.0	0.0	0.4	0.0	0.0	0.4
	Drill Op	95.0	0.0	2.1	2.9	0.0	0.0	0.0	0.0	0.0
	Electrician & helper	88.0	7.2	1.6	3.2	0.0	0.0	0.0	0.0	0.0
	Highlift Op/FEL	82.8	7.4	9.5	0.2	0.0	0.0	0.0	0.0	0.0
	Laborer	55.7	8.2	32.9	0.0	0.0	1.9	1.3	0.0	0.0
	Mechanic & helper	79.2	13.5	4.6	1.9	0.0	0.4	0.4	0.0	0.0
	Tipple Op	95.0	4.2	0.0	0.8	0.0	0.0	0.0	0.0	0.0
	Truck Driver	90.1	2.2	7.8	0.0	0.0	0.0	0.0	0.0	0.0
	Utility Man	73.2	23.0	0.5	2.4	0.0	0.0	0.5	0.0	0.3
	Other Surf. Workers	82.9	7.3	6.5	2.4	0.1	0.1	0.6	0.0	0.1

†Includes locations where MSHA has not determined the coal rank.

‡Under the successful implementation of the proposed rule, there should be no recurrence since the exposure limit would apply to each sampling location on each shift.

Table 28. — Reduction in excess risk (outcomes per 1000 exposed workers) expected to result from successful implementation of proposed rule. Part-90 miners are excluded from job categories.

	Occupation	Pneumoconiosis at Age 73			Severe Emphysema† at Age 73		NMRD Mortality	
		CWP1+	CWP2+	PMF	White	Non-White	by Age 73	by Age 85
Underground Workers	Auger Op	46	38	25	18	27	3	7
	Cont Miner Op	68	57	38	27	40	4	11
	Cutting Mach Op	105	102	75	35	50	6	15
	Drill Op	28	22	16	10	15	2	4
	Electrician & helper	18	12	7	8	12	1	3
	Laborer	30	21	14	12	20	3	7
	Loading Mach Op	7	5	4	3	4	0.4	1
	LW Headgate Op	50	39	26	20	30	3	8
	LW Jacksetter	55	46	30	22	32	3	9
	LW Tailgate Op	82	76	54	30	43	5	12
	Mechanic & helper	24	17	11	10	16	2	4
	Mobile Bridge Op	27	22	14	10	16	2	4
	Roof Bolter	32	24	16	13	20	2	5
	Shuttle Car Op	24	17	11	10	16	2	4
	Scoop Car Op	24	18	11	10	16	2	4
	Section Foreman	13	10	6	5	9	1	3
	Tractor Op	13	10	6	5	7	1	2
	Utility Man	25	18	11	11	17	2	4
	Other UG workers	43	35	25	17	26	3	7
Part-90 Miners		35	27	19	14	22	2	6
Surface Workers	Auger Op	3	2	1	2	3	0.2	1
	Backhoe Op	1	1	0	0.4	1	0.1	0.1
	Bull Dozer Op	1	1	1	0.3	1	0.04	0.1
	Crane/Dragline Op	2	1	1	1	1	0.3	1
	Cleaning plant Op	9	6	3	5	8	1	2
	Drill Op	5	3	1	3	4	0.4	1
	Electrician & helper	5	3	1	3	4	0.4	1
	Highlift Op/FEL	2	1	1	1	2	0.2	1
	Laborer	9	6	4	4	6	1	3
	Mechanic & helper	8	4	2	4	6	1	2
	Tipple Op	5	2	1	3	4	0.4	1
	Truck Driver	1	1	1	0.3	0.4	0.04	0.1
	Utility Man	9	6	3	5	8	1	2
	Other Surf. Workers	5	4	2	3	5	1	1

† Emphysema severity corresponding to $FEV_1 < 65\%$ of predicted normal value for never-smoking, racially "white" or "non-white" miners.

Finally, Table 29 shows the projected reductions in risks of PMF and severe emphysema at seven individual work locations, including the five identified in Table 8 as yielding unusually high MSHA measurements from 2004–2008. For all seven WLs, the AS estimate of current exposure is higher than the average value shown in Table 12 for WLs of the same category. Four of the five WLs from Table 8 show AS estimates of current exposure (which are based on 2008 data only) lower than their 2004–2008 MSHA measurement averages. (No MSHA samples prior to 2008 are available for the fifth.) These declines are consistent with the downward trends discussed earlier in connection with Table 6 and the ANCOVA described in Appendix D(c).[62] Still, since they are based on few measurements, the figures in Table 29 are not statistically reliable as estimates of long-term average exposures (notwithstanding their reliability as estimates of exposure levels on the sampled shifts). They are intended only to illustrate the proposed rule's potential effects at WLs where above-average dust concentrations have recently been recorded.

The last two WLs listed in Table 29 were selected because of abnormally high AS estimates of current exposure. The sixth WL is unusual in that its AS exposure estimate (4.26 mg/m^3) exceeds the average concentration obtained from either MSHA or operator samples in 2008. This is because the AS estimate was adjusted upward to reflect exceptionally high dust concentration measurements obtained from a few of the operator samples.[63]

Workers exposed to coal mine dust at the levels of Table 29 face a probability of developing PMF by age 73 that ranges from 4.6 percent to 93 percent (i.e., 46 to 928 cases per thousand). For "white" workers under these exposure conditions the probability of severe emphysema by age 73 ranges from 4 percent to 38 percent, and for "non-whites" it ranges from 7 percent to 44 percent. While not entirely eliminating such risks, successful implementation of the proposed rule would be expected to have a highly significant impact. At WL 4608845-01, for example, the estimated probability of developing PMF by age 73 would fall from 43 percent to 9.6 percent, and the estimated probability for "non-whites" of developing severe emphysema by age 73 would decline from 22 percent to 6.6 percent. Although the much lower average reductions shown in Table 28 are appropriate for assessing the proposed rule's overall impact, it is important to remember that larger improvements are expected at work locations currently showing abnormally high exposure levels.

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62 Additional explanation is warranted for the relatively low AS estimate associated with the first WL listed in Table 29 (cleaning plant operator). The 1.86 mg/m^3 average shown in Table 8 for this WL was based on 5 MSHA samples collected from 2004–2008. Only two measurements are available for 2008: an MSHA sample showing a dust concentration of 1.23 mg/m^3 and an operator sample showing 0.27 mg/m^3. In accordance with the procedure described in Appendix F for handling cases with only one 2008 MSHA sample, these two measurements were averaged to form the AS estimate of 0.75 mg/m^3. Although inclusion of the operator's measurement brings this estimate substantially down from MSHA's 2004–2008 average, anthracite dust at this WL presents an inordinately high risk of PMF even at the exposure level suggested by the reduced estimate: 62 excess cases per thousand exposed workers.

63 In 2008, five valid Day-1 MSHA samples and 19 valid operator samples were collected for the continuous miner operator at this WL. Four of the five MSHA measurements and four of the 19 operator measurements exceeded 1.0 mg/m^3. Although operator samples exceeded 1.0 mg/m^3 on a significantly smaller percentage of shifts, the average excess was significantly greater among the operator measurements: 4.14 mg/m^3 versus 0.96 for the four MSHA samples.

Table 29. — Projected reductions in risk of PMF and severe emphysema at seven selected work locations, including five identified in Table 8.

Occupation	Work Location	AS Estimate of 2008 Avg. Dust Conc. (mg/m^3)	Projected Avg. Dust Conc. Under Proposed Rule (mg/m^3)	Projected Risk Reduction (cases per thousand at age 73)		
				PMF	Severe Emphysema (whites/non-whites)	
Cleaning Plant Op.	3609210-01 [A,1]	0.75	0.62	15	9	13
Contin. Mining Op.	1518233-03 [H,3]	1.78	0.85	196	71	98
Cutting Machine Op.	1518659-01 [H,2]	1.47	0.86	113	45	63
Longwall Tailgate Op.	1102752-57 [L,2]	1.41	1.00	17	31	43
Roof Bolter	4609129-02 [H,3]	1.84	0.70	235	87	121
Contin. Mining Op.	4608365-02 [H,3]	4.26	0.91	805	323	359
Roof Bolter	4608845-01 [H,3]	2.16	0.71	334	114	155

[A] Anthracite
[H] High rank bituminous coal
[L] Low/medium rank coal

[1] {R1−}
[2] {R(1–2)}
[3] {R2+}

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Technical Appendices

A. Dust Sample Coding Definitions

B. Excluded MSHA Dust Samples

C. Statistical Analysis of Multi-Day MSHA Sampling Data

D. Statistical Analysis of MSHA Day-1 Sampling Data

(a) Frequency distributions of occupational dust concentration measurements

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K. Application of Attfield-Kuempel NMRD Mortality Model

Appendix A Dust Sample Coding Definitions

The coding definitions described in this appendix refer to the two sampling data files (InspSamp.txt and OpSamp.txt) placed into the public record in connection with the present rulemaking process. These files cover RCMD samples collected over the 5-year period from 2004 through 2008.

Table 30 lists the various reasons why MSHA may void an RCMD sample and displays the void code used in the sampling data files to identify samples voided for these reasons. Table 33 in Appendix B shows the number of MSHA inspector samples in InspSamp.txt voided for each reason specified.

Table 30. — Dust sample Void Code definitions.

ANP	DA not in producing status	MSS	Multiple samples same shift
ATR	Abnormal tamper resistant	NDO	Non-designated occupation
AWC	Abnormal white center	NON	Non-approved equipment
BRK	Broken	NSS	Part 90 miner not available
CNR	Cassette not received	OCC	Invalid occupation code
CON	Contaminated	OSP	Oversize particles
CUR	Times indexed by indx01.	OVE	Operator void; equipment
DBN	Dated before notice	OVL	Operator void; location
DIS	Discarded sample (too old)	OVM	Operator void; misc.
DNP	DWP not in producing status	OVP	Operator void; production
DNR	Dust data card not received	OVR	Operator void; rain
DTE	Invalid or missing date	OVT	Operator void; time
EXC	Excess sample	PDT	Predated
HLD	Sample received while in hold	PRO	Invalid production
IDO	Insufficient dust observed	QLV	Quartz laboratory void
IMI	Invalid part 90 miner ident	QNT	Unacceptable timeframe
INW	Invalid initial weight	QPN	Invalid certification number
IVR	Inspector void; rain	SAM	Invalid sample type
IWG	Insufficient weight gain	STL	Sample transmitted late
IWS	Invalid workshift	TME	Invalid or missing time
MFP	Malfunctioning pump	UNP	MMU not in producing status
MIM	Cassette did not match card	UWP	Unauthorized work position
MMO	Occp code-meth mining mismatch	WPE	Invalid work position
MNP	Mine not in producing status		

Table 31 contains the sample usage codes used for RCMD samples collected under the Mine Operators' Sampling Program (OpSamp.txt). Samples with code=1 are the normal, bimonthly samples routinely collected to monitor exposure levels for designated occupations and areas. Samples with codes 2 or 6 are additional *support* measurements, collected only after an initial single sample is found to exceed the applicable dust standard in a designated area or work position. Samples with codes 3, 4, or 7 are *abatement* measurements collected to demonstrate compliance with the applicable standard after noncompliance has been cited.

Table 31. — Sample usage codes for samples in Operators' Sampling Program.

Code	Definition
0	Not yet used in compliance determination
1	Bimonthly cycle/ transition period sample
2	in group of 5 additional samples
3	Citation (i.e., abatement) sample
4	Citation sample, split cycle
5	Void sample
6	in group of 5 additional samples, split cycle
7	Citation sample/ compliance during 1st seven days of cycle

Table 32 defines the aggregated occupational categories used in the QRA. The job codes shown are associated with samples listed in both data files, InspSamp.txt and OpSamp.txt. Note that the aggregated "roofbolter" category includes roofbolter area samples in addition to samples explicitly associated with one of the relevant job codes.

Table 32. — Aggregated occupational categories.

Occupational Category	Job Codes in Data Files					
Underground Mines						
Auger Op (UND)	70					
Continuous Miner Op	36					
Cutting Machine Op	38					
Drill Op	34					
Electrician or helper (UND)	2	3	102	103		
Laborer (UND)	16	116				
Loading Machine Op	43					
Longwall Headgate Op	40	64				
Longwall Jacksetter	41					
Longwall Tailgate Op	44	52				
Mechanic or helper (UND)	4	5	104	105		
Mobile Bridge Op	72					
Roof Bolter†	12	14	19	46	47	48
Scoop Car Op	54					
Section Foreman (UND)	49					
Shuttle Car Op (UND)	50	73				
Tractor Op/Motorman	74					
Utility Man (UND)	53					
All other underground jobs	All other job codes less than 200					
Surface Mines and Processing Facilities						
Auger Op	370					
Backhoe Op	324					
Bull Dozer Op	368					
Cleaning plant Op	374	380				
Crane/Dragline Op	378					
Drill Op (surface)	384					
Electrician or helper (surface)	302	303				
Highlift Op/Front End Loader	382					
Laborer (surface)	316					
Mechanic or helper (surface)	304	305				
Tipple Op	392					
Truck Driver	376	386				
Utility Man (surface)	328					
All other surface jobs	All other job codes from 300 to 399					

† Also includes all underground DA samples (UG Sample Type = 3) for which the job code is missing and the first digit of the entity code is 9.

Appendix B Excluded MSHA Dust Samples

Table 33 breaks down the number of valid and voided RCMD samples MSHA collected and processed during the five-year period from 2004 through 2008. All voided samples were excluded from statistical analyses carried out in support of the QRA. The void codes are defined in Table 30 of Appendix A.

Table 33. — Number of valid and voided respirable coal mine dust samples collected by MSHA inspectors, 2004-2008.

Void Code	2004	2005	2006	2007	2008	2004-2008
no Void Code (i.e., valid sample)	39,945	39,412	31,243	31,948	39,219	181,767
ANP	1	0	0	0	0	1
BRK	4	9	10	6	13	42
CON	86	76	79	87	96	424
DNR	1	0	0	0	0	1
DTE	0	0	1	1	0	2
IDO	15	3	0	11	15	44
IMI	0	0	0	0	2	2
INW	0	1	1	1	0	3
IVR	28	18	19	32	49	146
IWS	734	744	815	582	634	3509
MFP	140	124	118	140	146	668
MIM	1	9	3	4	2	19
MMO	3	5	2	5	11	26
OCC	0	0	0	1	0	1
OSP	15	34	21	24	23	117
PRO	1418	1181	2233	2411	3632	10,875
QNT	0	0	1	0	0	1
QPN	0	0	10	28	109	147
SAM	2	1	0	1	0	4
TME	386	371	317	382	517	1973
UWP	1	0	0	0	0	1
WPE	1	1	1	1	0	4
Total	42781	41989	34874	35665	44468	199,777

As shown in Table 33, MSHA collected a total of 181,767 valid inspector samples during the five-year period from 2004 through 2008. Table 34 breaks out these samples by sample type and the number of days from the initial day of an MSHA inspection. The 14,016 samples collected between one and 21 days of a prior MSHA inspection day were excluded from analyses for the QRA because they were generally collected in response to excessively high dust concentration measurements observed on the initial inspection day. Appendix C contains a statistical analysis of these samples and explains why retaining them would bias the occupational exposure estimates. This leaves 167,751 valid "Day-1" inspector samples.[64] One of these samples (Case No. 68,364 in InspSamp.txt) was excluded because the dust concentration measurement appears to have resulted from a coding error.

Table 34. — Number of valid respirable coal mine dust samples collected by MSHA Inspectors, 2004–2008, by sample type and days from initial inspection day.

Sample Type	First Day	1 to 7	8 to 14	15 to 21	Total
Designated Occupation	18,795	400	530	661	20,386
Non-Designated Occupation	72,031	1,745	2,072	2,602	78,450
Designated Area	19,922	324	477	571	21,294
Designated Work Position	6,924	114	130	108	7,276
Part-90 Miner...	1,119	121	87	77	1,404
Non-Designated Area	486	24	24	17	551
Intake Air	9,906	243	275	351	10,775
Non-Designated Work Position	38,568	1,770	840	453	41,631
Total	**167,751**	**4,741**	**4,435**	**4,840**	**181,767**

All 9,906 Day-1 intake air samples were excluded from the QRA because the existing epidemiologic literature does not provide any quantitative relationships linking the quality of intake air to the risk of adverse health effects. However, Appendix D(b) contains a statistical summary of MSHA's Day-1 intake air samples.

In addition, 10,927 Day-1 samples were excluded because they could not be linked to an occupational exposure. This consisted of: 9,592 samples with no occupation code but not identified as a roof bolter designated area; 34 samples coded with an underground occupation code but a surface sample type; 1,288 samples associated with management (occupation code ≥ 400) or having an obsolete occupation code (200 ≤ occupation code < 300); and 13 samples with a surface occupation code but a sample type designation reserved for designated areas (underground).

Therefore, the QRA relies on a total of 167,751 − 1 − 10,927 = 146,917 valid Day-1 MSHA inspector samples.

[64] Five samples collected on 5/25/2004 at Mine 1502240, entity 0100, were replaced as "Day-1" samples by samples collected the following day because the original samples apparently should have been voided but were not.

Appendix C Statistical Analysis of Multi-Day MSHA Sampling Data

A detailed description of the current criteria by which MSHA inspectors return to collect follow-up samples after an initial dust inspection is provided on MSHA's website at http://www.msha.gov/READROOM/HANDBOOK/PH89-V-1(21).pdf (pp 1.24 – 1.29). Briefly, there are two contrary reasons why inspectors would *not* currently return to collect follow-up samples after the first day of an inspection: (1) dust levels measured on the 1st day are so high that a citation is warranted without further compliance sampling; (2) dust levels measured on the 1st day are sufficiently low that no follow-up samples are warranted.

As shown in Table 34 (Appendix B), 14,016 (7.7 percent) of the 181,767 valid RCMD samples collected by MSHA inspectors from 2004 through 2008 were obtained within 21 days of obtaining at least one prior valid dust sample in the same production area of a mine. Since MSHA does not routinely perform dust inspections this frequently, it can safely be assumed that the overwhelming majority of these 14,016 were follow-up samples, collected in response to dust conditions observed during the initial inspection. Table 35 breaks down the 14,016 samples by mine type and the number of days from the initial inspection day. Peak sampling frequencies are evident on the 1st, 14th, and 21st days after an initial dust inspection.

Table 35. — Number of valid respirable coal mine dust samples collected by MSHA Inspectors, 2004–2008, by mine type and days from initial inspection day.

Days from Initial Inspection Day		Processing Facilities	Surface Mines	Underground Mines	Total
0	Initial Day	14,070	27,539	126,142	167,751
Week 1	1	91	578	1298	1967
	2	43	227	386	656
	3	1	45	74	120
	4	19	47	84	150
	5	26	188	246	460
	6	37	221	307	565
	7	25	312	486	823
Week 2	8	55	232	487	774
	9	29	71	349	449
	10	10	24	184	218
	11	12	58	111	181
	12	19	82	476	577
	13	29	136	776	941
	14	30	167	1098	1295
Week 3	15	30	142	817	989
	16	8	68	422	498
	17	2	30	191	223
	18	2	15	249	266
	19	7	44	518	569
	20	10	76	907	993
	21	15	89	1198	1302
Total		14,570	30,391	136,806	181,767

Because the current criteria for follow-up sampling depend on observed conditions, follow-up measurements of dust concentrations are likely, as a group, to differ systematically from measurements obtained on an initial inspection day. Furthermore, since MSHA does not provide mine operators with advance notice of the initial day of a dust inspection, "Day-1" measurements may provide the best available snapshot of dust conditions at each work location. Consequently, if follow-up measurements differ systematically from Day-1 measurements, including them in an assessment of current exposure conditions could make the results less representative of usual dust levels (i.e., dust conditions facing miners in the absence of an ongoing inspection).

An Analysis of Covariance (ANCOVA) was performed on MSHA's dust concentration measurements to determine whether, under current inspection procedures, MSHA's follow-up measurements do in fact differ systematically from MSHA's Day-1 measurements. The ANCOVA allows such a comparison to be made while simultaneously adjusting for differences in applicable dust standards and in the sample types described in Table 34 (Appendix B). To stabilize variance within the cells of this ANCOVA, the natural logarithm of each dust concentration was calculated and used as the dependent variable. Samples were classified according to the week in which they fell following the initial sampling day (i.e., weeks 1, 2, or 3 relative to the Day-1 samples, which were coded as week 0). The results, summarized in Table 36 and

Table 37, demonstrate that the degree to which Day-1 samples differ from follow-up samples is statistically significant at a high confidence level ($p < 0.0001$).

Table 36. — ANCOVA table comparing Day-1 and follow-up samples, based on all valid respirable coal mine dust samples collected by MSHA Inspectors, 2004–2008.

Source	Sum-of-Squares	Degrees of Freedom	Mean-Square	F-ratio	P-value
Sample Type[A]	9671.1795	7	1381.5971	1729.8582	<0.0001
Sample Week[B]	41.0065	3	13.6688	17.1143	<0.0001
Interaction between Sample Type and Week	193.9880	21	9.2375	11.5660	<0.0001
Dust Standard[C]	1423.9850	1	1423.9850	1782.9309	<0.0001
Residual[D]	144,560.4476	181,000	0.7987		

[A] See Table 34 (Appendix B) for definitions of the eight sample types.

[B] Day-1 samples were coded with Sample Week = 0. Follow-up samples were coded 1, 2, or 3 according to the week following initial sampling day.

[C] Applicable dust standard was modeled as a continuous covariate.

[D] 734 degrees of freedom were lost due to missing dust standards and/or codes for sample type.

Table 37. — Adjusted least square estimates of mean respirable coal mine dust concentration (natural log scale), by sample week relative to initial sampling day.†

Sample Week	Adjusted Least Square Mean	Standard Error of Estimate
0 (Initial Sampling Day)	-1.2201	0.0066
1	-1.0353	0.0295
2	-1.1805	0.0296
3	-1.0880	0.0335

†The NIOSH review of this QRA misinterpreted "relative" as referring to the concentration values. The intended meaning is that sample weeks 1, 2, and 3 are the 1st, 2nd, and 3rd weeks following the initial sampling day.

Appendix D Statistical Analysis of MSHA Day-1 Sampling Data

(a) Frequency distributions of occupational dust concentration measurements

Figure 20 and Figure 21 display RCMD concentration frequency distributions for all of the occupational categories considered in the QRA, based on the valid Day-1 samples collected by MSHA inspectors from 2004 through 2008. Note that dust concentrations are plotted on a logarithmic scale along the horizontal axis. The distribution for Part-90 miners is included in Figure 21 with the surface occupations. Vertical dashed lines are plotted at the proposed and existing exposure limits. It is evident from these plots that, with the exception of longwall jacksetters and tailgate operators, the majority of dust concentrations measured for every occupational category fell below 1.0 mg/m^3. (This observation may be relevant to determining technological and economic feasibility of the proposed exposure limit.)

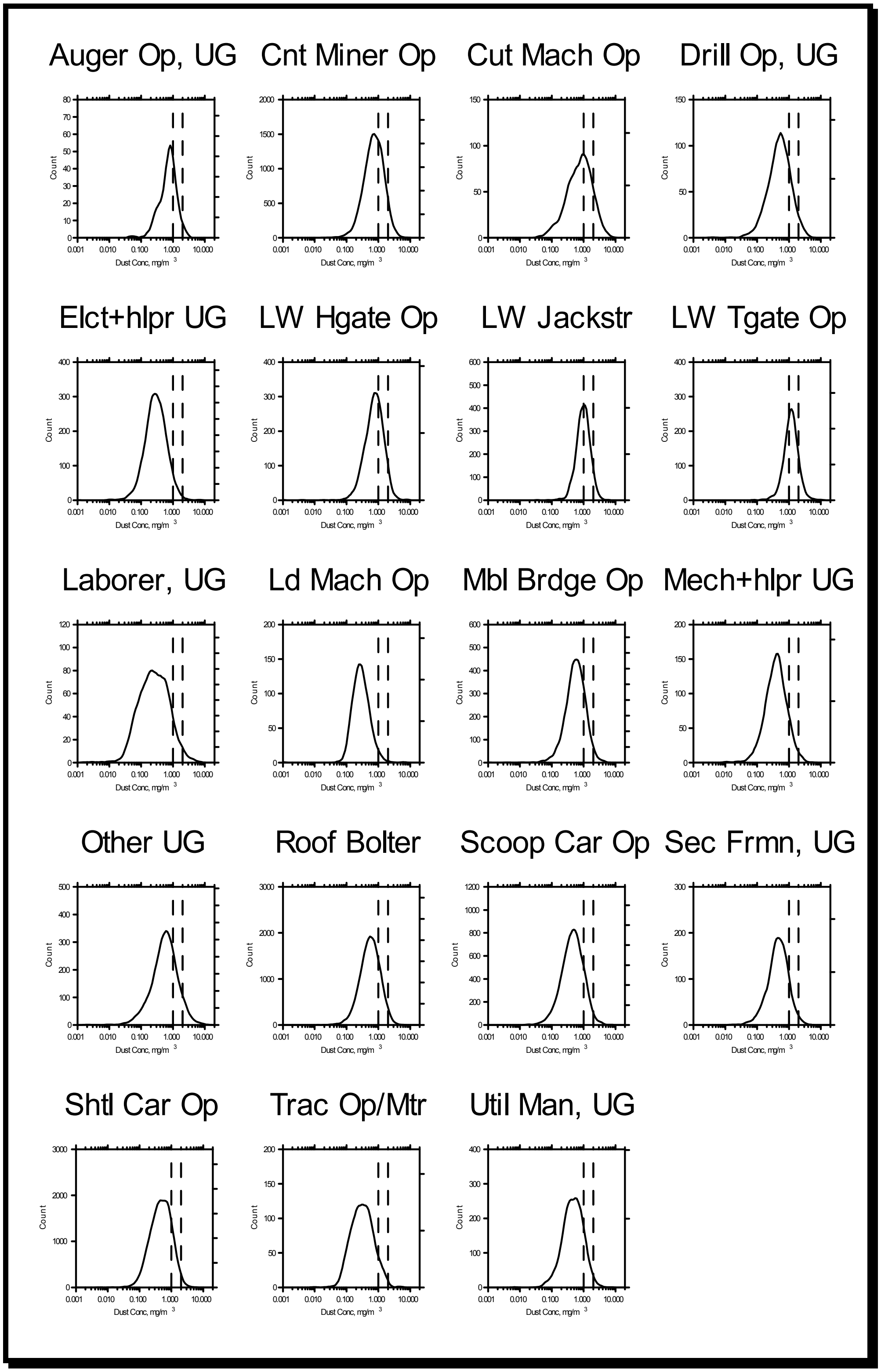

Figure 20. — Frequency distributions of underground respirable coal mine dust concentrations measured by MSHA inspectors, 2004-2008, plotted on a logarithmic scale by job category. Vertical dashed lines are plotted at proposed and existing dust concentration limits.

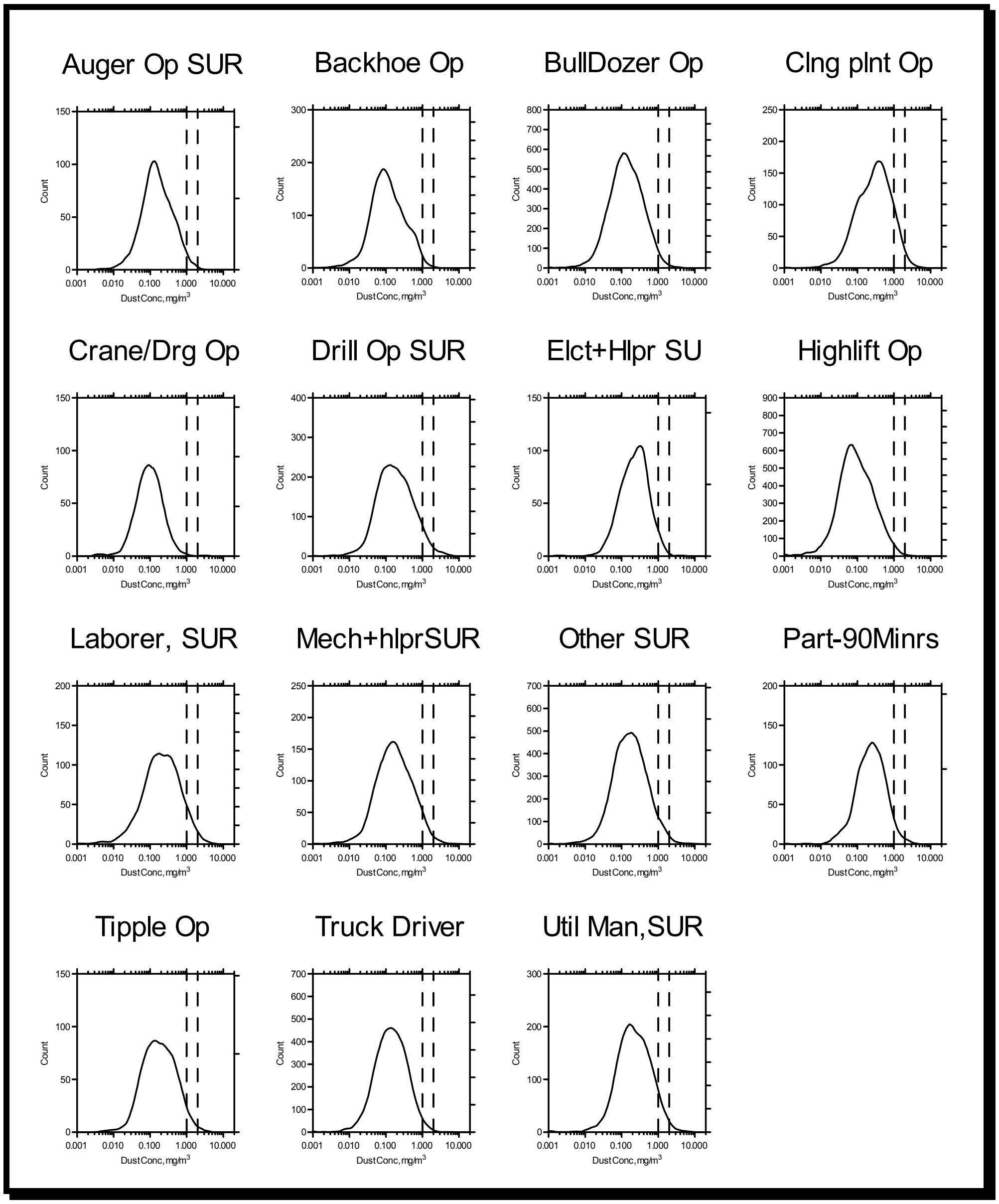

Figure 21. — Frequency distributions of Part-90 Miners and surface respirable coal mine dust concentrations measured by MSHA inspectors, 2004-2008, plotted on a logarithmic scale by job category. Vertical dashed lines are plotted at proposed and existing dust concentration limits.

(b) Frequency distribution of intake air sample measurements

Table 38 and Figure 22 summarize the respirable dust concentrations measured by the 9906 valid, Day-1 intake air samples collected by MSHA inspectors from 2004 through 2008. As shown in Table 38, 90 percent of these measurements fell at or below 0.308 mg/m^3. 107 of the samples contained a quantity of dust below MSHA's analytical laboratory's limit of detection, and these measurements are assigned a nominal value of 0.00 mg/m^3 in the calculations of statistics involving intake air dust concentration. Figure 22 displays the frequency distribution for the intake air measurements, excluding 59 measurements (0.6 percent) greater than 1.2 mg/m^3. Of the 9906 intake air measurements, 373 (3.8 percent) exceeded the proposed limit of 0.5 mg/m^3.

Table 38. — Dust concentrations measured by valid Day-1 intake air samples collected by MSHA inspectors, 2004–2008.

	Dust Concentration	Log_e(Dust Concentration)
Number of samples	9906	9799[A]
Mean	0.156 mg/m^3	-2.250
95% Upper Conf. Limit	0.160	-2.232
95% Lower Conf. Limit	0.152	-2.268
Standard Error	0.002	0.009
Standard Deviation	0.193 mg/m^3	0.901
Coefficient of Variation	0.193÷0.156 = 1.238	-0.401
Percentiles		
10 %	0.035	-3.297
25 %	0.060	-2.781
50 %	0.105	-2.244
75 %	0.185	-1.682
90 %	0.308	-1.171

[A] 107 samples are excluded from calculations involving a logarithmic transformation because they contained a quantity of dust below the MSHA analytical laboratory's limit of detection and were assigned a nominal dust concentration of 0.00 mg/m^3.

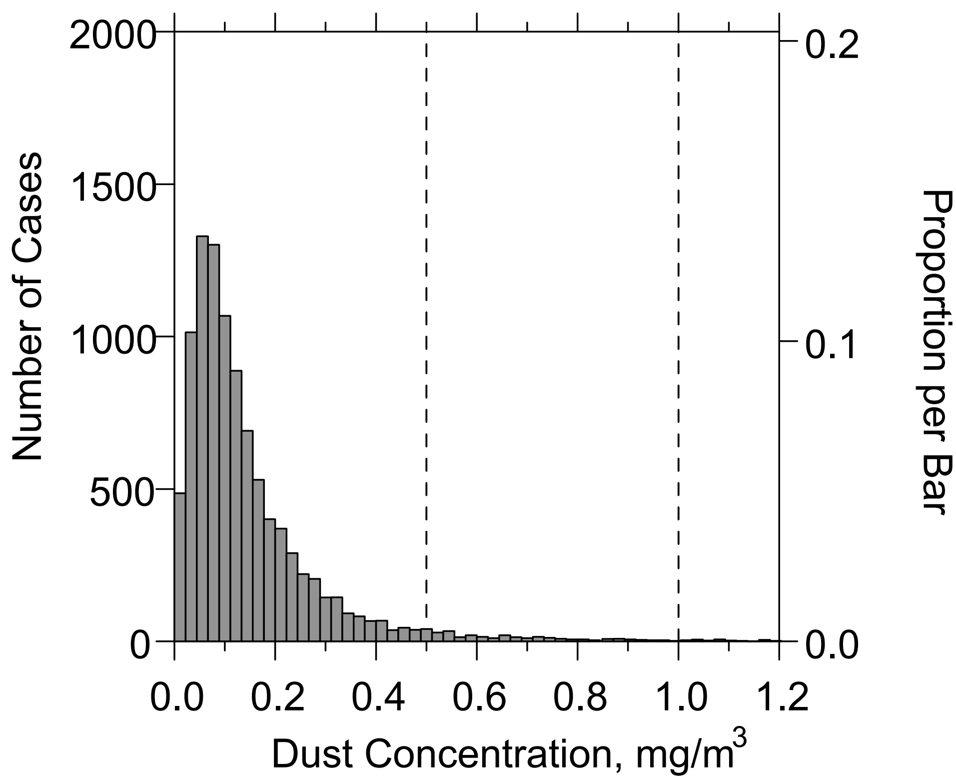

Figure 22. — Frequency distribution of 9,847 MSHA Intake Air dust samples, 2004–2008 (excludes 59 cases > 1.2 mg/m^3). Vertical dashed lines are plotted at proposed and existing dust concentration limits.

(c) Nested ANCOVA on work location, occupation, applicable dust standard, & sampling date

As noted in §1(c) of the QRA, a nested analysis of covariance (ANCOVA) was used to obtain unbiased estimates of the mean concentration associated with each occupation on shifts sampled by MSHA. The ANCOVA model employed adjusts for variability in the sample count and applicable dust standards at different WLs, as well as variability in environmental conditions at different mines, in different production areas within mines, and on different sampling dates. Although separate ANCOVAs were performed for underground and surface occupations, the underlying statistical model was identical in both cases and is expressed as follows:

(Equation 1)

$$\lambda \circ (Y_{ijkl}) = \mu + \alpha_i + \beta_{ij} + \gamma_k + \theta \cdot D_l + \phi \cdot S_{ijl} + \varepsilon_{ijkl}$$

where i indexes a specific mine;

j indexes a production area nested within a specific mine (identified in MSHA's sampling data files by the 2nd and 3rd digits of the 4-digit entity code);

k indexes a specific occupational category;

l indexes the date on which a specific dust concentration measurement was obtained;

Y_{ijkl} is the RCMD concentration measurement obtained for the k^{th} occupation in the j^{th} production area of the i^{th} mine on the date indexed by l;

$$\lambda \circ (Y_{ijkl}) = \begin{cases} \dfrac{Y_{ijkl}^{\lambda} - 1}{\lambda} & \text{if } \lambda \neq 0 \\ Log_e(Y_{ijkl}) & \text{if } \lambda = 0 \end{cases}$$

is the Box-Cox power transformation (Box and Cox, 1964) of the dust concentration measurement, used to normalize the residuals and minimize heterogeneity of variance within the ANCOVA cells;[65]

μ represents an effect corresponding to the overall mean dust concentration;

α_i represents an effect attributable to the i^{th} mine;

β_{ij} represents an effect attributable to the j^{th} production area nested within the i^{th} mine;

γ_k represents an effect associated with the k^{th} occupational category;

θ is the coefficient of the l^{th} measurement date, D_l, which is modeled as a continuous covariate and used to adjust for a monotonic upward or downward trend in dust levels over the 2004–2008 time period;

ϕ is the coefficient of the applicable dust standard, S_{ijl}, in effect at the j^{th} production area in the i^{th} mine on the l^{th} sampling date (S_{ijl} is modeled as a continuous covariate);

ε_{ijkl} represents residual variability that is left unexplained by the factors and covariates of the ANCOVA model.

[65] The optimal Box-Cox parameter, λ, was estimated from the data using a maximum-likelihood procedure.

For MSHA's underground RCMD concentration measurements, the maximum-likelihood estimate of the Box-Cox power transformation parameter was calculated to be $\lambda = 0.1$. Table 39 summarizes the ANCOVA results for the transformed underground data. All effects were found to be statistically significant at a high confidence level ($p < 0.001$).

Table 39. — Nested Analysis of Covariance for underground respirable coal mine dust concentration measurements, using Box-Cox transformation with $\lambda = 0.1$.

Source	Sum of Squares	Degrees of Freedom	Mean-Square	F-ratio	P-value
Overall Mean	182.275	1	182.275	483.339	< 0.001
Mine	5,708.162	745	7.662	20.317	< 0.001
Occupation	3,314.743	18	184.152	488.318	< 0.001
Sampling Date	41.835	1	41.835	110.934	< 0.001
Applicable Std.	31.689	1	31.689	84.029	< 0.001
Production Area	2,759.087	1065	2.591	6.870	< 0.001
Residual	37,512.045	99,471	0.377		

To obtain unbiased estimates of the mean dust concentration associated with each occupational category, it was necessary to apply the appropriate inverse transformation to the adjusted cell means provided by the ANCOVA. For underground occupations, this was done using the approximation method devised by Taylor (1986, §5.1). The results are shown in Table 40.

Table 40. — ANCOVA estimates of mean underground respirable coal mine dust concentrations by occupational category, using Taylor's method of inverse transformation.

Occupation	Transf'd ANCOVA Adj. Mean ($\lambda = 0.1$)	Std. Error	N	Estimated Mean (mg/m^3)	Lower 95% Conf. Limit	Upper 95% Conf. Limit
U-A	-0.498	0.069	118	0.71	0.62	0.82
U-Cont	-0.342	0.031	17,062	0.83	0.79	0.89
U-Cut	-0.433	0.042	569	0.76	0.70	0.83
U-D	-0.808	0.041	641	0.52	0.48	0.56
U-E	-1.158	0.033	2,354	0.36	0.33	0.38
U-L	-0.777	0.042	677	0.53	0.49	0.58
U-LM	-0.884	0.041	601	0.48	0.44	0.52
U-LWH	-0.662	0.037	1,943	0.60	0.56	0.65
U-LWJ	-0.426	0.037	2,006	0.77	0.71	0.82
U-LWT	-0.210	0.039	1,036	0.95	0.88	1.03
U-M	-1.061	0.038	891	0.39	0.36	0.43
U-MB	-0.607	0.033	3,403	0.64	0.60	0.68
U-RB	-0.595	0.031	27,517	0.65	0.61	0.69
U-SC	-0.772	0.031	26,755	0.54	0.50	0.57
U-Scoop	-0.774	0.031	8,678	0.54	0.50	0.57
U-SF	-0.790	0.036	1,150	0.53	0.49	0.57
U-TM	-0.904	0.040	821	0.47	0.43	0.51
U-UM	-0.780	0.034	1,989	0.53	0.50	0.57
U-misc	-0.520	0.033	3,091	0.70	0.65	0.74

For MSHA's surface RCMD concentration measurements, the maximum-likelihood estimate of the Box-Cox parameter was calculated to be $\lambda = 0.0$. This translates to a logarithmic transformation of Y_{ijkl}. Table 41 summarizes the ANCOVA results for the logarithmically transformed surface data. All effects other than the applicable dust standard were found to be statistically significant at a high confidence level ($p < 0.001$).

Table 41. — Nested Analysis of Covariance for logarithmically transformed surface respirable coal mine dust concentration measurements (Box-Cox $\lambda = 0.0$).

Source	Sum of Squares	Degrees of Freedom	Mean-Square	F-ratio	P-value
Overall Mean	22.49216	1	22.49216	24.358	< 0.001
Mine	7164.29766	1948	3.67777	3.983	< 0.001
Occupation	2000.85960	13	153.91228	166.682	< 0.001
Sampling Date	71.83350	1	71.83350	77.793	< 0.001
Applicable Std.	1.52742	1	1.52742	1.654	0.198
Production Area	3588.77031	1866	1.92324	2.083	< 0.001
Residual	37245.80494	40336	0.92339		

For surface occupations, the Method of Moments (MOM) was used to apply an inverse transformation to the adjusted cell means provided by the ANCOVA so as to obtain unbiased estimates of the mean exposure associated with each occupation. For each ANCOVA-adjusted mean of the logarithmically transformed data, the MOM estimate of mean dust concentration is

$\tilde{\eta}_k = \exp(\gamma_k) + \frac{(\text{S.E.})^2}{2}$, where S.E. is the standard error of the estimated value of γ_k. The results for surface occupations are provided in Table 42. For example, the estimated mean concentration for surface auger operators (S-A) is
$\exp(-2.017) + (0.39)^2/2 = 0.13 + 0.08 = 0.21$ mg/m^3.

Table 42. — ANCOVA estimates of mean surface respirable coal mine dust concentration, by occupational category.

Occupation	ANCOVA Adj Mean Log_e	Std. Error	N	Estimated Mean (mg/m^3)	Lower 95% Conf. Limit	Upper 95% Conf. Limit
S-A	-2.017	0.390	677	0.21	0.10	0.45
S-B	-2.175	0.388	1729	0.18	0.08	0.39
S-BD	-2.062	0.387	8097	0.20	0.09	0.43
S-CD	-2.168	0.391	471	0.18	0.08	0.39
S-CPO	-1.574	0.388	1678	0.33	0.15	0.70
S-D	-1.706	0.387	2827	0.29	0.13	0.62
S-E	-1.750	0.389	679	0.28	0.13	0.59
S-H	-2.391	0.387	9202	0.15	0.07	0.31
S-L	-1.743	0.388	1181	0.28	0.13	0.59
S-M	-1.857	0.388	1685	0.25	0.12	0.53
S-T	-1.867	0.389	741	0.25	0.11	0.53
S-TD	-2.017	0.387	6065	0.21	0.10	0.45
S-UM	-1.595	0.388	2211	0.32	0.15	0.69
S-misc	-1.834	0.387	6923	0.25	0.12	0.54

Appendix E Statistical Analysis of 2008 Operator Samples

(a) Comparison of periodic, abatement, and support samples

Mine operators collected a total of 41,981 RCMD samples in 2008, of which 6,734 (16 percent) were voided for various reasons. The two most frequent reasons why operator samples were voided were "EXC" (excess sample, not meeting the requirements to be included in MSHA's compliance or abatement determinations) and "PRO" (failure to meet minimum production requirement on sampled shift). A total of 3,323 operator samples were voided in 2008 for these two reasons.

31,566 of the remaining 35,247 valid operator samples for 2008 were associated with designated occupations or roofbolter designated areas (underground), designated work positions (surface) or Part-90 miners. Table 43 breaks these samples out by occupation and category of sample usage (see Appendix A). 77 percent (22,835 of 29,549) of the valid periodic (i.e., bimonthly) samples, and 75 percent of the valid abatement samples, were collected for continuous miner operators. 62 percent (559 of 900) of the valid support samples were collected for roofbolters.

Table 43. — Number of valid, occupational respirable coal mine dust samples collected by mine operators in 2008, by occupation and Sample Usage Code (SUC).

Occupation		Abatement (SUC = 3,4,7)	Periodic (SUC = 1)	Support (SUC = 2,6)	Total
Surface	Backhoe Op	0	31	0	31
	Bull Dozer Op	36	367	106	509
	Cleaning Plant Op	0	129	22	151
	Drill Op	28	259	63	350
	Electrician or helper	0	33	3	36
	Highlift Op/Front End Loader	0	71	0	71
	Laborer	0	62	5	67
	Mechanic or helper	0	74	10	84
	Tipple Op.	0	31	0	31
	Truck Driver	0	85	0	85
	Utility Man	20	137	40	197
	All other	25	324	56	405
Part-90		10	494	35	539
Underground	Auger Op.	0	109	0	109
	Continuous Miner Op.	833	22,835	1	23,669
	Cutting Machine Op.	10	433	0	443
	Drill Op.	0	23	0	23
	Electrician or helper	0	2	0	2
	Loading Machine Op.	0	5	0	5
	Longwall Jacksetter	65	502	0	567
	Longwall Tailgate Op.	15	706	0	721
	Mechanic or helper	0	1	0	1
	Mobile Bridge Op.	10	510	0	520
	Roofbolter	65	2,077	559	2,701
	Shuttle Car Op.	0	4	0	4
	Scoop Car Op	0	5	0	5
	All Other	0	240	0	240
Total		1117	29,549	900	31,566

RCMD concentration measurements from abatement, periodic, and support samples were separately compared within the occupational categories of continuous miner operator, roofbolter, and longwall jacksetter. This was done using a nested Analysis of Variance (ANOVA) model that adjusted for extraneous differences between mines and production areas that could otherwise bias the comparison. The same underlying statistical model was used in each of the three ANOVAs and is expressed as:

(Equation 2)

$$\lambda \circ (Y_{ijkl}) = \mu + \alpha_{ij} + \beta_k + \gamma_{ijk} + \varepsilon_{ijkl}$$

where i indexes a specific mine;

j indexes a production area nested within a specific mine (identified in MSHA's sampling data files by the 2nd and 3rd digits of the 4-digit entity code);

k indexes a sample usage category (abatement, periodic, or support);

l indexes a specific dust concentration measurement;

Y_{ijkl} is the l^{th} RCMD concentration measurement for the specified occupation obtained in the k^{th} sample usage category at the j^{th} production area of the i^{th} mine;

$$\lambda \circ (Y_{ijkl}) = \begin{cases} \dfrac{Y_{ijkl}^{\lambda} - 1}{\lambda} & \text{if } \lambda \neq 0 \\ Log_e(Y_{ijkl}) & \text{if } \lambda = 0 \end{cases}$$

is the Box-Cox power transformation (Box and Cox, 1964) of the dust concentration measurement, used to normalize the residuals and minimize heterogeneity of variance within the ANOVA cells;[66]

μ represents an effect corresponding to the overall mean dust concentration;

α_{ij} represents an effect attributable to the j^{th} production area nested within the i^{th} mine;

β_k represents an effect associated with the k^{th} sample usage category;

γ_{ijk} represents variable effects of the sample usage category at specific production areas;

ε_{ijkl} represents residual variability that is left unexplained by the factors of the ANOVA model.

For the ANOVA involving continuous miner operators, the optimal value of the Box-Cox transformation parameter was determined to be $\lambda = 0.2$, and all factors in the ANOVA were found to be statistically significant at a high confidence level ($p < 0.0001$).[67]

For roofbolters, $\lambda = 0.2$; and all factors of the ANOVA except for the overall ("main") sample usage effect, β, were statistically significant at a high confidence level ($p < 0.0001$). The re-

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66 The optimal Box-Cox parameter, λ, was estimated from the data using a maximum-likelihood procedure.

67 The one continuous miner sample coded as "support" was excluded from the ANOVA, so the comparison was between periodic (bimonthly) and abatement samples only.

lationship between mean dust concentrations associated with the three sample usage categories varied significantly in different mines and/or production areas, as indicated by a highly significant interaction effect, γ ($p < 10^{-14}$).[68]

For longwall jacksetters, the optimal value of λ was determined to be 0.3. Although the ANOVA overall model was statistically significant ($p = 0.016$), the only statistically significant factor detected was the mine/production-area effect, α. This may be due to the relatively small number of jacksetter abatement samples, which leads to relatively low power of the ANOVA to detect differences. However, as will be shown below, the ANOVA for jacksetters exhibited a relationship between abatement and periodic samples that was roughly consistent with the relationships detected for roofbolters and continuous miner operators.

Table 44 shows the ANOVA-adjusted estimates of the mean values associated with the three sample usage categories. (The ANOVA adjustment isolates these estimates from effects due to differences between mines and/or production areas.) Abatement samples for both continuous miner operators and roofbolters show a significantly lower mean value than periodic and/or support samples. Although the difference is not statistically significant, the mean value shown for abatement samples associated with longwall jacksetters is also lower than the mean shown for the corresponding periodic samples. Consequently, the QRA does not utilize any abatement samples in its calculations of estimated risks.

Table 44. — ANOVA-adjusted mean values associated with abatement, periodic, and support samples, using optimal Box-Cox transformation of respirable coal mine dust concentration measurements. Parenthetical figure is standard error of the estimate.

	Box-Cox λ	Adjusted Mean & Std, Error of Transformed Dust Concentrations		
		Abatement	Periodic	Support
Continuous Miner Op.	0.2	−0.900 (0.044)	−0.610 (0.006)	N/A
Roofbolter	0.2	−0.898 (0.155)	−0.779 (0.021)	−0.774 (0.042)
Longwall Jacksetter	0.3	0.071 (0.091)	0.076 (0.028)	N/A

(b) Frequency distributions of bimonthly dust concentration measurements

Figure 23 and Table 45 summarizes the statistical distributions of the valid, bimonthly RCMD concentration measurements obtained by mine operators in 2008 for Part-90 miners, continuous miner operators, longwall jacksetters, and roofbolters. As shown by the percentiles provided in Table 45: 75 percent of the continuous miner measurements fell at or below 0.95 mg/m^3; 75 percent of the roofbolter measurements fell at or below 0.86 mg/m^3; 75 percent of the

[68] A test on the combined effect of β and γ also showed a high level of statistical significance ($p < 10^{-14}$).

jacksetter measurements fell at or below 1.50 mg/m^3; and 75 percent of the Part-90 miner measurements fell at or below 0.46 mg/m^3.

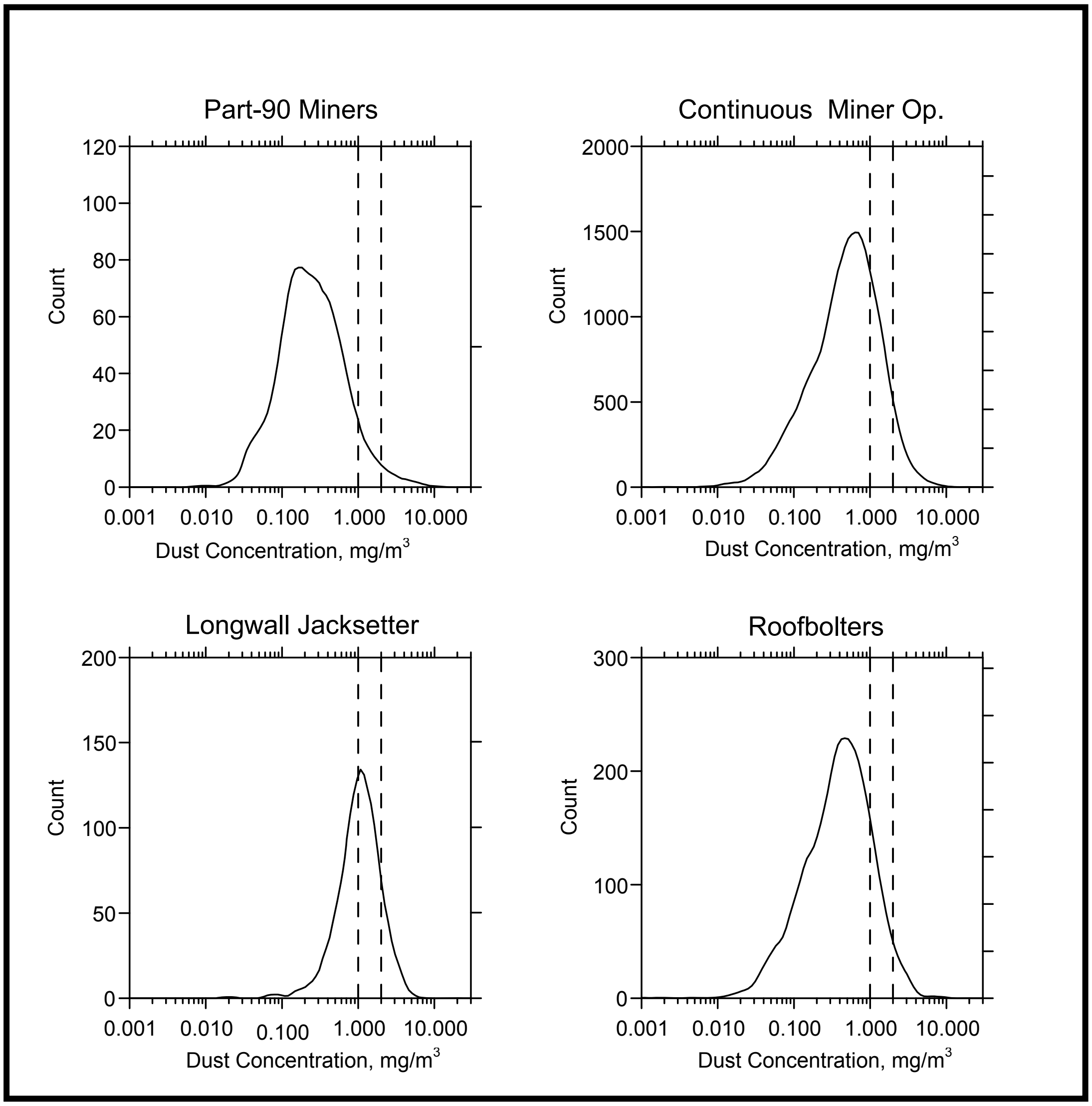

Figure 23. — Periodic (bimonthly) respirable coal mine dust concentrations measured by mine operators in 2008 for Part-90 miners and three underground occupations, plotted on a logarithmic scale. Vertical dashed lines are plotted at 1.0 mg/m^3 and 2.0 mg/m^3. Roofbolter category includes roofbolter designated areas.

Table 45. — Summary statistics for periodic (bimonthly) respirable coal mine dust concentrations measured by mine operators in 2008 for Part-90 miners and three underground occupations. Roofbolter category includes roofbolter designated areas.

		Continuous Miner Op.	Roofbolter	Longwall Jacksetter	Part-90 Miner
Number of valid bimonthly samples		22,835	2,077	502	494
Minimum	mg/m^3	0.00	0.00	0.02	0.01
Maximum	mg/m^3	22.48	7.90	5.07	7.77
Mean	mg/m^3	0.74	0.59	1.21	0.41
Std. Dev.	mg/m^3	0.81	0.62	0.73	0.63
Percentile (mg/m^3)	**5%**	0.07	0.06	0.33	0.05
	10%	0.11	0.10	0.46	0.08
	20%	0.20	0.16	0.64	0.11
	25%	0.25	0.20	0.74	0.13
	50%	0.52	0.41	1.06	0.23
	75%	0.95	0.76	1.50	0.46
	80%	1.10	0.86	1.69	0.52
	90%	1.57	1.25	2.12	0.80
	95%	2.11	1.64	2.75	1.22

(c) Comparison of Operator and MSHA dust concentration measurements

As indicated in §1(c) of the QRA, the mine operators' 2008 periodic (bimonthly) dust sample results were compared to MSHA's corresponding 2008 measurements for continuous miner operators, roofbolters, longwall jacksetters, and Part-90 miners. In order to avoid biasing the comparisons because of imbalances in the specific mines and/or production areas involved, each comparison was accomplished with a nested Analysis of Variance (ANOVA) designed to adjust for such imbalances. The same underlying statistical model was used in each of the four ANOVAs and is expressed as:

(Equation 3)

$$\lambda \circ (Y_{ijkl}) = \mu + \alpha_{ij} + \beta_k + \gamma_{ijk} + \varepsilon_{ijkl}$$

where i indexes a specific mine;

j indexes a production area nested within a specific mine (identified in MSHA's sampling data files by the 2nd and 3rd digits of the 4-digit entity code);

k indexes the origin of the sample (MSHA or mine operator);

l indexes a specific dust concentration measurement;

Y_{ijkl} is the $l^{\underline{th}}$ RCMD concentration measurement for the specified occupation obtained at the $j^{\underline{th}}$ production area of the $i^{\underline{th}}$ mine by either MSHA or the mine operator as specified by the value of k;

$$\lambda \circ (Y_{ijkl}) = \begin{cases} \dfrac{Y_{ijkl}^{\lambda} - 1}{\lambda} & \text{if } \lambda \neq 0 \\ Log_e(Y_{ijkl}) & \text{if } \lambda = 0 \end{cases}$$

is the Box-Cox power transformation (Box and Cox, 1964) of the dust concentration measurement, used to normalize the residuals and minimize heterogeneity of variance within the ANOVA cells;[69]

μ represents an effect corresponding to the overall mean dust concentration;

α_{ij} represents an effect attributable to the $j^{\underline{th}}$ production area nested within the $i^{\underline{th}}$ mine;

β_k represents an effect associated with the sample origin (MSHA or mine operator) as specified by k;

γ_{ijk} represents variable effects of the sample origin at specific production areas;

ε_{ijkl} represents residual variability that is left unexplained by the factors of the ANOVA model.

Table 46 summarizes results of the four ANOVAs and provides ANOVA-adjusted estimates of the mean transformed measurement ($\mu + \beta_k$) associated with mine operator or MSHA samples.

Table 46. — Summary of four ANOVAs comparing MSHA inspectors' and mine operators' respirable coal mine dust samples collected in 2008 for three occupations and for Part-90 miners. MSHA samples collected within 21 days of a prior sampling day are excluded. Operator samples include only those with sample usage code = 1 (i.e., abatement and support samples are excluded).

Dust samples addressed by ANOVA	λ	α p-value	β p-value	γ p-value	Adjusted mean and Std. error of transformed dust concentrations (parenthetical figure is Std. error)	
					Mine Operator	MSHA
Continuous Miner Op.†	0.2	<0.001	<0.001	0.019	−0.615 (0.007)	−0.283 (0.016)
Roofbolter‡	0.2	<0.001	<0.001	<0.001	−0.855 (0.019)	−0.552 (0.011)
Longwall jacksetter	0.3	0.039	0.002	0.115	0.095 (0.030)	−0.052 (0.036)
Part-90 Miner	−0.1	0.002	0.27	0.20	−1.578 (0.053)	−1.469 (0.084)

†Two operator samples showing dust concentration measurements > 15 mg/m^3 were identified as statistical anomalies and excluded from the ANOVA.

‡Includes roofbolter designated areas.

[69] The optimal Box-Cox parameter, λ, was estimated from the data using a maximum-likelihood procedure.

For both continuous miner operators and roof bolters (the job categories most commonly sampled by mine operators), the ANOVA found, after adjusting for the specific mines and production areas involved, that the bimonthly operator samples yielded lower average dust concentration measurements than MSHA's Day-1 inspector samples. As shown in Table 46, the differences were statistically significant at a high confidence level ($p < 0.001$). The ANOVA for Part-90 miners also showed a tendency for operator measurements to be lower than MSHA measurements, but (perhaps owing in part to fewer samples being available for comparison) the relatively small difference observed was not statistically significant ($p = 0.27$).

For longwall jacksetters, the ANOVA showed a small but statistically significant elevation in the operators' dust concentration measurements as compared to MSHA's. As shown in Table 46, the main "sample origin" effect (β) is statistically significant ($p = 0.002$), and the adjusted mean of the transformed dust concentration measurements obtained by mine operators (0.095±0.03) exceeds the corresponding value for MSHA measurements (−0.052±0.036). This agrees with the finding in MSHA (1993) that, at longwall face areas, the average dust concentration experienced by the designated occupation on shifts sampled by mine operators tends to exceed the corresponding average on shifts sampled by MSHA. (The same 1993 MSHA report also found that, at longwall face areas, production on shifts sampled by MSHA tends to fall below production on shifts sampled by mine operators.)

Another comparison, directly of the untransformed MSHA and operator 2008 RCMD concentration measurements, was also performed. This was done using a paired t-test for selected occupational categories, as well as for the combination of all matched work locations, based on the difference between the mean values of MSHA and operator measurements made within each work location (WL). The results are shown in Table 47.

Table 47. — Paired t-test comparisons of MSHA and operator respirable coal mine dust concentration measurements within work locations, based on samples collected at matched WLs in 2008. MSHA samples collected within 21 days of a prior sampling day and operator abatement samples are excluded.

Occupation	Number of Matched WLs	Mean Difference (MSHA − Op) mg/m^3		Paired-t	Degrees of Freedom	p-value
		Mean	95% Conf. Interval			
Part-90 Miner	51	0.02	−0.033 to 0.077	0.80	50	0.43
Continuous Miner Op.	987	0.09	0.061 to 0.126	5.60	986	<0.0001
Roofbolter	405	0.11	0.067 to 0.147	5.29	404	<0.0001
Longwall Jacksetter	22	−0.10	−0.266 to 0.075	−1.17	21	0.26
Longwall Tailgate Op.	30	0.12	−0.048 to 0.292	1.47	29	0.15
Surface Utility Man	30	0.10	−0.216 to 0.419	0.65	29	0.52
Cleaning Plant Op.	32	0.01	−0.107 to 0.124	0.15	31	0.88
Highlift / FEL Op.	18	0.16	−0.046 to 0.361	1.63	17	0.12
Bull Dozer Op.	70	0.04	−0.020 to 0.100	1.34	69	0.19
All Occupations	1892	0.09	0.069 to 0.113	8.00	1891	<0.0001

For Part-90 miners, continuous miner operators, roofbolters, and longwall jacksetters, the results shown in Table 47 confirm the conclusions drawn from the ANOVAs summarized in Table 46. In the case of the jacksetters, the paired t-test does not yield a statistically significant result, but the mean difference suggests slightly higher dust concentration measurements from the operator samples. Although none of the other individual occupations considered show a statistically significant difference between MSHA and operator samples, it is statistically significant that eight of the nine categories show a difference in the same direction (MSHA > Op., $p = 0.004$ based on 2-tailed sign test). Furthermore, the paired t-test on all 1892 matched WLs shows, at a 95-percent confidence level, that MSHA's measurements exceed the operators' by an amount averaging somewhere between 0.069 mg/m^3 and 0.113 mg/m^3. It is important to note that this confidence interval applies to the mean excess across all WLs. Hence, the average amount by which MSHA's measurements exceed those of the operator is liable to be far greater in some specific WLs.

Appendix F Estimation of Current Average Exposure Levels

$\Re$ is defined as 0.5 mg/m^3 for Part-90 Miners and 1.0 mg/m^3 for all other job-categories.

For each job-category in a given work location:

Let $\boldsymbol{K_g}$ denote the number of valid, 1st-day MSHA (**g**overnment) dust concentration measurements collected in 2008; let $\boldsymbol{K_o}$ denote the number of valid **o**perators' periodic and support dust concentration measurements collected in 2008 for the same job-category and work location.[70]

Let $\sum X_g$ denote the sum of the $\boldsymbol{K_g}$ MSHA measurements, and let $\sum X_o$ denote the sum of the $\boldsymbol{K_o}$ operator measurements.

$$\text{Let } \tilde{\mu} = \begin{cases} \dfrac{\sum X_g + \sum X_o}{K_g + K_o} & \text{if } K_g < 2 \text{ or if } \dfrac{\sum X_g}{K_g} < \dfrac{\sum X_o}{K_o} \\[2ex] \dfrac{\sum X_g}{K_g} & \text{otherwise} \end{cases}$$

Let $\overline{XS} = \dfrac{\sum_{X_g > \Re}(X_g - \Re) + \sum_{X_o > \Re}(X_o - \Re)}{k_g + k_o}$, where k_g and k_o are the number of MSHA and operator samples exceeding $\Re$, respectively.

$$\text{Let } \overline{XS}_o = \frac{\sum_{X_o > \Re}(X_o - \Re)}{k_o}$$

Let $\boldsymbol{K}$ denote the number of samples used to form $\tilde{\mu}$ (i.e., either K_g or K_g+K_o), and let $\boldsymbol{k}$ denote how many out of these K samples exceed $\Re$.

Then the estimate of the current average dust concentration level for the specified job-category at the given work location is:

$$\tilde{\tilde{\mu}}_{\text{now}} = \begin{cases} \tilde{\mu} & \text{if } \overline{XS}_o \le \overline{XS} \\[2ex] \dfrac{K \bullet \tilde{\mu} + k \bullet (\overline{XS}_o - \overline{XS})}{K} & \text{if } \overline{XS}_o > \overline{XS} \end{cases}$$

[70] Operators' abatement samples and 2 anomalous periodic operator measurements > 15 mg/m^3 are excluded.

Appendix G Characterization of WL Exposure Distributions

(a) Effects of variability in production and applicable dust standard.

Although industry-wide occupational exposure distributions, such as are presented in Appendices D(a) and E(b) can be helpful in targeting those occupations that present the greatest health risks, miners are not generally exposed to an industry-wide frequency distribution of dust concentrations. Instead, they are faced with the distribution of dust concentrations at the specific locations where they work. Within each WL, dust concentrations fluctuate from shift to shift, subject to variations in shift production, application of dust controls, and the applicable dust standard (which may vary due to changes in quartz content of the coal being mined).

To isolate the effects of variability in production and applicable standard on dust concentrations experienced within WLs, separate nested analyses of covariance (ANCOVA) were performed on dust concentration measurements for continuous miner operators and longwall tailgate operators. So as to utilize a sufficient number of fairly consistent samples within WLs, these analyses relied on regular, bimonthly designated samples collected by mine operators in 2008 for the designated occupation in a production area (sample usage code and sample type both equal to 1). For WLs involving either continuous miner operators or longwall tailgate operators, the ANCOVAs showed small but statistically significant effects of production on RCMD concentration.

The underlying statistical model was identical for both ANCOVAs and is expressed as:

(Equation 4)

$$\lambda \circ (Y_{ijk}) = \mu + \alpha_i + \beta_{ij} + \theta \cdot T_{ijk} + \phi \cdot S_{ijk} + \varepsilon_{ijk}$$

where i indexes a specific mine;

j indexes a production area nested within a specific mine (identified in MSHA's sampling data files by the 2nd and 3rd digits of the 4-digit entity code);

k indexes the date and shift on which a specific dust concentration measurement was obtained;

Y_{ijk} is the RCMD concentration measurement obtained in the $j^{\underline{th}}$ production area of the $i^{\underline{th}}$ mine on the date indexed by k;

$$\lambda \circ (Y_{ijk}) = \begin{cases} \dfrac{Y_{ijk}^{\lambda} - 1}{\lambda} & \text{if } \lambda \neq 0 \\ Log_e(Y_{ijk}) & \text{if } \lambda = 0 \end{cases}$$

is the Box-Cox power transformation (Box and Cox, 1964) of the dust concentration measurement, used to normalize the residuals and minimize heterogeneity of variance within the ANCOVA cells;[71]

μ represents an effect corresponding to the overall mean dust concentration;

α_i represents an effect attributable to the $i^{\underline{th}}$ mine;

[71] The optimal Box-Cox parameter, λ, was estimated from the data using a maximum-likelihood procedure.

β_{ij} represents an effect attributable to the j^{th} production area nested within the i^{th} mine;

θ is the coefficient of the raw tonnage, T_{ijk} recorded on the date and shift indexed by k in the j^{th} production area nested within the i^{th} mine (T_{ijk} is modeled as a continuous covariate);

ϕ is the coefficient of the applicable dust standard, S_{ijl}, in effect at the j^{th} production area in the i^{th} mine on the k^{th} sampling date (S_{ijl} is modeled as a continuous covariate);

ε_{ijk} represents residual variability that is left unexplained by the factors and covariates of the ANCOVA model.

For continuous miner operators, 22,800 valid bimonthly operator samples, collected in 2008, were used in the ANCOVA,[72] which was performed on the data after transformation with Box-Cox transformation parameter $\lambda = 0.2$. The mean dust concentration was 0.74 mg/m^3, and 75 percent of the measurements fell at or below 0.95 mg/m^3. 90 percent of the shift production values reported fell between 227 and 1540 tons. Table 48 summarizes the results from the ANCOVA and shows that all factors considered, except the applicable dust standard, were statistically significant at a high confidence level ($p < 0.0001$). The statistical significance of the effect found for the dust standard was marginal, with a confidence level of approximately 90 percent ($p = 0.1$). However, some portion of the dust standard effect may have been masked by adjustments in production due to changes in the applicable dust standard. The estimated coefficient of raw tonnage in the transformation metric was 1.9×10^{-4}. Hence, using the approximate method of inverse transformation described by Taylor (1986, §5), a 500-ton production increase from 700 to 1200 tons on a shift was associated with an expected increase in dust concentration of approximately 0.10 mg/m^3 for the continuous miner operator working on that shift.

Table 48. — Nested ANCOVA on respirable coal mine dust concentrations for continuous miner operators, showing effects of variability in production (raw tonnage) and applicable dust standard. Based on 22,800 valid bimonthly samples collected by mine operators in 2008. Box-Cox transformation parameter λ = 0.2.

Source	Sum of Squares	Degrees of Freedom	Mean Square	F-ratio	p-value
Mine	3860.596	391	9.87365	18.63	<0.0001
Production Area	1299.140	476	2.72928	5.15	<0.0001
Applicable Dust Std.	1.409	1	1.40901	2.66	0.10
Raw Tonnage	39.915	1	33.91483	64.00	<0.0001
Residual	11,621.926	21,930	0.52996		

A total of 706 valid, bimonthly operator samples from 2008 were used in the ANCOVA on longwall tailgate operators.[73] The mean dust concentration was 1.08 mg/m^3, and 75 percent of

[72] Samples showing dust concentrations less than 0.01 mg/m^3 or missing production values, as well as abatement or support samples were excluded. Samples showing anomalous dust concentrations (>15 mg/m^3) or shift tonnages (>10,000 raw tons) were also excluded.

[73] Samples showing dust concentrations less than 0.01 mg/m^3 or missing production values, as well as abatement or support samples were excluded.

the measurements fell at or below 1.38 mg/m^3. 90 percent of the shift production values fell between 2300 and 9973 tons. For this ANCOVA, dust concentrations were transformed using Box-Cox parameter $\lambda = 0.5$, and the results are summarized in Table 49. The specific mine, production area within mine, and production on the sampled shift were all found, at a high confidence level, to be statistically significant factors affecting the dust concentration ($p < 0.0001$); however any effect of changing the applicable dust standard was masked by variability due to production adjustments, differences between production areas (including differences in the average applicable standard for 2008), or other (i.e., residual) factors. The estimated coefficient of raw tonnage in the transformation metric was 3.1×10^{-5}. Using the approximate method of inverse transformation described by Taylor (1986, §5), a 2000-ton production increase from 5000 to 7000 tons on a longwall shift was associated with an expected increase in dust concentration of approximately 0.10 mg/m^3 for the longwall tailgate operator working on that shift.

Table 49. — Nested ANCOVA on respirable coal mine dust concentrations for longwall tailgate operators, showing effects of variability in production (raw tonnage) and applicable dust standard. Based on 706 valid bimonthly samples collected by mine operators in 2008. Box-Cox Transformation parameter λ = 0.5.

Source	Sum of Squares	Degrees of Freedom	Mean Square	F-ratio	p-value
Mine	19.486	19	1.02557	18.04	<0.0001
Production Area	1.919	5	0.38381	6.75	<0.0001
Applicable Dust Std.	0.004185	1	0.00419	0.07	0.79
Raw Tonnage	1.732	1	1.73168	30.47	<0.0001
Residual	38.594	679	0.05684		

(b) Distributional forms of dust concentrations within WLs

The form (i.e., shape) of RCMD concentration distributions within WLs, was investigated using measurements collected over the five-year period 2004–2008. The main goal of this investigation was to check whether it is valid to assume that dust concentrations measured on different shifts for the same WL follow a lognormal frequency distribution. The analysis was restricted to WLs with at least 150 valid, bimonthly measurements on the designated occupation during the study period. Abatement samples were excluded. Although some of the WLs examined exhibited dust concentrations that could be adequately approximated by a lognormal distribution, others did not. Based on this analysis, it appears that assuming a lognormal distribution for every WL would be severely misleading in many cases. The range of distributional forms found at these WLs is shown below through a series of six examples (WLs "A" through "F"). Each of these examples is associated with a pair of charts, beginning with Figure 24 and Figure 25 for Example A, illustrating the frequency distribution of dust concentration measurements and graphically checking for approximate lognormality.

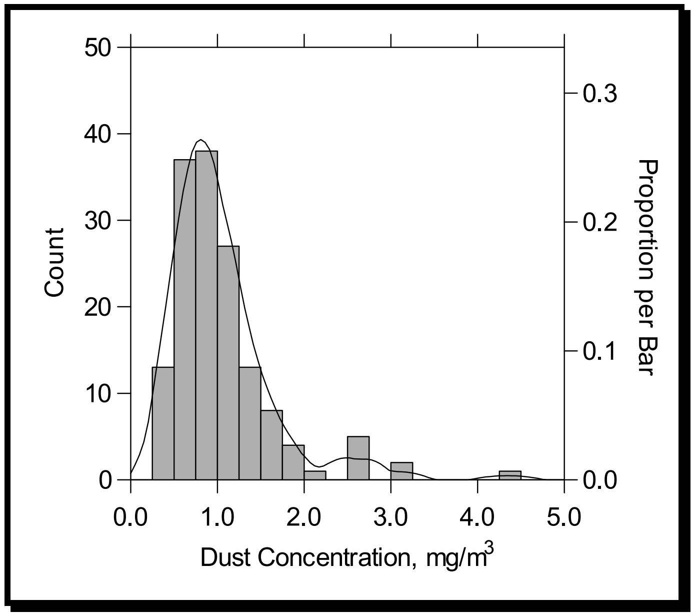

Figure 24. — Example "A": a WL where the frequency distribution of respirable coal mine dust concentrations can be adequately modeled as being lognormal. One measurement exceeding 5.0 mg/m^3 was excluded from chart.

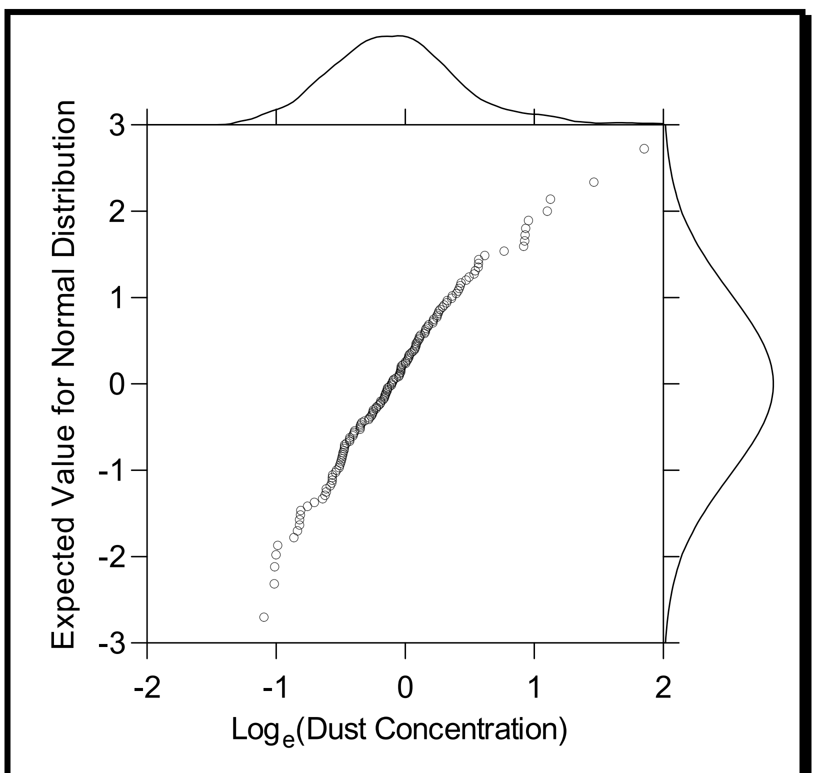

Figure 25. — Lognormal probability plot for the respirable coal mine dust concentrations measured on 150 different shifts at WL "A." Validity of lognormal approximation is indicated by points' falling approximately along a straight line.

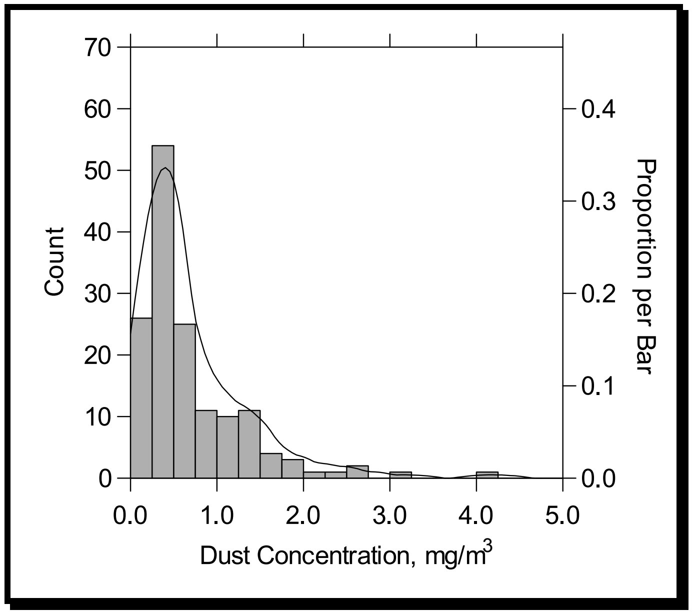

Figure 26. — Example "B": a WL where the frequency distribution of respirable coal mine dust concentrations diverges significantly from a lognormal model.

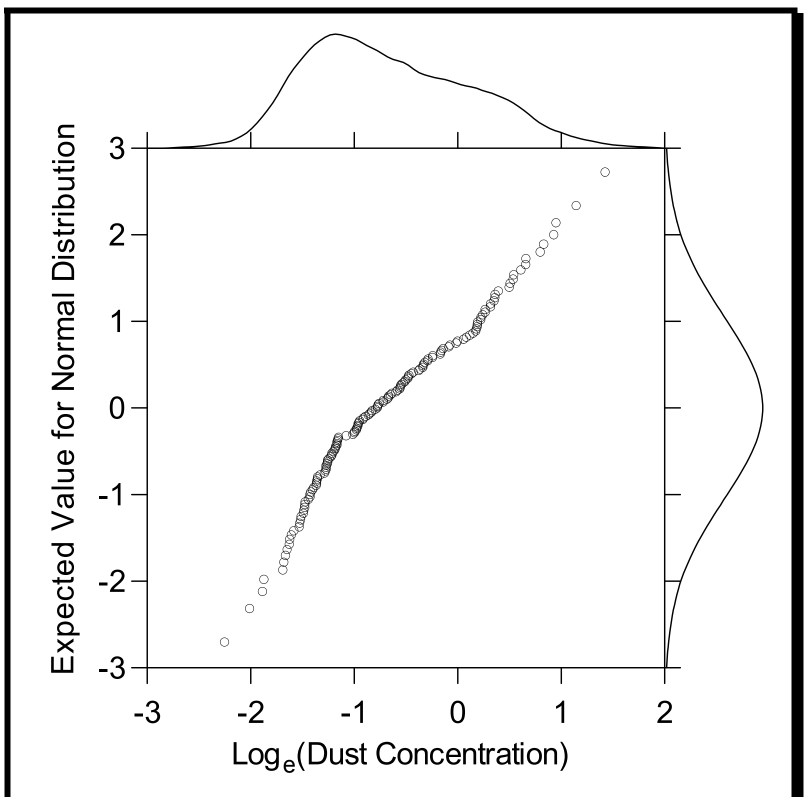

Figure 27. — Lognormal probability plot for the respirable coal mine dust concentrations measured on 150 different shifts at WL "B." Divergence from lognormal distribution is indicated by deviation of points from a straight line.

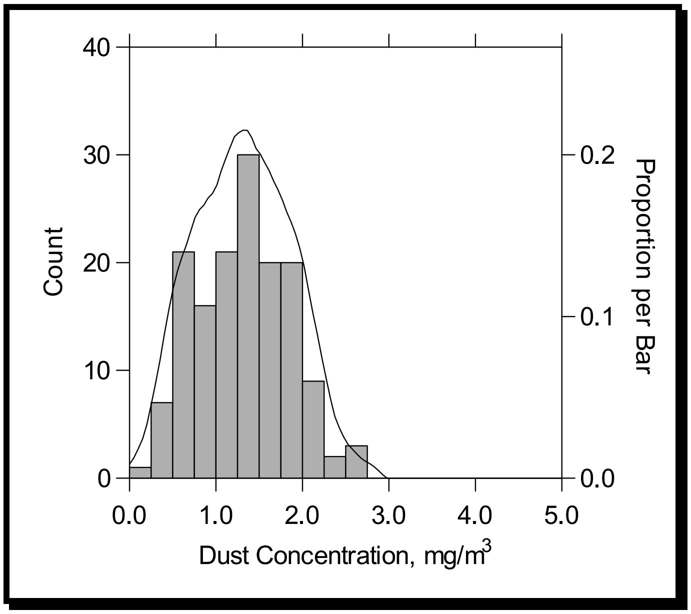

Figure 28. — Example "C": a WL where the frequency distribution of respirable coal mine dust concentrations diverges significantly from a lognormal model.

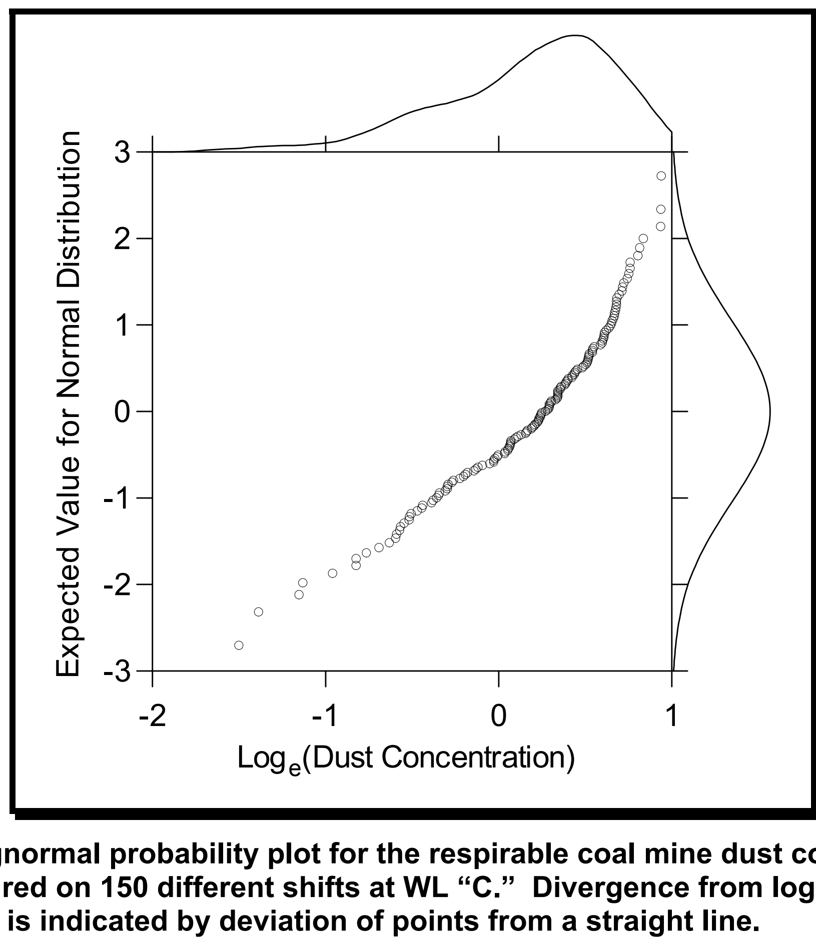

Figure 29. — Lognormal probability plot for the respirable coal mine dust concentrations measured on 150 different shifts at WL "C." Divergence from lognormal distribution is indicated by deviation of points from a straight line.

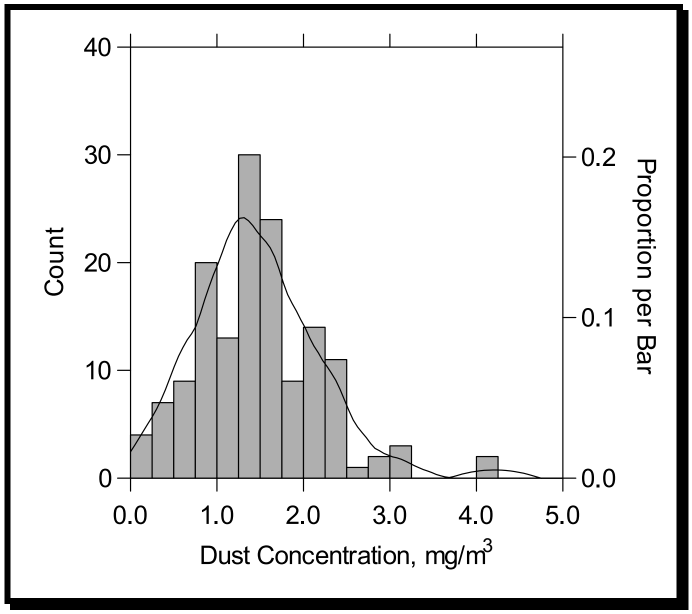

Figure 30. — Example "D": a WL where the frequency distribution of respirable coal mine dust concentrations diverges significantly from a lognormal model. One measurement exceeding 5.0 mg/m^3 was excluded from the chart.

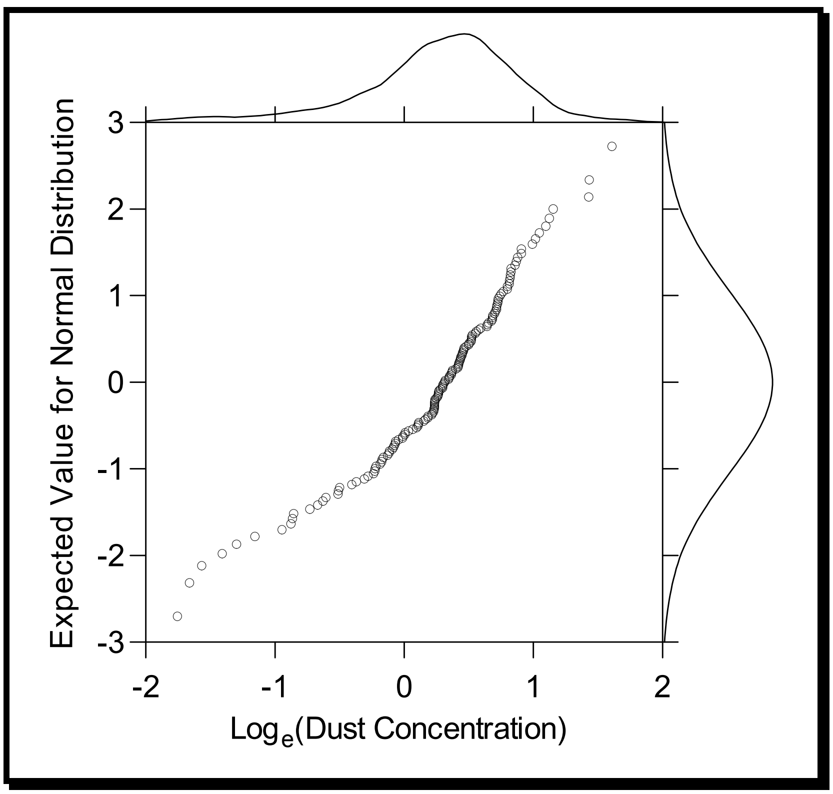

Figure 31. — Lognormal probability plot for the respirable coal mine dust concentrations measured on 150 different shifts at WL "D." Divergence from lognormal distribution is indicated by deviation of points from a straight line.

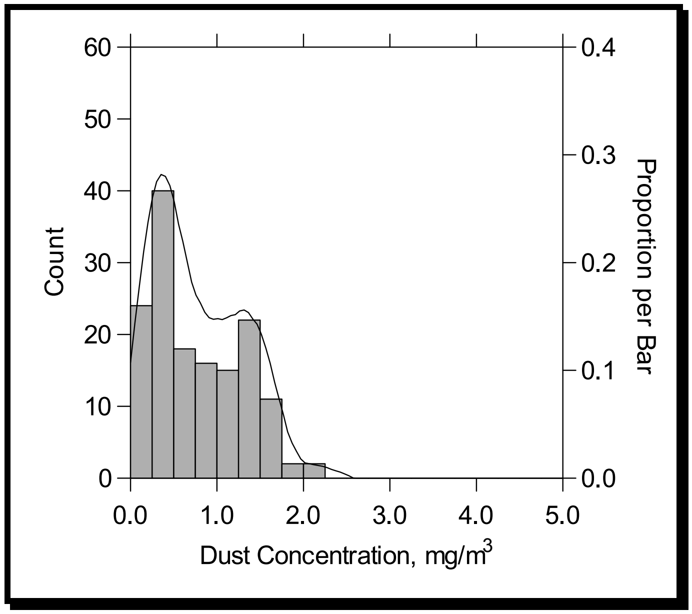

Figure 32. — Example "E": a WL where the frequency distribution of respirable coal mine dust concentrations diverges significantly from a lognormal model.

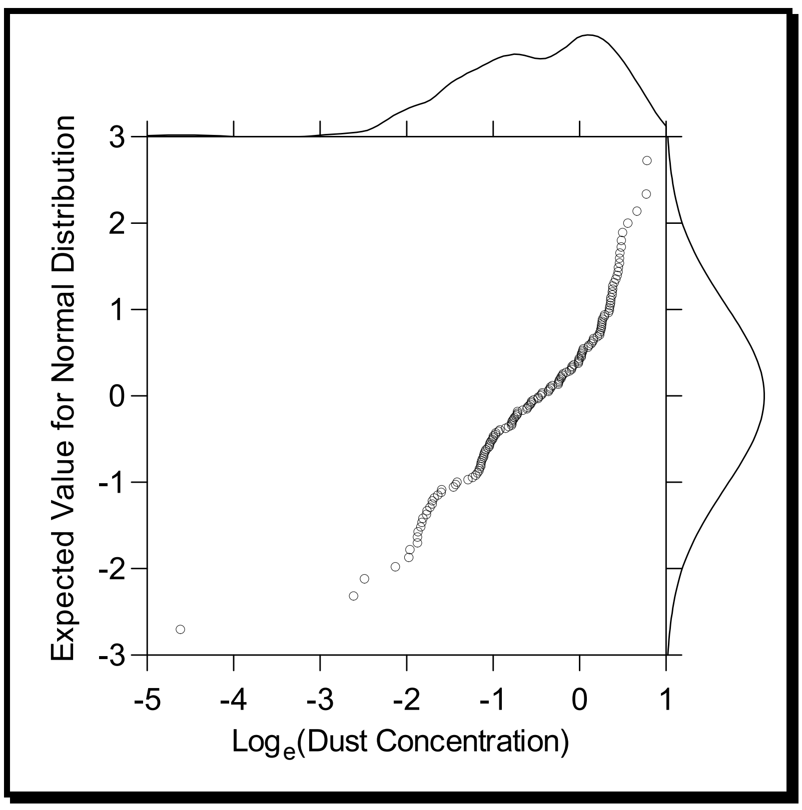

Figure 33. — Lognormal probability plot for the respirable coal mine dust concentrations measured on 150 different shifts at WL "E." Divergence from lognormal distribution is indicated by deviation of points from a straight line.

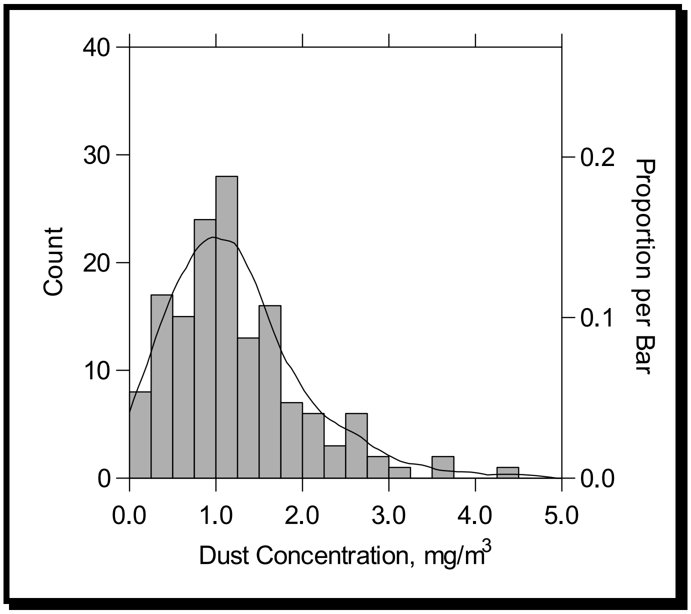

Figure 34. — Example "F": a WL where the frequency distribution of respirable coal mine dust concentrations diverges significantly from a lognormal model. One measurement exceeding 5.0 mg/m^3 was excluded from the chart.

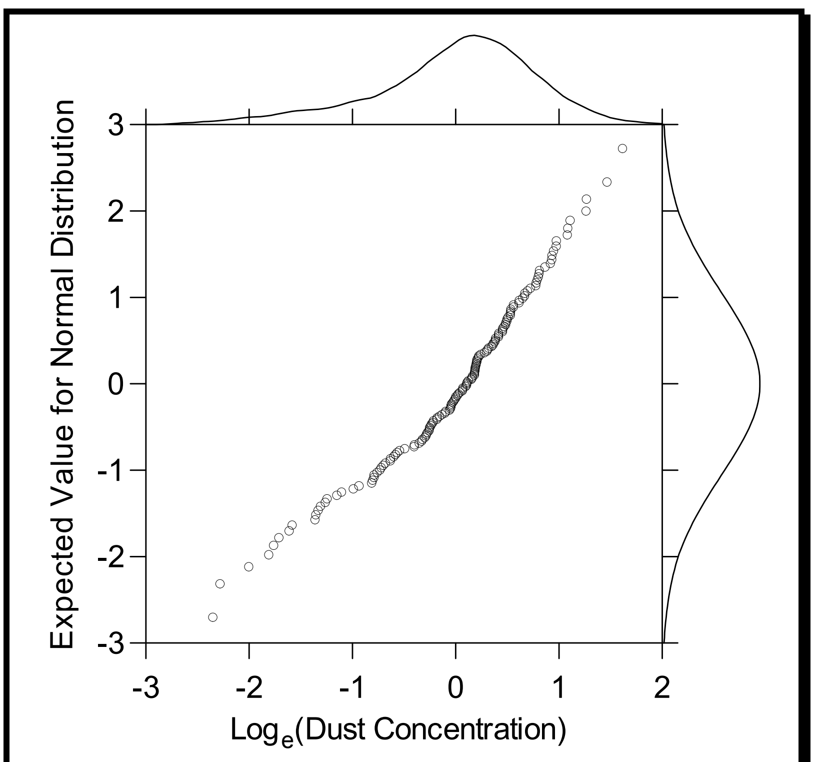

Figure 35. — Lognormal probability plot for the respirable coal mine dust concentrations measured on 150 different shifts at WL "F." Divergence from lognormal distribution is indicated by deviation of points from a straight line.

Work location "A" (continuous miner operators at Mine 0504674, production area #2) exemplifies a case of dust concentration measurements that can be adequately modeled by a lognormal distribution. A good lognormal fit is indicated by the points in Figure 25, the "lognormal probability plot" associated with Example A, falling approximately along a straight line. (The ends of the plot, containing few points, are less significant than the more populated central portion.) Although the fit is not perfect, it is close enough in this example to be useful for many practical applications. In the remaining examples, dust concentration measurements diverge significantly and substantially from a lognormal model. The degree of divergence is represented by the degree of curvature in the associated lognormal probability plot.

Table 50 contains a more formal evaluation of the lognormal hypothesis applied to the six example WLs. For each WL, maximum likelihood estimates of the lognormal parameters were calculated as shown in Table 51 (Aitchison and Brown, 1957), and the lognormal hypothesis was tested by three different methods. The resulting p-value for each of the three different test statistics is provided in Table 50.

For Example A, the Shapiro-Wilk test rejects the lognormal hypothesis at a 99-percent confidence level (i.e., $p < 0.01$). However, neither the Chi-square nor the Kolmogorov-Smirnov test rejects lognormality ($p > 0.1$). This confirms the graphic evidence from Figure 25 that dust concentrations in this WL may adequately, though imperfectly, be modeled by a lognormal distribution. For each of the other five examples, however, all three tests reject lognormality with at least 95-percent confidence ($p < 0.01$).

Table 50. — Tests of lognormal distribution hypothesis for respirable coal mine dust concentrations at six WLs, based on 150 valid bimonthly samples from each WL. All samples were collected by mine operators on the designated occupation from 2004 through 2008.

Work Location Example	Mine	Production Area	Occupation	Test of Lognormal Hypothesis, p-value		
				Shapiro-Wilk	Chi-square	Kolmogorov-Smirnov
A	0504674	2	Continuous Miner Op.	0.0021	0.54	0.17
B	1202249	1	Continuous Miner Op.	0.0011	3.2×10^{-5}	2.1×10^{-4}
C	1502132	27	Continuous Miner Op.	3×10^{-6}	3.0×10^{-5}	2.3×10^{-4}
D	1517587	2	Continuous Miner Op.	2.7×10^{-3}	2.7×10^{-3}	2×10^{-6}
E	3608862	2	Continuous Miner Op.	1×10^{-6}	1.1×10^{-5}	2.3×10^{-3}
F	4201890	10	Longwall Jacksetter	1.7×10^{-4}	5.7×10^{-3}	4.6×10^{-4}

Effects of assuming lognormality at WLs where it is not appropriate can be demonstrated by comparing observed to expected lognormal-theoretic frequencies of exceeding 1.0 mg/m^3 or 2.0 mg/m^3. Table 51 presents this comparison, along with maximum likelihood estimates of the lognormal parameters calculated for each example. In each example except "A," assuming a lognormal distribution would lead to substantial underestimates of the percentage of measurements exceeding 1.0 mg/m^3. In three of the examples (C, F, and especially E) the lognormal assumption would also lead to a substantial overestimate of the percentage exceeding 2.0 mg/m^3. In two of the examples, assuming lognormality would also lead to substantial overestimates of the probability and frequency of exceeding 2.0 mg/m^3.

Table 51. — Expected and observed frequency of dust concentration measurements exceeding 1.0 mg/m^3 and 2.0 mg/m^3 at six WLs, based on 150 valid bimonthly samples from each WL. All samples were collected by mine operators on the designated occupation from 2004 through 2008.

Work Location Example	Max. Likelihood Estimates of Lognormal Parameters		Percentage of measurements > 1.0 mg/m^3		Percentage of measurements > 2.0 mg/m^3	
	Location (μ)	Scale (σ)	Lognormal expectation (%)	Observation (%)	Lognormal expectation (%)	Observation (%)
A	−0.06752	0.4958	44.58	41.3	6.24	6.7
B	−0.6587	0.7486	18.95	22.7	3.55	4.0
C	0.1686	0.4911	63.43	70.0	14.27	9.3
D	0.2538	0.5853	66.77	73.3	22.64	22.0
E	−0.5320	0.8429	26.40	34.7	7.30	1.3
F	−0.008261	0.7470	49.56	57.3	17.39	14.7

As in Example A, a lognormal model could probably serve as an acceptable approximation for the distribution of dust concentrations at many WLs addressed by the QRA. However, as shown by Examples B through F, other WLs exhibit a wide variety of distributional forms (see Figures 26, 28, 30, 32, and 34) that cannot adequately be approximated by a lognormal model. For this reason, the QRA makes no assumption of lognormality within MMUs and, instead, adopts an empirical, nonparametric method of projecting dust concentration levels under successful implementation of the proposed rule. Details of this method are provided in Appendix H.

Appendix H Expected Exposure Reductions under Proposed Exposure Limits

(a) Introduction

As noted in §3 of the QRA, estimated current exposures for a given WL can be divided into two components: the first representing shifts on which the dust concentration already falls at or below the proposed limit and the second representing shifts on which the proposed limit is currently exceeded. The proposed rule would not only lower the limit but also enforce compliance with the new limit on every shift. The method adopted in the QRA for projecting exposure levels under the proposed rule assumes:

- that the first component of current exposure would decline by an amount proportional to the lowered exposure observed at WLs whose applicable dust standard has already been reduced, because of quartz content, from 2.0 mg/m^3 to 1.0 mg/m^3 (or from 1.0 mg/m^3 to 0.5 mg/m^3 for Part-90 miners);
- that the second component of current exposure will be reduced only so far as necessary to comply with the proposed exposure limit on every shift.

Section ***b*** of this appendix describes how the Expected Reduction Factors (ERFs) in Table 19 were calculated. The ERFs are the factors used to project reductions in the first component of current exposure. Section ***c*** notates the second component and lays out the formula by which the two reduced components of estimated current exposure were combined to form the projected exposure levels shown in Table 20.

(b) Derivation of change factors

The occupational ERFs presented in Table 19 were derived from an analysis of covariance (ANCOVA) performed using only those MSHA, Day-1 dust samples for which the applicable dust standard was either 2.0 mg/m^3 or 1.0 mg/m^3 and the RCMD concentration measurement fell below 1.0 mg/m^3. Excluding samples for Part-90 miners, a total of 97,031 valid MSHA Day-1 samples meeting these criteria were collected from 2004 through 2008 and used in the analysis. (Part-90 miners were studied separately, as will be described later.) The object was to quantify the effect of reducing the applicable standard from 2.0 mg/m^3 to 1.0 mg/m^3 for each occupation while accounting for extraneous job-specific trends over time. To stabilize residual variance within cells, the analysis was performed on natural logarithms of the dust concentration measurements. The model used for this ANCOVA is expressed as follows:

(Equation 5)

$$Log_e(Y_{ijkl}) = \mu + \alpha_i + \delta_j + \beta_{ij} + \theta_i \cdot D_k + \varepsilon_{ijkl}$$

where *i* indexes a specific occupational category;

j indexes the applicable dust standard in effect when the sample was collected — i.e., j = 2 for 2.0 mg/m^3 or j = 1 for 1.0 mg/m^3;

k indexes the date on which a specific dust sample was obtained;

l indexes the specific WL and shift on which a dust sample was obtained;

Y_{ijkl} is a RCMD concentration measurement obtained for the i^{th} occupation, subject to the applicable standard indicated by j, on the date indexed by l;

μ represents an effect corresponding to the overall mean dust concentration on shifts under consideration (i.e., those subject to an applicable dust standard of either 2.0 mg/m^3 or 1.0 mg/m^3 on which the RCMD concentration is less than 1.0 mg/m^3);

α_i represents an effect associated with the i^{th} occupational category;

δ_j represents an effect associated with the applicable standard indicated by j;

β_{ij} represents an interaction effect associated with the applicable standard indicated by j as applied to the i^{th} occupational category;

θ_i is the coefficient, for the i^{th} occupation, of the k^{th} measurement date, D_k, which is modeled as a continuous covariate and used to adjust for a monotonic upward or downward occupation-specific trend in dust levels over the 2004–2008 time period;

ε_{ijkl} represents residual variability that is left unexplained by the factors and covariates of the ANCOVA model.

Table 52 summarizes the results of the ANCOVA described by Equation 5. All factors in the model were found to be statistically significant at a high confidence level. Accordingly, when the dust concentration does not exceed 1.0 mg/m^3 under either standard, the expected change in dust concentration for occupation i attributable to reducing the dust standard from 2.0 mg/m^3 to 1.0 mg/m^3 can be represented as $(\delta_1 - \delta_2) + (\beta_{i1} - \beta_{i2})$.

Table 52. — Analysis of Covariance on valid, Day-1 respirable coal mine dust samples collected by MSHA inspectors from 2004 through 2008. Samples subject to applicable dust standards other than 2.0 mg/m^3 or 1.0 mg/m^3, samples showing dust concentrations that exceed 1.0 mg/m^3, and samples on Part-90 miners are all excluded.

Source	Degrees of Freedom	Mean Square	F-statistic	p-value
Occupation, α	32	111.753	176.84	<0.0001
Applicable Std., δ	1	7.626	12.07	0.001
Occupation × Std, β	24	1.737	2.75	<0.0001
Occupation × date, θ	32	3.222	5.10	<0.0001
Residual	96,941	0.632		

Based on the ANCOVA, $(\delta_1 - \delta_2)$ was estimated to be −0.151, and, as described in the QRA, this value was used as the "general effect" or "norm" in constructing Table 19. Also, the "estimated modification" shown for each occupation in Table 19 is the corresponding value of $(\beta_{i1} - \beta_{i2})$ as estimated from the ANCOVA. The "score" is the ratio of the absolute value of this estimate to its standard error. The value identified in Table 19 as the "estimated total effect" for the i^{th} occupation is the ANCOVA estimate of $(\delta_1 - \delta_2) + (\beta_{i1} - \beta_{i2})$, capped at zero, or simply the estimated value of $(\delta_1 - \delta_2)$ if the score does not exceed 1.0. As stated in the QRA, the expected reduction factor (ERF) listed for each occupation in Table 19 is obtained by calculating the antilog of the "estimated total effect."

Part-90 miners were excluded from the ANCOVA because no samples were available from Part-90 WLs subject to an applicable standard of 0.5 mg/m^3. Therefore, the ERF for Part-90 miners was based on a simple regression analysis using dust samples from 767 shifts on which the dust concentration was already at or below 0.5 mg/m^3. The independent variable in this analysis was the applicable dust standard, and the dependent variable was the natural logarithm of the dust concentration measurement. Only 12 of these samples were from shifts subject to an applicable dust standard less than 1.0 mg/m^3. Although the result was not statistically significant ($p > 0.1$), the analysis suggested a reduction in the logarithm of about 0.14 per 0.1 reduction in the applicable dust standard. Extrapolating this result to a reduction of 0.5 mg/m^3 in the applicable standard leads to an estimate of $\exp(5\times(-0.14)) \approx 0.5$ for the ERF.

(c) Formulation of projections

Expanding on the notation introduced in Appendix F, note that for each occupational work location:

$$\tilde{\mu} = \frac{\sum_{X \le \Re} X + \sum_{X > \Re} X}{K},$$

where X represents the dust concentration measurement for an individual shift entering the summation. The first summation represents shifts on which the dust concentration already falls at or below the proposed exposure limit, and the second represents shifts on which the proposed limit is currently exceeded. There are $(K-k)$ measurements in the first summation and k measurements in the second, where K and k are defined as in Appendix F

Let f denote the expected reduction factor (ERF, shown in Table 19), specific to the job-category and work location under consideration, for shifts with dust concentrations currently less than or equal to $\Re$. The intent in formulating the projected estimate is to reduce just the $(K-k)$ values of X representing these shifts by a factor of f and, conservatively, to reduce the remaining k values of X (which represent shifts on which $\Re$ is currently exceeded) down no further than $\Re$. The latter reduction amounts to replacing each value of X in the second summation with an instance of $\Re$. Therefore, the projected average dust concentration for the specified work location is:

$$\tilde{\tilde{\mu}}_{\text{prj}} = \frac{f \bullet \sum_{X \le \Re} X + k \bullet \Re}{K}$$

Appendix I Application of Attfield-Seixas CWP Models

Attfield and Seixas (1995) provide separate logistic regression models for CWP1+, CWP2+, and PMF as a function of cumulative RCMD exposure (mg-yr/m^3). These models all have the following form:

(Equation 6)

$$\frac{p}{1-p} = e^{a_0 + a_1 \times \text{age} + a_2 \times \text{exposure} + a_3 \times \text{rank} \times \text{exposure}}$$

where ***p*** is the probability of disease at a specified age and cumulative exposure. The constant ***e*** is the base of the natural logarithms. The empirically estimated coefficients a_0 (the intercept), a_1, a_2, and a_3 differ for the three health effects considered and are presented in Table IV of Attfield and Seixas (op cit), reproduced here as Table 53.

Table 53. — Coefficients and related statistics from logistic regression modeling of CWP1+, CWP2+, and PMF.

(Reproduced from Table IV of Attfield and Seixas, 1995.)

	CWP 1+			CWP 2+			PMF		
	Coef-ficient	SE	p	Coef-ficient	SE	p	Coef-ficient	SE	p
Intercept	−7.5			−12.5			−13.2		
Age (years)	0.077	0.014	.0001	0.134	0.037	.0002	0.137	0.051	.007
Dust exposure (mg-yr/m^3)	0.015	0.002	.0001	0.016	0.004	.0003	0.013	0.006	.046
Additional effect of exposure for high rank miners (mg-yr/m^3)	0.009	0.002	.0001	0.014	0.003	.0001	0.017	0.004	.0001

The coefficient (a_3) of "rank" refers to an additional effect of cumulative exposure to coal mine dust in central Pennsylvania or southeastern West Virginia, which the authors attribute to the high rank of the coal mined in those areas. This additional effect is applied to all WLs identified in the QRA as "high rank bituminous" or "anthracite" (e.g., in Table 12 and Table 20).

In the QRA, it is assumed that miners are occupationally exposed to RCMD for 45 years at an average of 1920 exposure hours per year. From Equation 6, it follows that for a 73-year old miner who has accumulated 45 years of exposure at a mean dust concentration equal to $\mathcal{X}$ mg/m^3, the probability of disease is given by the following equation:

(Equation 7)

$$P_{\mathcal{X}} = \frac{y}{1+y}$$
$$\text{where } y = e^{a_0 + a_1 \times 73 + (a_2 + \delta \cdot a_3) \times (45 \cdot \mathcal{X})}$$
$$\text{and } \delta = \begin{cases} 1 & \text{if the exposure is to high rank bituminous or anthraacite coal} \\ 0 & \text{otherwise} \end{cases}$$

Since $P_{\mathcal{X}} > 0$ even when $\mathcal{X}$= 0, not all of the risk indicated by $P_{\mathcal{X}}$ is attributable to RCMD exposure. According to the Attfield-Seixas model, the probability of CWP at age 73 when total accumulated occupational exposure is zero is given by:

(Equation 8)

$$P_0 = \frac{z}{1+z}$$
$$\text{where } z = e^{a_0 + a_1 \times 73}$$

The excess risk — i.e., that portion of the risk that is attributable to RCMD exposure —is obtained by subtracting P_0 from $P_{\mathcal{X}}$. Therefore, the number of attributable adverse outcomes expected per thousand workers can be expressed as:

(Equation 9)

$$\mathcal{R}_{\mathcal{X}} = 1000 \times (P_{\mathcal{X}} - P_0)$$

$\mathcal{R}_{\mathcal{X}}$ is plotted as a function of $\mathcal{X}$ in Figure 10 and Figure 11 (along with corresponding relationships using 65 instead of 73 for the age) and used in the QRA to estimate excess risks of CWP1+, CWP2+, and PMF under current and projected exposure conditions.

Appendix J   Application of Kuempel Pulmonary Impairment Model

Kuempel et al. (2009a) provide a logistic regression model for the probability of developing emphysema severity associated with FEV_1<65% of predicted normal values (designated "severe emphysema" in this QRA). This model estimates the probability of developing severe emphysema as a function of cumulative RCMD exposure (mg-yr/m^3) and has the following form:

(Equation 10)

$$\frac{p}{1-p} = e^{\alpha_0 + \alpha_1 \times \text{dust exposure} + \alpha_2 \times \text{cigarette exposure} + \alpha_3 \times \text{age} + \alpha_4 \cdot \delta}$$

$$\text{with } \delta = \begin{cases} 0 & \text{for racially "white" miners} \\ 1 & \text{for racially "non-white" miners} \end{cases}$$

where ***p*** is the probability of disease at a specified age, cumulative dust exposure, and cumulative cigarette exposure. The constant ***e*** is the base of the natural logarithms. The empirically estimated coefficients a_0 (the intercept), a_1, a_2, a_3, and a_4 are presented in Table 2 of Kuempel et al (op. cit.), reproduced here as Table 54.

Table 54. — Logistic Regression Model: parameters for estimating probability of emphysema severity associated with FEV_1<65% of predicted normal values.[a]

(Reproduced from Table 2 of Kuempel et al, 2009(a).)

Parameter	Estimated Coefficient	Standard Error	P-value
Intercept	-4.5	0.82	
Cumulative exposure (mg/m^3 x years)	0.010	0.0027	0.0003
Cigarette smoking (packs/day x years)	0.0099	0.040	0.01
Age at death (years)	0.036	0.012	0.003
Race (non-white)	0.80	0.28	0.004

[a] N=342 miners and non-miners. Likelihood ratio (4 d.f.)=56.3, p<0.0001.

In the QRA, it is assumed that miners are occupationally exposed to RCMD for 45 years at an average of 1920 exposure hours per year. From Equation 10, it follows that for a 73-year old never-smoking miner who has accumulated 45 years of exposure at a mean dust concentration equal to $\mathcal{X}$ mg/m^3, the probability of disease is given by the following equation:

(Equation 11)

$$P_{\mathcal{X}} = \frac{y}{1+y}$$
$$\text{where } y = e^{-4.5 + 0.01\times(45\cdot\mathcal{X}) + 0.036\times 73 + 0.8\times\delta}$$
$$\text{and } \delta = \begin{cases} 0 & \text{for racially "white" miners} \\ 1 & \text{for racially "non - white" miners} \end{cases}$$

Since $P_{\mathcal{X}} > 0$ even when $\mathcal{X}$= 0, not all of the risk indicated by $P_{\mathcal{X}}$ is attributable to RCMD exposure. According to the model expressed by Equation 10, the probability of severe emphysema for unexposed never-smokers at age 73 is given by:

(Equation 12)

$$P_0 = \frac{z}{1+z}$$
$$\text{where } z = e^{-4.5 + 0.036\times 73 + 0.8\times\delta}$$

The excess risk — i.e., that portion of the risk that is attributable to RCMD exposure —is obtained by subtracting P_0 from $P_{\mathcal{X}}$. Therefore, the number of attributable adverse outcomes expected per thousand workers can be expressed as:

(Equation 13)

$$\mathcal{R}_{\mathcal{X}} = 1000 \times (P_{\mathcal{X}} - P_0)$$

$\mathcal{R}_{\mathcal{X}}$ is plotted as a function of $\mathcal{X}$ in Figure 14 (along with corresponding relationships using 65 and 80 instead of 73 for the age) and used in the QRA to estimate excess risks of severe emphysema under current and projected exposure conditions.

Although cigarette smoking and coal mine dust exposure appear as independent factors in Equation 10, curvature in the joint exposure-response relationship expressed by Equations 12 and 13 amplifies the predicted response to RCMD exposure for smokers. (This is an inherent characteristic of the logistic model employed.) Furthermore, the portion of emphysema risk attributable to dust exposure is greater for smokers than for non-smokers, by an amount that increases with the intensity and duration of smoking.

For example, suppose that a never-smoking white miner is exposed for 45 years to an average coal mine dust concentration of $\mathcal{X}$= 1.2 mg/m^3. Then the miner's cumulative exposure is 54 mg·yr/m^3. Therefore, at age 73,

$$y = e^{-4.5 + 0.01\times 54 + 0.036\times 73} = 0.264 \quad \text{and} \quad z = e^{-4.5 + 0.036\times 73} = 0.154$$

Consequently, using Equation 13, the risk of severe emphysema at age 73 attributable to the dust exposure is $\mathcal{R}_{\mathcal{X}}$= 75 excess cases per thousand exposed workers.

Suppose now that, at age 73, the same miner has smoked 0.5 packs per day for 53 years. Then

$$y = e^{-4.5 + 0.01\times54 + 0.0099\times0.5\times53 + 0.036\times73} = 0.343 \quad \text{and} \quad z = e^{-4.5 + 0.0099\times0.5\times53 + 0.036\times73} = 0.200$$

so $\mathcal{R}_{\mathcal{X}}$ = 89 excess cases per thousand exposed workers. If, instead, the miner smoked two packs per day, then

$$y = e^{-4.5 + 0.01\times54 + 0.0099\times2.0\times53 + 0.036\times73} = 0.754 \quad \text{and} \quad z = e^{-4.5 + 0.0099\times2.0\times53 + 0.036\times73} = 0.439$$

and $\mathcal{R}_{\mathcal{X}}$ = 125 excess cases per thousand exposed workers. This example demonstrates that because of the logistic form of the Kuempel pulmonary impairment model, the estimated excess risk of severe emphysema attributable to coal mine dust exposure increases with increased cigarette smoking.

Appendix K   Application of Attfield-Kuempel NMRD Mortality Model

Attfield and Kuempel (2008) provide a proportional hazards model for the relative risk of NMRD mortality as a function of cumulative RCMD (mg-yr/m^3). This model has the following form:

(Equation 14)

$$
\begin{aligned}
\text{RR} &= e^{\alpha_i + \beta_1 \cdot \text{dust exposure} + \beta_2 \cdot \text{age} + \sum \gamma_j \cdot \text{smoking factor}_j} \\
&= e^{\alpha_i} \times e^{\beta_1 \cdot \text{dust exposure}} \times e^{\beta_2 \cdot \text{age} + \sum \gamma_j \cdot \text{smoking factor}_j} \\
&= e^{\alpha_i} \times e^{\beta_1 \cdot \text{dust exposure}} \times \text{K}
\end{aligned}
$$

where RR is the relative risk of NMRD, expressed as a multiple of the risk for a background or reference population. The constant ***e*** is the base of the natural logarithms. The empirically estimated coefficients, represented by Greek letters in Equation 14, are presented in the "NMRD" column of Table X in Attfield Kuempel (op. cit.), reproduced here as Table 55. The proportional hazards model permits evaluation of the RR attributable to dust exposure and coal rank (represented by geographic region) irrespective of age and tobacco smoking effects (represented in Equation 14 by the aggregated factor "K").

Table 55. — Coefficients of proportional hazards mortality models.

(Reproduced from Table X of Attfield and Kuempel, 2008)

	Coefficients			
Variable	**Nonviolent**	**NMRD**	**Pneumoconiosis**	**CAO**
Region[a]				
Anthracite	0.5602	1.4844	2.2580	−2.2756
East Appalachia	0.4531	0.2187	0.4108	0.4516
West Appalachia	0.3252	−0.3477	−0.5770	−0.4667
Mid-west	0.2886	−0.2870	−1.2156	−0.0758
Age at start of follow-up (year)	0.0932	0.1079	0.1005	0.1138
Smoking[a]				
Current	−0.0554	0.1097	0.2102	−0.1191
Ex-	0.4298	0.6577	0.5216	1.0093
Pack-years	0.00678	0.00262	−0.00022	0.0126
Cumulative coal mine dust exposure (mg-year/m^3)	0.00215	0.00709	0.00870	0.00811

NMRD, nonmalignant respiratory disease; CAO, chronic airways obstruction.
All exposure coefficients are statistically significant ($P < 0.005$).
[a]Regional coefficients relative to West region, and smoming status relative to never smokers.

The estimated coefficients identified with Anthracite and East Appalachia ($\boldsymbol{a_1}$ = 1.4844 and $\boldsymbol{a_2}$ = 0.2187, respectively) represent increases in RR that may be attributed to the high rank of coal mined in those areas. As noted by the authors, "…any variations in lifestyle, health care, and non-coalmine exposures across geographic regions are also confounded with coal rank in this comparison." (Attfield and Kuempel, op. cit.)

In the QRA, it is assumed that miners are occupationally exposed to RCMD for 45 years at an average of 1920 exposure hours per year. In evaluating NMRD mortality risks for the QRA, a_1 = 1.4844 was applied to all WLs identified "Anthracite," and a_2 = 0.2187 was applied to all WLs identified as "High Rank Bituminous" (e.g., see Table 18 and Table 26). For all other WLs, the relative risk calculations were based solely on accumulated exposure to RCMD. From Equation 14, it follows that for a miner who has accumulated 45 years of exposure at a mean dust concentration equal to $\mathcal{X}$ mg/m^3, the relative risk (RR) of NMRD mortality is given by the following equation:

(Equation 15)

$$\text{RR} = e^{\alpha + 0.00709 \times (45 \cdot \mathcal{X})}$$

$$\text{where } \alpha = \begin{cases} 1.4844 \text{ for anthracite WLs} \\ 0.2187 \text{ for high rank bituminous WLs} \\ 0 \text{ for all other WLs} \end{cases}$$

Equation 15 was applied to the estimated current exposure levels shown in Table 12 to obtain the relative risk of NMRD mortality after 45 years of exposure under current conditions. The results are provided in Table 56. Similarly, Equation 15 was applied to the projected exposure levels shown in Table 20 to project the relative risk of NMRD mortality under successful implementation of the proposed regulations. These projections of RR are provided in Table 57. As noted in the QRA, a competing-risk life-table analysis of the existing and projected RRs in Table 56 and Table 57 was used to obtain the excess NMRD mortality risks shown in Table 17, Table 18, Table 25, and Table 26.

Even with cumulative coal mine dust exposure set at zero, the Attfield–Kuempel exposure–response model produces relative risk estimates of 4.4 and 1.2 for miners regionally associated with anthracite and high rank bituminous coal ($e^{1.4844}$ and $e^{0.2187}$, respectively).[74] This suggests that the regional effects are primarily due to geographic factors other than coal rank and, therefore, that the relative and excess risks shown for NMRD mortality at WLs with anthracite and high rank bituminous coal should be interpreted with extreme caution. However, since the same regional effect is present for NMRD mortality risk estimates under both current and projected conditions, geographic effects unrelated to occupational coal mine dust exposure should be cancelled out when calculating the projected improvements in risk for Table 28. That portion of the regional effect *not* cancelled out is attributable to dust exposure, as explained below.

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[74] This would have been avoided if the model had instead incorporated a factor representing coal rank that approached zero as exposure approached zero (e.g., the product of cumulative exposure and the indicator variable for geographic region). Attfield and Kuempel (op. cit.) do not state whether such a model was considered.

Table 56. — Relative Risk of NMRD mortality after 45 years of occupational exposure at current levels as shown in Table 12.

Occupation		Recurrency Class {R1−}			{R(1–2)}			{R2+}		
		Low/Med. Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite	Low/Med Rank†	High Rank Bituminous	Anthracite
Underground Workers	Auger Op				1.29	1.82		1.47	1.73	
	Cont Miner Op	1.23	1.52		1.37	1.66	6.07	1.55	1.92	6.72
	Cutting Mach Op	1.17	1.45		1.62	1.82		1.43	2.17	
	Drill Op	1.20	1.54			1.73				
	Electrician & helper	1.12	1.40	5.22	1.34					
	Laborer	1.20	1.45	4.78						
	Loading Mach Op	1.06	1.38			1.65				
	LW Headgate Op	1.23	1.57		1.40	1.69		1.49		
	LW Jacksetter	1.27	1.58		1.46	1.71		1.56	1.91	
	LW Tailgate Op	1.27	1.71		1.54	1.87		1.55	2.12	
	Mechanic & helper	1.19	1.42	4.90		1.85				
	Mobile Bridge Op	1.14	1.47	4.90	1.36	1.64		1.39	1.70	
	Roof Bolter	1.19	1.48	5.24	1.37	1.66		1.56	1.82	
	Shuttle Car Op	1.18	1.43	4.98	1.37	1.69	6.07	1.61	2.01	
	Scoop Car Op	1.20	1.49		1.50	1.79				
	Section Foreman	1.19	1.47	4.89		1.97	5.79			
	Tractor Op	1.11	1.45	4.81		1.59				
	Utility Man	1.21	1.47						2.53	
	Other UG workers	1.24	1.51	4.81	1.60	1.83	6.37	2.54	3.18	
Part-90 Miners		1.13	1.36		1.16	1.44		1.21	1.98	
Surface Workers	Auger Op	1.07								
	Backhoe Op	1.06	1.28	4.62						
	Bull Dozer Op	1.06	1.29	4.73	1.25					
	Crane/Dragline Op	1.04		4.59						
	Cleaning plant Op	1.13	1.39	4.83	1.37		6.09			6.69
	Drill Op	1.10		4.81	1.38					
	Electrician & helper	1.09	1.33	4.92	1.38					
	Highlift Op/FEL	1.05	1.31	4.64	1.42					
	Laborer	1.09	1.37	4.94			5.92	1.74		
	Mechanic & helper	1.09	1.37	4.57	1.55		6.53	1.84		
	Tipple Op	1.09	1.31		1.22					
	Truck Driver	1.06	1.28	4.68						
	Utility Man	1.12	1.34	4.43	1.55			1.47		9.11
	Other Surf. Workers	1.08	1.32	4.78	1.36	1.59	5.99	1.90		6.30

†Includes locations where MSHA has not determined the coal rank.

Table 57. — Relative Risk of NMRD mortality, after 45 years of occupational exposure at projected levels as shown in Table 20.

	Occupation	Recurrency Class {R1−} Low/Med. Rank†	{R1−} High Rank Bituminous	{R1−} Anthracite	{R(1–2)} Low/Med Rank†	{R(1–2)} High Rank Bituminous	{R(1–2)} Anthracite	{R2+} Low/Med Rank†	{R2+} High Rank Bituminous	{R2+} Anthracite
Underground Workers	Auger Op				1.23	1.65		1.33	1.53	
	Cont Miner Op	1.15	1.43		1.23	1.51	5.55	1.27	1.55	5.50
	Cutting Mach Op	1.15	1.42		1.30	1.56		1.31	1.61	
	Drill Op	1.15	1.46			1.60				
	Electrician & helper	1.08	1.34	4.91	1.25					
	Laborer	1.10	1.34	4.58						
	Loading Mach Op	1.05	1.36			1.58				
	LW Headgate Op	1.14	1.44		1.23	1.53		1.25		
	LW Jacksetter	1.23	1.51		1.29	1.59		1.31	1.62	
	LW Tailgate Op	1.19	1.60		1.33	1.65		1.30	1.68	
	Mechanic & helper	1.12	1.35	4.73		1.60				
	Mobile Bridge Op	1.12	1.44	4.83	1.26	1.54		1.25	1.52	
	Roof Bolter	1.14	1.41	5.01	1.25	1.52		1.27	1.51	
	Shuttle Car Op	1.13	1.38	4.83	1.26	1.53	5.53	1.29	1.57	
	Scoop Car Op	1.15	1.41		1.30	1.58				
	Section Foreman	1.15	1.43	4.80		1.63	5.35			
	Tractor Op	1.09	1.41	4.76		1.54				
	Utility Man	1.14	1.39						1.71	
	Other UG workers	1.15	1.41	4.66	1.31	1.63	5.27	1.38	1.69	
Part-90 Miners		1.05	1.31		1.09	1.36		1.09	1.45	
Surface Workers	Auger Op	1.06								
	Backhoe Op	1.06	1.28	4.62						
	Bull Dozer Op	1.06	1.29	4.73	1.20					
	Crane/Dragline Op	1.03		4.56						
	Cleaning plant Op	1.10	1.37	4.75	1.26		5.47			5.83
	Drill Op	1.09		4.81	1.21					
	Electrician & helper	1.07	1.32	4.84	1.28					
	Highlift Op/FEL	1.04	1.30	4.60	1.28					
	Laborer	1.08	1.35	4.81			5.55	1.32		
	Mechanic & helper	1.07	1.35	4.55	1.26		5.24	1.22		
	Tipple Op	1.07	1.30		1.18					
	Truck Driver	1.06	1.28	4.68						
	Utility Man	1.09	1.33	4.43	1.29			1.26		6.07
	Other Surf. Workers	1.07	1.31	4.72	1.24	1.50	5.67	1.23		5.37

†Includes locations where MSHA has not determined the coal rank.

Because of the concave, exponential structure of the Attfield–Kuempel exposure–response relationship, the effects associated with anthracite or high rank bituminous coal are inherently multiplicative rather than additive. Although the model contains no explicit interaction term, increases in occupational exposure produce a greater absolute increase in NMRD mortality risk when $\boldsymbol{\alpha} > 0$ than when $\boldsymbol{\alpha} = 0$. Therefore, not all of the increased risk regionally associated with anthracite or high rank bituminous coal is cancelled by subtraction. The portion that is not cancelled is attributable to occupational exposure.

For example, current and projected dust concentrations at class {R2+} continuous miner WLs in low/medium rank coal are approximately the same as in anthracite, and the projected changes in average exposure levels are nearly identical (see Table 12 and Table 20). According to Table 18, the excess risk of NMRD mortality at these WLs under current conditions is 266 per thousand for anthracite and 32 per thousand for low/medium tank coal. According to Table 26, the corresponding projections are 222 per thousand and 16 per thousand. So essentially the same change in exposure levels is expected to produce a change of 266−222 = 44 deaths per thousand in anthracite and 32 − 16 = 16 deaths per thousand in low/medium rank coal. Since the same extraneous regional effects are present in risks calculated under both existing and projected exposure conditions, the difference in projected impact is attributable to the difference in type of coal mine dust.

OSHA Review of

Draft Quantitative Risk Assessment In Support of the Mine Safety and Health Administration Proposed Rule for Respirable Coal Mine Dust

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Introduction

The draft document under review is a quantitative risk assessment (QRA) prepared under contract for the Mine Safety and Health Administration (MSHA). The QRA estimates the excess risk of lung disease expected to occur in miners occupationally exposed at current levels of respirable coal mine dust (RCMD) for a 45-year working lifetime. The QRA also projects the reduction in risk expected to occur from implementation of provisions in the MSHA's proposed RCMD regulation. MSHA statutes and subsequent court decisions require that the agency be able to demonstrate, based on the best available evidence, that RCMD exposure leads to a material impairment of health or loss of functional capacity. It must also be shown that the existing exposure levels experienced over a working lifetime may place miners at significant risk of impairment, and that the proposed regulation will substantially reduce that risk.

The standard risk assessment paradigm used by the Federal Government was established by the National Academy of Sciences in 1983. It laid out four essential components of risk assessment. *Hazard Identification* characterizes the hazards attributable to a toxic agent. *Dose – response assessment* evaluates the relationship between exposure to the toxic agent and the health effects of concern. *Exposure assessment* characterizes the conditions under which the population of interest is exposed to the toxic agent. *Risk characterization* describes the likelihood of health impairment in the exposed population as well as the degree of confidence and uncertainties inherent in the assessment. Our review of the QRA considers whether the analysis carried out for each of the four steps was clearly explained in a manner that is reasonable, scientifically sound and appropriate to the purpose of satisfying the findings needed to promulgate the rule. Because of time constraints, the scope of our review only considers the information contained in the MSHA document and does not include evaluation of referenced study data relied upon in the QRA.

Overall Evaluation

The draft QRA is a well organized document structured according to the key findings with regard to (1) the association between current exposures levels and material impairment of health, (2) the analysis of risk under current workplace conditions, and (3) the projected reduction in risk under implementation of the proposed rule. The exposure measurements collected under the MSHA inspector program from 2004 to 2008 contains over 100,000 RCMD samples that cover all major job categories in US underground and surface coal mines. The exposure distributions from this rather large data base have been rigorously analyzed by job category, work locations, and trends over time. It is a broader, more robust collection of exposure measurements than the smaller, less well characterized adjusted supplemental (AS) exposure data set used for the present risk analysis. We strongly recommend that the QRA rely, as much as possible, on the five year MSHA inspector samples to determine the job-specific exposure estimates for risk characterization. The reasons for this are explained in Exposure Assessment section below.

The selection of data sets, health outcomes, exposure metric, and risk models are well supported. The risk analysis and risk characterization are scientifically reasonable. The results clearly demonstrate significant risk of material impairment from a 45 year working lifetime exposure to RCMD under current exposure conditions. As explained in the Exposure Assessment section, the procedure used to project RCMD levels under successful implementation of the proposed rule may underestimate the actual reductions in exposures that would occur. Despite these understated exposure projections, the analysis still shows a substantial reduction in risk as a result of the new RCMD standard. We agree that MSHA has satisfied its statutory obligations to show that current exposures lead to significant risk of material impairment and that the proposed rule will substantially reduce the risk

The risk analysis would be improved by calculating confidence bounds on the key risk estimates of interest. Further discussion should be provided for the featured exposure-response studies relied upon for this analysis. This would more fully address uncertainty in the risk estimates and credibility of the underlying data. The risk reduction would be more compelling if reported as a population risk (e.g. number of expected cases) in addition to the individual risk descriptor per 1000 exposed miners. These improvements are more fully explained in the sections on Exposure – Response Assessment and Risk Characterization. While failure to address the suggested revisions does not endanger the MSHA risk findings, we believe that attention to these areas will lead to a more favorable response during expert peer review and review by the Office of Management and Budget. Other suggested improvements of lesser consequence are also provided the sections below.

<u>Hazard Identification</u>

The QRA focuses on two types of lung disease associated with exposure to RCMD. These are coal workers pneumoconiosis (CWP) and chronic obstructive pulmonary disease (COPD). The document clearly and correctly recognizes CWP and COPD as progressive and serious health conditions that lead to disabling loss of pulmonary function in affected individuals. These diseases have resulted in substantial number of fatalities in the US and undoubtedly qualify as material impairment under the Mine Act.

The QRA does not provide an evaluation of the scientific evidence that would lead to a conclusion that mining exposure to RCMD is causally related to CWP, COPD, or other serious adverse health effects. This assessment usually consists of a weight of evidence approach that takes into account the strength and consistency of key adverse outcomes in study populations, the existence of an exposure-response relationship, control for bias and confounders, the mode of action, and biological plausibility. The hazard identification should identify mining subpopulations particularly vulnerable to health outcomes associated with RCMD. Scientific information about the background rate of the diseases associated with exposure to RCMD in the general population should be characterized.

We suspect that this important risk assessment component is probably contained in a separate MSHA review of the scientific literature. If so, it would be helpful if the document was referenced and the salient findings briefly summarized. For workplace health standards, OSHA also conducts its hazard identification as part of the health effects review that is separate from the exposure – response assessment. However, OSHA health effects evaluations are included in the outside expert peer review process required for influential risk assessments that support OSHA workplace regulations.

Assessment of Exposure – Response

The quantitative assessment of CWP and COPD risk with RCMD exposure relies on published empirical models from three studies of US coal miners. One model quantitatively relates cumulative RCMD exposures with three internationally agreed-upon severity categories of CWP. Another model quantitatively relates cumulative RCMD exposures with the incidence of severe emphysema. Emphysema is a major form of COPD. The risk was indexed to lung pathology associated with moderate to severe loss of pulmonary function (i.e. FEV_1 < 65 percent of normal). A third model quantitatively relates cumulative RCMD exposure to mortality from non-malignant respiratory disease (NMRD) as an approximate measure of combined CWP and COPD. All models accounted for age as a significant co-variable. The emphysema and NMRD models had terms to account for the effect of cigarette smoking. The CWP and NMRD models had terms to account for the type of coal mined (e.g. anthracite, high rank bituminous, low/medium rank bituminous). Supporting models showed the relative risk of CWP and COPD mortality attributable to cumulative RCMD exposure.

The assessment decisions with regard to selection of data sets, health outcomes, exposure metric, and risk models are generally appropriate and well supported. The CWP morbidity data is based on radiographs from over 3000 miners. The emphysema data is based on standardized pathology reviews of over 600 deceased miners. There is mortality data from large mining cohorts of roughly 10,000 to 20,000 miners followed over an average of some 23 to 55 years. The cumulative exposure metric is well suited for these chronic lung diseases that likely result from dust burdens that accumulate in the lung over many years. Logistic regression models show a strong and highly significant fit to the morbidity data. The same is true for the relative risk models used to fit the mortality data.

The predicted risk estimates attributable to a 45 year working lifetime exposure to RCMD are clearly significant for all outcomes. For example, the projected excess risk of progressive massive fibrosis (end stage CWP) range from about 30 to 100 excess cases per 1000 miners exposed to an average 1.0 mg/m^3 RCMD by age 73. The excess risk estimate of severe emphysema for a 73 year old non-smoking miner under identical exposure conditions is about 60 cases per 1000 miners. A full shift 8-hour time-weighted average (TWA) 1.0 mg/m^3 is the final exposure limit (FEL) to be proposed in the new RCMD rule and is within the range of 8-hr TWA exposures currently experienced by underground mining operations. The projected risks are even greater at the current FEL of 2.0 mg/m^3 RCMD. These risk projections for a 45-year lifetime exposure would satisfy the MSHA requirement to demonstrate significant risk of material impairment under current exposure conditions.

The assessment would be improved with additional information from the key exposure-response data sets (Attfield and Seixas, 1995; Kuempel et al., 2009; Attfield and Kuempel, 2008, Miller et al., 2007) and resulting estimates of risk. There should be a discussion of whether the data sets contained adequate dust measurements across job operations and over a sufficient proportion of the study period to reliably estimate RCMD exposures experienced by the coal miners. The range of exposure levels, cumulative exposures, durations of exposures and number of case outcomes should be presented. The 95 percent confidence limits on the risk model estimates should be determined for the critical dust exposures of interest (e.g. 2.0, 1.0, 0.5 mg/m^3 RCMD). These considerations address the degree of confidence in the risk estimates as well as the credibility and relevance of the underlying data.

The assessment would benefit from further explanation and clarification in some instances. The risk analysis assumes that cumulative exposures based on arithmetic mean dust concentration is preferred over the median or geometric mean as the appropriate measure of central tendency. This should be further explained in the context of the expected distribution in exposure measurements. Unlike the other risk models, the Attfield-Seixas regression model does not appear to account for the effects of cigarette smoking. The reasons for this should be explained. The assumptions regarding progression of radiographic lesions from CWP1+ to CWP2+ to PMF in the absence of further RCMD exposure when projecting excess risk for 73 year old miners (see Figures 10 and 11) needs to be stated and clarified. The Attfield-Seixas models attribute a greater exposure-specific risk for regions with high rank bituminous coal than areas with low/medium rank coal. The assessment should explain the scientific basis for this empirical observation and potential confounding by quartz content. The relative risks of CWP and COPD mortality presented in figures 12 and 15 would be more meaningful with some discussion of the background rate of these lung diseases in the unexposed population. Possible explanations for why the Attfield-Kuempel model predicts higher COPD mortality risk than the Miller model at RCMD levels of interest should be discussed. The loss in FEV_1 with increasing dust concentration presented in figure 13 would be more meaningful if this reduction was discussed in terms percent of normal values.

The assessment correctly points out the uncertainties with regard to applying the Attfield-Kuempel risk models of NMRD mortality in anthracite and high bituminous coal miners. This is due to the sizable relative NMRD mortality risk projected to occur as a result of factors unrelated to RCMD exposure. The exposure-specific risk estimates lead to inconsistencies in the subsequent risk characterization (see later section). MSHA may wish to revisit the need to rely on these uncertain NMRD mortality risks considering the availability of more reliable risk estimates from the other impairment outcomes.

Exposure Assessment

The MSHA inspection exposure data is an exceptional dataset in that it covers a census of U.S. coal mines and major job categories in both underground and surface coal mines. Quarterly sampling is conducted in underground mines by regulation with less intensive sampling at surface mines, between once or twice yearly (see Table 2). For this analysis the QRA initially used current data from 2004 to 2008. Employer exposure data was also available for the same time period. The QRA stated and supported (page 3) that the MSHA inspector data had two advantages over employer data: the MSHA inspector data covered more occupations and had less distortion due to selection bias. Limitations in MSHA data were also addressed principally by elimination of some samples which were re-inspection samples of high exposure situations and use of employer data to supplement the MSHA inspection data by the set of rules explained below.

MSHA worker exposure data was reduced from 181,767 samples to a remaining 146, 917 valid "Day-1" samples. "Day-1" worker exposure is used as a basic unit of measurement throughout most of this analysis. In contrast to the previous QRA conducted in 2003, this QRA evaluated 33 mutually exclusive job titles (19 underground jobs, 13 surface jobs and a special job title Part-90 Miners) for radiological signs of CWP. The concept of unique work locations (WL) by job title is also introduced. The WL represents a unique job process or mine area per job title and reflects variability in job title exposure by mine and work process. Tables 1-5 show the distribution of this rich data set by job title, year, type of mine and the number and rate of exposure measurements of work locations per year by job title. This discussion of "day- 1"samples, job title selection and work locations (WL) was logically explained and well developed.

In contrast, Section 1 (c) Estimating Exposure Levels by Occupation could be better developed. It appears that the author of the QRA first tried to characterize worker exposure by the results of an ANCOVA analysis of working locations by job title and later by an adjusted and supplemented model. The final mean exposure value used in the QRA was calculated based on the MSHA exposure inspection data by job titles, with the year truncated (2008 data only) and then adjusted by applying equal weights to working locations. Finally the WL-job was supplemented by employer exposure data.

Key quantitative data is presented in Table 6. Table 6 shows the MSHA inspector data 2004-2008 (unadjusted). The data shows the number of samples, work areas, mean, median, coefficient of variability and the percentage of samples that exceeds 0.5 1.0 and 2.0 mg/m^3 of RCMD. Trends over time 2004-2008 showed a statistical decrease in exposure for nine job categories and a statistical increase of exposure in two categories. A Pearson correlation confirmed a positive association between working location exposure measurements and job title indicating that more highly exposed jobs were sampled more often. As a result, the distribution of exposure measurements will tend to overestimate the true distribution of exposure levels in the population sampled.

An ANCOVA analysis identified sources of variability which included the mine, sampling date and the dust standard (coal dust or silica and coal dust) that was in effect when sampling at that work location. With the presentation of Figures 7-9, the discussion becomes a little unclear. Figure 7 shows the adjusted point estimates of average exposure levels by job title and the 95 percent confidence limits. It is inherent to the ANCOVA analysis to reduce the within and between job variability due to bias and to, therefore, reduce the confidence interval around the mean estimate for each job title. The author of the QRA also recognizes that the heterogeneity of the exposure data is underestimated by the ANCOVA analysis represented by Figure 7 in the discussion on the bottom of page 19. The presentation of Figures 8 and 9 compares mean exposure estimates for the ANCOVA 2004-8 analysis and the Adjusted and Supplemented (AS) 2008 data for various job titles (see further description of AS exposure data below) In general AS 2008 data shows higher average exposure estimates and a wider range in the average exposure (greater variability) across underground job titles than the ANCOVA 2004-8 analysis. Also, note that Figure 8 and 9 no longer shows confidence limits around the mean for AS 2008. To avoid confusion, it should be made clear in the discussion of Figure 7 and in the legends for Figure 8 and 9 that the AS 2008 data rather than the ANCOVA data is being used in the subsequent risk characterization.

Key to the QRA analysis is corrections for potential biases introduced by MSHA inspection compliance sampling, in particular oversampling highly exposed working locations. As stated on page 18 of this analysis "This QRA addresses imbalances (biases) in the number of available samples by developing separate exposure estimates for each WL. Results are then aggregated by occupational category, assigning equal weight to the mean dust concentrations observed at each WL." We concur that it is reasonable to assign equal weightings for each working location with the consequence that the data will show lower mean exposure concentrations. This adjusted data for equal WL by job title could be shown in a table similar to Table 6 so that adjusted and non-adjusted data can be compared.

As shown on page 23, prior to making the data adjustment for equal WL weighting, the author of the QRA restricted the data to 2008 only, to account for a time-dependent decrease in exposures evident in nine job titles. Although, this is a reasonable analytical approach in many situations, it has the consequence of creating many working locations with too few observations in this data set. The assessment, therefore, chooses to supplement the 2008 MSHA inspection data with employers' exposure data. The elimination of the 2004-2007 sampling data may have also reduced variability within the exposure variable (1 versus 5 years). An alternate approach is recommend in which the QRA retains and adjusts the five years of exposure data or retains as much of that data as is possible.

Table 6 shows that 22 of 33 job titles showed no statistical change in the time trend analysis, therefore, all five years of data can be used for those 22 job titles. The remaining 11 job title should be looked at qualitatively and quantitatively. Various methods can be used to retain existing exposure data including, interpolating data from work locations with similar jobs in the same mine where exposure data is thin, using a similar approach by development of a quantitative model to directly adjust the data to correct for time trends, the use of existing data for multiple years if not statistically different from the 2008 sampling or determine time trends by alternate measures of central tendency, such as the geometric mean or the median value.

The data on trend analysis did not appear to differentiate exposure changes due to large changes in a few mines or smaller changes in most mines. If the former case was true, the midpoint estimate would have minimal change while the 90^{th} percentile measurement would be substantially larger than in the latter case. Additional descriptive time trend analysis for exposures by mine and job title is suggested

The assessment supplements the MSHA inspector data with employer data. Prior to analysis the operator (employer) data was purged of abatement confirmation samples considered to be non-representative of employee exposure. Rules 3 and 4, shown as bullets on page 23, show the detailed adjustments that are applied to each WL-job title. Rule 3 is pretty clear and does not need any further clarification, but its effect on the data overall could be better explained. On the other hand, the rationale for Rule 4 is not clear and needs to be more fully explained or revised. Also, the description of the employer database was not fully developed so the reader is not in a position to evaluate the quality of the employer data. It appears from Table 5, last column, if five years of data is retained in the analysis, there would be two or more "Day-1" exposure observations per WL - job title and, therefore, there would be no need to incorporate the employer data in the development of exposure estimates in accordance with rule 3.

In summary, the development of the exposure measures appeared to be overly complex, likely reduced important variability in worker exposure estimates, and possibly introduced unintended bias by supplementing with the employer data. Furthermore, introduction of employer sampling to adjust and supplement MSHA inspection data may lead to exposure estimates that are no longer connected to an underlying distribution of data in which standard error and confidence intervals can be accurately expressed. We concur with the author that the outer-extremes, particularly the upper confidence interval, are an important element of the exposure data. The data presentation on Table 9 captures this concept very well, and a similar data table should be maintained in any revised document.

The QRA breaks the exposure estimates into three categories (R1-, R1-2, and R2+). While this is a good technique for demonstrating exposure data distribution, ranking of exposures into three groups is dilutive in comparison to the job title-WL exposure estimates for characterizing exposure relationships to disease endpoints. A suggested alternative approach is to adjust the WL-job exposure estimate by placing an equal weighting on working locations in developing the midpoint estimate for each job title. This would allow all, or as much of the five years of exposure data to be retained and avoid supplementing with employer exposure data. Five years of data should be statistically robust (See Table 2), and where it may not be, data interpolation may be used to estimate values. The mean exposure by WL-job title is thought to be the best measurement of its central tendency; however, the median value should also be used in the QRA. There are other advantages to this recommended approach for data analysis.

- The data has less manipulation and therefore easier to explain and support.

- The exposure midpoint estimates by WL-job title can be associated with a standard error and confidence limits or 90^{th} or 95^{th} percentile exposure values. The modification of the WL exposure estimate by operator exposure data, as done in this QRA, may make it inappropriate to show confidence limits around these numbers as they come from different underlying distributions.

- Employer (Operator) exposure data can be compared independently of the MSHA inspector exposure estimate, to confirm or not confirm data trends and conclusions.

In section 2, the quantification of current risk is developed from applying exposure-response risks from select epidemiological studies to a distribution of 2008 (current) measured exposures. Clusters of similar risks are defined by clustering working locations by job title, coal rank and record of excess dust concentrations. A fourth variable of hours worked per year by employee would also effect this quantification of cumulative exposure, but these records were not available by miner so it was assumed in the analysis that working hours was equal to 1920 hours per year and was equally divided by cluster groupings.

WL-job title has been previously discussed. The two remaining factors, coal rank and record of excess dust concentrations, are both divided into three mutually exclusive clusters. Coal ranks are related to the risk models found in the epidemiological literature and are discussed elsewhere. This critique will be limited to a record of excess respirable dust concentrations or as stated in the previous 2003 QRA a "pattern of recurrent over exposures." The QRA states that previous studies had indicated that two or more MSHA inspector or operator elevated samples (recurrent exposures) were associated with six or more exposures during a year. In essence the QRA expanded on a concept in the 2003 QRA that creates three ranked groups for underground and surface mine exposures based on the number of elevated exposures measured in that working location. The categories are:

- R2+ (two or more operator or MSHA inspector exposures > 2.0 mg/m^3 for 2008),

- R1-2 (not in the R2+ class and having two or more MSHA inspector or operator measurements exceeding 1.0 mg/m^3 for 2008), and

- R1- (all WLs in which in no more than one MSHA or operator exposure measurement was >1.0mg/m3.)

These ranked groups had reasonable distributions for underground coal mines (R2+ having 9 percent of the WLs, R1-2 having 21 percent of the WLs and R1- having 70 percent of the WLs). This distribution was less meaningful for surface coal mining with 99 percent of the WL falling into the R1- category.

This rough categorization adds back some of the within job variability that was lost during adjustment/supplementation of the data. The recurrent classification adds some perspective about the higher exposed working locations. This is enhanced by Table 11, Figures 16-17, and their related discussions. It also appears reasonable to look at the number of excursions above 1.0 or 2.0 mg/m^3 of RCMD using either MSHA inspector data or operator (employer) exposure data.

Consistent with the discussion above, we believe that showing the percentage of measurements of WL-job title that exceed 0.5, 1.0 and 2.0 mg/m^3 of respirable dust is a more precise or refined descriptor and will enhance characterization of risk. Similarly, the assessment can show the exposure estimate of the 10th, 50th, 90th or 95th percentile of working locations for any given job title. The 90% or 95% confidence limits can be derived around these estimates based, in most cases, on five years of collected data. For example, the number and percentage of working locations estimated to exceed 1.0 mg/m^3 RCMD for any given job title can be determined. These distributions could be adjusted by coal rank for better risk characterization.

Section 3 of the QRA, titled *"Risk under implementation of the proposed rule"*, describes the procedures used to project average RCMD exposure levels by job category, coal rank and recurrency class under successful implementation of the proposed rule. The analysis considers separately the effects of two proposed changes in the FEL: 1) a reduction in the exposure limit; and 2) a prohibition of exposure to RCMD above the proposed limit on every shift. Larger reductions in exposure can be expected for WL-jobs in which current exposure levels exceed the proposed FEL compared with WL-jobs that are currently in compliance with the proposed FEL. Therefore, these two components of the projected reductions are derived using different methods, and then combined to develop the estimates of projected average exposures under the proposed standard.

Exposure reduction factors (ERFs) were used to project the reduction in exposure attributable to a reduction in the FEL from 2.0 mg/m^3 to 1.0 mg/m^3 for jobs already below the proposed limit of 1.0 mg/m3. The ERFs were based on comparison of samples taken at WLs with an applicable exposure limit of 2.0 mg/m^3 to samples taken at WLs with applicable exposure limit of 1.0 mg/m^3 when the silica content of the dust is less than 5%. When the silica content exceeds 5%, a lower limit is enforced based on the formula 10 divided by percent silica (e.g. for RCD containing 10% silica, the limit is equal to 1.0 mg/m^3).

The ANCOVA analysis predicts an overall 14% reduction in average exposure levels across all mines for WL currently in compliance with the proposed standard (i.e. <1.0 mgm3). The ANCOVA model included an interaction term to calculate reduction factors by occupation. The ERFs, as presented in Table 19, ranged from 14 percent (multiple job titles) to 54.7 percent (laborer). These reductions appear reasonable for WL-jobs already in compliance with the proposed limit.

The exposure reduction factors (ERFs) were based on comparison of samples taken at WLs with an applicable exposure limit of 2.0 mg/m^3 to samples taken at WLs with applicable exposure limit of 1.0 mg/m^3 when the silica content of the dust is less than 5%. When the silica content exceeds 5%, a lower limit is enforced based on the formula 10 divided by percent silica (e.g. for RCD containing 10% silica, the limit is equal to 1.0 mg/m^3).

In the QRA, MSHA measurements were dichotomized based on an applicable standard of either 2.0 mg/m^3 or 1.0 mg/m^3. However, it's not clear on what basis the applicable standard for a particular WL was determined, and whether the general 14% difference based on the ANCOVA can be attributed to efforts made to comply with an effective limit of 1.0 mg/m^3, or whether these measurements can be considered truly representative of conditions likely to occur under the proposed standard. For example, exposures for bull dozer operators were found to be higher when the exposure limit was 1.0 mg/m^3 than when it was 2.0 mg/m^3. In addition, the ERF were calculated by excluding all measurements greater than 1.0 mg/m^3, further attenuating the observed reductions. Finally, estimates for which the standard errors of the coefficient were larger than the absolute value of the coefficient were replaced by the general value of 14%, resulting in smaller ERFs for these occupations.

The expected reduction percent for surface mines, which also appears on Table 19, is bimodal, with either a 14 percent reduction or zero percent reduction. All zero reduction job titles were for heavy vehicle operators (backhoes, drills, bulldozers, trucks), thus the estimate of zero reduction appears related to use of enclosed air conditioned cabs with pre-filtered air and the expectation of 100 percent compliance. If this is so, it is not transparent to the reader and should be explained. Secondly, the "simulation" or model only shows a generalized effect for the rest of the surface job titles. This maybe an artifact or reflect that 99 percent of WLs of surface mines are less than 1.0 mg/m^3. Again, a discussion of this point would be helpful.

Larger reductions in average exposure levels are projected for WL-jobs in which the current levels exceed the proposed limit of 1.0 mg/m^3. For these WL-jobs, the assumption was made that compliance would be achieved if the average exposure levels are reduced to 1.0 mg/m^3, and no further. This assumption potentially underestimates the reduction in exposures, but is consistent with the approach generally taken by OSHA to project job-specific exposures likely to occur as a result of compliance with a proposed permissible exposure limit. A less conservative approach would assume that successful compliance with the proposed limit of 1.0 mg/m^3 results in a downward shift in the overall distribution of daily average exposures such that the long-term average exposure levels for all jobs would be reduced to no more than 50% of the FEL, and that any exposures currently below 50% of the FEL would remain unchanged.

The projected average dust concentrations for each occupation was then calculated based on the ERFs for WLs below 1.0 mg/m^3 and a projected exposure of 1.0 mg/m^3 for WL above the proposed standard, weighted by the number of measurements. This calculation assumes that the percentage of measurements above the FEL represents the relative frequency of exposure days above the FEL. The projected average RCD exposure levels under successful implementation of the proposed standard are presented in Table 20, and graphically in Figures 18 and 19.

Risk Characterization

The assessment applies the cumulative exposure – response models to project excess risks of CWP, severe emphysema, and NMRD mortality from a 45 year working lifetime exposure (assuming 1920 working hours per year) to the average full-shift RCMD concentrations estimated for the 19 underground mining and 14 surface job categories. The risks were characterized as cases of impairment per 1000 exposed miners. For each job category, CWP risks were projected by age 73 for low/medium coal rank, high coal rank, and anthracite locations, where exposure estimates were available. This same job/coal rank scheme was used to project job-specific NMRD mortality risks by age 73 and 85. Emphysema risks were projected for non-smoking 'white' and 'non-white' miners by age 73 for the job categories but the model lacked the capability to estimate risk by coal rank. With the addition of the three recurrency exposure classes, there were as many as eight risk estimates per health endpoint for some job categories. Risk estimates for every job category/recurrency class/coal rank or race combination were determined at the current exposure and at the exposure expected following implementation of the proposed rule. The aggregated reduction in risk for each health endpoint and job category was calculated by summing the weighted risk difference pre- and post-implementation for the job subcategories (e.g. recurrency class and coal rank).

The greatest risks of disease were projected for several underground mining jobs where average working lifetime exposures exceeded 1.0 mg/m^3 RCMD. The current CWP risk estimates were in excess of 10 percent (100 cases per 1000 miners) for these jobs in high bituminous coal and anthracite locations. Current emphysema risks were also around 10 percent for certain high recurrency (2+) underground jobs such as continuous miner, cutting machine, and longwall tailgate operators. CWP and emphysema risks for most surface workers were lower but still significant at around 1 percent (10 cases per 1000 workers). Implementation of the proposed rule is projected to reduce CWP and severe emphysema risk of the aforementioned underground jobs by 25 to 100 cases per 1000 miners. The proposed rule is projected to save as many as 10 NMRD deaths per 1000 miners in the high risk occupations. These findings meet the MSHA requirement to demonstrate substantial reduction in risk as a result of the new RCMD standard.

The risk reduction findings would be clearer and more compelling if the risks were reported as projected cases of impairment *within each job category* (i.e. population risk estimate) in addition to the individual risk descriptor per 1000 exposed miners. For example, the proposed rule is projected to reduce risk of PMF (progressive massive fibrosis) among continuous underground mining operators by 38 cases per 1000 workers exposed (see table 28). If there are 10,000 continuous mining operators in the U.S., the resulting risk reduction among this population would be an impressive 380 cases of

PMF avoided by the proposed MSHA rule. However, if there are 100 of these mining operators in the U.S., then the risk reduction would be only 4 PMF cases avoided. Table 27 presents the percentage of miners across recurrency class and coal rank within a job category but does provide the number of workers *in each job category*. The later information would allow a more in-depth characterization of population risk.

The QRA presents the excess risk estimates at current exposure levels for the five health outcomes across job category/recurrency class/coal rank or race combination in tables 13 through 17 on pages 44 to 50. The projected excess risk comparisons for the same exposure groups from implementation of the proposed rule are presented 20 pages later in tables 21 to 25. However, the assessment lacks complete tables for the risk reduction breakouts by job category/recurrency class/coal rank forcing the reader to subtract estimates contained in multiple tables across several pages. This could be rectified by providing either another set of tables or some risk comparison charts that display the information across a three dimensional grid. The later was effectively done in figures 18 and 19 (pages 60-61) to show the reduction in exposure estimates under current conditions and the proposed rule.

There are inconsistencies between the excess risks of morbidity (e.g. CWP, PMF, emphysema) outcomes and NMRD (non-malignant respiratory disease) mortality among anthracite workers in some of the low exposure job categories. Such workers are estimated to have greater mortality risk of NMRD attributable to RCMD than expected based on the combined morbidity risk of CWP and emphysema. A prime example is a white surface utility man in recurrency class R1-. This worker is projected to have an excess NMRD mortality risk (7.8 percent) more than three times his combined morbidity risk of CWP1+, CWP2+, PMF, and severe emphysema (2.3 percent). This type of disease pattern is highly implausible. There are other job categories that display similar, though less severe, inconsistencies. Such incompatible risk estimates should be pointed out in the document. The likely explanation is the uncertainty in the NMRD risk model used to predict risk in anthracite coal miners as discussed in the section on exposure – response assessment. We agree that the uncertainty is reduced when calculating risk reduction where sources of error in predicted risk can potentially get cancelled out.

In summary, the approaches used to estimate excess risk of CWP, emphysema, and NMRD at current exposures and following implementation of the proposed rule were appropriately applied and characterized. The results show a considerable reduction in lung disease among many job categories. The findings meet the MSHA requirement to demonstrate substantial reduction in risk as a result of the new RCMD standard. The risk characterization would be improved by including population risk estimates, adding charts that specifically show the risk reduction across job categories/exposure groups, and identifying inconsistencies in the risk estimates at anthracite locations.

NIOSH Review
of
Quantitative Risk Assessment
in Support of Proposed Respirable Coal Mine Dust Rule

This is a very thorough and detailed quantitative risk assessment (QRA). It is structured in three main parts: 1) the derivation of coal mine dust concentrations for U.S. coal mines that are intended to be free of artifacts introduced by the compliance process; 2) an examination of pertinent exposure-response models; 3) the application of the data from 1) and 2) in order to derive the reduction in excess risk that would result through application of the lower recommended dust standard and associated rules. Full and detailed appendices that cover further issues and expositions of the methods are supplied.
In the first part, recognition is taken of the factors that can impact measurements made in the course of enforcing dust regulations. These extend to the issues engendered by the current sampling process, involving both operator and inspector sampling, as well as the fact that the current procedures do not rely on single samples. Sophisticated methods are used to resolve these issues, as far as they can be resolved, coupled with careful selection of data so as to exclude samples that are potentially likely to be unrepresentative (e.g., inspector follow-up samples).

The second part presents information on the exposure-response models used. This material is up-to-date and the information is interpreted correctly as well as employed properly. There is a proper focus on different health outcomes, including both coal workers' pneumoconiosis (CWP) and chronic obstructive pulmonary disease (COPD). End outcomes include both morbidity and mortality, and within each type of outcome, various endpoints are considered (e.g., simple CWP and PMF, or ventilator function and pathologic emphysema).

The final part derives information on the benefits to be gained by adopting the proposed new coal mine dust standard and associated regulations. The logic behind this is to derive the distribution of recent exposure levels (using information from the first part), the distribution of exposure levels expected by imposition of the proposed standard, and compute the benefit in terms of numbers of cases that would be prevented by the reduction in exposure levels. The report properly concerns itself with sample distributions rather than a restricted focus on mean levels, and pays great attention to valid methods of estimation.

Overall, the QRA indicates that the proposed coal mine standard would have the effect of substantially reducing the number of occupational respiratory disease cases. This is the same conclusion that NIOSH came to in 1995 using much of the same epidemiologic information. It therefore is consistent not only with NIOSH policy but is based on the same basic approach employed by NIOSH.

Comment on format

The document is well-written and I could find only a few typos and inaccuracies. Nevertheless, it is a large and detailed document, full of facts and data, and it is very hard to digest. Even though I have been intimately involved in most of the studies and with the data, I found it hard to determine the broad analytical approach. In this, the style of the document is discursive, rather than directive. For example, in part 1, the data are described, discussed, decisions made, and then further issues are raised and decisions made, and we finally get to the estimates that are employed. In part 3, the text starts with a description of the method used by NIOSH, rather than getting directly to the chosen approach by MSHA. In both cases, it would be better to tell us about the MSHA approach, and later compare it to prior or alternative approaches, citing the pros and cons, of course. Overall, the pace of the document is rather slow and the text tends to belabor points that should be familiar to the expected readership of this document.

Overall, it would be much better to get to the main points much more directly, so the reader can rapidly comprehend the whole process. One way to do this is including some summary material, presented initially in each chapter, which gives the objective, issues, and a brief overview of the methods employed. This would outline the steps of the analysis based on the final data and methodology chosen for the analysis. Any justification would be brief, with references made to the later sections where the topic is handled in detail. Having understood from that how the whole analysis is put together, the reader can then choose to read further as needed. Perhaps in this, there is room for more of the discursive text to be moved to further appendices.

Major comments on methods

As noted above, great attention was paid to assessing recent dust levels in U.S. mines. The various reasons why certain data might be biased were presented, discussed, and, where necessary, appropriate steps were taken to adjust or exclude potentially biased measurements. However, at NIOSH we have been concerned over the last few years that something is gravely wrong in certain areas concerning how well the U.S. underground coal mine environment has been controlled. In this respect, various papers and reports have been published on hot spots of CWP prevalence or progression. More recently, we have been investigating the observed CWP prevalence in comparison with the prevalence that might be expected given dust concentration levels derived from the same dataset employed in this QRA. Overall, we have found that in certain coal mining regions considerably more CWP has been recorded than is predicted using the reported dust levels in the MSHA dataset. There are a number of potential explanations for the observed phenomenon:

1) the epidemiologic models employed in the published papers might be wrong;
2) dust levels have systematically been under-reported;
3) longer working hours have effectively been increasing overall exposures;
4) some other constituent of the dust, such as silica, is at work;
5) all of the above factors, including underestimation, are at work.

The fact that the effect is absent in some coal mining regions (that is, observed and predicted prevalences are similar to each other) appears to rule out reason 1).

With respect to dust levels (point 2), one tabulation undertaken for West Virginia miners has shown that mean concentration levels of 3 mg/m^3 or higher would have had to been experienced to get the CWP prevalences observed. These levels are more consistent with the example given of the continuous miner job in Table 29 of the QRA than the <1 mg/m^3 level given in Table 6, and point to a consistent underestimation of the actual coal mine dust levels in recent years. It seems that these NIOSH findings regarding observed and predicted CWP prevalences ought to be mentioned in the QRA. They do not undercut the QRA at all – if underestimation of dust concentrations is a major problem, it is clear that adoption of the new dust limits, ***if effectively enforced***, would lead to considerably greater benefits than are indicated in this QRA.

The QRA comments on the impact of longer hours. Although, there are no epidemiologic or other data that conclusively implicates working longer hours as a factor in the development of CWP, it seems prudent to suspect it does. The QRA comments on this issue and correctly notes that its results are conservative in this regard.

Lastly, there is the issue of silica exposure. This is not dealt with at all in the QRA, which has a focus totally on mixed mine dust. To a large extent, this focus is reasonable – historically silica exposure has not featured greatly in findings concerning CWP development (at low levels it did not appear as a major predictor) – and there are no epidemiologic models from the U.S. that include silica exposure as a predictor variable. Ultimately, this QRA accomplishes what it is intended to do – to justify a reduction in the dust standard for mixed coal mine dust. This is the same conclusion as promulgated by NIOSH in 1995. However, in concentrating on this particular exposure-response relationship with coal mine dust, we must not forget that miners today are being exposed to excess silica levels, particularly in thinner seam and small mines, and that this situation could well get worse as the thicker seams are mined out. Hence, since silica is more toxic than mixed coal mine dust, tomorrow's miners could well be at greater risk, despite a reduction in the mixed coal mine dust standard. It seems appropriate that this fact should be noted in the QRA.

My second major concern relates to the outcome endpoints being set for miners at fairly advanced age. Not only does a focus on 80-year old miners undercut the obvious seriousness of the intent of the QRA – some might wonder why, if a miner can reach to his 80s, whether there could be anything seriously wrong! But, more importantly, extrapolating the epidemiologic findings well beyond the age range of the study participants stretches credibility. All of the morbidity studies were based on coal miners of working age, often with an average age of around 45, with only a minority close to retirement age. In essence, we don't know much about about the disease status of retired coal miners. Although it does seem very plausible that occupational respiratory disease, once it has developed, could well exacerbate without further exposure, there is little solid evidence on this. Consequently, I have a concern that the validity of the results could be questioned by those opposed to change. Using only the age 73 outcome would minimize the possibility of this type of criticism.

Other comments

a) On p. 37 the text notes:

"Therefore, MSHA classified each WL as belonging to one of three coal rank categories — anthracite, high-rank bituminous, or low/medium rank.[35] At most work locations in U.S. underground coal mines, exposures are to high rank coal dust. Except for District 1 (all anthracite), it was assumed that exposures at surface mines and facilities are to low/medium rank coal mine dust."

This may be a matter of definition, but my understanding is that most coal that is mined underground is low/medium rank. High rank coal, by my definition, is only mined underground in western Virginia and the very south-east of West Virginia. In fact, that coalfield actually includes some semi-anthracite coal (although I do not know if it is mined currently). My definitions come from a reference book on coal, that is, in Table 1.5 of Speight *The chemistry and technology of coal* [1]. Here, I equate high rank with low- and medium-volatile coal. My understanding is that the majority of coal mined underground in the U.S. is high-volatile bituminous coal, which I equate with low/medium rank.

b) There is no reference to the Miller et al. (2007) report. I suspect it was an Institute of Occupational Medicine technical report. I also suspect that the Miller and MacCalman [2](2009) publication contains the essentials of the report (although not the modeling coefficients used in this QRA).

c) It would be good to have some words interpreting Table 37. The caption says that the figures are relative to the first day. If this is so, the first day should be 0 (exp(0)=1). If they are not relative to the first day, then it seems that subsequent measurements are higher than those from the first day (-1.0353>-1.2201), which seems contrary to the supposition that the inspector returned to sample because dust levels were high and had then been corrected.

d) On p. 27 the text says:

"Attfield and Seixas used two or three specially selected B readers…"

This appears to make the methods look rather casual. The text of the paper notes that three readers were used and that the median reading of the three was taken. (Fewer *readings* might have been available if one or more readers found the radiograph to be unreadable, but these cases were few.)

e) The Kuempel et al. coal risks paper [3], which provides more information on the risk assessment used in the NIOSH criteria document should be cited. The fact that the procedures passed peer review for publication adds validity to those results, and by implication, to those of the QRA.

References

[1] Speight,J.G. The chemistry and technology of coal, Marcel Dekker, New York, 1994.

[2] Miller,B.G., MacCalman,L. Cause-specific mortality in British coal workers and exposure to respirable dust and quartz, Occup. Environ. Med.(2009).

[3] Kuempel,E.D., Smith,R.J., Attfield,M.D., Stayner,L.T. Risks of occupational respiratory diseases among U.S. coal miners, Appl. Occup. Environ. Hyg. 12 (1997) 823-831.

Index Of Responses To Peer Reviews

* Presumably addressed in Health Effects Section of NPRM, as noted on p. 1, ¶1.
** Published information insufficient to construct suggested confidence limits.