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.

Hazard Identification

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 90th 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 90th or 95th 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.