

September 22, 1993

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Dear Ms. Kuempel:

Enclosed, you will find my final response on the review of the draft document "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust." This review represents my comments as a Peer Review Panel member.

I hope you will find these comments useful in finalizing the draft criteria document. If I can be of additional assistance, or if you require further clarification on any of these comments, please contact me at :

Sincerely,

Review of Draft Document

CRITERIA FOR A RECOMMENDED STANDARD  
OCCUPATIONAL EXPOSURE TO RESPIRABLE COAL MINE DUST

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Public Health Service  
Centers for Disease Control and Prevention  
National Institute for Occupational Safety and Health  
Division of Standards Development and Technology Transfer  
Cincinnati, Ohio

JUNE 14, 1993

1. Is the derivation of the Recommended Exposure Limit (REL) supported by the scientific data?

The document does not present adequate scientific data to explain or support the derivation of proposed RELs. It is unclear what exposure data was used as part of the epidemiological studies to relate exposure to incidence? What specific data was used to determine incidence levels? Was exposure determined from the 1969 Bureau study? Was the MIDAS database used for exposure levels? Was the NIOSH NSCWP study used to determine incidence rates? How does the low participation in Rounds 3 & 4 affect the validity of this data? If standards truly need to be revised, that fact must be obvious from epidemiological data.

This document makes vague references to studies that allegedly show that "substantial risk" of lung diseases still exist with current PELs. The report states "some risk of PMF remains even at 0.9 mg/m<sup>3</sup>." The document only cites these studies; it does not adequately report or explain their contents. What is the level of risk at 0.9? On what basis is this an assumed acceptable level of risk? On what basis was the level of risk at 1.2 mg/m<sup>3</sup> or higher determined to be an unacceptable level of risk? Even after a revision of the PELs, recommendations require that exposures be kept as far below the new standards as possible.

The report states that "a definitive determination cannot be made from the chest radiograph alone as to whether changes consistent with pneumoconiosis have resulted from carbonaceous dust or silica dust," that "silica exposure may be a factor in the rapid progression from CWP to PMF," and that "among miners with PMF, 20% had no radiographic evidence of simple CWP at the beginning of the previous 5-year period." This seems to indicate that silica is the key agent in the development of PMF, and supports the recommendation to reduce the silica dust standard to 0.05 mg/m<sup>3</sup>. However, the rationale for proposing the elimination of the 5% quartz trigger approach has not been presented. Reducing the quartz PEL would require a particular body of data not addressed within this document. No analysis of ambient quartz levels is presented. Depending on specific location, weather conditions, and level of human activity, current or proposed quartz PELs may be exceeded in various ordinary environments. The validity of occupational PELs for quartz has never been evaluated in this context. The lower the proposed quartz PEL, the more relevant is the issue of ambient quartz exposure to the general population.

It would appear that silica is the critical component of respirable coal mine dust that must be controlled. The epidemiological data presented in the report does not seem to build a strong case for the impact of coal dust; exposure to coal dust may have an impact on the development of CWP, however PMF is most affected by exposure to silica dust. Information in the Criteria Document appears to support reducing the silica dust standard, but may not contain sufficiently valid scientific data to support reducing the coal mine dust standard to the proposed  $0.9 \text{ mg/m}^3$  level. Recent studies by the Generic Mineral Institutes for Respirable Dust also appear to support this indication. They have been conducting studies on "Interaction of Coal Dust and Nonhuman Primate Lungs," "Human Alveolar Macrophage and Coal Mine Dust Interactions," "Intervention in the Production of Fibrotic Mediators by the Dust-Exposed Alveolar Macrophage," "Molecular and Biochemical Studies of Dust Lung Interactions," "Dust-Lung Interaction in Coal Miners - Airway Reactivity in Coal Miners," and "Immunological and Inflammatory Pulmonary Mechanisms Associated with Chronic Coal Dust Inhalation in Coal Miners." Have the results of these studies been considered in developing this document?

The report states that cigarette smoking is a major cause of COPD, and that the relative contribution of coal mine dust exposure to decrement of lung function cannot be determined. The report also states that the effectiveness of reducing exposure among coal miners with early development of airways obstruction (before such changes become irreversible) remains to be determined. There does not appear to be sufficiently valid scientific data to support the recommendations concerning chronic obstructive pulmonary disease. Additional studies may be needed before a valid recommendation can be proposed.

2. Are the RELs for respirable coal mine dust and respirable crystalline silica technically feasible?

This question cannot be answered in the abstract. Existing PELs often present significant technical challenges. For example, if the primary source of airborne respirable dust on a longwall mining operation is due to face spalls, no known technology exists to control the dust from this source. Each individual mining operation has varying levels of respirable dust from the various dust sources. What has been shown to be an effective control at one operation will not be effective at a second operation if the rank of the source proportionment is not the same. While the document reports encouragingly that many mine environments would already meet future standards, the more important factor is that many existing exposures do not yet meet current standards. The document claims that one-third to one-half of compliance samples were below  $1.0 \text{ mg/m}^3$ . The document presents no evidence that getting the remaining one-half to two-thirds of samples into compliance is technically feasible. Recent studies have shown that the physical parameters of the coal seam itself can impact the level of airborne respirable dust by an order of magnitude. Thus, even if the source proportionment is equal between the two mines, mine B may have as much as 10 times more airborne respirable dust to control than mine A. Because one mine can reduce dust levels to  $1.0 \text{ mg/m}^3$ , it is invalid to assume that all other mines are able to obtain this level. Existing dust control technology can barely cope with current noncompliance situations in spite of many years of research and

implementation. If dust RELs are cut in half, ordinary intake air may be considered a significant problem. If quartz RELs are cut in half, trace quartz in limestone rock dust may become a problem.

The report states that "for most strip mine occupations, the average concentration of respirable crystalline silica exceeds the recommended REL of 0.05 mg/m<sup>3</sup>. Thus, control of respirable crystalline silica should be a priority for surface coal mining operations." The above cited factors apply equally to surface mining operations. Without an in-depth technical feasibility analysis, it is impossible to speculate whether surface mining operations can obtain the recommended REL for silica.

It is impossible to render a sound scientific judgement without an in-depth analysis of the technical feasibility for the coal mining industry to meet the recommended dust standards.

3. Should the proposed international definition of respirable dust be recommended as the criteria for sampling respirable coal mine dust and respirable crystalline silica?

The report contains results of studies and discussions conducted by the ISO, CEN, and ACGIH. The data presented in Figure 5-2(a) does not show convincing evidence that the ISO/CEN/ACGIH definition fits the data any better than the ACGIH definition of 1985. Currently, there is no compelling reason to adjust the definition of respirable dust. NIOSH must make a specific argument for its choice.

4. Should improvements in the coal mine dust personal sampling unit (CMDPSU), including all-metal construction to minimize charge effects, be recommended? Should performance criteria be developed for the approval of more than one type of sampling device?

The scientific community should always be open to documented improvements in dust sampling devices. Convincing data must exist, however, proving that the change in design or implementation will truly be an improvement. However, one must answer the question, "is there a valid technical need?" If so, how may this be off-set by the enforcement/administrative issues?

Regarding metal versus nylon cyclones, static charge is not the only consideration. Metal cyclones are not necessarily more dependable or more desirable dust collectors. Differences in surface textures will affect surface particle interception and particle collection. Metal and nylon collectors may therefore be subject to errors of similar magnitude, but from different physical phenomena. In recent years, countries that have traditionally used all-metal collectors are adopting more nylon components. This trend seems to weaken opinions that all-metal construction is inherently superior.

Addressing the issue of sample flowrate, a limited mathematical exercise appears to validate the conversion factor cited in the report. However, This is only for the particle size range cited in the report. The use of cited

aerosol mass size distribution data for coal mine dust, Burkhart et al, (1987) and Mutmansky and Lee (1987), to derive a correction factor between results using the current MSHA sampling methods and those using the ISO/CEN/ACGIH sampling criteria needs to be reexamined with coal mine aerosol size distributions measured with other than the Sierra Model 298, Rubow, Cantrell, and Marple (1990). The Sierra sampler has severe limitations in the high dust concentration level environment of underground coal mines. Measurements using this device are subject to challenge. The absence of answers in this regard points to a deficiency in the document or a need for more research.

5. Is the recommended sampling strategy reasonable on the basis of both statistical validity and practical considerations for measuring airborne concentrations of respirable dust in the coal mine environment?

Addressing statistical validity:

It is unclear how requiring the mine operator to submit a written dust control plan every six months improves the current system? If the operation is in compliance at the established REL, what is the value of resubmitting the plan?

It is unclear what the biweekly sampling by coal mine operators is to be used to accomplish? What is the scientific basis for requiring the biweeking sampling?

It is unclear why mine operators' sampling cannot be used for noncompliance? What is the scientific basis for recommending a distinction between compliance sampling by coal mine operators and noncompliance sampling by MSHA inspectors?

The report states "whenever changes in operational conditions might result in exposure concentrations above the REL, air sampling shall be conducted by the mine operator as if it were an initial monitoring survey." How does one define "changes which might result?" The report also states "a sufficient number of samples shall be collected to characterize each miner's exposure." How does one define "a sufficient number of samples?"

The recommendation that "noncompliance be determined on the basis of single full-shift concentrations, including a statistical comparison of the probability that the single sample exceed the REL" appears to be technically valid.

Much of the statistical consideration in sampling depend heavily on the writings of Leidel. However, Mr. Leidel has stated that his publications have been overused and overemphasized to an extent never intended. The suggestions for greater accuracy in gravimetric measurements are probably justified, but the matter of quartz analysis is not so clear.

Addressing practical considerations:

The report recommends that "the mine operator shall conduct an initial monitoring survey to determine the exposure of miners to respirable coal mine dust and respirable crystalline silica," and that "every two weeks, the mine operator shall measure the exposure of each DO, DA, DWP, and/or Part 90 miner." Who will be responsible for processing and certifying the results of this sampling? What is the potential financial/administrative burden on MSHA if they are to process these samples?

The report recommends that "the number of samples analyzed for respirable crystalline silica should be increased to one sample per biweekly sampling period for roof bolters, drillers, and other "high-risk" occupations for exposure to respirable crystalline silica" and that "sampling and analysis for respirable crystalline silica should be performed in accordance with NIOSH method 7500 or 7602." Who will be responsible for processing and certifying the results of this sampling? What is the potential financial/administrative burden on MSHA if they are to process these samples?

The report recommends that "medical records be maintained for workers for at least 40 years after termination of employment, and that copies of environmental exposure records for each worker must be included with the medical records." Who will be responsible for maintaining these records if the mining company no longer exists? Will these records move with the individual as the individual changes employment from mine to mine? What is the potential financial/administrative burden associated with this recommendation?

6. Is the inclusion of spirometry tests in the medical surveillance program justifiable for the prevention of chronic obstructive lung disease in underground and surface coal mines?

Both spirometry and radiology have been under-utilized to detect incipient dust-induced or dust-aggravated lung diseases. However, the report states "unlike PMF, chronic occupation pulmonary disease (COPD) also occurs among individuals without occupational exposure," "cigarette smoking is a major cause of COPD," "commonly used spirometric tests may not be useful for identifying specific diseases," "age, height, and cigarette smoking are important nonoccupational factors that affect lung function," and that "the relative contribution of coal mine dust exposure to a measured decrement of lung function in an individual cannot be determined." Thus, this issue appears to be open to debate. The absence of answers in this regard points to a deficiency in the document or a need for more research.

7. Is the transfer of miners with evidence of Coal Worker's Pneumoconiosis (CWP) or Chronic Obstructive Pulmonary Disease (COPD) to low dust areas of the mine medically justifiable at the recommended concentrations of respirable coal mine dust or respirable crystalline silica?

Transfer of miners may appear to be a logical and medically justifiable approach. However, the report states "some risk of progressive massive fibrosis (PMF) remains even at 0.9 mg/m<sup>3</sup>," results of "a study estimated that only .01% of PMF cases would be prevented if all eligible miners transferred to less dusty jobs, these studies indicate that secondary preventive measures such as transfer are not effective in preventing PMF," "studies indicate that PMF may continue to progress even in the absence of further dust exposure," and "the relative contribution of coal mine dust exposure to a measured decrement of lung function in an individual cannot be determined." This issue appears to be open to debate. There does not appear to be sufficiently valid scientific data to support the recommendations concerning transfer of miners. Additional studies may be needed before a valid recommendation can be proposed.

8. Are there additional issues or interpretations of information that need to be considered in the development of this criteria document?

The apparent original intent of Congress, as stated in the 1969 Mine Health and Safety Act, was to establish an environmental standard to insure that the environment to which a miner is exposed be maintained at or below an established standard. One must view the proposed recommendations in light of this original intent. The intent was to provide the mine worker the highest level of protection feasible. One must insure that these proposed changes do not potentially decrease the health protection currently afforded to the coal mining workforce.

Almost every aspect of dust measurement and enforcement would be adjusted, revised, or reformed by this document. The burden of proof is therefore on the authors to show in the clearest and most decisive manner that the current compliance program is inadequate and would be inadequate if pursued to its fullest potential. The document does not present decisive reasons and clear, definitive data for a program overhaul.

The document should do a better job of differentiating between simple CWP, radiological opacities, and actual impairment and disability. As with workers exposed to iron oxide, radiological opacities are common, but their status is not pathological. The relation of the prevalence of lesions in autopsies and the existence of pathology must also be clarified. The clinical significance of data in the document must be greatly clarified to prove that a change in RELs is really needed.

The report states that "belt haulageways are a significant source of respirable dust," (NIOSH, 1988). A recent report by the U. S. Bureau of Mines (BuMines RI-9426) concludes: "Using the belt entry as an intake entry may result in additional outby dust sources, however it may also increase the amount of air available for dust dilution. If the belt entry air represents additional air brought to the face; and if belt entry dust levels... are lower than face dust levels, belt entry air may reduce face dust levels. The magnitude of outby dust sources and the dilution effect are mine specific. Any decision to use the belt entry as an intake entry for dust control should be supported with a field study." Based on this study, one may question if "belt haulageways are a significant source of respirable dust." The other

safety concerns expressed in the document are addresses in the "Final Report of the Department of Labor's Advisory Committee on the Use of Air in the Belt Entry to Ventilate the Production Areas of Underground Coal Mines and Related Provisions." This report appears to resolve may of the concerns expressed in the 1988 NIOSH report.

The data scatter in figure 5-4, 5-8, and 5-9 regarding applicability of a new definition of respirable dust and use of correction factors is very disconcerting. The potential for major error is very real for individual samples or dust distributions with particular characteristics. There is nothing in the text to dispel such concerns.

Page 14, Who will conduct the initial and daily fit checks of respirators? What does a "quantitative" fit test entail?

The document states that "evaluation of the economic feasibility, including consideration of the cost of upgrading or retrofitting mining equipment or of reduced production levels, are beyond the purview of NIOSH." It is appropriate that this economic feasibility study, as well as the previously mentioned technical feasibility study be conducted.