

U. S. Department of Labor

Mine Safety and Health Administration
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Arlington, Virginia 22203-1984



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National Institute for Occupational
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Dear Dr. Niemeier:

Enclosed are the Mine Safety and Health Administration's responses to the specific questions posed in your June 28, 1993, letter as well as other comments on the National Institute for Occupational Safety and Health (NIOSH) draft document entitled, Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust. We recognize that considerable thought has gone into the development of many of the concepts presented in the document.

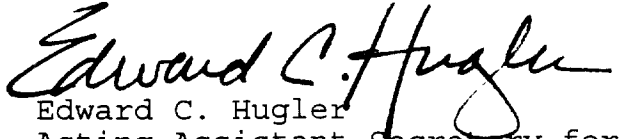
Due to the complexity and scope of the draft document, and the time afforded for comments, we are only able to provide general responses. This is particularly true in those instances where we have been unable to review the references upon which some of the recommendations were based. We look forward to receiving the remaining references.

The existing mandatory health standards, most of which were established in Title II of the Federal Coal Mine Health and Safety Act of 1969, were intended by Congress to be interim standards. That Act specifically provided that those provisions should be superseded, in whole or part, by improved health standards promulgated by the Secretary of Labor. Accordingly, we fully support NIOSH's efforts to review the existing medical evidence to determine if there is a scientific basis for the Secretary to propose revised respirable dust standards for coal mines. Our Agency is committed to providing miners with the highest degree of health protection in their workplace.

As you know, the release of a final criteria document will trigger specific statutory obligations for MSHA. To enable us to be better prepared and to more effectively carry out these responsibilities, coordination between our two agencies prior to the issuance of the final document will be needed.

If you have any questions or require additional information, please contact Patricia W. Silvey, Director, Office of Standards, Regulations and Variances, at (703) 235-1910.

Sincerely,

A handwritten signature in black ink that reads "Edward C. Hugler". The signature is written in a cursive style with a large, prominent "H".

Edward C. Hugler
Acting Assistant Secretary for
Mine Safety and Health

Enclosure

cc: Dr. Richard A. Lemen

MSHA Comments on NIOSH Draft Criteria Document

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

The draft criteria document does not provide sufficient information to permit MSHA to ascertain whether the RELs are supported by the scientific data. Certain issues would need to be clarified before MSHA can make an informed decision on the validity of the RELs. In the limited time allowed for response, MSHA has been able to evaluate only some of the studies referenced and relied upon in the document. The Agency's review of the criteria document, along with limited review of some of the referenced documents, has raised the following issues and questions:

- a. To what extent is the regression model used to derive the prevalences presented in Table 7-2 empirically supported at the exposures and age levels for which projections are presented -- i.e., to what extent are the prevalence estimates based on extrapolating the model outside the range of the available data?
- b. The British data referred to in Table 7-2 and all of the data referred to in Table 7-3 appear to lack any assessment of the statistical significance of projected differences in prevalence at 2.0 mg/m³ vs. 1.0 mg/m³.
- c. To what extent has the sensitivity of the projections to potential inaccuracy of the supporting exposure estimates been examined? With respect to random error (imprecision) in each miner's estimated lifetime dust exposure, was a "mixed effects" regression model used to construct confidence intervals for prevalence projections at 2.0 mg/m³ and 1.0 mg/m³? In the Attfield/Morrison model, what account is taken of variability within the occupational exposures used to generate lifetime exposure estimates?
- d. For every coal rank, the Attfield/Morrison model projects higher PMF prevalence at age 58 and zero exposure than at age 29 and 139 gh/m³. This indicates possible misspecification of the model.
- e. The exposure/response models make no allowance for a possible threshold effect. What would be the impact on projected prevalences of estimating a threshold effect within the exposure/response models? Since the models project a continuously increasing response for exposures greater than zero, what was the statistical basis of picking 1.0 mg/m³ as the respirable dust REL? The choice of 1.0 seems arbitrary from a statistical standpoint.
- f. The study by Attfield and Morrison appears to lack control groups for establishing the probability of false posit-

ives. Was the single reader who interpreted the x-rays aware that they were coal miner x-rays?

g. Were such variables as silica content, residence time of the dust deposition, and cumulative smoking exposure tested for inclusion in the exposure/response regression model? In particular, what is the impact of not including silica exposure and residence time in the model?

h. Are the U.S. model projections consistent with observed prevalences for miners employed since 1970? To what extent have the models been validated by comparison against these post-1970 data?

i. Much higher prevalences of CWP and PMF were observed in a relatively small segment of the study -- i.e. anthracite and low-volatile bituminous coal regions. Is there evidence for a statistically significant difference between PMF projections at 1.0 mg/m^3 and 2.0 mg/m^3 for coal rank regions other than anthracite and low volatile bituminous coal?

j. In Table 7-2, U.S. and British PMF prevalence projections at either 1.0 mg/m^3 or 2.0 mg/m^3 generally differ by a greater percentage than the projections at 1.0 mg/m^3 vs. 2.0 mg/m^3 within either the U.S. or British results. How does this impact the statistical significance attributed to differences between the 1.0 mg/m^3 and 2.0 mg/m^3 projections?

k. The criteria document provides no evidence to support a lower crystalline silica dust standard. Additionally, there is no basis in the criteria document for the recommendation that MSHA eliminate the current practice of using the percentage of quartz in respirable coal mine dust to establish the applicable standard for respirable coal mine dust.

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

Although there is extensive discussion in the draft criteria document of personal exposure sampling, NIOSH has not explicitly stated whether it is recommending a shift to a personal exposure standard from the current environmental standard. Whether the RELs are technically feasible depends to a great extent on whether NIOSH is recommending such a change.

A move to a personal exposure standard could result in situations where the mine environmental dust levels could exceed the RELs but the operator would be in compliance if the personal exposure levels are at or below the RELs. If NIOSH intends that the RELs be personal exposure standards, compliance with the RELs may very well be technically feasible at many mining operations, if administrative controls are equated with engineering controls.

However, if the RELs remain as environmental standards, with primary reliance for compliance on engineering controls, the technical feasibility of compliance with the RELs may be more problematic, particularly on longwall sections and at mining operations with high quartz levels.

Although the criteria document states that engineering controls should be the primary method of dust control, it is unclear where administrative controls fit into the control hierarchy. Would NIOSH consider miner rotation to achieve compliance to be equivalent to engineering controls? (Currently, MSHA would consider rotation only after available engineering control methods have been exhausted).

Has NIOSH considered whether the exclusive use of personal sampling may result in an elevation of the environmental dust levels? Additionally, does NIOSH anticipate that a shift to a personal exposure standard may result in greater reliance on the use of PPE for maintaining exposures below the RELs?

NIOSH's conclusion that the majority of mining operations can comply with the RELs, based on the fact that the average concentration of the industry is at that level, may be invalid. In arriving at this conclusion, did NIOSH consider the impacts of methods of mining, production levels, geological factors, dust sources, and the variability of the effectiveness of dust control methods from mine to mine?

The requirement that intake air be maintained at the "lowest attainable level" is impractical from an enforcement standpoint because the criteria document fails to specify how to set that level. Does NIOSH envision that the "lowest attainable level" will be a floating level that will vary depending on in-mine conditions? If so, at what frequency does NIOSH recommend that this level be evaluated for possible change, and what factors should be considered in setting the level?

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

Yes, provided that the definition is enforceable. To accomplish this, NIOSH should establish a program for validating that instrument performance conforms to the international standard, and provide MSHA with a recommended standard reference sampling device.

4. Should improvements in the coal mine dust personal sampling unit, 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?

An essential element of an effective dust sampling program is the continuing evaluation of the performance of the instrumentation used for sampling. Accordingly, MSHA recommends that NIOSH maintain such a program, and that recommendations on sampling devices be supported by data obtained from comparative in-mine studies. NIOSH's program should also consider recommendations to reduce the susceptibility of sampling systems to tampering or damage, as has been recommended by MSHA in the Report of the Respirable Dust Task Group.

MSHA endorses the establishment of performance criteria to facilitate the approval of more than one type of sampling device. Additionally, MSHA supports NIOSH's recommendation that a continuous monitor be developed, and NIOSH should develop procedures for approving this type of device.

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

Our review of the document has raised the following questions about NIOSH's proposed sampling strategy.

NIOSH Recommendations Regarding MSHA Sampling

What is the basis for NIOSH's recommendation for the frequency of MSHA sampling (6 times per year)?

The criteria document fails to address the type of sampling procedures required, once an operator is cited for exceeding the dust standard, to demonstrate that the violation has been corrected. Specifically, the criteria document fails to discuss the number of samples to be collected or by whom, to demonstrate compliance, or how MSHA should determine that the violation has been abated.

NIOSH Recommendations Regarding Operator Sampling

There is no statistical support for the recommended number of operator samples; specifically, whether the number of samples and the frequency of sampling are appropriate in reasonably assuring that miners' exposures are being maintained at or below the RELs or in assessing the continuing adequacy of the operator's dust control practices. Further, no attempt has been made to derive the recommended number of samples based on the shift-to-shift variability of the dust levels. Finally, NIOSH has not presented evidence that a biweekly single-shift measurement will provide

reasonable assurance that miners' exposures are being maintained at or below the RELs.

NIOSH has recommended that operators not be cited for exceeding the dust standard based on operator-collected samples. This recommendation raises two specific issues. First, is this recommendation based on the belief that not citing would make it more likely that operators would sample under typical operating conditions? This may not be true because, under NIOSH's proposed program, operator samples would be used by MSHA to upgrade the operator's dust control plan as well as to target mines for increased inspections. Additionally, two consecutive operator NDE samples falling below the lower confidence limit of the REL can significantly reduce the operator's sampling burden. Consequently, operators may still have an incentive to collect and submit unrepresentative samples.

Second, under this recommendation MSHA would be provided with evidence of a violation of a mandatory standard, i.e., operator samples sent in for processing by MSHA are found to exceed the standard, but would not cite based on this evidence. Section 104(a) of the Mine Act requires that an inspector who believes that an operator has violated a mandatory standard issue a citation. Therefore, MSHA would be compelled to issue citations once the Agency became aware of the violative results of operator samples, contrary to NIOSH's recommendation.

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

MSHA supports any program whose aim is to prevent the development of respiratory disease. MSHA therefore supports the inclusion of spirometry tests as part of the medical surveillance program. These tests can serve as a valuable screening tool to identify miners who should seek further medical evaluation of the etiology of the impairment and the prognosis for further reduction in lung function.

7. Is the transfer of miners with evidence of Coal Workers' Pneumoconiosis or Chronic Obstructive Pulmonary Diseases to low dust areas of the mine medically justifiable at the recommended concentrations of respirable coal mine dust or respirable crystalline silica?

The information provided does not establish that the transfer of miners with evidence of CWP to low-dust areas is medically justifiable. The evidence presented indicates that the transfer program will not protect an individual who has been exposed to coal dust from developing CWP or PMF, and that transfer to a less dusty environment will not retard the rate of progression of PMF or CWP.

The recommended reduction in the respirable dust and quartz standards raises questions about the continued relevance of or need for any transfer program. As the RELs are so low, there may be little if any benefit in transferring miners to areas of the mine where dust levels are marginally lower than dust levels in other areas of the mine.

There is no evidence in the criteria document demonstrating any beneficial effect of transferring miners with COPD to areas in the mine with dust concentrations lower than the REL. If such benefit exists, it should be included in the criteria document.

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

Program Issues

Surface coal miners are exposed to similar hazards from respirable dust as are underground coal miners, and are entitled to the same level of health protection. MSHA therefore supports NIOSH's recommendation that surface miners be included in the X-Ray Surveillance Program.

Does NIOSH envision that the initial and follow-up medical examinations would become a condition of employment? If yes, how does NIOSH recommend that this requirement be enforced? Would this recommendation be consistent with the requirements of the Americans With Disabilities Act?

If NIOSH is recommending a change from an environmental standard to a personal exposure standard, the criteria document should include information to support or explain the shift.

Although NIOSH advocates engineering controls as the principal means of controlling dust, if NIOSH is recommending a shift to a personal exposure standard, engineering controls are effectively equated with administrative controls. Does NIOSH anticipate that this will reduce the use of engineering controls, increase the application of administrative controls, and encourage increased use of PPE? Finally, how does NIOSH contemplate that personal exposures will be assessed when miners are wearing PPE?

NIOSH should demonstrate that the sampling and analytical procedures recommended in the document meet the standards for the Class B analytical method.

Does NIOSH support a reduction in the REL for miners who work more than 11 hours per shift and more than 5 days per week? If so, how does NIOSH propose that such a REL be determined?

NIOSH needs to provide specific details on the quality control program recommended to insure that sampler performance in the

field is comparable to NIOSH's recommended sampler performance criteria.

How does NIOSH envision maintaining individual exposure records if personal samples will not be tied to personal identifiers to the individual who was sampled? How does NIOSH envision that records would follow the miner from mine to mine during his working life? If the samples cannot be linked to an individual miner, how is it possible to determine when the 40 year post-retirement record retention period begins to run? Finally, if exposure records are not to be used for research purposes, why should they be retained for 40 years after a miner's retirement?

The criteria document should only contain peer-reviewed references and footnotes. Also, information not available to the public should not be referenced in the document. Otherwise it is impossible to effectively review the basis of the document. (See, for example, first footnote to Table 7-2; Lorberneau, 1990; Bartley et al., 1993; and Heederik D, Miller BG 1988.

Finally, NIOSH's recommended sampling strategy has many similarities to the enforcement program in effect in the 1970's. In 1980, MSHA made significant regulatory changes to that program.