NATIONAL
COAL
ASSOCIATION

BRUCE H. WATZMAN
Vice President
(202) 463-2657

September 13, 1993



Dr. Richard W. Neimeier, PH.D.
Director
Division of Standards Development
and Technology Transfer
National Institute for Occupational
Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, Ohio 45226-1998

Re: Draft "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust."

Dear Dr. Neimeier:

This letter and the attached report are submitted for your consideration on the above referenced report. The National Coal Association (NCA) appreciates having the opportunity to file these comments.

For background purposes, NCA is an association whose members constitute a substantial percentage of the Nations's coal-producing capacity, and includes companies that own and operate coal-mining facilities or engage in businesses that are directly related to the production of coal, such as equipment manufacturers, coal sales companies, transporters, consultants, and resource developers. As such, our members are keenly interested in this proceeding as they will be directly affected should the Mine Safety and Health Administration adopted NIOSH's recommended exposure limit (REL).

In filing these comments we hope that NIOSH is sincere and that all comments will be seriously analyzed before a final report is prepared. We are extremely concerned that final decisions have already been made and that the comments of the affected community will be given, at best, cursory consideration. This is based upon the extraordinarily compressed comment period provided to the public and more importantly, a letter dated 25 August 1993 from NIOSH to NCA which states:



1130 Seventeenth Street, N.W.
Washington, D.C. 20036-4677

(202) 463-2625

> "Based on the significance of the health risks observed among coal miners, we feel compelled to make available the information contained in the criteria document and to recommend that the Mine Safety and Health Administration (MSHA) undertake the necessary actions to address these concerns."

To the potentially regulated community it appears as if NIOSH intends to summarily dismiss comments and objective criticism. This letter and the attached report highlight our concerns with NIOSH's discriminating and selective use of the reference documents and the conclusions reached. We request that you address each of our concerns prior to finalizing the criteria document and submitting it to MSHA.

## GENERAL COMMENTS

Most industrially developed nations around the world adopted a new respirable coal mine dust standard nearly 20 to 25 years ago. The U.S. standards are by far the most stringent at 2 $mg/m^3$ for respirable coal mine dust and 0.1 $mg/m^3$ for crystalline silica. In these two decades all countries in general, and the U.S.A. in particular, have seen a significant reduction in the incidence and prevalence of Coal Workers' Pneumoconiosis (CWP). So far, no one except NIOSH has felt the need for further reduction in the dust standards.

Epidemiological studies here in the U.S.A., the U.K. and Germany have failed to determine an absolutely safe level of respirable coal mine dust which does not constitute any hazard to anyone working in the mine. Realizing this, perhaps, the 1969 Coal Mining Health & Safety Act authorized MSHA only to control the progression of CWP to avoid disabling disease and not to completely "prevent the incidence" of non-symptomatic CWP.

Control of CWP is dependent on three fundamental principles.

1. Periodic medical examination of each individual miner. This should include:
   - (a) Personal susceptibility to respirable dust
   - (b) Health habits, e.g. smoking and nutrition
   - (c) Changes in the lungs' characteristics (radiography) and lung functions (spirometry).

2. Maintaining the respirable coal mine dust standard at a level that is medically warranted and monitoring life-long doses for each individual. If the safe life-long dose level is likely to be exceeded, protective equipment, such as air helmets must be used by the individual.

3. Monitoring the presence of crystalline silica in coal mine dust since silica appears to be a complicating factor in causing disabling disease.

## PERIODIC MEDICAL EXAMINATION

In a typical year of 8760 hours (365 days at 24 hours a day), a miner is likely to spend no more than 23% of the time (2000 hours; 250 days at 8 hours/day) in the mining environment. While it is important to know what happens in these 2000 hours spent in the mining environment, it is equally, if not more, important to find out what happens in the remaining 6760 hours outside the mining environment. Specific factors that need to be considered are:

1. The dust levels (and its composition) of the environment the miner lives in.

2. The general health of the miner and his/her sensitivity to dust, allergens, etc.

3. Smoking habits. A coal miner must not smoke.

4. General nutrition, particularly the presence of nutrients which produce protective anti-oxidants in the body, e.g. N Acetyl Cysteine. The lack of this chemical in the body is often associated with the occurrence of several upper respiratory system diseases. Conversely, a well-balanced diet rich in Vitamin C and certain amino-acids that can synthesize in the body to form N Acetyl Cysteine can provide some safeguard against chronic occupational pulmonary diseases (COPD) and CWP.

The U.S. dust standards are already so low that only workers who are highly sensitive to low levels of dust in mines should be a cause for concern. Medical examination at the beginning of employment, and subsequently at a reasonable intervals, therefore, is of paramount importance. Workers who are extra-sensitive to airborne dust

should be transferred to the surface or required to wear protective equipment.

## THE THRESHOLD LIMIT FOR RESPIRABLE COAL MINE DUST AND CRYSTALLINE SILICA

NIOSH has taken a fundamentally different approach to the development of respirable dust standards compared to the European countries. NIOSH intends to lower the coal mine dust and crystalline silica threshold limit values (T.L.V.) to be number low enough to prevent the occurrence of progressive massive fibrosis or conglomerate silicosis in any worker, regardless of its technical feasibility, or the worker's personal susceptibility to the disease. In so doing, NIOSH ignores the workers' smoking and other personal habits which will, if not controlled, adversely affect health to a greater degree than low dust exposures. The European countries recognize that even at very low dust concentration, some individuals may contract simple CWP or simple silicosis and that the present state-of-the-art in dust control may not be able to achieve excessively low dust standards. They set their standards at a technically achievable value, and carefully monitor the health of the workers. If any signs of CWP/silicosis susceptibility appears, the worker is transferred to a less dusty work area.

NIOSH appears to be preoccupied with the idea of reducing silica T.L.V. They published a "Criteria Document for a Recommended Standard-occupational Exposure to Crystalline Silica" (NIOSH Report No. 75-12) in 1974 advocating reduction of silica T.L.V. to 0.05 $mg/m^3$. For lack of necessary and sufficient data supporting this criterion, MSHA and the scientific community, has rejected the document. Unless NIOSH submits necessary and sufficient data the scientific and mining community will waste precious resources to address again a flawed and unsupported recommendation.

We believe that the reliable dust exposure data for the period 1969-1992 should be analyzed using well-known statistical tools, namely, linear and non-linear multiple regressions, analysis of variance and Markov chain analysis to establish probabilities of contracting CWP/silicosis as a function of dust concentrations. This would provide a scientific basis for dust standards in U.S. coal mines, furthermore, even medically warranted T.L.V.'s must be practical (i.e. technically feasible) and economically sustainable. NIOSH has not examined or addresses these essential concerns.

## THE ROLE OF CRYSTALLINE SILICA IN THE PROGRESSION OF CWP TO PROGRESSIVE MASSIVE FIBROSIS (PMF)

NIOSH has done a poor job of explaining this issue. There is at present insufficient evidence that PMF can occur in the absence of Category I CWP. While some studies have reported that it is possible that crystalline silica exposure plays a role in the progress of CWP others have reported no conclusive results. The subject has been researched by the Generic Mineral Institute for Respirable Dust.

The Institute is funded by the U.S. Bureau of Mines and has done considerable work on both medical and engineering aspects of respirable coal mine dust during the past ten years (1983-1992). NIOSH has, unfortunately, failed to include their findings in the criteria document. The findings of this institute should be carefully examined by NIOSH and if the pathogenicity of silica particles is severe enough, special precautions must be taken.

NIOSH data (1969-1988) show that in the U.S. coal mines all categories of CWP have continuously and significantly declined. It would be correct to say that CWP is a vanishing or dying disease and that the current dust standards of 2 $mg/m^3$ for all respirable dust and 0.1 $mg/m^3$ for crystalline silica are fully protective. Government and industry should, instead, focus their attentions on the following:

(1) Educating the miners on the risks of smoking and requiring that they must not smoke.

(2) Educating the miners on the value of good nutrition in relation to CWP & COPD.

(3) Timely medical check-up to see if the individual is sensitive to dust and encourage use of protective air helmets.

(4) Examine the role of crystalline silica in dust more carefully and study the reduction of its pathogenicity by proper chemical treatments prior to inhalation.

## REPORT OF SCIENCES INTERNATIONAL

To analytically critique the draft criteria document, NCA retained the services of Sciences International, Inc. In their review Sciences was asked to:

- determine if the conclusions reached by NIOSH were adequately supported by the document and if they were accurate reflections of the scientific literature; and

- determine if the conclusions were necessary and warranted given the current safety and health programs and practices of the coal mining industry.

Sciences report, a copy of which is attached, contains a series of recommendations which must be considered by NIOSH before a final criteria document is published. More generally however, Sciences has concluded that, **"there are significant data gaps which must be addressed before a lower permissible exposure limit can be addressed."**

The members of the National Coal Association, like NIOSH, want to assure that miners are provided as healthful a work environment as is feasible, but this determination must be based upon sound, unbiased science. We cannot, and indeed should not, be required to adhere to a standard predicated upon the selective use of scientific data. NIOSH owes it to all members of the regulated community to present data in an impartial manner so that decisions can be rendered to lower health risks in the workplace. The report by Sciences has identified data gaps and we implore NIOSH to respond to this critique prior to determining whether a final criteria document recommending a change of the coal dust standard is warranted.

Again, we appreciate having the opportunity to provide these comments and look forward to working with NIOSH in the future.

Sincerely,

Bruce H. Watzman

Enclosure

# A Critique of the NIOSH "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust"

**Prepared for:**
**National Coal Association**

**Submitted by:**
**Sciences International, Inc.**
**1001 19th Street North, Ste. 1500**
**Arlington, VA 22209-1722**

September 13, 1993

## Executive Summary

## Review of the NIOSH "Recommended Criteria for Occupational Exposure to Respirable Coal Mine Dust", 1993.

NIOSH recently published the "Recommended Criteria for Occupational Exposure to Respirable Coal Mine Dust." NIOSH has reviewed the existing scientific literature to assess the adequacy of the current permissible exposure level, 2.0 mg/M³ (MRE) for the prevention of respiratory diseases of coal miners such as coal mine workers pneumoconiosis (CWP), pulmonary massive fibrosis (PMF), chronic obstructive pulmonary disease (COPD), and chronic bronchitis. Additionally, NIOSH has provided additional recommendations regarding the Mine Safety and Health Administration's (MSHA's) program to control exposure to respirable coal mine dust and free crystalline silica. In this document, NIOSH has made the following recommendations:

- Adoption of the ISO/CEN/ACGIH definition of respirable dust.
- The permissible exposure level for respirable coal mine dust be reduced from 2.0 to 0.9 mg/M³.
- Imposition of a complex exposure monitoring program, and,
- The use of pulmonary function testing to assess miner's respiratory health.

We have reviewed the scientific basis for this document and NIOSH's recommendations. **We have concluded that there are significant data gaps which must be addressed before a lower permissible exposure limit can be addressed. NIOSH has not provided a sufficient scientific or medical rationale for the adoption of a 0.9 mg/M³ permissible exposure level.** The epidemiologic studies relied on for proposed standard are heavily influenced by high respirable coal mine dust exposures (miner's working prior to 1969) to a small part of the cohort. Additionally, before recommending an exposure and biological monitoring program, NIOSH

should address the scientific uncertainties and inconsistencies identified in the Criteria Document. The following recommendations are provided:

- NIOSH must revaluate the relationship between exposure to respirable coal mine dust and PMF, CWP, COPD and chronic bronchitis using a variety of models so that the model that best represents the shape of the dose-response curve is used to model the data.
- NIOSH must consider funding research to evaluate the effect of dose-rate on the dose response model.
- NIOSH should consider a strategy that addresses environmental variability. There appears to be great variability in exposures to coal dust and crystalline silica, as shown by the tables presented in the document that is not explained by sampling and analytical variability. If environmental variability were considered and a recommended standard included a REL with an exposure distribution and an allowable exceedence fraction instead of basing noncompliance on a single value, mine operators would not be penalized for collecting samples. At the same time, the goal of maintaining the miners' long-term average exposures below a desired value is possible.
- NIOSH needs to define terms or provide guidance for the exposure monitoring scheme. Terms such as "high risk worker" and "sufficient number of samples" without further clarification will cause problems for the design of a monitoring scheme. Sufficient data exist, both with MSHA and in the published literature, to allow analyses of exposure distributions to help define these terms.
- NIOSH needs to edit the document to remove contradictory recommendations and clearly delineate NIOSH recommendations from current practice. The exposure monitoring plans, as described in this document, are confusing because one must refer to

different parts of the document for various recommendations, and these recommendations sometimes conflict with one another.

- NIOSH should retain the recommendation for separate analysis of respirable coal mine dust and respirable crystalline silica. This recommendation will eliminate a needless step in the determination of airborne concentrations of respirable silica.
- **The recommendation for the reduction in the airborne silica standard is not supported by the available current scientific data.** NIOSH made this recommendation in 1974 and has still not developed the epidemiology to support it.
- Determinations of noncompliance should be based only on MSHA inspector-collected samples. This recommendation is similar to strategy used by OSHA. This type of program will encourage mine operator's to assess and control miners' exposures to respirable coal mine dust, while not bearing the burden of a potential citation.
- NIOSH needs to reconsider the use of pulmonary function tests considering the potential problems with interpretation, the specificity for determining occupational lung disease related to respirable coal mine dust exposure, and the potential interferences from smoking, etc.

**Review of the NIOSH "Recommended Criteria for Occupational Exposure to Respirable Coal Mine Dust", 1993**

On June 14, 1993, NIOSH released for public comment their "Recommended Criteria for Occupational Exposure to Respirable Coal Mine Dust." In this document, NIOSH has reviewed the existing scientific literature to assess the adequacy of the current permissible exposure level, 2.0 mg/M$^3$ (MRE) for the prevention of respiratory diseases of coal miners such as coal mine workers pneumoconiosis (CWP), pulmonary massive fibrosis (PMF), chronic obstructive pulmonary disease (COPD), and chronic bronchitis. Additionally, NIOSH has provided additional recommendations regarding the Mine Safety and Health Administration's (MSHA's) program to control respirable coal mine dust and free crystalline silica exposures. In this document, NIOSH has addressed the following issues:

- The definition of respirable coal mine dust
- The adequacy of the epidemiological base of the existing respirable coal mine dust standard, 2.0 mg/M$^3$, to prevent CWP, PMF, COPD, and chronic bronchitis.
- The adequacy of existing sampling procedures and equipment to assess respirable coal mine dust exposures, and
- The sampling strategy to assess compliance with the existing and proposed standards.

NIOSH released this document August, 1993, for peer review.

Because of the limited time for the completion of this review, a complete review of research papers and reports that have been published on this topic was not possible. It was, therefore, necessary to limit our comments to the document, how the arguments are developed,

and the conclusions drawn by NIOSH in their recommendations. NIOSH is proposing sweeping changes in how the coal mining industry defines respirable dust, what is an acceptable level of exposure to prevent pulmonary disease in workers exposed to coal mine dust and free crystalline silica. the frequency and number of air samples to be collected to assess compliance with the recommended exposure limit (REL) and the statistical model used to assess regulatory compliance. Additionally, NIOSH proposed the use of pulmonary function testing (PFT) as a tool to assess respiratory health of coal miner's.

NIOSH is proposing that:

- The current limit of 2.0 mg/M$^3$ for respirable coal mine dust reduced to "0.9 mg/M$^3$ for up to 10 hours/day, during a 40 hour workweek." NIOSH has also recommended that exposure to crystalline silica be limited to 0.05 mg/M$^3$, in keeping with a review conducted for NIOSH in 1974.
- The current definition of respirable dust used by the Mine Safety and Health Administration (MSHA) be changed to reflect more current definitions (ISO/CEN/ACGIH)and concerns.
- Exposure monitoring shall consist of full-shift **personal** air samples collected during an 8 to 10 hour workday.
- The mine operator shall conduct an initial monitoring survey to determine the exposure of miners to respirable coal mine dust and silica. A sufficient number of samples shall be collected to characterize each miner's full shift exposure.
- If the miner is exposed to respirable coal mine dust or respirable crystalline silica (at concentrations for which the upper 95% confidence limit, or

UCL (95%)), exceeds the recommended exposure limit (REL) for respirable coal mine dust or silica, then the miner's exposure shall be monitored at least every two weeks. They further recommend that the monitoring frequency may be reduced to once every 6 months when the UCL (95%) of the measured concentrations for respirable coal mine dust and/or silica are below the standard, 0.9 or 0.05 mg/M$^3$, respectively. Designated occupations (DOs) and transferred miners exposures shall be monitored once every two weeks. Exposure monitoring shall be conducted "whenever changes in operations conditions might result in exposures concentrations above the REL."

- Intake air concentrations shall be maintained at the lowest attainable level, full shift samples shall be collected from each working section (within 200 ft. outby) at least once every 6 months.
- Pulmonary function testing, both at the initial medical examination and at intervals specified in the CWXSP (Coal Worker's X-Ray Surveillance Program).

This review was conducted by:

Nurtan Esmen, Ph. D., CIH

President and founder of Esmen Engineering and

former faculty member of the University of Pittsburgh School

of Public Health

Robert Golden, PH. D.

Respiratory Physiologist and Partner at Karch and Associates, Inc.

Marcia Francis, Ph. D., CIH

Director of Industrial Hygiene and Senior Staff Member of Technical Assessment Systems, Inc.

and Thomas A. Hall, Ph. D., CIH

Director of Industrial Hygiene at Sciences International, Inc.

A brief biographical sketch of each reviewer is located in Appendix I. Each of these investigators was asked to review specific components of the NIOSH proposed criteria document to determine if:

- The conclusions reached by NIOSH were adequately supported by the document and if they were accurate reflections of the scientific literature?
- The conclusions and proposals proffered by NIOSH were necessary and warranted given the current safety and health programs and practices of the coal mining industry.

The reviewer's comments and recommendations are provided below. Each author provided comments and recommendations in their area's of expertise. Specifically, Dr. Hall commented on the epidemiological analysis used to support the proposed REL, Drs. Esmen and Francis provided comments on the definition of respirable dust, the proposed sampling strategy, and the proposed regulatory compliance strategy. Dr. Golden supplied comments and recommendations focusing on the use of PFTs to assess miner's respiratory health.

**ISSUE: Is the REL, 0.9 mg/M³, supported by the epidemiologic literature?**

NIOSH bases their recommendation primarily on the work of Attfield and Morring (1992), and Hurley et al. (1987). Both of these authors have reported an increased risk for PMF in coal mine workers exposed to cumulative coal mine dust concentrations equivalent to average exposures of 2.0 mg/M³ for 45 years .

Both of the studies are problematic with respect to assumptions of exposure. Attfield and Morring estimated exposure from a combination of personal exposure measurements (1970-1979) (not truly personal, many of these samples represent area concentrations which may or may not be correlated to personal exposures), cumulative exposure estimates up to 1970 (at best a crude estimate, based on studies conducted by MSHA which have been demonstrated to exhibit a positive bias), and work histories after 1979. How well these data estimate cumulative exposures to respirable coal mine dust will affect the precision of the exposure-response estimates and therefore the risk estimates at given levels of exposure. Attfield and Morring have assumed that any bias incorporated will affect the risk estimates in a negative manner, implying that their estimates are actually conservative. If the exposure estimates are underestimates of the actual exposures, the risk estimates will be overstated at any given level of exposure. NIOSH should have considered this potential outcome in their analysis.

A more problematic issue is the choice of models used to model the dose-response relationships. The use of logistic regression models by both of the studies relied upon by NIOSH imposed a linear relationship on the exposure-response data. NIOSH has not discussed nor have they assumed any other data structures (non-linear dose-response) which could result in vastly different dose-response relationships. The assumption of a linear dose-response relationship

assumes that for every increase in cumulative dose, there is an increase in the risk. They attempt to support this assumption with a "weak" discussion of "lung overloading" based on animal studies where the animals were exposed to very high doses.

The issue of dose-rate is still unresolved. NIOSH has also identified this as a data gap where additional research is needed. This again is problematic in the recommendation of a REL based on exposures where the dose-rate was probably much higher (much higher exposures for study subjects whose exposure started in the early 1970's) than those subjects who entered into the studied cohort after 1969. The risk from PMF may well be related to high initial doses of respirable coal mine dust or silica.

The dose-rate issue is also a necessary part of the discussion of crystalline silica exposures and their relationship to the development of PMF. If high silica exposure is a necessary component to the development of PMF, then the study of coal mine workers from the early 1970's when crystalline silica exposures were typically higher probably bias the results toward increased risk.

NIOSH has supported the need for a lower REL primarily on the reported increase in PMF even if the radiographic category of the miner is category 0 (pg. 201). The investigations of Hurley et al., indicate that the relative risk of PMF incidence with cumulative exposures <180 gh/M$^3$ is less than 1 (Figure 4-4, page 86). The PMF relative risk does not rise above 1 with exposures exceeding 500 gh/M$^3$. NIOSH interprets this data differently. NIOSH correctly reported that the incidence of PMF in miners with category 0 was 0.2%. They go on to state that because the greatest number of miners studied were category 0, the number of PMF cases 0.2% represents is approximately 20% of all observed cases. This type of representation tends to skew

the presentation because of the size of the category 0 group. Small percentages increases in incidence rates from large study groups can contribute more cases to the total number of cases than large percentages from much smaller study groups. The most important observation is that the estimated prevalence in the category 0 group is approximately 1/40$^{th}$ that miner's who were category 1 at the start of the study period.

A final issue is the use of data from the CWXSP. Although NIOSH stated that "Valid interpretation of data from either the National Study of Coal Worker's Pneumoconiosis (NSCWP) or the CWXSP is difficult for rounds with poor participation rates", these studies probably have the most relevant response data. These studies have been conducted on U.S. coal mine workers during the relevant time frame (workers included in rounds 3 and 4). Exposure-response studies need to be conducted on populations that are relevant to current exposed populations.

**Issue: Is the recommendation to change the definition of respirable dust warranted by the scientific literature and how will this effect measurements of airborne dust?**

The international definition of respirable dust is based on the aerodynamic properties of the aerosol which are dependent penetration probability of dust into the non-ciliated regions of the human lung and it represents the most recent advances in the understanding of the aerodynamic behavior of dusts in the human respiratory tract. As it is well argued in the draft criteria document (DCD), a criterion definition based on particle penetration would estimate the delivered dose and, ideally, a dust deposition based criterion would be more realistic and scientifically more rigorous. However, as it is well presented in the DCD, the practicability of sampling in a coal mine with the instrumentation required for the estimation of respiratory tract deposition is, at best, uncertain. Therefore, the international definition of respirable dust is a workable compromise and

its use as the criterion for sampling respirable coal dust is appropriate. The two instruments currently available to conform to the international definition of respirable dust would enable a smooth transition from the old to the new definition, consequently, the use of the international definition in respirable dust criteria can be implemented without any delay or confusion.

The advances in many fields which relate to the design and operation of sampling devices can result in two distinct improvements in the sampling technology. If in the future, instruments which can routinely quantify a lung deposition based definition of respirable dust become available, then a new set of criteria for the prevention of respiratory disease in coal workers would have to be developed. In the near future, the improvements in the design of penetration based respirable dust sampling instruments are more likely. Consequently, the inclusion of a set of specific sampling instruments into an exposure criteria is not a good idea. Therefore, any proposed criteria should encourage the incorporation of future advances into the sampling methodologies. The incorporation of performance criteria and instrument approval procedures is strongly recommended. It should be recognized that NIOSH has the capability to develop the instrument approval procedures in a very short time, since they have sufficient experience in approval procedures. The benefits of the encouragement of developments is obvious and immediate. For example, the reduction in the coefficient of variation suggested for existing devices through changes in the analytical and reporting techniques can be furthered by the development of a personal respirable dust sampling instrument which operates at a higher flow rate than those hitherto approved. In addition, potential markets for more than one type of instrument can spur development with obvious economic benefits. The single sampler approach has more disadvantages than the performance criteria approach to sampler specification and we disagree with

the statement in section 5.1.3 that the performance-based approach would require extensive and expensive testing before samplers could be approved.

The limitations of the 10 mm nylon cyclone with respect to charged aerosols has been well documented. While there might be some economic arguments for their continued use, there is no corresponding scientific argument to that effect. The DCD does in fact point out the deficiency of the nylon cyclone with respect to static charging of the nylon body. The nylon cyclone should be phased out and any new performance criteria for aerosol sampling should include a statement on the electrical conductivity properties of the material used to construct the sampling instrument construction material.

Over the last fifteen years, repeated scientific and legal concerns have been raised regarding the variability inherent in the current sampling collection and analysis process (Hall, et al., 1985). Further, the performance of the current sampler has rendered it subject to criticism based on the collection of large non-respirable dust particles, as well as its susceptibility to dust dislodgement. If the scientific and regulated community embarks on the development and adoption of a new standard sampling process, these issues must be addressed to provide credibility to any new system.

**Issue: Is the exposure assessment approach recommended by NIOSH supported by the scientific literature?**

The choice of Leidel's single full shift sample determination for estimating compliance is at best unfortunate. The accuracy and variability considerations of the *sampling and analysis method only* and the single sample method proposed strictly tries to estimate the level crossing probabilities. In other words, the sampling is based on the existence of measured values in excess

of a given point of reference. All arguments presented in the Criteria Document suggest that the exposure criterion is based on the prevention of a cumulative effect. Estimates of dose for cumulative effects are of necessity based on an integrated value of the received dose and therefore best estimated by the behavior of the arithmetic average dose (mean dose) received from day to day. The mean dose is dependent upon the exposure distribution and it may be shown that mean exposure is a good predictor of mean dose [Esmen (1984), Rappaport (1991)]. If the estimate of the mean is based on a single sample, the confidence limits of the estimate are undefined for all levels of confidence. The inclusion of the analytical method coefficient of variance as the basis of mean estimator confidence level is confusing. If a sample shows that it is in excess of the criteria with a 95 percent confidence level, then the interpretation that the expected value of that worker's exposure is in excess of the criteria with a 95 percent confidence is totally erroneous. The correct interpretation would be that we have 95 percent confidence that *the sample* was in excess of the criteria. If the criteria is a ceiling level which should never be exceeded then it should be proposed and defended on that basis. However, the criteria is proposed and defended on the basis of an average. Obviously, by definition, some samples are going to be higher and some samples are going to be lower than the "average." Therefore, an average exposure significantly and consistently lower than the criterion would be unacceptable by the provisions of this test. For example, more than 20 percent of samples are expected to exceed criteria, if random samples come from job - task classification with a log-normally distributed exposure universe with a mean (arithmetic average) exposure 3/4 of the criterion and a geometric standard deviation of 2. According to the compliance procedures for DO's, DA's, DWP's, and Part 90 miner's, the job classification scheme carries better than a one in five chance to be wrongly labeled as a

noncompliance. The sampling results shown for the workers with MSHA code 307 shown on tables 7.6 and 7.7 are good examples of this discrepancy. The average shown for this job classification gives an arithmetic mean value of 0.71 mg/M$^3$ with 20 percent of the values in excess of 1.0 mg/M$^3$. Had these samples come from the same location, the mine would have carried a one in five risk of being in non-compliance. If a coal mine operator desires to be in compliance with a very small probability of non-compliance, then the average exposure for each job classification would have to be reduced to a level less than the criterion as determined by the dispersity of the exposure for that job classification. In other words, the inspector sampling procedure requires the de facto reduction of REL and this reduction is not uniform for all job classes. In an ironically illogical way, the reduction would not necessarily have a correlation with the perceived or documented hazards of the job or task.

Leidel's single sample procedure is defended on page 146 by a rather narrow and legalistic referral to the Coal Mine Health and Safety Act of 1969 (amended 1977). Unfortunately, what seems to be a valid justification at a glance creates a very serious dichotomy which must be addressed in full. While the definition in the Act clearly defines "average concentration" as that measured "over a single shift only"; under this definition the cumulative exposure levels used in the epidemiologic studies become invalid. Consequently, the epidemiologic findings can not be used in setting the criterion without adjustment. In other words, the parameter used for the definition of the acceptable environment and the estimated parameter for the comparison of a coal mine environment to the acceptable environment must be the same parameter. If NIOSH does not want to offer a clarification to the definition of the average given in the Act, it is incumbent upon them to make the necessary adjustments in the proposed criteria to take the variation in the mine

environment into account. This is possible but would be needlessly complicated, and would probably result in some sort of adjustable criteria for tasks and jobs. I am sure that NIOSH would not want to come up with an extremely complicated and cumbersome recommendation which would be certain to create an enforcement nightmare.

Coal mine operator sampling procedures:

It may be possible to argue heuristically, albeit not very convincingly and rigorously, that single sample estimation of the mean is necessary for MSHA inspector samples due to lack of resources. In addition, the single sample strategy may be improved upon by a number of re-sampling schemes to be developed or available [e.g. Esmen (1992)]. However, there is no good argument to justify the use of a similar single sample concept for an operator sampling strategy. In fact, the level exceedence strategy proposed would defeat the purpose of sampling strategy, which is essentially to monitor dust control measures for their effectiveness. There are a large number of quality control monitoring strategies available to adapt for this purpose. Therefore, we suggest that the statistical and logical basis for the recommended coal operator sampling strategy is dubious.

In addition, the specifics of the strategy, as listed in the DCD, are ambiguous. For example, a costly and complicated task such as the re-approval of the dust control plan may be required at the whim and fancy of MSHA inspectorate. This would be the direct consequence of entry 5 (page 143) when "frequently" is not defined. As it was shown in the example above, one might consider 20 percent as frequently, or based on the dispersity of the exposures, a perfectly acceptable place may even exceed the level at a rate larger than 20 percent.

One of the main problems of the operator based strategy is trying to mold competing, and to some extent contradictory information needs to a single strategy based on the information needed to enforce a regulation. The basis of any sound sampling strategy should be the information needed from the samples gathered. A background survey, periodic re-surveys, verification of improvement after changes in dust control and similar single worker defined samples and sampling strategies have different characteristics from quality control measurements. Suppose a job classification associated with an operation is found to be satisfactory. So long as one can measure some parameters of the airborne dust by one means or another, which would indicate that the conditions under which the satisfactory results are obtained, the sampling need not to conform to an approved sampling and analysis method. The important attribute of quality control sampling as it relates to monitoring the effectiveness of exposure control, is that it should be able to forecast deteriorating conditions. If the satisfactory base line measurement data for a specific job or task can be shown to be non changing, only periodic verification of the baseline measurements would be needed. A number of strategies can be suggested by NIOSH, National Coal Association, operators, unions, consultants or academics to provide a variety of tools and guidance to achieve the goal of healthy workers, without a set general strategy, which of necessity has to be compromised to fit all circumstances and yet be simple enough to be contained in a short document.

This is a very important point with respect to how the samples are collected and their results are interpreted. An operator may want to utilize daily samples taken by an automatic dust sampler with all its attendant problems and inaccuracies to monitor environmental quality in a rapidly changing portion of the coal face in one place, use biweekly personal samples at another

location, and use monthly samples at yet another location in the same mine. So long as the quality control information can be obtained from the data provided by the sampling method and strategy used, the specific values indicated by each sample may be shown to be not important.

For the specific purposes of monitoring worker exposures and keeping exposure records, a certain fraction of the miners selected randomly from total or stratified populations can be sampled at a reasonable frequency. So long as the production rates, job, and task are noted, these personal samples can provide a basis for future epidemiologic investigations, can keep track of the level of exposures, and can, through annual or biennial analysis, determine the need for reconfirmation of the baseline. The monitoring and record-keeping strategy is independent of the quality control strategy and it may or may not be used for that purpose based on the needs of a specific mine. It is both proper and important to provide recommendations and guidance in the details of the monitoring and record-keeping sampling strategies. However, the proposed strategy unsuccessfully tries to satisfy the enforcement, monitoring, record keeping, and the quality control sampling needs in one mandated sampling program. This approach is both counterproductive and inefficient. We don't believe that the proposed coal operator sampling strategy would serve any of the sampling needs satisfactorily.

Elements of the recommended exposure monitoring plan are described in scattered sections of the Criteria Document. These plans are combined into two sections (one for mine operators and one for MSHA inspectors) for ease of understanding. The scientific merit of these plans is discussed.

NIOSH has chosen to separate monitoring performed by the mine operators and monitoring performed by MSHA inspectors. As stated in the Criteria Document, Section 5.1.5.2, coal-mine-

operator-collected samples are not used for compliance purposes except that MSHA may use these data "for analysis of dust concentrations or to target MSHA sampling or inspection efforts." Mine operators, however, will not be cited based on the results of their sampling. Citations will be issued based only on valid samples collected by the MSHA inspectors.

NIOSH has also chosen to recommend a change in the current monitoring plan for the determination of exposure to respirable crystalline silica and respirable coal mine dust. Analysis of all samples for both respirable coal mine dust and respirable crystalline silica is recommended. NIOSH presents two separate RELs, 0.9 $mg/M^3$ for respirable coal mine dust and 0.05 $mg/M^3$ for respirable crystalline silica as an 8- or 10-hour TWA (Time Weighted Average). This differs from the current practice of determining a PEL (Permissible Exposure Limit) for respirable dust based on the percent of respirable silica in a single sample or set of samples.

NIOSH recommendations for sampler specifications are presented in Section 5.1.3.2. Gravimetric analysis of respirable coal dust is recommended. The sampling and analytical procedures for respirable crystalline silica are those of NIOSH Methods 7500 and 7620 (See Section 1.2.2).

Exposure Monitoring Plan for Mine Operators

The exposure monitoring plan for respirable coal mine dust and for crystalline silica determined by the mine operator is presented in basic form in Section 1.3, detailed in Section 5.1.5.2.3 and shown in Figure 5-5. It contains the following elements:

1. Exposure to respirable coal mine dust and respirable crystalline silica is to be determined by full-shift, personal air samples collected during an 8- to 10-hour work day.

2. An initial monitoring survey shall be performed by the mine operator, and a "sufficient

number" of samples shall be collected to characterize each miner's full-shift exposure. Every six months the coal mine operator submits to MSHA a written plan for controlling dust in each MMU (Mechanized Mine Unit). MSHA will make an initial determination of which occupations or areas are to be classified as DO (designated occupations), DA (designated areas), DWP (designated work positions) or NDE (nondesignated occupations or areas).

3. Every six months, the mine operator measures exposure for each NDE specified by MSHA.

4. If any miner's exposure exceeds the 95% UCL (Upper Confidence Limit) of the REL for respirable coal mine dust or respirable crystalline silica, then the miner's exposure must be monitored at least every two weeks. The miner must be notified of the exposure, and control measures must be implemented.

5. If two consecutive biweekly measurements are below the 95% UCL, monitoring frequency is reduced to once every six months unless there are changes in operational conditions. If there are changes in operational conditions, monitoring must be performed as if it were an initial monitoring survey.

6. DOs and DAs for each MMU, DWPs and/or transferred miners' exposures shall be monitored every two weeks (current practice, 30 CFR Part 90). If exposures exceed the 95% UCL of the REL, the employees must be notified, respirators issued, controls checked and modified, and changes recorded.

7. Intake air concentrations to respirable dust must be monitored every six months. Full-shift samples must be collected within 200 feet of the working faces of each section.

8. The coal mine operator shall provide records to MSHA on each MMU (Mechanized Mine Unit) to determine production levels and to certify the ventilation system and methane and dust control plan.

There is some confusion and contradiction in the NIOSH recommendations. This is due partly to the fact that the elements of the sampling plan are described in different sections of the Criteria Document and partly to the fact that the Criteria Document does not clearly separate recommendations from current practice.

It appears that NDEs will be monitored every six months unless exposures exceed the 95% UCL of the REL. Figure 5-5 in the NIOSH Criteria Document is confusing, however, because there are two arrows leaving the center box [Daily check of the dust control parameters]. If one continues horizontally, then it would seem to indicate that DOs, and DAs in each MMU, NDE, DWP and Part 90 Miners be monitored every two weeks unless two consecutive exposures remain below the 95% UCL of the REL. Section 1.3.3 states that if a miner's exposure is less than the 95% UCL of the REL monitoring must be performed every 6 months except for DOs and Part 90 miners.

The NIOSH recommendations do not describe who should be sampled and how many samples should be collected. Section 1.3 recommends a "sufficient number" of samples. There is an implication, however, on page 137 that current practice should be followed -- five valid respirable samples from DOs in each MMU (Mechanized Mine Unit) every two weeks during normal production.

Section 5.1.3.2 states: "NIOSH 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." This sentence appears to contradict Section 5.1.5, in which NIOSH recommends "analysis of all samples for both respirable crystalline silica and respirable coal mine dust."

Recommendations for clarifying the current NIOSH Criteria Document exposure monitoring requirements for coal mine operators:

1. NIOSH must clearly delineate recommendations that differ from current practice, then present a complete integrated monitoring plan. As it is now, one must flip through the document to find detailed information.

2. NIOSH should remove contradictory recommendations.

3. NIOSH must clearly define who should be sampled (which miners, mine occupations or groups of mine occupations) and the frequency of sampling for each group.

4. NIOSH must offer specific guidelines on the number of samples that should be collected and over what time period.

5. NIOSH should make Figure 5-5 options mutually exclusive.

6. NIOSH should examine the sampling data base with goal of eliminating excessive, and unnecessary sampling and focus the sampling strategy on problem areas.

Exposure Monitoring Plan for MSHA Inspectors

The MSHA inspector sampling plan is described in Section 5.1.5.1. Inspector sampling is much more clearly defined in this document. The elements of the recommended sampling plan include:

1. Random, spot inspections be conducted approximately six times a year.

2. Inspectors determine which entities to sample based on:

a. The compliance record of the mine

b. The adequacy of dust control parameters

c. The number of entities sampled by the operator as DOs,DAs, Part 90 Miners or DWPs

d. The number of entities available for sampling, and

e. Changes since the last inspection

3. DO, DA, NDE and intake samples are area samples, and Part 90 samples are personal samples.

4. Citations be based only on samples collected by the inspectors.

NIOSH has recommended an increasing number of mine inspections by MSHA inspectors—from four times a year to six times a year. No detailed recommendations have been made on specifically who to sample and now many samples to collect.

The major contradiction in this section is that NIOSH recommends that exposure determination be based on personal sampling (Section 1.3.1). Many of the inspector-collected samples are area samples (Section 5.1.5.1).

The elements of the proposed monitoring plan that are best supported by the scientific literature are those that recommend analysis of more samples for silica content and change from a PEL based on percent crystalline silica to two separate RELs, one based on coal dust and one on crystalline silica (see for example, Villnave, 1991).

Three other features of the recommendations have value for increasing the validity on the sampling results. NIOSH recommends changing the practice of truncating filter weights at the 0.1

mg level to rounding the weight to one decimal place. This change has a small effect on the determination of weighing imprecision. Weighing imprecision is discussed in great detail in Section 5.1.4 of the Criteria Document.

NIOSH suggests that MSHA define normal production for the purposes of approval of the dust control plan and for determining when routine sampling should be performed. While this may be difficult to do, it may remove a portion of the observed environmental variability caused by production level changes. Basing compliance determinations on samples collected only by MSHA inspectors appears to be an attempt to address recent allegations of tampering with mine-operator-collected samples.

The element of the proposed monitoring plan that is contradicted by the current scientific literature is the reliance of action based on a single sample value. This strategy addresses the sampling and analytical error of the method ignoring environmental variability. For example, assume that more than one sample is collected from the same entity in the same time period. One sample collected by the mine operator for respirable coal mine dust is reported as 0.75 mg/M$^3$ while the other one was 0.10 mg/M$^3$. Action would be required increasing the sampling frequency from biannually to biweekly and other requirements, such as employee notification, would also go into effect. Such a requirement discourages the collection of more than the minimum number of samples. This is a practice detrimental to complete exposure characterization (Rappaport, 1984). Further, this strategy bases action on an inappropriate level of confidence.

NIOSH's basis for consideration of compliance based on a single, full-shift sample (see Section 5.1.5.4) is based not on statistical validity (despite the reference to Liedel *et al.*, 1977) but on an interpretation of Coal Mine Health and Safety Act of 1969 (amended 1977) which defines

the "average concentration" as that measured "over a single shift only." The Secretary of Labor has determined that a series of samples (5 samples collected over consecutive shifts or days) should be used to establish the "average exposure." The understanding of what constitutes valid exposure measures and environmental variability has progressed since 1969. The existing scientific literature supports the need for using monthly sample averages. See the discussion in Question 2, below.

NIOSH uses a number of statistically laudable but undefined terms and conditions. These include "high risk" worker (see page 133), "sufficient number" of samples (see page 5) and a "high level of confidence" (see page 113). Words such as these, without definition, will present problems for those who may be responsible for implementation of these recommendations. The statistical and industrial hygiene literature has many examples of methods for determining a "sufficient number" of samples, what should be considered a "high level of confidence," and how to identify "high risk workers."

Environmental variability has a significant effect on the statistical model used in the sampling strategy. As has been shown by Nicas *et al.* (1991) sampling and analytical variability is generally at least an order of magnitude smaller than the environmental variability.

Estimates of the environmental variability for exposure to coal dust may be made from some of the tables in the NIOSH Criteria Document. Assuming a normal distribution, an estimate of environmental variability may be made using the arithmetic means and standard deviations presented in Table 3-9. The coefficient of variation (CV=sd/mean) for underground mine job categories ranges from 71% for the longwall shear or plow operator to 359% for the shuttle car operator, whereas the sampling and analytical variability as measured by the coefficient of

variation for respirable coal mine dust is a maximum of 17% (Table 5-3). Environmental variability for these groups ranges from four to twenty-one times greater than the sampling and analytical variability.

The assumption of normality used above is probably incorrect but on the conservative side. If the data in Table 3-9 fit a lognormal distribution, the geometric standard deviations of the exposure distributions for the job categories listed for underground miners range from 1.9 for longwall shear and longwall jack setter to 5.1 for utility man. At a geometric standard deviation of 2 and an REL of 0.9, the environmental CV would be 78%. The corresponding CV for a geometric standard deviation of 4 would be 500%.

These analyses, however, ignore the fact that there may be a component of the variability due to differences in location (i.e. different mines) that might not enter into the consideration of sampling strategy for a single mine operator. Nevertheless, these data show that sampling and analytical error, even at its worst, is small compared to the environmental variability.

In addition to environmental variability (that due to day-to-day changes in the work environment of a single individual) there is another component of the total exposure variation. NIOSH is not recommending that all workers be monitored (see section 5.1.5.2.3). There is an underlying assumption that workers who are "similarly exposed" may be grouped. Such grouping is usually based on job title and/or location. The variability due to worker differences within a similarly exposed group is also ignored by the recommended sampling strategy.

Components of total variability, including environmental variability and between-worker variability, have been described in many articles recently. See, for example, Spear *et al.* (1987) and Heederik *et al.* (1991). Designing a sampling strategy that includes estimates of these

components would be much more representative of the worker's true exposures, if only for the fact that more samples would be collected. This would only happen if mine operators were not discouraged from collecting samples, as is the case with the current scheme.

The true purpose of exposure monitoring is to determine the worker's long-term average exposure to respirable coal mine dust and to respirable silica (see section 5.1.5.5). This is the exposure variable that is most relevant for assessing health outcomes to respirable coal mine dust and crystalline silica. An exposure monitoring scheme that allows a certain fraction of exposure measurements to exceed or fall below (inherent in an average is the understanding that some of the values will be above and some of the values will below the average) the REL could recognize environmental variability and at the same time assure that the long-term average exposure is not exceeded (see, for example, Spear *et al.*, 1987, and Tuggle 1982).

With the exception of analyzing samples for oversized, non-respirable particles, NIOSH has more than adequately considered the impact of sampling and analytical variability on the assessment of a single sample. Section 5.1.4 is extremely detailed and covers the questions persons in the past have had regarding problems with weighing, truncating values and the large coefficient of variation (CV) of the sampling and analytical method. Reduction of the CV for the sampling and analytical error, however, ignores the overwhelming component of variability discussed in Question 2.

Discussion of the components of the CV and of bias, as well as Appendix G are complicated to read. This is particularly true of Appendix G. Clarification is necessary on this analysis.

The most radical change in the environmental monitoring plan appears to be the analysis of all samples for respirable crystalline silica. There are obviously economic considerations here for analysis of samples, but none that relate to an increased sampling burden. If anything, the flow chart for the recommended sampling plan is simpler to follow than the current MSHA scheme, which determines the PEL based on percent crystalline silica in a prior sample, or a series of three prior samples.

Some basic items would need to be clarified if the NIOSH recommendations were to be adopted. Definitions are needed concerning who should be sampled, how many samples to collect, and how to define a high-risk worker.

**Issue: Will the recommended pulmonary function test (PFT) program provide the information required to adequately protect workers?**

There is no question that PFTs can provide useful information on the respiratory system, particularly in detecting some lung abnormalities. The recommendation of this test for use in the mining industry has not been well thought out. It is well established in the medical literature that PFTs are not a specific diagnostic tool for the detection of PMF. The critical question concerns whether or not PFTs (particularly $FEV_1$ and FVC) are sufficiently sensitive in detecting the kind of early changes that might be associated with exposure to either the current PEL (2 $mg/m^3$) or the proposed revision (0.9 $mg/m^3$). In other words, is there a scientific/clinical justification, based on the use of pulmonary function testing, that lowering the PEL from 2 $mg/m^3$ to 0.9 $mg/m^3$ will result in improved health for coal miners?

The NIOSH report incorporates two separate but related issues, i.e., reduce the PEL from 2 $mg/m^3$ to 0.9 $mg/m^3$ and implement extensive use of PFTs into a medical surveillance program.

NIOSH notes that the estimated mean loss of pulmonary function of 100 ml over 40 years occurs at the PEL level of 2 mg/m$^3$ coal dust. The clinical significance of this value is highly questionable. It is a well documented phenomenon that individuals with no exposure to respirable coal mine dust can lose as much as 25 ml/yr. Part of the justification for lowering the PEL is that the average loss may be masking a more severe decline in more sensitive workers. However, there is no attempt to identify such a subgroup, even assuming that such a group exists. In fact, the report notes that no U.S. study has identified a sensitive subgroup (p. 170), further noting that studies thus far have not included "examiners." What exactly is meant by an "examiner?"

If pulmonary function declines 100 ml (after correcting for loss due to aging) following 40 years exposure to the current PEL, one wonders how small the average loss of pulmonary function will be at the proposed PEL of 0.9 mg/m$^3$ and whether PFTs (particularly $FEV_1$ and FVC) will have sufficient sensitivity to detect a difference in effects between exposure to either the current PEL (2 mg/m$^3$) or the proposed revision (0.9 mg/m$^3$). This may be a problem given that approximately a 50 percent decline in $FEV_1$ below predicted is required to produce exertional dyspnea and a 75 percent decline for shortness of breath at rest.

While PFTs are useful for certain purposes, the NIOSH report may be overly optimistic concerning the accuracy, reliability, and utility of PFTs, particularly as screening devices in large populations. Even in the best clinical settings, there are considerable and persistent errors in PFTs, such as in the machine (ATS 1987 accepts machine error +/- 3 percent), intraindividual (3 percent short term; Cochrane et al. 1977), longitudinal (3 percent; Hankinson 1986; Cochrane et al. 1977), interindividual (approximately 9-14 percent before correction by equations; Cochrane et al. 1977), as well as a variety of problems in interpreting test results. The additive or interactive effects of

such errors are not addressed. These errors noted above are for the most reproducible PFTs, the FVC and $FEV_1$, and can be much greater for tests such as the $FEV_{50-75}$ which occur later in expiration and have been proposed as more sensitive tests to detect early peripheral airways disease.

In proposing PFTs ($FEV_1$ and FVC) as a screening methodology, NIOSH also needs to more clearly define and justify the specific disease(s) they are seeking to detect. or prevent. Hankinson et al. (1977; NIOSH) noted that standard PFT results bore no association to the category of simple coal workers pneumoconiosis or the coal content of lungs, until progressive massive fibrosis supervened. This calls into question the use of the PFTs as advocated by NIOSH for the prevention of progressive massive fibrosis.

Additional problems may also plague heavy reliance upon PFTs as a widespread screening methodology. The results cited and relied upon by NIOSH were generally performed by university academics under controlled, experimental circumstances. Once in widespread general field use, the accuracy of such tests may decline, particularly when they might be performed by minimally trained technicians (albeit NIOSH approved courses) far removed from a university facility. Furthermore, the attitudes of the test subjects themselves may influence test results, particularly given the consequences of the pulmonary function test results. While "poor cooperation" patterns have been identified in pulmonary function testing, widespread implementation of PFTs, may trigger the ingenious use of other methods.

Because of their lack of sufficient sensitivity, reliance on PFTs may provide a false sense of security. PFTs are not capable of detecting early changes indicative of COPD (Wilson et al. 1992. Cherniack 1992). The effects of inhaled contaminants are thought to be cumulative, and

once changes occur there may be a continuing diminution in function even in the absence of continuing exposure.

Although the distinction between an individual result and a population mean was clearly noted by NIOSH (p. 167), this clarity of separation blurs in other parts of the document. The separation is important because test results and trends that may be statistically significant on a population basis may not be significant in an individual, especially when one is trying to determine whether an "apparent" decline is real or a stochastic phenomenon. For instance, it would be difficult enough to detect a 100 ml difference in $FEV_1$ (over 40 years at 2 $mg/m^3$ exposure) between carefully matched populations in an epidemiological study, let alone to try and distinguish a 100 ml change in an individual over this same time period from normal background variation. This problem will be accentuated if the PEL is lowered to 0.9 $mg/m^3$, making the detection of such a decline virtually impossible in the average miner.

Finally, it is essential to be able to distinguish between a change on a laboratory test (e.g., 100 ml change in $FEV_1$) and any real clinical correlate, especially when using PFTs as a basis for determining whether there is a need to move an individual from one job category to another, less exposed category. If NIOSH is relying on PFTs and X-rays to detect pneumoconioses in individuals (rather than as an epidemiological experiment), then it appears that NIOSH may have tacitly accepted the fact that some diminution in lung function will occur due to occupational or non-occupational factors before it can be detected. The question merely remains as to how much exposure-related loss is deemed acceptable. Such a determination then requires an assessment as to what constitutes an acceptable loss of lung function over a working lifetime (over and above the normal declines with aging), which in turn requires a clinical judgment rather than a minor

change (e.g., 100 ml in $FEV_1$) in a laboratory parameter, not associated with any clinically adverse pulmonary effects.

**Issue: Has NIOSH adequately established the criteria for assessing pulmonary deficits in coal mine workers?**

The specifics of the NIOSH pulmonary testing recommendations are rather limited, consisting of $FEV_1$ and FVC done at 3 months after employment, every three years, and at termination of employment, using the protocols of the ATS (1987) and NIOSH (1980) (p. 7 - 8). The discussion in the NIOSH document on PFTs provides a general justification for their usefulness with respect to the early detection of adverse pulmonary effects. There is a brief discussion of how a single result can be determined as being outside the normal limits (p. 184), but beyond noting that the ATS criterion of a 15 percent decline is more sensitive, the discussion provides no detailed guidance. As an employment criterion, is one "abnormal" PFT result a sufficient basis to reject a worker as unacceptable or to transfer to a different job? What statistical tests should be performed comparing the baseline and "abnormal" result to determine the significance of this difference? What confirmatory PFTs are necessary? Is it critical to determine trend criteria in assessing individual disability, noting the necessary 6-8 years before a trend can be distinguished?

Of possible interest is the suggestion that adherence to ATS reproducibility criteria (p. 181) may result in biased estimates of $FEV_1$. While none of the supporting references were checked, this issue and the implications that ATS criteria may not be adequate was not addressed by Hankinson and Wagner (1993) in a state of the art review of medical screening using periodic spirometry for detection of chronic lung disease.

Other factors are not addressed in the NIOSH document that clearly require some form of standardization and further detail, including what kind of pulmonary function testing device should be used. Some instruments are better than others. Other considerations include the effect of changing test machines, use of flow volume/volume time, use of a spirometer or a pneumotachograph, and whether a body temperature pressure standard (BTPS) correction is valid and required.

The problem of determining whether a test result is actually indicative of an abnormality is accentuated by the ATS quality control criteria for test results. The criteria stipulate no more than 5 percent or 100 ml difference between the best and second best PFT tracings. It has been shown that people with airways disease (and short people) have a higher incidence of inadequate blow to blow reproducibility on their pulmonary function tests, and tend to fail this criteria. Subjective factors, whatever the cause (e.g., trying to get a job change), also cause failure with respect to the reproducibility criteria. Is failure based on the ATS criteria indicative of COPD? Clearly, further guidance is needed. On p. 182, there is a suggestion that further lung function testing for individuals who fail ATS reproducibility criteria be undertaken. Is this a recommendation, and if so, which specific tests should be undertaken and what are the consequences of abnormal test results?

In determining whether there is an abnormality in pulmonary function based on PFTs, it is necessary to utilize equations that adjust for height, gender, age, sometimes weight, and possibly even ethnicity. While this issue is seemingly resolved in the NIOSH draft (pp. 177-8), the selection of specific adjustment equations may have a significant effect on disability determinations. For this reason, the end results of using different adjustment equations and criteria

should have been covered in more detail.

As previously noted, NIOSH acknowledges that studies of U.S. coal miners have not identified a sensitive subgroup (p. 170). Nevertheless, based on studies of workers from several countries, NIOSH concludes that there is an average decline of 100 ml over 40 years at 2 $mg/m^3$. However, a study of British coal miners reported a decrement of 600 ml, and Soutar et al. (1989) estimated a 10 percent risk of a similar decrement following cumulative exposure (40 years) to 2 $mg/m^3$. The presence of two populations with a six-fold difference in average decrement following presumably similar exposures needs to be clarified with respect to population means and distributions, with a more critical analysis of whether or not these differences are indicative of increased sensitivity.

Finally, there is the issue of confounding by smoking. How does NIOSH propose to separate the known effects of smoking from those of coal dust in their causation and job modification criteria? It appears that pulmonary decrements from smoking and from exposure to coal dust will be treated administratively in much the same manner. This would seemingly permit cigarette smokers, who have voluntarily accepted a greatly increased risk of adverse pulmonary effects, to be transferred to cleaner jobs while more health conscious workers are forced to continue in jobs associated with greater exposure to coal dust. Other occupational factors in coal mining, e.g., exposure to silica, etc. also need to be considered when assessing potential causes of small longitudinal declines in pulmonary function.

What are the data gaps in the medical surveillance program proposed by NIOSH?

Many potentially important data gaps are noted in the above comments and observations. Several are highlighted below for additional emphasis.

- Which specific adjustment equations will be used as predictors of normal values, and will there be a provision for alterations should new data dictate more accurate methods?
- A related question concerns the extent of the contribution of smoking (including sidestream smoke (unaged cigarette smoke)) to the adverse pulmonary consequences of coal dust inhalation. Because smoking is a known cause of pulmonary deficits, the extent and nature of its interaction with coal dust needs to be determined so coal workers who smoke will not unduly influence a medical surveillance program.
- There is a need to develop and use specific PFT quality control criteria such that test results and their consequences from different areas of the country will be comparable.

## RECOMMENDATIONS AND CONCLUSIONS

1. NIOSH must revaluate the relationship between exposure to respirable coal mine dust and PMF, CWP, COPD and chronic bronchitis using a variety of models so that the model that best represents the shape of the dose-response curve is used to model the data.

2. NIOSH must consider funding research to evaluate the effect of dose-rate on the dose response model.

3. NIOSH should consider a strategy that addresses environmental variability. There appears to be great environmental variability in exposures to coal dust and crystalline silica, as shown by the tables presented in the document. NIOSH has the perfect opportunity with this document to advance the science of exposure assessment. If environmental variability were considered and a recommended standard included a REL with an exposure distribution and an allowable exceedence fraction instead of basing noncompliance on a single value, mine operators would not be penalized for collecting samples. At the same time, the real goal of maintaining the miners' long-term average exposures below a desired value is possible.

4. Define terms or provide guidance for the exposure monitoring scheme. Terms such as "high risk worker" and "sufficient number of samples" without further clarification will cause problems for the design of a monitoring scheme. Sufficient data exist, both with MSHA and in the published literature, to allow analyses of exposure distributions to help define these terms.

5. Edit the document to remove contradictory recommendations and clearly delineate NIOSH recommendations from current practice. The exposure monitoring plans, as described in this document, are confusing because one must refer to different parts of the document for various

recommendations, and these recommendations are sometimes at odds with one another.

6. Keep the recommendation for separate analysis of respirable coal mine dust and respirable crystalline silica. The current practice of determining a PEL based on a percent of crystalline silica in a sample and only determining the percent silica in some samples is not as beneficial for assessing long-term health effects as is the current NIOSH recommendation. Part of the reason for this is that the silica concentrations in the air may be extremely variable depending on the job and the size of the coal seams.

7. Determinations of noncompliance should be based only on MSHA inspector-collected samples. This recommendation is similar to that used by OSHA, and at the same time does not remove the requirement that the mine operators be responsible for assessing and controlling the miners' exposures.

**References**

AMERICAN THORACIC SOCIETY (ATS). 1987. Standardization of spirometry - 1987 update. Am. Rev. Respir. Dis. 136:1285-1298.

Cherniack, R. M. 1992. Pulmonary Function Testing, Second Edition. W.B. Saunders Company, Harcourt Brace Jovanovich, Inc., Philadelphia.

Cochrane, G. M., Prieto, F., and T. J. H. Clark 1977. Intrasubject variability of maximal expiratory flow volume curve. Thorax 32:171-176.

Esmen, N. A, (1984): On estimation of occupational health risks : In: Recent Advances in Occupational Health (N.A. Esmen & M. A. Mehlman, Eds.) Princeton Science Publishers, Princeton NJ. pp. 45-84.

Esmen. N. A, (1992): A distribution free double sampling method for exposure assessment. App.Env. and Occup. Hyg, 7:613-621.

Hall T. A., M. Corn, S. Zeger. Respirable Dust and Free Silica Variation in Mine Environments. VII International Pneumoconioses Conference, August 23-26, 1988.

Hankinson, J. L. 1986. Pulmonary function testing in the screening of workers: Guidelines for instrumentation, performance, and interpretation. J. Occup. Med. 28:1081-1092.

Hankinsin, J. L. and G. R. Wagner. 1993. Medical screening using periodic spirometry for detection of chronic lung disease. Occup. Med. 8:353-361.

Leidel N., K. Busch and J. Lynch (1977) Occupational Exposure Sampling Strategy Manual. U.S. DHEW, PHS, CDC, NIOSH, Cincinnati, OH. DHEW (NIOSH) Publication number 77-173.

NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH (NIOSH). 1980. Department of Labor, Mine Safety and Health Administration, 30 CFR Part 71. Respirable Dust; Operator Sampling Procedures. Rules and Regulations. Fed. Reg. 45(236), December 5, 1980.

Nicas, M., B. P. Simmons and R. C. Spear: Environmental versus analytical variability in exposure measurements. Am. Ind. Hyg. Assoc. J. 52(12)533-557.

Rappaport, S. M. (1991): Assessment of long-term exposures to toxic substances in air: review. Ann. Occup. Hyg; 35:61-121.

Rappaport, S. M. (1984): The rules of the game: an analysis of OSHA's enforcement strategy. Am. J. Ind. Med. 6:291-303.

Soutar, C. A., S. J. Cambell, D. C. Gurr, M. H. Lloyd, R. G. Love, H. A. Cowie, A. J. Cowie, and A. Seaton 1989. Cross sectional studies of respiratory disease in British coalminers. Institute of Occupational Medicine, Edinburgh, Report No. TM/88/06.

Spear, R. C., S. Selvin, J. Schulman and M. Francis (1987): Benzene exposure in the petroleum refining industry. Appl. Ind. Hyg. 2(4):155-163.

Tuggle, R. M. (1982): Assessment of occupational exposure using one-sided tolerance limits. Am. Ind. Hyg. Assoc. J. 43(5): 338-346.

Villnave, J. H., M. Corn, M. Francis and T. Hall (1991): Regulatory implications of airborne respirable free silica variability in underground coal mines. Am. Ind. Hyg. Assoc. J. 52(3):107-112.

Wilson, H. D., E. Braunwald, K. J. Isselbacher, R. G. Petersdorf, J. B. Martin, A. S. Fauci and R. K. Root (editors). 1991. Harrison's Principles of Internal Medicine, Twelfth Edition. McGraw-Hill, Inc., New York.

## Biographical Sketches of Reviewer's

**Nurtan Esmen, Ph. D., CIH** is the President and founder of Esmen Engineering and a former faculty member of the University of Pittsburgh School of Public Health. Dr. Esmen has published extensively on topics of exposure assessment, environmental health engineering, and statistical issues relating to the use of air samples to determine compliance. Dr. Esmen has over 20 years of experience assessing and controlling occupational hazards.

**Robert Golden, PH. D.** is a respiratory physiologist and partner at Karch and Associates, Inc. Dr. Golden has recently completed a literature review on the use of pulmonary function tests to assess respiratory health in non-occupational populations. Dr. Golden is also wide published in the area of pulmonary toxicology. Dr. Golden has more than 20 years of experience in pulmonary toxicology and respiratory physiology.

**Marcia Francis, Ph. D., CIH**, is the director of Industrial Hygiene and a Senior Staff Member of Technical Assessment Systems, Inc. Dr. Francis has published numerous articles in the area of statistical issues of exposure monitoring and air sampling strategies for assessing regulatory compliance. Dr. Francis has worked as a compliance officer for U. S. Department of Labor's Occupational Safety and Health Administration. Additionally, Dr. Francis was a faculty member of the Johns Hopkins School of Hygiene and Public Health where she conducted research on statistical issues related to exposure monitoring. Dr. Francis is a member of the American Conference of Governmental Hygienists and the American Industrial Hygiene Association where

she is a member of the Occupational Epidemiology Committee.

**Thomas A. Hall, Ph. D., CIH** is the director of Industrial Hygiene at Sciences International, Inc. Dr. Hall has more than 15 years of experience in industrial hygiene and occupational exposure assessment. Dr. Hall has participated in the design and conduct of numerous epidemiology studies and has published several articles related to air sampling and regulatory strategies in mining environments. Dr. Hall is a member of the American Industrial Hygiene Association. Dr. Hall is also an active member of the Occupational Medicine and Epidemiology committees.