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CONGRESS**

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September 10, 1993

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RECEIVED

SEP 13 1993

OFFICE OF  
DIRECTOR, OSHA

Dear Dr. Niemeier:

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

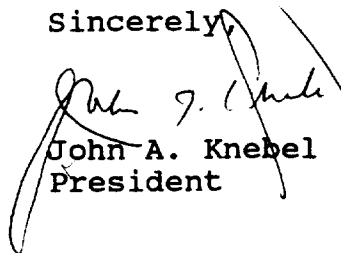
Enclosed for your consideration are the comments of the American Mining Congress (AMC) on the above-referenced draft document prepared by the National Institute for Occupational Safety and Health (NIOSH). As you know, AMC represents (1) producers of the majority of the nation's coal, metals, industrial and agricultural minerals; (2) manufacturers of mining and mineral processing machinery, equipment and supplies; and (3) engineering and consulting firms and financial institutions that serve the mining industry. We appreciate the opportunity to participate in the peer review process on health science policy issues that affect our industry.

For ease of understanding, we have divided our comments into three sections. The first section contains general comments, the second section contains specific comments and the third section contains responses to questions posed in your transmittal letter dated June 28, 1993. Although we have divided our comments into sections, they should not be considered in isolation but as a whole.

Our comments reflect the collective experience and expertise of the safety and health professionals from our member companies. We hope our assessment of your interpretations of the data and your recommendations prove helpful. Incorporation of these comments into any final policy recommendation will help us attain our common goal of protecting the health of the nation's coal miners.

Should you have any questions about the comments we have made,  
please telephone AMC Senior Counsel Mark Ellis at 202/861-2860.

Sincerely,



John A. Knebel  
President

Enclosure

**Comments of the American Mining Congress  
on the National Institute for Occupational Safety and Health  
Draft Criteria Document Entitled,  
"Criteria for a Recommended Standard:  
Occupational Exposure to Respirable Coal Mine Dust."**

Introduction

The American Mining Congress (AMC) appreciates the opportunity to participate in the peer review process of the draft document entitled, "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust," prepared by the National Institute for Occupational Safety and Health (NIOSH). AMC has a continuing interest in the well-being of the nation's coal miners, as is partially evidenced by our comments on this draft and two predecessor documents. Our basic conclusions regarding the current draft are as follows:

- ◆ NIOSH has not demonstrated that miners at current levels of exposure with little or no evidence of coal workers pneumoconiosis will rapidly progress to progressive massive fibrosis, that exposure to high concentrations of crystalline silica contribute to this purported disease endpoint, or that coal miners become disabled from chronic obstructive pulmonary diseases independent of the effects of cigarette smoking;

- ◆ As such, there is no basis for the recommended reductions in the permissible exposure limits for respirable coal mine dust and crystalline silica;
- ◆ Consequently, the recommended program changes in exposure monitoring, medical surveillance, job transfer rights, respirator use, records retention, etc., are not merited; and
- ◆ Finally, AMC believes that the current permissible exposure limits for respirable coal mine dust and crystalline silica, properly monitored and enforced, are fully protective of the health of the nation's coal miners.

With these conclusions in mind, we offer the following comments on the most recent NIOSH draft criteria document recommendations.

## General Comments

Before providing comments on the substantive recommendations of the draft criteria document, it may be useful to air a difference of opinion on the proper scope of the document. The document states that it was developed in accordance with Section 20 (a)(3) of the Occupational Safety and Health Act of 1970 (OSH Act) and responds to Section 2.2 (c)(1) of that act. The document further states that it responds to Section 501 of the Federal Mine Safety and Health Act of 1977 (Mine Act). While we recognize that NIOSH interprets its mandate to protect all workers, AMC believes that NIOSH may exceed its statutory authority under the Mine Act if it recommends to the Mine Safety and Health Administration (MSHA) a mandatory standard intended to prevent any impairment, as opposed to controlling disability, from occupational diseases among miners.

Section 101 (a)(6)(A) of the Mine Act provides in pertinent part:

The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents under this subsection, shall set standards which most adequately assure on the basis of the best available evidence that no miner will suffer

material impairment of health or functional capacity even if such miner has regular exposure to the hazards dealt with by such standard for the period of his working life ... (emphasis added).

Section 201 (a) and (b) of the same Act provide, also in pertinent part:

(a) The provisions of sections 202 through 206 of this title ... shall be interim mandatory health standards applicable to all underground coal mines until superseded in whole or in part by improved mandatory health standards promulgated by the Secretary under the provisions of section 101 ...[;]

and

(b) ... provide, to the greatest extent possible, that the working conditions in each underground coal mine are sufficiently free of respirable dust concentrations in the mine atmosphere to permit each miner the opportunity to work underground during the period of his entire adult working life without incurring any disability from

pneumoconiosis or any other occupation-  
related disease during or at the end of such  
period (emphasis added).

In light of these provisions, the NIOSH recommendations contained in the draft criteria document intended to prevent simple pneumoconiosis (which can be asymptomatic) or any lifestyle-related, versus occupation-related, disease are inappropriate.

The draft criteria document recommends that exposure to respirable coal mine dust be limited to  $0.9 \text{ mg/m}^3$  as a time-weighted average for up to 10 hours per day over a 40-hour workweek. The ostensible reason for this is to prevent coal workers' pneumoconiosis (CWP) and chronic obstructive pulmonary diseases (COPD) in coal miners. In NIOSH's opinion, some risk of progressive massive fibrosis (PMF) remains even at a dust level of  $0.9 \text{ mg/m}^3$  and every effort should be made to keep exposures to respirable coal mine dust well below the recommended exposure level.

A  $3.0 \text{ mg/m}^3$  respirable coal mine dust standard was recommended by the U.S. Surgeon General based upon studies conducted in the U.K. which indicated a relationship between increasing category of simple coal workers' pneumoconiosis and the development of progressive massive fibrosis. Public Law 91-173 established a  $3.0 \text{ mg/m}^3$  respirable coal mine dust standard

and, after a period of three years, that standard was reduced to the current  $2.0 \text{ mg/m}^3$  standard. PMF is associated with respiratory impairment, disability and premature death. The risk of PMF increased markedly among miners with radiographic category 2 or greater CWP. Therefore, the standard was based on the prevention of category 2 or greater simple CWP. Preventing progression of disease and disability either during or at the end of a miner's working life was the purpose of the standard.

Through recommendations contained in the draft criteria document, NIOSH now appears to be attempting to prevent the incidence or development of any CWP and COPD, on tenuous interpretations of data, by recommending a more stringent dust standard with little regard for the original intent of the Mine Act relative to the prevention of material impairment of health or functional capacity. NIOSH should reconsider the draft recommendations accordingly.

A basic tenet of the draft NIOSH criteria document is that some miners with no evidence of simple CWP will rapidly progress to progressive massive fibrosis. The draft suggests that exposure to high concentrations of respirable crystalline silica may contribute to this rapid progression to PMF. In addition, NIOSH postulates that coal miners also can become disabled from chronic obstructive pulmonary diseases independent of the effects of cigarette smoking. The recommended  $0.9 \text{ mg/m}^3$  respirable coal



mine dust and  $0.05 \text{ mg/m}^3$  crystalline silica standards are proposed to prevent these diseases, though NIOSH maintains there still remains a risk of PMF below the recommended  $0.9 \text{ mg/m}^3$  standard.

Throughout the NIOSH document considerable reliance has been placed on British studies and data, the Pneumoconioses Field Research (PFR) studies and the Periodic X-ray Scheme. At the outset, one must take into account the fact that much of the technical equipment used in the PFR studies was less sophisticated and more imprecise than what is now available and this obviously influences the precision and reliability of certain of the early measurements. Many of the early methods used in that study were less than optimal and some of the problems and defects that were subsequently noted detracted to some extent from the reliability of the data that were collected. Smoking history information, spirometric measurements, dust exposure estimates, etc., all involved problems of accuracy.

More troubling still are the inferences drawn and interpretations given to the data. It seems that the greater the time lapse between the original PFR studies and the less actual involvement of those who carried out the later analysis, the more reliance and more certainty these authors place on the validity of the measurements made, in some instances, more than 50 years ago. Moreover, those who are reanalyzing PFR data, applying

these data to present-day situations and making definitive pronouncements had no responsibility or involvement in the administration or design of the early questionnaires, in the performance of the spirometry or in the measurement of dust.

There are a number of papers from the U.S. and Britain that are quoted in the draft that are cited to support NIOSH's opinion. The critical papers on this subject are by Hurley et al., Hodous and Attfield, and Hurley and Maclaren. All have been misinterpreted by many, and that includes the authors of the draft criteria document. None say, nor were they intended to say, that PMF develops on no background of disease or on a background of minimal CWP.

The methodology of the papers by Hurley et al. and Hodous and Attfield was to ascertain the number of large opacities occurring in coal miners who have various categories of simple coal workers' pneumoconiosis. In some instances such opacities have been noted in category 0 and from this the authors inferred that PMF can occur in category 0. The interpreters they used to read the films were instructed to record the presence of PMF when a large shadow was seen on the x-ray that did not suggest some other diagnosis, such as lung cancer. The study designs were flawed in that there has been no comparable control group with whom to compare the prevalence of such large opacities and no anatomical verification that the opacities were due to PMF.

Both the Hurley et al. and Hodous and Attfield papers do not concern themselves with the notion that PMF develops in the absence of simple CWP. However, NIOSH attempts to claim otherwise with the following statement: "PMF develops more frequently in miners already affected by simple CWP; yet PMF also develops in miners with no previous evidence of CWP (Hodous and Attfield 1990, Hurley et al 1987)." What NIOSH is trying to say is that PMF can and does develop on a background of no simple CWP. This is clearly not what is contained in the papers cited. For example, in the Hodous and Attfield paper, the "PMF" which developed at a specific point in time, did not exist five years earlier, but a background of small lesions did exist five years earlier and this background was not necessarily minimal. Of 69 cases, only three for sure, but possibly 10 miners, had a clear chest at the start of the risk period. It is clear from the distribution of small lesions at the point in time that PMF was found that the simple CWP had progressed.

Any massive lesion in a coal worker that exists on no background of simple CWP is likely not PMF. In addition, the 30 cases with PMF who also had category 1 simple CWP are suspect. Interestingly, the sub-categories (1/0, 1/1, 1/2) of the simple CWP of these cases were not given -- were they all (or most) 1/0? This could be a reason for great concern due to variability in x-ray reading. The massive lesions seen clearly could represent something other than PMF.

On the surface, the Hodous and Attfield article demonstrates that at a point in time, there were 69 cases, most of whom had some degree of simple CWP at the beginning of a risk period. Five years then went by and the data suggest that the simple CWP progressed and PMF also occurred. In fact, if the data are taken at face value, it appears that based upon the distribution of small opacities at five-year examination dates quite rapid progression of simple CWP had taken place over the five year interval.

While one of the authors initially judged which cases (pairs of x-rays) were and were not incident PMF cases, he did not re-evaluate the cases according to simple CWP, but relied totally on previous "A" and "B" readings for this determination. Thus, different interpreters at two points in time might have dramatically affected this distribution. Several critical questions and concerns need to be addressed before these data could be judged acceptable:

1. What was the exposure during the five year interval between examinations? While the article calls only for stricter dust control, it is implicit in the draft NIOSH criteria document that all of this (i.e., progression of simple CWP and PMF development) might be taking place at  $2.0 \text{ mg/m}^3$ . If, in fact, the "A" lesions developing on a background of simple CWP are truly PMF, then with high likelihood past

exposures as well as exposures in the risk interval were excessive.

2. It is suspect that true stage B or C PMF (eight subjects) develops in five years over a background of no to minimal simple CWP at the beginning of a risk period. If it did, the lesions are likely other than PMF. Also, large lesions (A) on minimal to no background are likewise suspect and could represent a condition other than PMF. Details of exposure, job, past history, and objective re-reading of the films needs to be done and tabulated on a case by case basis.

3. These data are difficult to evaluate as only the distribution of simple CWP for the PMF cases are given at two points in time and the attack rates of PMF for those with 0, 1, 2 and 3 simple CWP at the initial five-year period are unknown.

4. The issues regarding "r" opacities, rapid progression, and silica "overexposures" are pure speculation. Exposure information is absent in this report and is needed to shed more light on this subject.

5. These cases are not confirmed pathologically. Clinical follow-up to gain details on these cases would be sensible.

The Hurley et al. report appears methodologically sound. Nonetheless, the PMF cases identified are not proven pathologically and could represent a coalescence of small shadows (ax), tb, and other nonoccupational conditions. However, critical to the Hurley et al. paper is the notion that those with category 0 simple CWP at the beginning of the risk period and who had less than 100 gh/m<sup>3</sup> up to the beginning of the risk period would not develop PMF. These data are shown in Table 4 of the Hurley et al. paper. For example, those miners starting the risk period with category 0 (no CWP) by age group who did and did not develop PMF had accumulated dust exposure in gh/m<sup>3</sup> up to the start of the risk period as follows:

	<u>&lt;35</u>	<u>35-44</u>	<u>45-54</u>	<u>&gt;54</u>	<u>All ages</u>
Category 0 who developed PMF	110	181	232	283	234
Category 0 who did not develop PMF	46	103	144	170	100

Assuming unrealistically that the PMF diagnosed for these British miners is real and not some other condition mimicking PMF, simple calculation shows that a miner exposed to the current

standard of  $2.0 \text{ mg/m}^3$  for a working year would have an annual exposure of around  $3.5 \text{ gh/m}^3$ . Thus, using the  $\text{gh/m}^3$  exposure data from Table 4 of the Hurley et al paper, at the level of  $2.0 \text{ mg/m}^3$ , miners would generally have to work longer than they are old to achieve the average exposure necessary to produce PMF. For example, the distribution of average years required to develop PMF by age for those with category 0 at the beginning of the risk period would be roughly:

	<u>&lt;35</u>	<u>35-44</u>	<u>45-54</u>	<u>&gt;54</u>	<u>All ages</u>
Years required for those with category 0 to develop PMF, given exposure was $2.0 \text{ mg/m}^3$	31	52	66	81	67

This does not even consider the exposure these individuals might receive during the 5-year interval between examinations. A miner cannot work while in the womb. Put another way, on average, a miner starting work at age 20 with a clear chest and working year after year at  $2.0 \text{ mg/m}^3$ , would be 87 years old before he had a risk of developing PMF. Even then, this presumes that two basic assumptions are true: that the British dust data are accurate and that the PMF diagnosed is truly PMF and not some

other condition. The validity of both assumptions is highly questionable.

The report by Hurley and Maclaren is a product of estimating dust-related risks of radiological changes in coal miners over a 40-year working life. To be exact, the charge given the Institute of Occupational Medicine (IOM) by NIOSH was to estimate what would happen to American miners given the experience of the British. What would happen means basically what proportion of American miners would develop CWP if they worked day in and day out in  $2.0 \text{ mg/m}^3$  of coal mine dust and, if they did develop CWP and opted to transfer to  $1.0 \text{ mg/m}^3$ , what effect would this transfer option have?

To be sure, the information given is based on specific models and certain assumptions and thus estimates are derived. While the British dust data are likely superior to U.S. dust data, they are not without their drawbacks. There is little argument with the models employed, but the assumptions are, to say the least, questionable. More to the point, this information provides estimates and does not relate to observable information. The three basic assumptions, i.e., exposures, tenure, and workforce composition, are all not likely true. As the report states, these are worst-case situations. Take for example the assumption relating to exposures -- "assume the worst case that the miner receives  $2.0 \text{ mg/m}^3$  all of his working life unless he



transfers, in which case he receives  $1.0 \text{ mg/m}^3$ ." This assumption is far from reality. Under the  $2 \text{ mg/m}^3$  standard (if it is met), a miner would be exposed to possibly peak doses of  $2 \text{ mg/m}^3$  but his cumulative exposure would be far less than hypothesized under the situations given in the report. Prior data have shown that the cumulative dose is critical and a cumulative dose under the current  $2.0 \text{ mg/m}^3$  standard would clearly be far less than hypothesized.

For coal rank somewhat representative of the U.S. experience (83%), the 0.71 percent estimated who will obtain PMF under the  $2.0 \text{ mg/m}^3$  standard is firstly, overestimated because of the validity of the assumptions used. Secondly, if it were in fact true, the PMF that developed would likely not be PMF but another "A"-type lesion that mimics PMF. Assume for a moment that 0.71 percent really develop stage "A" PMF. This, in and of itself, is not disabling and does not lead to premature death. This was demonstrated by Ortmeier et al. amongst Appalachian bituminous coal miners. NIOSH uses the data from Althouse et al. as partial justification for the estimates derived. There it was shown that while there has been a general decrease in the prevalence of CWP over the years, a slight increase is noted between 1985 and the present. These data are from the x-ray surveillance program which is totally unreliable due to extremely poor participation rates and these data are thus not generalizable. The reported slight upturn in the prevalence rate

can be a consequence of who read the x-rays, especially if profusion is quite low, i.e., in the 1/0 area, which it likely is.

By contrast, Attfield and Althouse suggest that the prevalence of CWP appears to be at around background levels for what might be seen in an unexposed population. In fact, a direct quote from the article is revealing: "Although low participation in the surveillance program and other problems complicate the findings, it appears that reductions in dust exposure mandated by federal act in 1969 have led to lower prevalence of pneumoconiosis among underground coal miners." This position is also maintained by Attfield and Castellon. NIOSH's own publications demonstrate that attack rates of simple CWP over 0, 1-9, and 9+ working years are consistent with the onset of a disease process, possibly mimicking CWP, in an unexposed population.

To reiterate, none of the critical papers on this subject say, nor were they intended to say, that PMF develops on no background of disease or on a background of minimal CWP. In fact, the distribution of simple CWP at the point in time where "PMF" is diagnosed suggests otherwise, e.g., 1%, 43%, 38% and 17%, for simple CWP categories 0, 1, 2 and 3. The 43% for category 1 seems quite far-fetched and the massive lesions seen on this background could more likely be another disease entity.

What the papers suggest is that PMF is developing, over a five year period, in individuals who had no to minimal simple CWP at the beginning of a risk period. If, in fact, this is happening, these individuals are indeed very rapid simple CWP progressors and the dust burden in the five-year interval in question would have had to be astounding. Unfortunately, the dust data in the risk interval is not available in either the U.S. or U.K. data. Thus, if even a portion of the cases thought to be developing PMF in the risk interval is real, the problem lies with compliance with an existing  $2.0 \text{ mg/m}^3$  standard and not with lowering the standard. The best illustration of this is contained in Table 4 of the Hurley et al. paper. Over all ages, men with category 0 at the start of the risk period who had accumulated an average of  $100 \text{ gh/m}^3$  were without PMF at the end of the risk period. In other words, they were disease free. This equates to their working around 30 years at  $2.0 \text{ mg/m}^3$ . Of course, added to these years at  $2.0 \text{ mg/m}^3$  would be another five years in the risk interval (35) years at  $2.0 \text{ mg/m}^3$  for the disease-free group. Equally important, the other side of the coin involves  $234 \text{ gh/m}^3$  of exposure up to the start of the interval for those with category 0 simple CWP who were said to develop PMF. At  $2.0 \text{ mg/m}^3$  over a working year, this amounts to around  $3.5 \text{ gh/m}^3$  annually. Thus, on average, these workers would have had to work in such exposure around 67 years plus five more in the interval (72 years) to be at risk. Quite obviously, if we are dealing

with real PMF and rapid progression of simple CWP, we are looking at data reflecting astoundingly high dust exposures. Back calculation using the mid-point of the age range of miners and assuming they started working at around 20 years of age shows that exposures would have to have been (e.g., 50-year-old miner who worked 30 years) quite high -- more than double the current U.S. standard.

Thus, compliance at  $2.0 \text{ mg/m}^3$  would clearly be sufficient, even considering shortcomings in the dust data and the very likely misdiagnosis of PMF on a background of very low profusion of simple CWP.

While not stated, it is likely that most incident PMF cases that were thought to exist in the U.S. were found at the very beginning of the NIOSH research and surveillance studies and thus these were workers who previously were exposed to dust far in excess of the current standard of  $2.0 \text{ mg/m}^3$ . Moreover, the PMF cases found in both the U.S. and U.K. on minimal to no background of simple CWP at the beginning of a risk period are suspect as the cases are not pathologically proven and the mostly "A" shadows seen could be other conditions of a nonoccupational origin.

The authors of the draft make the statement that there is no background of PMF in the general population. This may be true,

but there is certainly a background of large opacities, many of which remain completely undiagnosed. To ascertain whether PMF occurs in category 0, one would have to look at a comparable large group of subjects with the same socioeconomic circumstances who are not exposed to coal dust to ascertain the frequency of such opacities. Even for someone with experience at interpreting chest x-rays and relating them to the clinical features causing the large opacity, it is difficult to attach a definitive diagnosis to an opacity or opacities greater than one centimeter in diameter occurring in an otherwise normal chest film.

There is no evidence whatsoever that PMF occurs in the absence of category 1 CWP. This conclusion remains hypothesis despite the pronouncements of the draft. If the British data and estimates from the report by Hurley and Maclaren in 1987 are so valid, why then have the British themselves not acted on this report in the past five years and why is the British dust standard around twice what we now have in the U.S?

The belief in the U.S. coal industry is that the present 2.0 mg/m<sup>3</sup> respirable coal mine dust standard, properly monitored and enforced, is fully protective. Coal workers' pneumoconiosis is a vanishing disease in the U.S., as it is in Britain. If NIOSH can show otherwise, there is indeed poor communication between health science public policy agencies and the mining industry. The NIOSH and MSHA procedures for not reporting results of its

radiographic surveys to the mine operators who handle arrangements and pay for the program fosters poor communication. Those procedures should be changed.

The draft criteria document also recommends that exposure to respirable crystalline silica be limited  $0.05 \text{ mg/m}^3$  as a time-weighted average for up to 10 hours per day over a 40-hour workweek. The draft appears to adopt a more rigid standard for those who work in a coal mine than for people who work elsewhere and are exposed to silica, where the standard remains at  $0.1 \text{ mg/m}^3$ . It is illogical to have two different respirable crystalline silica standards.

AMC takes strong exception to the manner in which the authors of the draft criteria document attempt to "backdoor" the recommendation for a reduced silica standard in a recommendation for a reduced respirable coal mine dust standard. Not only is the title of the draft document misleading, but the proffered justification for a  $0.05 \text{ mg/m}^3$  exposure limit is woefully lacking. NIOSH is not well-served by the incorporation of a superficial discussion of the health effects of crystalline silica exposure, in a coal mine dust document, as the basis for a NIOSH recommended exposure limit for crystalline silica. If NIOSH believes a reduced silica standard is merited for general industry workplace exposures, it should revise or develop a separate criteria document. If this recommended standard is

unique to the coal industry, NIOSH also should adequately document it in a separate criteria document.

These criticisms aside, there is merit in expressing a standard for respirable crystalline silica exposures in coal mines separate and distinct from respirable coal mine dust. AMC believes the current  $0.1 \text{ mg/m}^3$  standard, properly monitored and enforced, is fully protective. There clearly are insufficient data available to suggest that the  $0.1 \text{ mg/m}^3$  silica standard is not sufficient. In fact, the Australian experience shows that under their  $0.2 \text{ mg/m}^3$  standard, incident cases of silicosis are essentially nil. The cases that do occur are most likely a consequence of non-compliance and higher exposures.

Regarding silica and coal workers, conflicting and inadequate British data exist on this subject. The work by Seaton et al. suggests that miners exposed to coal mine dust with high silica content develop CWP quicker and progress faster. These data are far from convincing. The information contained in Table III of that report shows clearly that while the 21 cases in question were exposed to dust containing proportionately more silica than the controls, their total dust exposure burden was considerably and significantly higher at around 60 percent higher. The authors of this report provide no information that could logically be used as justification for lowering the quartz level to  $0.05 \text{ mg/m}^3$ . In fact, they plainly state that the risk

exists in miners with exposures greater than  $0.1 \text{ mg/m}^3$  -- although pneumoconiosis has not developed in all those exposed. The work by Hurley et al. suggests that there was no evidence that the quartz concentration experienced (averaged 5 percent of mixed dust) affected the probability of developing coalworkers' simple pneumoconiosis.

AMC believes that NIOSH should remove the silica discussion and recommendation from this document and, if merited, develop a separate criteria document for silica.

The draft criteria document recommends that pulmonary function tests be included as part of the medical surveillance program for coal miners. The basis for the recommendation is the conclusion that miners may develop chronic obstructive lung diseases that will not be identified on the basis of chest radiographs. The diagnosis of COPD will be based on the findings of an FEV<sub>1</sub>/FVC% below the LLN (lower limit of normal) or because of an accelerated decline in the FEV<sub>1</sub>. As such the miner who meets these criteria will have the option of transferring from his or her position to another area of the mine where the concentration of coal dust is as low as feasible, i.e., below  $0.9 \text{ mg/m}^3$ . This recommendation, if accepted, will permit those miners who are smokers and who suffer from the effects of cigarette smoking to become Part 90 miners with transfer rights to less dusty positions at their option.



The relative contributions of cigarette smoking versus coal dust have been debated for many years. Most authorities believe that smoking has at least three to five times the effects of exposure to coal dust. Cigarette smoking has a more profound effect and produces disabling lung impairment and premature death. This cannot be shown in nonsmoking miners in the absence of PMF. Transfer rights, therefore, will be awarded almost entirely to smokers. Moreover, such rights will not prevent their further deterioration if they continue to smoke.

The draft states that Attfield and Hodous have found that the effects of cigarette smoking and exposure to coal mine dust are similar. This is a solitary observation that has not been confirmed at the Institute of Occupational Medicine or anywhere else. It has been quite clear, as mentioned above, that cigarette smoking has at least three times the effect of coal dust inhalation, even though COPD develops in only about 10 to 13 percent of cigarette smokers. Moreover, Attfield in the past has found that the effects of cigarette smoking to be at least three times greater than those of dust exposure.

To recommend a set decrement expressed as a percentage as a criterion for transfer is also misleading. If a person has small lungs, a much smaller volume change may be necessary for him to qualify for transfer rights than would be the case in a larger person because a given volume decrement will represent a greater

percentage of total volume. The whole problem of obtaining reliable spirometry has been vastly underestimated by NIOSH and without reliable spirometry the issue of transfer rights becomes a confused tangle of uncertainty.

The draft criteria document recommends extension of the Coal Workers' X-Ray Surveillance Program (currently afforded to underground coal miners) to include surface miners as well. The basis for the recommendation is the conclusion that surface coal miners in the U.S. have shown that they, like underground coal miners, are at risk of developing pneumoconiosis, silicosis and chronic obstructive pulmonary diseases.

This is an issue AMC previously addressed in considerable detail in commenting on two predecessor draft documents prepared by NIOSH. The criticisms of the proposal to medically survey surface coal miners articulated in our comments dated December 19, 1990, remain valid. NIOSH has not demonstrated an increased risk of pneumoconiosis in the general surface coal mining workforce. While NIOSH has identified a limited number of occupational categories of surface coal miners at slightly increased risk for developing silicosis, the categories appear to be based on isolated, worst-case instances where poor work practices, antiquated equipment or exceptionally high silica content played a role. The results of those few evaluations have been generalized as standard industry practice. NIOSH has not

demonstrated that a general medical surveillance program for all surface drillers, let alone all surface coal miners is warranted. Even the population potentially at slightly increased risk would be protected by the current  $0.1 \text{ mg/m}^3$  respirable crystalline silica standard if properly monitored and enforced. Mandated medical surveillance of all surface coal miners is viewed by industry as a misuse of scarce occupational health resources. As far as we know, there are no published studies linking COPD to surface coal mining. Therefore, there is no demonstrated reason for doing pulmonary function tests on surface miners. Copies of our earlier comments are attached as Appendix 1.

NIOSH contends that the epidemiologic studies of U.S. coal miners form the primary basis for the recommended exposure limit proposed in this draft criteria document. In these studies, the quantitative exposure-response relationship was determined for exposure to respirable coal mine dust over a 40-year working lifetime and the risk of developing simple CWP, PMF or clinically significant impairment of pulmonary function. NIOSH suggests risk estimates based on the studies of U.S. coal miners are consistent with those based on studies of British coal miners. These studies indicate that each year, between seven and 89 miners out of 1,000 who are aged 58 will have developed PMF, following 40 years of exposure to respirable coal mine dust at the current standard of  $2.0 \text{ mg/m}^3$ . For exposure to a mean concentration of  $1.0 \text{ mg/m}^3$  for a working lifetime, the risk of

PMF is reduced by more than one-half, to 3-34/1,000. In addition, the exposure-related risk of developing a severe impairment in lung function among nonsmokers is 8/1,000 at 2.0 mg/m<sup>3</sup> and 3/1,000 at 1.0 mg/m<sup>3</sup>.

This risk assessment exercise assumes some knowledge of U.S. coal mine dust exposure levels prior to 1970 in order to estimate quantitative exposure over a 40-year working lifetime. We have some notion of exposure levels for underground coal miners since 1970, but retrospective extrapolation is pure guesswork. The published data show that respirable coal mine dust levels ranged from about 1.0 to over 50.0 mg/m<sup>3</sup>. Moreover, since about 1980, respirable coal mine dust exposure data has not been traceable. There are no individual identifiers attributable to each personal exposure sample. Therefore, the cumulative exposure cannot be used as a basis for epidemiological findings. A central question remains. How can NIOSH recommend an occupational exposure limit for U.S. coal miners without ever developing some valid notion of cumulative dose-response?

Apparently, we still are depending on the British data. Only the U.K. and the Germans, during the periods they were studying CWP and its relation to PMF, developed cumulative dose-response relationships. Those same countries also mandate respirable dust standards greater than the 2.0 mg/m<sup>3</sup> standard currently in effect for U.S. mines. Presumably, the governments

of these countries are just as interested in preventing material impairment of health in their coal miners as we profess.

Even if there is still new disease in miners, it does not necessarily follow that reducing the PELs will help. Overexposures still occur, and the possibility that some individuals are overly sensitive to dust and would be harmed by any exposure is a hypothesis that NIOSH wants to posit and should test. Even the most stringent exposure limits may not protect all hypersensitive subpopulations. Proper preventative measures are to identify these individuals and remove them from all occupational exposure, unless there is effective treatment for the hypersensitivity.

The draft criteria document recommends that compliance with the REL shall be determined by full-shift sampling with a device operated in accordance with the criteria of the proposed international (ISO/CEN/ACGIH) definition of respirable dust, as developed by the International Standards Organization (ISO), the Comite' Europeen de Normalisation (CEN) and the American Conference of Governmental Industrial Hygienists (ACGIH). The basis for recommending the adoption of the proposed international definition is that it better approximates the deposition efficiency of particles in the human respiratory tract, eliminates the bias associated with the current use of the British Mine Research Equivalence (MRE) factor, facilitates the

determination of the concentrations of both respirable coal mine dust and respirable crystalline silica from the same sample and encourages improvements in the design and performance of the sampling device. A correction factor is provided in the draft document for comparison of measured concentrations of respirable dust collected with the current and recommended sampling criteria.

All new sampling data would be obtained with personal samplers operating at 1.7 liters per minute (L/min). NIOSH previously has asserted that a nylon cyclone sampler operating at 1.7 L/min best approximated the Atomic Energy Commission or ACGIH size selection criteria (see p. 114, fig. 5-1). This same operating condition also agrees with the proposed international definition.

Tomb et al. in 1970 and 1976 reported the penetration characteristics of the nylon cyclone operated at different flowrates and also the results of work conducted by other investigators. Basically, it does not appear to make any difference which operating criteria is followed. Test data show that airborne dust measured with personal samplers operating at 1.7 and at 2.0 L/min gave results that are linearly related. The empirically derived linear relationship between concentrations of airborne dust measured with MREs and personal samplers operating at 2.0 L/min, the 1.38 conversion factor, is an example.

Monitoring of respirable dust levels in U.S. coal mines can be accomplished with whatever device and operating criteria are mandated. The appropriate conversion factor need only be applied. Relationships also have been determined for dust measurements made in operating coal mines using a variety of other samplers, including midget impingers, cascade impacters, cyclones and various designs of other presize selectors.

The draft criteria document recommends that cyclones made of metal or other materials, in addition to nylon, would have no effect on results. This has not been adequately tested for inclusion under 30 CFR 74. Tomb and Raymond reported in 1970 that limited studies indicated results obtained using metal and nylon cyclones differed. There is concern that static electrical charge on particles passing through the nylon cyclone can lead to bias. This phenomenon was reported by Tomb in 1970 when he reported that metal cyclones retained about 10 percent less dust than nylon cyclones. Although this was attributed to static electrical charge, the parameters influencing the generation and retention of charges on dust particles was not studied.

In the extraction areas of underground coal mines, the atmospheres are normally saturated with moisture resulting from water sprays and a slight increase in temperature of the volume encompassing the dust generating interface. As soon as this air volume leaves the relatively thin interface, the temperature

drops to ambient resulting in total saturation, normally about 95 percent relative humidity. The question remains, do static charges on dust particles affect sampling in high humidity mining areas?

The charge effects may have a more significant impact when dust levels are measured in surface mines. Therefore, use of nylon and metal cyclones could complicate the evaluation of exposure concentrations. For example, did the approved sampler have a metal or a nylon cyclone, and was the weather humid or dry when the operation was sampled?

NIOSH is naturally concerned with the size-selective sampling criteria considering deposition and retention of particles in the respiratory system. These concerns may not be warranted because the exposure information gathered by the U.K. and U.S. scientists using MRE and MRE equivalent samplers can be converted to concentrations meeting the proposed international ISO/CEN/ACGIH respirable dust definition.

The effect of the NIOSH recommended change of operating flowrate for the sampler from 2.0 to 1.7 L/min, must be considered. Each and every sampler must be recalibrated and the flowrate indicator marked to show the quantity of air passing through the sampling head assembly. Since NIOSH is responsible for the approval of all the samplers used to meet 30 CFR Part 70,



71 and 90 requirements, will they perform this conversion for all mine operators? At what charge? Or will NIOSH declare all existing samplers unapproved because they do not meet the new criteria?

The primary purpose of maintaining a total sampler concept is to prevent interchange of components resulting in erroneous sampling data. Metal cyclones, H-D cyclones or any other size selectors apparently are acceptable, that is, providing the approved sampling device containing these elements meet the requirements of 30 CFR 74. All components: pump, sampling head assembly, filter and charger, must be approved as a complete sampling device, not as individual modules. A manufacturer cannot insure the quality of its approved sampler when other components are substituted.

The draft criteria document's recommended sampling strategy for respirable coal mine dust distinguishes between the purposes of sampling by coal mine operators and MSHA inspectors. The proposed biweekly collection of single, full-shift samples by mine operators ostensibly is intended to provide frequent feedback on the effectiveness of dust controls and to ensure that concentrations are maintained below the REL. Those single, full-shift samples collected by MSHA inspectors would be used to determine, with a high degree of confidence, whether the standard had been exceeded.

While the Mine Act expresses a goal of single shift exposure measurement, the validity of the statistical technique advanced by NIOSH will not accurately represent atmospheric conditions during a single shift. While the approach may consider sampling and analytical error, it fails to take into account the variability inherent in the ever-changing mining environment. Single-shift samples essentially are random events that do not, and cannot, reflect average long-term concentrations. More research is needed into the variability of dust generation, dissemination and the dust levels in any and all extraction processes and mine environments. NIOSH itself recognizes that "single, full-shift sample[s] do[] not accurately represent the long-term average concentrations of respirable coal mine dust." However, it is the long-term average concentrations that are related to chronic health risks. A long-term mean strategy also is more consistent with the approach used to derive the REL (i.e., long-term mean exposure).

As a Federal government agency, MSHA should not perform routine services, such as weighing of operator's dust samples of respirable coal mine dust for noncompliance purposes. Under the present regulations, the operator's samples become the property of the Secretary upon receipt. Compliance decisions are mandatory.

There should not be a requirement that mine operators take

periodic dust samples. Mine operators should take samples, if they wish to, for industrial hygiene purposes, for evaluating changes in controls, etc. MSHA should take samples for compliance purposes. Research investigators should take samples for exposure monitoring/standards recommendation purposes. This approach is consistent with MSHA's proposed air quality standard. In general, AMC endorsed that approach.

The NIOSH recommendation to change the average production level from 50 percent for valid bimonthly sampling and 60 percent for MSHA approval of dust control plans to more closely approximate actual production levels demonstrates a lack of knowledge of the variability or the mechanics of airborne dust environments. Production levels in continuous or conventional mining sections should have little overall effect when adequate ventilation and application of dust suppression are used during the extraction process, as reflected in the dust control plan. On the other hand, dust control on longwall faces is more dependent on production levels, in addition to dust suppression and ventilation. Dust control in underground and surface coal mines is dependent on the extraction system being used, as well as ventilation (wind velocity and orientation on the surface) and methods of dust allaying. The dust control plans presently required are the best attempt to simplify the maintenance of control without introducing too many variables.

NIOSH recommends that MSHA inspectors issue a citation if the dust control parameters as measured or checked by the mine operator do not match those logged for that day, regardless of whether the dust level is at or below the standard. NIOSH further recommends that MSHA inspectors collect samples for compliance decisions approximately six times per year per mine. In large mines, having up to 10 operating sections or faces, this would provide only a token evaluation of conditions in the mine. The sampling strategy outlined by NIOSH clearly focuses the bulk of MSHA's enforcement effort on dust control plan compliance, rather than on respirable dust exposure compliance.

NIOSH recommends the mine operator's sampling program include determination of a sufficient number of individual exposures, although not everyone, to characterize the exposure of all miners potentially exposed. The sampling program originally mandated in 30 Part CFR 70 (1970) contained this same approach, with the requirement that the exposure levels of each and every miner be evaluated at least every 180 days. Revision of the regulations in the late 1970s resulted in the removal of all identifiers related to the miner's exposure level. At present 30 CFR Parts 70 and 71 do not require quantification of the miner's exposure, but rather the determination of average dust levels for certain occupations or areas. As stated previously, dust measurements made to determine dust control plan effectiveness do

not provide sufficiently accurate miner exposure levels for inclusion in medical records or for dose-response determinations. NIOSH should recommend the use of individual identifiers in any and all personal sampling to help redress this deficiency.

Specific Comments

Page 6      1.3.6      Intake Air Concentrations

Why should the intake air concentrations of respirable dust be maintained at the lowest attainable level? No justification is offered. This is not a reasonable requirement and would be impossible to enforce. The current respirable coal mine dust standard for intake air of 1.0 mg/m<sup>3</sup> provides an identifiable and feasible level for mine operator compliance.

Page 9      1.4.1.5      NIOSH-Approved Facilities

NIOSH should not be in the business of evaluating or approving health care facilities. Instead NIOSH should make recommendations for regulations that will provide quality medical evaluation programs and establish a collaborative reporting system between the mine operator and the government agencies. The present program precludes the mine operator from taking an active role in medical intervention

decisions.

Page 9      1.4.1.6      Smoking

A mine operator may have a problem trying to enforce a policy prohibiting smoking at all work areas at the mine site because of labor contracts. Smoking is the mining industry's number one health problem. NIOSH should recommend a standard prohibiting smoking on mine property.

Page 16      1.10.2      Showering and Changing Facilities

Sections 1.10.2, 1.10.3 and 1.10.4 bear no reasonable relationship to the recommended occupational exposure limit for respirable coal mine dust. As such, these recommendations have no place in this document and should be deleted.

Under Public Law 91-173 the Secretary of Health Education and Welfare (HEW) provided all health standards to the Secretary of the Interior for promulgation. The bath house and toilet facilities regulations for

underground coal miners were promulgated as safety standards in Part 75, apparently in the absence of information from HEW.

The last time Parts 70 and 71 were revised, this issue was examined by NIOSH with the intention of recommending a standard. The result was NIOSH could not find any case of illness or disease resulting from inadequate facilities. So instead of recommending a standard, the Institute produced a guideline document. AMC is not aware of any problems with this approach.

Page 16    1.10.3    Drinking Water

NIOSH is mistaken. 30 CFR 75.1718 addresses drinking water supply and quality.

Page 17    1.11    Recordkeeping

Mine operators may not be in business for 40 years. The only conceivable class of records worthy of retention for any appreciable amount of time are individually identified personal exposure records, which the NIOSH



draft recommended standard fails to address.

Page 20    2.3.1.    Background Information

The reference to coal mining being among the most hazardous occupations is not consistent with Bureau of Labor Statistics or National Safety Council data. The trends reflect a steady decline in incidence rates within the last five years. The coal mining industry soon could find itself below the average of all private industry rates.

The reference to tampering allegations and increases in CWP in the late 1980s is intentionally misleading. A comprehensive evidentiary hearing on the science concerning abnormal white centers was held. An administrative law judge (ALJ) rendered a decision holding that the presence of an abnormal white center, by itself, is not conclusive evidence of intentional tampering. A copy of the ALJ's decision is attached as Appendix 2.

Imputations of dishonesty in sample collection have no place in a discussion of occupational exposure limits. Accurate sampling and analysis are the linchpins of any industrial hygiene, research or enforcement program. These are assured by a variety of administrative and training procedures that are independent of numerical standards. Elsewhere, AMC recommends that compliance samples be collected by MSHA. One reason for this recommendation is that MSHA is the disinterested agency in charge of standards enforcement. All parties involved in sample processing must be trained, responsible and honest, regardless of who employs them.

Page 25    2.3.3.2    The Need to Improve Preventive Measures

NIOSH seems to have concluded that the Part 90 transfer program is not effective, yet is recommending its continuance and expansion. If the industry was faced with a significant number of transfers, a problem of decreased safety and productivity would result. If the transfer program is not effective, it needs

to be eliminated.

Chemical and Physical Properties of Coal Mine  
Dust

NIOSH referenced studies that indicate a relation of prevalence of CWP with coal rank. The coal rank was determined by ASTM procedures for clean coal and are reported on a dry, mineral matter-free basis. Tomb et al. reported that the incombustible content of respirable coal mine dust ranged from about 10 to 80 percent. This supports the concept that respirable coal mine dust is somewhat different than respirable coal dust.

In Britain, the prevalences for pneumoconiosis for each coal mine show quite conclusively great variations in prevalence from region to region. These variations have been remarkably consistent however dust exposure was measured, i.e., particle counting pre-1970 and gravimetrically post-1970. The most striking contrast is that between the Scottish and South Wales coalfields. Dust exposures whether measured

by particle count or gravimetrically have not been shown to vary greatly, certainly not gravimetrically. And yet the prevalences of CWP in South Wales has been consistently six to ten times that of Scotland, both for simple and complicated pneumoconiosis. Clearly there is more than cumulative dust exposure important in the causation of coal workers' pneumoconiosis in the U.K. The French had, and may still have, a logical approach to setting dust standards. Each coal mine is allocated a dust level based on several factors, which include prevalences of pneumoconiosis and measured dust exposures.

Anthracite coals are high-rank coals, while bituminous coals are medium-rank, and lignite is a low-rank coal. As the coal rank increases, the percentage of fixed carbon increases. However, the percentage of free crystalline silica may also increase as the rank increases. Further, the dust from high-rank coals may contain a greater concentration of respirable crystalline silica because the anthracite seams are dominated by quartzitic rock in the roof and

floor.

Anthracite coal accounted for 3.2 million tons of the total U.S. production and bituminous coal accounted for 894.8 million tons (1987), while 2285 and 146,505 miners were employed, respectively (1990). It would be improper for NIOSH to recommend a reduced coal mine dust standard for bituminous and lignite mines based upon the apparently greater toxicity of anthracite coal mine dust.

Page 36    3.2    Coal Production and Mining Methods

NIOSH's attempt to describe coal mining in a few pages suffers in the process. It should be eliminated or be more accurately informed.

Page 52    3.3    Number of Miners Potentially Exposed in U.S. Coal Mines

It is obvious from the outset that NIOSH has used data loosely to fit its own purposes. On the one hand, for example, while attempting to show that the coal mining

industry is not responsible in meeting the current respirable coal mine dust PEL of 2.0 mg/m<sup>3</sup> by showing the number of samples that exceed the PEL (section 3.3), it utilizes the same data to show that the proposed REL (section 7.3) is technically feasible. If the data clearly show that miners have been significantly exposed above the current PEL of 2.0 mg/m<sup>3</sup>, perhaps it is prudent to focus on MSHA's compliance methodology in the current standard, rather than to recommend lowering the health standard.

As an illustration of fair-play turnaround, a linear regression performed on the five most recent Bureau of Labor Statistics average coal employment data points suggest that in 21 years, no miners will be employed in coal mining. The correlation coefficient or "goodness of fit" for the five data points equals 0.93. According to the "data," in the not too distant future, exposure of miners to respirable coal mine dust and crystalline silica will no longer pose a potential problem. A table reflecting this admittedly loose data interpretation is attached as

### Appendix 3.

Page 72    4.1.1.2.4.    Abnormalities in Pulmonary Function  
Tests

It is stated that abnormalities in pulmonary function tests have been associated with exposure to coal mine dust and include changes in ventilatory capacity, lung volumes, etc., and finally hemodynamics. Morgan and Lapp are cited in support of this statement. In reality, changes in hemodynamics are seen virtually entirely limited to progressive massive fibrosis (PMF). Exposure to coal mine dust, even in the presence of simple coal workers' pneumoconiosis, does not affect pulmonary hemodynamics.

Page 74    4.1.2.1.1.2    Studies of CWP and PMF, 1969-88

4.1.2.1.1.3    Other Studies of Pneumoconiosis and  
Silicosis

There is extensive discussion about the Attfield and Moring paper (1992) and the

Attfield and Hodous paper (1992) in the American Review of Respiratory Disease. A copy of the letter to the editor is attached as Appendix 4. Many of the references are to internal documents that have not been published in peer-reviewed journals.

Attfield and Hodous in their 1992 paper in the American Review made a number of cardinal errors. First, they included the anthracite miners as part of the National Coal Study in their analysis. This was inappropriate because the methods of mining anthracite were radically different from those used in bituminous mines and no dust data were available from the now defunct anthracite mines. The Bureau of Mines collected dust data predominantly from bituminous mines. Only two anthracite mines were surveyed, in 1970. The initial dust data between 1970 and 1972 were invalid and these data were used by Attfield and Moring. Considering the paucity of anthracite dust measurements made, it seems entirely inappropriate for them to derive prevalence data for anthracite-induced PMF as shown in the figure on page 80.



Page 84 4.1.2.1.3 Irregular Opacities on Chest Radiographs

There is discussion of irregular opacities on chest radiographs. The suggested criteria gave transfer rights to persons who had either type of small opacities, namely, rounded or irregular. Despite the paragraph on page 84 which suggests that irregular opacities are also produced by exposure to coal dust, it is quite clear that the predominant cause of irregular opacities is cigarette smoking as shown by Dick et al. (1992). There is a further reference to Dick et al. (1984) which does not appear in the references at the back. A detailed discussion of the significance of irregular opacities is to be found in the second paper by Dick et al. (1992).

Page 84 4.1.2.1.4 Radiographic Opacities Among Nonminers

At the bottom of page 84 the draft cites a paper by Castellán (1985). Castellán chose blue collar workers who were not exposed to dust and, in addition, were relatively young with an average age of 35.8 years. Thus,

their choice of population excluded the effects of dusts as a whole and, in addition, excluded the effect of smoking since to a large extent the subjects were young and it is known that irregular opacities are related to years smoked and, in addition, to age.

Page 85    4.1.2.1.5 Studies of Mortality Among U.S. and U.K. Coal Miners

In the paragraph that starts on page 85 and continues on page 87, it is interesting to note that the mortality rates from lung cancer, heart disease, and coronary artery disease among coal miners are lower than among noncoal mining men from the same regions. NIOSH explains this by the Healthy Worker Effect. In reality this is not true. The Healthy Worker Effect applies to working coal miners. The SMRs are derived from populations one presumes have ceased working. Moreover, Ortmeyer has studied ex-coal miners as did Lainhart et al. (1969). This also applies to certain of Costello's studies.

Page 95    4.1.2.2.4 Emphysema

A paper by Leigh et al. (1983) is quoted in which they were unable to find that emphysema and chronic bronchitis at autopsy were related to cigarette smoking. This is a reflection of the selection of subjects. Bronchitis and emphysema have been shown to be related to smoking the world over.

There are many faults with the papers that are cited in support of the draft criteria document, especially since most of them use disability claimants who are notoriously unreliable in regard to their smoking histories, their symptoms, and other matters. For example, it is well known that those who apply for compensation are much more likely to provide inaccurate smoking histories.

Page 132 5.1.5

#### Sampling Strategy for Respirable Coal Mine Dust

There should not be a requirement that mine operators take periodic dust samples. Mine operators should take samples, if they wish to, for industrial hygiene purposes, for

evaluating changes in controls, etc. MSHA should take samples for compliance purposes. Researchers should take samples for exposure monitoring/standard recommendation purposes. This approach is consistent with MSHA's proposed air quality standard.

The appropriateness and validity of using exposure data collected by one means for a specific purpose, for an entirely different purpose, i.e., dose-response, is an issue that requires particular scrutiny.

Engineering control, industrial hygiene and compliance sampling are not the same type of sampling, have different goals and endpoints and, in most cases, are not compatible.

Page 139 5.1.5.2.1 Ventilation System and Methane and Dust Control Plan

NIOSH recommends an elaborate scheme for ventilation, methane and dust control plans, including certification of production levels for each mechanized mining unit. A dust control plan log, including such parameters as pressure of water sprays, quantity and

velocity of air currents, etc., would be kept daily and be subject to periodic review by MSHA inspectors.

AMC questions the value of such actions to the health and well-being of miners, to the mine operation, and to the effectiveness of compliance enforcement. The bureaucracy implicit in the draft NIOSH criteria document may have no significant impact on exposures. The more resources diverted from the workplace into administrative functions, the less likely operational compliance with regulatory standards will be achieved.

Page 160 5.2

#### Medical Surveillance

It is not appropriate for NIOSH to have a role in the medical surveillance of coal workers as proposed in the draft criteria document. The NIOSH proposal greatly increases the direct involvement of NIOSH in routine medical examinations "at NIOSH-approved facilities" without describing what such a facility must be or do, and it provides that "NIOSH will evaluate the test

results (of the medical examinations),  
conduct follow-up and store the records."  
This is not the proper function of NIOSH and  
is in contrast to any existing or other  
proposed method of assuring appropriate  
medical surveillance of U.S. workers.

Page 215 7.3

### Technical Feasibility of Achieving the REL for Respirable Coal Mine Dust and Respirable Crystalline Silica in Underground and Surface Coal Mines

It is obvious from the outset that NIOSH has  
used data loosely to fit its own purposes.  
On the one hand, for example, while  
attempting to show that the coal mining  
industry is not responsible in meeting the  
current respirable coal mine dust PEL of 2.0  
mg/m<sup>3</sup> by showing the number of samples that  
exceed the PEL (section 3.3), they utilize  
the same data to show that their proposed REL  
(section 7.3) is technically feasible. If  
the data clearly show that miners have been  
significantly exposed above the current PEL  
of 2.0 mg/m<sup>3</sup>, perhaps it is prudent to focus  
on MSHA's compliance methodology in the

current standard, rather than to recommend lowering the health standard.

NIOSH seems to base its belief that the industry can comply with a  $0.9 \text{ mg/m}^3$  standard based on past history and a belief that more research will provide some breakthroughs. However, mining methods of the future are not being taken into consideration. As the industry moves more toward longwall mining, as longwall panels become wider and deeper, and as companies mine deeper seams, problems of compliance with the  $2.0 \text{ mg/m}^3$  standard will develop, let alone a recommended  $0.9 \text{ mg/m}^3$  standard.

As we increase ventilation and air velocity, we compound the problem of compliance with reentrainment of dust. MSHA's data on violations of the  $1.0 \text{ mg/m}^3$  standard for intake air might be revealing. BOM research, in the recent past, has been cut in the area of respirable dust due to the general consensus that compliance with the  $2.0 \text{ mg/m}^3$  standard is no longer a problem.

NIOSH is silent on what they consider "reasonable levels of production" (p. 216). There is also a failure to recognize that water cannot be used in all mines for dust suppression due to mining conditions (i.e., soft bottom).

In some coal seams with varying thickness of partings and unfavorable roof conditions (mostly soft shale), compliance with the current  $2.0 \text{ mg/m}^3$  respirable coal dust standard is not technologically feasible. On some longwall sections, this can occur even during unidirectional cutting. In such cases, let alone under the  $0.9 \text{ mg/m}^3$  recommended exposure limit, airstream helmets should be recognized as an effective means to protect miners from excessive exposure.

NIOSH has failed to recognize the role that the powered air-purifying helmet can play in protecting the health of miners. Although NIOSH mentions respirator protection, it is treated in the traditional sense of selection, fit and maintenance. The air stream helmet represents a technology that



transcends the traditional respirator approach. The draft document inadvertently addresses this on pages 217 and 226. When discussing engineering controls it states, "... containment of the dust away from the miners by localized air streams and water sprays, ..." (emphasis added). Providing a localized air stream is just what these devices were designed to accomplish. The demonstrated effectiveness of these personal environmental controls merits their recommended use as engineering control measures.

Page 229 7.4

#### Other Factors Considered in Determination of the REL for Respirable Coal Mine Dust

The NIOSH draft criteria document does not weigh the cost of implementation as an element of analysis. NIOSH states, "[e]valuation of the economic feasibility, including consideration of the cost of upgrading or retrofitting mining equipment or of reduced production levels, are beyond the purview of NIOSH. Because consideration of economic factors is excluded from the NIOSH

mandate (29 U.S.C. 669 and 671 (1985), such factors do not influence the recommendation of an REL."

Making recommendations for improved occupational safety and health is laudable, but making them "at any cost" is totally irresponsible. Injuries, illnesses and deaths in the coal mining industry could be cut to zero if we just promulgated a rule that forbids the mining of coal. But, that would not make any sense. Similarly, a NIOSH interpretation of its mandate that produces a recommendation for an agency rule while refusing to consider economic cost at all is just as ridiculous.

The draft criteria document also states, "[t]he NIOSH mandate of protecting 'any worker' implies that the standard should apply to individuals with the greatest sensitivity to the exposure, and not just to individuals with an average response." The NIOSH mandate implies no such thing. Why should a standard be required to protect those who are hypersensitive to the natural

environment of the occupation they choose? As AMC previously observed, hypersensitive subpopulations cannot be protected by even the most stringent exposure limits. Proper preventative measures are to identify these individuals and remove them from all occupational exposure, unless there is effective treatment for the hypersensitivity.

Page 246 8.8

#### Medical Monitoring

NIOSH proposes that medical examinations must be done by physicians. Medical examinations may be done, and are being done, by other licensed and certified health care providers i.e., Nurse Practitioners and Physicians Assistants. Utilizing these qualified health professionals will improve the availability of medical services and will be more cost effective.

NIOSH should make recommendations that will stimulate quality surveillance programs appropriate to the disease endpoint. The programs should be cost effective and should

permit medical examinations and evaluations by qualified health care professionals who are licensed and certified in their respective states. The data that is obtained should remain confidential medical information with consent to compile information for longitudinal studies as related to work exposures and health risks.

Page 250 9

The pathogenicity of silica particles and their ability to release oxygen free-radicals in lung tissue is an emerging area of research. The fibrogenic and free-radical potential of crystalline silica occurring in coal mine dusts may or may not be biologically available. That potential appears greater in inhaled particles freshly generated by machine cutting. Often, however, the assayed quartz is coated by other mineral or coal phases and, therefore, should not be bioavailable.

The subject has been researched by the Generic Mineral Institute for Respirable Dust. Some water-soluble surfactants and organosilanes mixed with spray water in very

diluted concentrations show promise in detoxifying silica particles prior to inhalation. The topic deserves further research.

## Questions

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

CWP incidence and prevalence data related to those miners employed in U.S. coal mines since 1970 have not been adequately addressed. The incidence of CWP in U.S. miners is decreasing and progression is rare. Industry medical personnel and their consultants reviewing miner medical records and peer-reviewed literature of miners exposed under the  $2.0 \text{ mg/m}^3$  standard believe the standard is effective in preventing category two and above CWP and PMF. The existing standard is working and there is no reason to recommend the proposed exposure limit.

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

There are no experimental data collected using the recommended sampling procedure to indicate whether the REL of  $0.9 \text{ mg/m}^3$  is feasible or even achievable. A response to the REL for silica is not merited because the need for a  $0.05 \text{ mg/m}^3$  exposure limit has not been demonstrated. The fact that the coal mining industry has reduced the level of dust exposure in many operations to  $1.0 \text{ mg/m}^3$  is certainly

no reason to recommend an REL at or about that level.

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

According to the documentation, it apparently makes no difference. Up to now the U.K. and the U.S. accepted the BMRC definition. The same groups of scientists that accepted the BMRC and the ACGIH definitions now advocate the new ISO/CEN/ACGIH definition. Sampling data obtained using one technique can be converted from one standard to the other. Why change the definition or technique? The critical factor is that the mass of dust collected by the sampler must correlate highly with the mass of dust deposited in the lungs.

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

Development of more than one type of approved sampling device should be encouraged. However, NIOSH approved the current sampler without demonstrating or documenting the

performance of the device. How will NIOSH determine whether a sampler performs in an approved manner when used in a mine or even in its testing laboratory? The variability of results in sampling with different techniques and procedures have been reported by Tomb. Flow rates and the design of the classifying device should be adjusted until the average lung deposition curve is mimicked.

Improvements for "approved" samplers must be considered seriously before recommendations can be made. Material differences in the performance of samplers can result in data that are useless for determining exposure. If performance criteria are developed for approval for more than one type of sampler, then the requirements for meeting the criteria must include all components operating as a unit. This means that the applicant for an approval must provide the pump, size selector, the filter, etc., and must be able to assure quality control for each part.

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

The statistical validity as applied to the sampling strategy is lacking, in that environmental variability is not



addressed. Time and spatial variation also are significant factors. The variance in sampling data is so high that only a large number of samples can give any confidence in the reliability of the mean dust exposure. That amount of sampling, for a variety of reasons, may be impractical.

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?

The recommended use of PFTs in medical surveillance and inclusion of COPD as an occupational disease of coal miners give the NIOSH document a scope far beyond that implied by its title. The performance and interpretation of PFTs is an art as well as a science, and reliable mass screenings using PFTs are rare. Diagnosis of COPD based on PFTs alone is not valid. Cigarette smoking is by far the most common cause of COPD. Inclusion of this group as letter-carriers (and later, one assumes, as disability claimants) would put a large and unjustified burden on the coal industry.

7. Is the transfer of miners with evidence of Coal Workers' Pneumoconiosis (CWP) or Chronic Obstructive Pulmonary Diseases (COPD) to low dust areas of the mine medically

justifiable at the recommended concentrations of respirable coal mine dust or respirable crystalline silica?

As a matter of logic, either this approach works or it does not work. If it works, it should be mandatory. If it does not work, it should be dropped. The NIOSH document seems to contradict itself in this regard. On page 15, it cites a study estimating almost zero benefit of the transfer option in preventing PMF. Yet NIOSH recommends continuing to offer miners this option, recommends a dust limit at a level letter-carriers now transfer into, and recommends that surface miners and all miners with COPD be offered the letter-carrier option. This procedure also would have the presumably unintended effect of transferring smokers regardless of seniority to low-dust environments (which will do them no good unless they stop smoking) while leaving non-smokers in the higher dust areas. Go figure!

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

Smoking is the mining industry's number one health problem. NIOSH should recommend a standard prohibiting smoking on mine property.