September 14, 1993

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Dear Ms. Kuempel:

Enclosed are my final comments on the proposed criteria document concerning respirable coal mine dust. I think this is one of the most important criteria documents that NIOSH has produced. Thank you for your excellent work. I look forward to the final document.

I hope my comments are useful. If I can provide any additional assistance, please let me know.

Enc.

Final Comments on a

DRAFT CRITERIA for a RECOMMENDED STANDARD:
OCCUPATIONAL EXPOSURE to RESPIRABLE COAL MINE DUST

1. Is the derivation of the recommended exposure limit supported by the scientific data?

When the British dust standard was first published in 1964, a graph summarized the considerable data and quickly conveyed the relationship between exposure to coal mine dust and risk of progression of CWP. The health objective was defined as preventing progression to PMF. It was then a straightforward procedure to select the exposure level that corresponded to the desired level of risk. I had hoped to see something similar to this graph, something that would relate exposure to risk of developing PMF and of COPD.

The 1964 paper had two other virtues: it was short and it was published in a peer reviewed journal (Nature) with very high standards and wide circulation. These are worthy goals for NIOSH to emulate. This document does not have such a graph, it is long, and it has not been submitted for publication in a peer reviewed journal.

But these shortcomings are easily fixed. On the whole, this is an outstanding document that focuses debate on a wide variety and considerable volume of scientific literature.

One important scientific finding recognized in this document is that breathing coal mine dust causes not only CWP and silicosis (if respirable silica is present) but also obstructive lung diseases. This occurs in miners who smoke and in those who do not. While decrements in lung function have been recognized in research over the past four decades, conceptually, it was often treated as secondary to CWP rather than a separate disease process caused by inhalation and deposition of dust. If a miner had impaired lung function and a chest x-ray read as positive for CWP, the impairment was attributed to CWP. If, on the other hand, a miner had impaired lung function but a negative film, the impairment was attributed to something else, usually smoking. But improved used of exposure data and more careful analysis of impaired function made it possible to establish a cause and effect relationship between exposure to dust and impairment, distinguishing it not only from CWP but also from the well known and similar effects of cigarette smoking. And it also makes it

both possible and necessary to use the exposure-response relationship in setting a revised PEL.

This finding also lays the foundation for the use of spirometry in medical monitoring of miners and adds another tool for disease prevention. But since there are other causes of COPD, cigarette smoking being most prominent, it also complicates effective preventive measures. Neither dust control nor smoking cessation alone would be sufficient to prevent COPD among coal miners; both are necessary.

Another important finding is a change in the conventional wisdom concerning the natural history of CWP. According to the conventional paradigm, PMF was the final stage of disease progression from simple CWP to PMF. This progression was assumed to be slow and regular; a miner exposed to excess dust was thought to progress steadily from one stage to another. However, with the recognition that some miners proceed rapidly to PMF against a background of normal or nearly normal lungs, the validity of the conventional paradigm was questioned. And along with it, was questioned whether the 2 mg standard was adequate to prevent progression to PMF.

Both of these developments -- the recognition of the relationship between dust and impaired lung function and the change in the conception of the natural history of CWP -- are well described in this document. These two conclusions lay the foundation for estimating risk associated with occurrence of PMF and COPD.

The risk estimations are reasonably well founded in the scientific literature. Papers by Attfield (1992), Attfield & Morring (1992, 1993) provide the exposure-response relationships needed to set exposure limits.

Attfield and Morring (1992, 1993) provide comprehensive analysis of exposure and prevalence of CWP. These papers are relatively free of selection bias that has been a problem in other papers because of the high proportion of miners that participated in the medical monitoring. And, since the same researchers acquired the data concerning the medical status of workers, it is relatively free of inconsistent assessment of outcome.

Although there is little measurement of exposure for the time period over which miners had been exposed (prior to when the first gravimetric measurements were made in 1969), Attfield & Morring's (1992) estimate of job-specific exposure appears a reasonable approximation. However, exposure may have been underestimated for the pre-1969 period. For example, there are some exposure estimates -- based on particle counts -- as early as 1935 and 1941 (Sayers et al., 1935) and 1941 (Flinn et al.,

1941) that suggest that gravimetric exposure may have been much higher than that estimated by Attfield & Morring. Specifically, these earlier investigations report that some miners were exposed to dust concentrations as high as 300 mppcf (million particles per cubic foot).

Conversion of particle count measures to gravimetric measures results in very crude estimates in the absence of knowledge of the density and size distribution of particles. With that caution in mind, however, 300 mppcf could be translated into a gravimetric concentration about 48 mg/m^3 if the mass median diameter is assumed to be about 1.5 micrometers. Even if this is a significant overestimate, it suggests that exposure around 1940, before the widespread introduction of continuous mining machines, could have been higher than the estimates by Attfield & Morring (1992b). When continuous mining machines were introduced, exposure could have been higher still. If exposure is underestimated then risk is over-estimated.

Estimating the effect of coal rank is incomplete. Findings of an increased prevalence of CWP with higher rank coal have not adequately assessed exposure. If there is a coal rank effect, then one would find increased occurrence of CWP among workers exposed to higher rank coal compared to workers exposed to lower rank coal when exposed to the same concentration of respirable dust. The "same concentration" should in principle include not only the respirable mass, but also the particle size distribution and the occurrence of free radicals. My own hunch is that respirable anthracite coal may contain more small particles and a higher level of free radical activity. To my knowledge, such an analysis is not in the literature.

Even in the absence of such an analysis, however, the occurrence of CWP as a function of the carbon content of the coal has been found in studies in the U.S. and Britain and in independent studies over time. Given the consistent finding of this difference, NIOSH should consider a separate exposure limit based on the carbon content of coal. At the least, this issue needs further discussion. There is a separate exposure limit based on the crystalline silica content, why not for carbon too? Perhaps the data would not support such a finely tuned analysis; if so, then perhaps the discussion should be limited to whether there should be separate exposure limits for anthracite and bituminous coals.

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

For surface mines, these RELs for both respirable dust and crystalline silica are feasible with little additional attention to technologically feasible dust control measures. Achieving

the REL for respirable silica will be somewhat more difficult than achieving that for mixed mine dust but it is feasible to do so. Dust control methods, especially for high-wall drills, exist and are effective. What is needed is their conscientious application. The problem of achieving these exposure limits is not technical; it is a problem of whether MSHA is going to enforce these limits.

For most room and pillar mining sections, the proposed REL's are feasible. Successfully meeting the REL will require conscientious use of effective and feasible engineering control of dust - coal cutting methods, maintenance of bit sharpness, ventilation controls, and use of water. Making these effective requires careful evaluation and oversight of operators' dust control plans. There are some technologies that would aid dust control, such as the constant depth linear cutter developed by the Bureau of Mines. Such research should continue. Engineering controls have been described for some continuous mining sections that maintain average concentration of respirable dust to 0.5 mg/m^3. (BOM: 1985)

For longwall sections, however, it will be difficult to reduce exposure to the proposed REL's with the exclusive use of engineering controls. This is especially true of longwalls with very large panel dimensions: up to 1000 ft. faces by 10,000 ft. entries. However, control may be possible with very careful attention to established engineering dust controls for longwall sections, employing the same sorts of generic methods mentioned above and employing homotropal mining (i.e., having the longwall shear, chain conveyor, and air across the face all moving in the same direction.) At the least, with careful attention to the mining cycle, most workers on a longwall face can work in relatively clean air but some -- e.g., the tail-gate operator and jack-setters who work inby the shear -- may be in high concentrations of dust. In some circumstances, personal protective equipment may be necessary.

The question of the feasibility of engineering controls on longwall sections needs to be addressed carefully and I think is the critical factor limiting the feasibility of operating at or below the REL. I recommended at the meeting of the peer group panel that NIOSH should convene a working group consisting of experienced miners and mining engineers to address this issue. This group (not a formal panel because that structure might inhibit discussion) would be expected to recommend whether achieving the REL is feasible using existing dust control methods and if not, to recommend specific research and development that would be needed to develop feasible engineering controls. For example, it might be feasible to develop a machine-mounted scrubber on the longwall shear analogous to machine-mounted scrubbers currently used on continuous mining machines. This

could reduce exposure generated by cutting but it would not control exposure caused otherwise, such as by moving shields.

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

Yes. The use of international standards has an obvious appeal for facilitating comparison and use of data from other coal mining countries. Our own experience in the U.S., relying heavily on data acquired in British mines, is ample testimony to the need for international comparability in exposure assessment. Perhaps the most important reason why research was and is needed in the U.S. is because of the lack of comparability between respirable dust measured in Britain and in the U.S. Development and use of the conversion factor of 1.38 would have been unnecessary if there were an international definition of respirable dust. There is an international definition for outcome (the ILO standard for CWP and silicosis); there should also be an international standard for exposure.

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

Yes, to both questions. The current sampling unit is burdened with two problems. First, it operates at 2 lpm which is inconsistent with physically identical samplers used elsewhere in the U.S., most of which operate at 1.7 lpm. Second, it is necessary to use a conversion factor to obtain an MRE equivalent concentration. This adjustment should no longer be necessary. The lack of precision in the current sampling unit is also no longer tolerable, given our ability to develop better performing sampling devices.

NIOSH should develop generic performance criteria in order to facilitate development and use of alternative units. For example, direct-reading instruments could be very useful to either operators, miners, or MSHA for conducting surveys to identify specific sources of dust or for conducting compliance sampling. Direct reading instruments include light scattering devices such as the RAM, the TEOM (tapered element oscillating monitor), or older instruments such as the "beta-gage." Some of these instruments also use a cyclone to separate the non-respirable portion and in these instances, use of the metal rather than the nylon cyclone to reduce charge effects would be a positive development. The obvious advantage of a direct-reading instrument is that it provides information at the time and place where it is needed rather than two weeks later, thus facilitating identification of sources of dust and more effective controls.

Change in the flow rate (from 2 to 1.7 lpm) and elimination of the 1.38 MRE correction factor seem to be changes in the right direction. A change in the flow rate would bring coal mine dust sampling in line with sampling for industrial aerosols used throughout the U.S. Elimination of the correction factor would simplify the interpretation and analysis of data.

However, additional experimentation is needed to insure comparability of measurements over time. We need not duplicate the problem the British had when they converted from particle counts to gravimetric measures. When they (and we, in the U.S.) did so, they lost the utility of valuable historical data. If we change from the current sampling method, calibrated to the MRE data and do not insure continuity, we could similarly render much data useless. Therefore, I suggest experimental analysis of four samplers running side by side in the same environment in a lab and in a mine. The four instruments would be the current pump run at 2 lpm, the MRE instrument, a third and a fourth running at 1.7 lpm one with a metal, the other with a nylon cyclone.

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 strategy is reasonable on the basis of statistical validity. The steps taken to increase the precision of sample analysis -- changing the flow rate, use of the metal cyclone, reducing errors introduced with robotic weighing, and rounding off values rather than truncating -- all validate (1) determination of compliance for operator samples and (2) the use of single MSHA samples for issuing citations if exposure exceeds the lower confidence limit of the PEL.

Current practices of issuing citations based on truncated averages of operator samples or if a single MSHA sample exceeds 2.5 mg/m^3 are insufficiently protective of miners and are not, to my knowledge, sufficiently validated statistically, as the Mine Act requires that they be.

The sampling strategy is a partial solution to a practical problem not described in the document. While NIOSH referred to the MSHA task force on dust sampling, the situation that prompted this task force was not mentioned. That situation was the documentation of wide-spread fraud and tampering of dust samples by mine operators and their agents.

The more fundamental problem inhibiting a valid dust monitoring program is not technical, it has to do with the organization of the program. Recent and numerous convictions of mine operators for fraud and for tampering is ample evidence that

the program is vulnerable to fraudulent practices. An invitation to fraud is built on two pillars. The first is that mine operators are given wide and unsupervised discretion to manage sampling. The second is that the very samples that operators take are the principal means for determining compliance with the PEL.

The proposal in NIOSH's report -- to have mine operator take "compliance samples" for the purpose of controlling exposure -- removes one important pillar. By relieving mine operators of the responsibility for taking samples that would be used to make compliance decisions, there is less of an incentive to perpetrate fraud.

Having MSHA determine whether a standard had been violated seems sensible also. With improved precision and accuracy of the sampling device (due to technical changes in the sampling unit and due to a generally higher level of expertise among MSHA inspectors when compared to a mine operator's certified person) the confidence limits are smaller and consequently, MSHA could more easily issue a citation based on exceeding the exposure limit determined by a single sample. Current practice is for MSHA to issue citations based on a single sample only when exposure is documented at 2.5 mg/m^3, 0.5 mg/m^3 above the current exposure limit. MSHA could, according to the Mine Act, issue citations based on a single sample if the exposure itself were violated.

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

Yes. COPD is, <u>in part</u>, caused by exposure to mine dust. Spirometry is the best measure of COPD suited for medical screening. In is inexpensive, not requiring expensive equipment (such as an x-ray machine) and informative. COPD includes both chronic bronchitis and emphysema. Chronic bronchitis is, to some extent reversible with cessation of exposure and development of emphysema probably could be arrested. Thus, spirometry satisfies some important requirements of a useful screening test. (See Weeks, et al., 1992, p 24-30) Therefore, inclusion of spirometry in medical monitoring may yield positive results, perhaps more positive than use of the chest x-ray. If use of spirometry followed with improved dust exposure can aid the reversal of chronic bronchitis and can arrest development of others, on this basis alone, it would be an improvement over the use of the chest x-ray whose aim is merely to halt progression of CWP.

A potential but solvable problem, however, is the distribution of spirometers and trained technicians in coal mining communities. An effective monitoring program using

spirometry would requires some sort of certification analogous to that already provided for chest x-ray facilities.

7. Is the transfer of miners with evidence of CWP or COPD to low dust areas of the mine medically justifiable at the recommended concentrations of respirable mine dust or respirable crystalline silica?

The answer to this question is unknown. The use of the chest x-ray with transfer to less dusty areas appears to have marginal benefit. This is due to several factors: low participation in the x-ray surveillance program, a low proportion of miners exercising their option to transfer, and goal that is difficult to measure (i.e., halting progression of CWP). In addition, there is considerable variation in interpreting chest x-ray films. In short, there are small numbers used to measure subtle changes using a blunt instrument. Under the proposed plan, with dust exposure in the dustiest jobs reduced by half, it could be even more difficult to measure any benefit. Even so, it is intuitively sensible to reduce the exposure those persons that have early signs of CWP.

For COPD, the situation is quite different. First of all, as mentioned above, some aspects of COPD are reversible upon cessation of exposure. That is, the objective can be to actually improve one's clinical status rather than merely halting progression. Second, spirometry is a more objective measure of lung function than is the chest x-ray of lung anatomy. Third, however, COPD is also caused by smoking so that benefits from removing a miner from exposure to dust could be reduced or eliminated unless the miner can be persuaded to stop smoking.

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

Doubtless, there are. This could include considering the feasibility of using spirometry, including developing (or adopting ATS's) standards, and certification of facilities and technicians.

EDITORIAL COMMENTS on the RECOMMENDED STANDARD.

The opening sentence of this recommended standard recognizes, as it should, that occupational exposure to coal mine dust causes several respiratory diseases rather than a single disease. These diseases include coal workers pneumoconiosis (CWP), chronic bronchitis, and emphysema, the latter two often

encompassed in the generic term, chronic obstructive pulmonary diseases (COPDs). (The plural form of COPDs is noted.) This is a welcome development because it makes explicit that breathing coal mine dust affects miners' lungs in more ways than are apparent with the chest x-ray.

It is also welcome because of the precise use of terminology. This second point requires some explanation. Throughout the history of attempts to prevent "black lung" and to compensate persons disabled by it, many important questions have depended on definitions of terms. Terms that have been subject to intense scrutiny include "pneumoconiosis" and "miner," for example. In the course of debates, scientific documents, such as this one, have been invoked to buttress one side or another. Therefore, I consider it very important to be careful, explicit, and consistent in the use and definition of terms used in this and related documents and to use terms that serve our purpose -- which is to prevent occupational lung disease among coal miners. Therefore, I recommend that certain terms in Section 1.1 be defined and used carefully.

Specifically, I suggest the following:

1.1.1 The definition of a miner should include persons who are <u>not</u> currently employed as miners (as defined) but who, at some time past, had worked in a mine and thus were exposed to mine dust. The reasons to include this population arises from two important features of most occupational lung diseases caused by dusts: they are irreversible and chronic. Thus, a person in retirement or otherwise not working as a miner could have occupational dust diseases and not be a "miner" under the proposed definition even at the same time that he (or she) was subject to the intent of this standard. Therefore, I suggest that "miner" refer to, in addition to those definitions enumerated, add "or (4) was employed as a miner at some time past." I would not, however, expect a mine operator to provide a medical surveillance services to miners who have retired but I would expect an operator to provide services to miners who were temporarily not employed due, for example, to temporary illness or disability, layoff subject to recall, labor dispute, or similar situations in which a miner was temporarily not employed as such.

1.1.3 There are innumerable nits to pick in this paragraph. For example, the ILO scheme classifies chest x-ray films on size, shape, and profusion of opacities and not on profusion alone. Classification of films based on profusion includes normal, simple, and complicated pneumoconiosis rather than for simple pneumoconiosis alone. The twelve point scale is not a twelve point interval scale but rather a three-class ordinal scale (normal, simple CWP, and complicated CWP) with fuzzy boundaries. Rather than refine this definition, I suggest eliminating most of

it and adopting the ILO definitions by reference to the latest ILO document.

Other definitions that should be added include "pneumoconiosis," "coal workers' pneumoconiosis," "silicosis," and "coal mine dust." These are terms that refer to fundamental and generic concepts of outcome and exposure.

I suggest that NIOSH not define "pneumoconiosis" because it is already defined in the Mine Act and in Regulations in ways that are not entirely satisfactory to scientists. Rather than fight this issue, I suggest ignoring it altogether and defining the terms "coal workers' pneumoconiosis" or CWP and "silicosis" instead.

For CWP and silicosis, I suggest adopting or incorporating by reference, a definition taken from a standard medical text and adding, for clarity's sake, the proviso that in practice, the definitions of CWP and of silicosis depend on results of a biopsy, autopsy, or, most often, the interpretation of a chest x-ray film combined with a history of exposure. This focuses attention on the what I believe is the common practice of referring to interpretation of the chest x-ray film as the definition CWP or silicosis. And it makes it possible to refer to COPDs as distinct and different entities that are caused by exposure to dust rather than caused by CWP or silicosis. CWP and silicosis are effects, not causes.

In such a definition, there should be no reference to "impairment" or "disability" connected with a diagnosis of either CWP or silicosis. "Impairment" is a measure of limitations on a person's normal range of physical activity that is caused by exposure to dust, and "disability" is a term left for the lawyers to masticate. Interpretation of the chest x-ray measures lung anatomy, not impairment.

"Coal mine dust" requires a definition as well both to be precise about whether referring to respirable or other dust and to be precise about exposure to silica. The current term, "respirable dust," (in 30 CFR 70.2(n) refers neither to mining, nor coal, nor to anything medical. It defines respirable dust as ". . dust collected with a sampling device approved by the Secretary [of Labor] and the Secretary of Health and Human Services [i.e., NIOSH." This is a bureaucratic definition, not a scientific one.

I suggest defining "coal mine dust" as a mixed dust found in coal mines. It contains particles of coal and may contain any of several other mineral species including kaolinite, illite, calcite, pyrite, and silica as described later in this document at 3.1.1. "Respirable" dust refers to the fraction of coal mine dust that can penetrate to the portions of the lung where gas

exchange occurs (where one stage of respiration occurs, hence, "respirable"). I suggest that it is more precise to refer to exposure to "coal mine dust" (as defined) rather than to "respirable dust" (as defined) as the cause of CWP, silicosis, and COPDs. (NIOSH's proposal of adopting the new international consensus definition achieves the same purpose.)

With these terms defined, we can systematically refer to using the chest x-ray as a monitor of the occurrence of the uniquely occupational diseases (CWP or silicosis) and to measuring exposure to respirable coal mine dust as the dust most precisely known to cause them. And it makes for a clearer (I hope) discussion of COPDs and their likely cause, the less precise "coal mine dust." Considering that COPDs include disorders of the large airways of the lung, it is reasonable to suspect that the cause would include coal mine dust including the full range of particles by size, specifically, thoracic dust. Incidentally, I suggest that the title of the document refer merely to coal mine dust rather than <u>respirable</u> coal mine dust.

1.1.6. The definition of coal preparation facilities should be separated from the definition of surface work areas of an underground mine. Some prep plants are facilities that process coal from either surface or underground mines and some are quasi-independent entities. A definition should reflect these factors.

Since the term "engineering controls" is introduced later (1.2.1), it should also be defined. This definition should refer to any of the usual techniques for reducing the generation or dispersion of dust. These include variations in coal cutting methods, ventilation, and the use of water. It would <u>not</u> include the use of respirators or administrative controls such as rotating workers out of dusty jobs.

1.2.1. Prevention of CWP and of COPDs are appropriate goals of setting an exposure limit. But it should be recognized that by controlling exposure to mine dust, it is possible to prevent CWP entirely but it allows one to prevent only that portion of COPDs that are caused by inhaling coal mine dust. COPDs are, as is recognized in the document, also caused by non-occupational exposures.

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References:

Attfield MD. British Data on Coal Miners' Pneumoconiosis and Relevance to U.S. Conditions. Am J Pub Health 82:978-83. (1992).

Attfield MD and Morring K. The Derivation of Estimated Dust Exposures for U.S. Coal Miners Working Before 1970. Am Indu Hyg

Assoc J. 53:248-55 (1993).

Attfield MD and Morring K. An Investigation into the Relationship Between Coal Workers' Pneumoconiosis and Dust Exposure in U.S. Coal Miners. Am Ind Hyg Assoc J. 53:486-92 (1992).

Flinn RH, Seifert HE, Brinton HP et al., Soft-Coal Miners' Health and Working Environments. U.S. Public Health Bulletin 270, 1941.

Sayers RR, Bloomfield JJ, Dalla Valle JM et al., Anthraco-Silicosis among Hard-Coal Miners. U.S. Public Health Bulletin 221, 1935.

Weeks JL, Levy BS, and Wagner GR, eds. Preventing Occupational Disease and Injury. Washington, DC: American Public Health Association, 1991.

U.S. Bureau of Mines. How Twelve Continuous Miner Sections Keep Dust Levels at 0.5 mg/m^3 or Less. Technology News. No. 220, July, 1985.