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August 19, 1993

Richard Niemeier, Ph.D., Director
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Dear Dr. Niemeier,

Thank you for the opportunity to review NIOSH's Criteria Document for Occupational Exposure to Coal Mine Dust. The document represents a very substantial review of the literature and thoughtful recommendations for this challenging problem. You and your staff deserve praise for your efforts. I have identified a number of issues that I believe need further consideration and these are detailed on the attached review.

Sincerely,

Noah S. Seixas, Ph.D.

Review Comments on NIOSH's
Criteria For A Recommended Standard
Occupational Exposure To Respirable Coal Mine Dust

Submitted by
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August 19, 1993

General

The document needs editing and condensing. There is an overabundance of background material which is unnecessary for the development of main tenet of the document. A more focused presentation of the relevant background material would provide a more effective case for the recommended exposure standard. Furthermore, the organization of the document should be improved so that the same material is not presented and discussed several times as is currently true. The redundancy of the presentation makes understanding of NIOSH's interpretation of particular issues very difficult.

There are numerous errors in the cited references (citations in the text do not exist in the reference list; references in the list are not cited in the text; reference dates are incorrect) and need to be carefully checked.

Epidemiology of COPD

On page 94 references is made to "Seixas et al. 1992, 1991a,b but in the reference list there is only one 1991 citation. The 1992 reference (Am J Ind Med 21:715-734) is appropriate for the point made but reference is also required to the longitudinal aspects of this work. This work is contained in my dissertation which may be cited as "Seixas, NS. Dust exposure and respiratory disease in US Coal Miners. doctoral dissertation, University of Michigan, Department of Environmental and Industrial Health, 1990" and is available from University Microfilms. However, the longitudinal aspects of the work are also in press in the British Journal of Industrial Medicine (proofs have been completed and I would expect the article to appear before NIOSH goes to press). A copy of the accepted manuscript is attached.

I don't agree with the interpretation of my analyses given on page 94. You suggest that the reason for a non-linear response observed in these studies is from the kinetics of dust clearance. This hypothesis would suggest that at low lung burdens where clearance is first-order, the response to the dust is greater

than at high lung burdens where clearance may be overloaded and dust accumulates at a greater rate. This would suggest that response is proportional to the rate of clearance, not the rate of dust retention. It is hard to imagine a mechanism through which this hypothesis could work. The alternative explanation which I argued in the paper is that the inflammatory response to dust is greatest during the first period of exposure and less change in response is apparent during later exposure periods. This seems a more plausible explanation of these findings. This explanation is given more play on p170-171 where the same observations are revisited. The self-selection process suggested on page 171 is not plausible given the longitudinal aspects of this work as cited above.

Additional discussion of the striking difference between the estimated loss in my studies (3.39 ml per gh/m3) and the other studies cited in Table 4.9 is needed. I would suggest emphasizing that the cohort that I observed were new miners at substantially younger ages than in the other studies.

On page 172, 6 lines from the bottom I believe this should read FVC rather than FEV1.

The issue of dust overloading is, I believe, overstated. While this is an interesting phenomenon, and may have implications to improving the epidemiology of dust diseases, and perhaps to understanding the mechanism of dust-related damage to the lungs, it is by no means a central requirement for making the argument for a safe exposure level. If anything, the overload mechanism would argue that below some as yet to be identified level or threshold, no damage would result. Since the epidemiology and risk assessments cited in support of a reduced standard make no use of such a threshold model, it could be argued that the models used were inadequate, given the overload hypothesis, and that the risk of disease at these low levels are overstated. I would advocate providing information on the overload of clearance only as general interesting background, and certainly not as part of the rationale for the standard implied by its appearance in section 7.1 (p210).

Particle Size Distributions

On pages 36, 101 and elsewhere reference is made to the potential importance of dust depositing in the tracheo-bronchial region to the development of COPD. While this is a reasonable hypothesis, evidence exists to doubt it. First, the studies that demonstrated differences in particle size distributions (Potts 1990 and Burkhart, 1987) were based on area samples. For the most part the areas which showed large differences were at the extremes of processes that would generate high and low mean diameter distributions such as intake airways (large particles have settled and the distributions are very small)

compared to downwind of the shearer where the freshly cut and entrained coal and rock would have large particle sizes.

For addressing the potential impact of particle size distributions on disease, personal samples are much more relevant. We have produced data with personal samplers that show that average distributions are similar between a variety of different underground jobs including both face and non-face jobs, longwall, continuous and conventional sections and in a few mines. These data may be present in the cited memo (Hewett, 1993). The data is also attached in a draft manuscript that has not yet received review and clearance from NIOSH so it is not yet publicly available. If NIOSH would like to expedite its review and include it in this criteria document we would work to ensure its completion and revision.

Further evidence of the lack of importance of tracheo-bronchial exposures to COPD in miners is provided in Mark D, Cowie H, Vincent H, et al. The variability of exposure of coalminers to inspirable dust. Final report. Institute of Occupational Medicine, Edinburgh EH8 9SU, January, 1988. (The reference given on page 101 as Mark et al, 1981 does not exist in the reference list.) In this study, personal samples were taken and particle size distributions estimated for various jobs in underground British coal mines. While the ratio of respirable to inspirable dust varied, there was little evidence of variation in the smaller dust fractions including tracheobronchial. These authors concluded that respirable dust should be adequate for predicting obstructive lung disease in miners.

Reference "CEN 1990" given in Table 5-1 on p 114 is not in the reference list.

Sampling Methods and Strategy

I do not follow the discussion of truncation bias on p 129. In the middle of the page, the error is described as a saw-tooth falling from 0 to -1 between each integer with the expected bias as -1/2. I believe the expected error is -0.05 since the truncation is to the next lowest 0.1 value. Furthermore, the statement that "The bias cancels the difference between two such independent truncated numbers..." is either misleading or false. The expectation of the difference between two parameters that are biased in the same direction (-0.05) has the same bias (-0.05). Despite this criticism, I agree with the recommendation that the analytic results be rounded rather than truncated to increase precision.

I am quite concerned about NIOSH's recommendation to remove compliance decision making from operator-collected data. While this approach has the advantage of discouraging data or sample tampering, it puts a greater reliance on inspector compliance activities. Since individual high operator samples may still trigger a compliance inspection, it has not completely avoided the tampering incentive. More importantly, this strategy will only be effective to

the degree that there is sufficient, in fact increased resources for compliance inspection activities. Given the general mood in the country for decreasing government activities, and especially regulatory activities, I am not sure such support can be expected. The recommendation that inspections be required 6 times per year per mine is inadequate given that some mines contain many MMUs - only one of which can be visited on an individual day. I would increase this requirement is six times per year per MMU. I believe this may be a substantial increase over current MSHA inspection activities and may not be economically (or politically) feasible.

A further problem with removing compliance from the operator sampling program is that it may make the operator sampling appear irrelevant or unnecessary in the minds of some operators. Since the ability for adequate monitoring of dust control and the ability to do risk analyses relies on the quantity of data that only the operator can collect, the strength of the dust monitoring program may be undermined. In particular I would be concerned that in developing the regulations the importance of operator sampling would be significantly under-represented and perhaps even eliminated from activities required of mine operators.

On the bottom of page 136 the text states that a DO is an area sample: this is incorrect.

Sentence 1 of #1 (p 141) should be separate from the rest of that paragraph. The contents of the written plan must be specified. For instance, I would require the inclusion of a report of all sampling results from that MMU.

The description of the initial monitoring survey requirements on the bottom of p 141 is very mushy and needs to be highly specific. "A sufficient number of samples," "all miners," and "miners who are potentially exposed" are not adequately defined.

The general point is made in several places that the monitoring strategy is not adequate for assessing the mean exposure levels. I disagree in that the data generated by the biweekly samples on the DO will provide information about any parameter of the exposure distribution for that occupation. What is missing is any information (mean or otherwise) on all other occupations in the mine.

The document acknowledges this limitation of the proposed sampling strategy in reducing the quantity of information on miners other than those in the DO and therefore limiting the utility of the data generated for future epidemiologic analyses. This is a major limitation and should not be overlooked, especially by NIOSH which is charged with ensuring adequate information on occupational risks.

One way to remedy this limitation would be to expand upon the concept of sampling in the NDE. The required sampling for the NDE should more specifically address the need for general exposure information. I would consider adding the NDE to the list of required biweekly samples, and expand the requirement to 2 or 3 NDEs. The removal of the NDE sampling requirement after 2 consecutive samples below the standard entirely defeats this advance and should be removed. I would recommend developing a list of occupations other than the DOs which would be assigned as NDEs on a rotating basis. For instance, identify the 50 most common occupations in underground mines and require that each of them be sampled a minimum number of times per year as NDEs. Over time, the resulting data would provide information about the exposure distribution in all areas of the mine, and would provide the basis for epidemiologic risk analyses on a population basis. The information generated would also be useful to the mine operator in considering the adequacy of exposure controls in all parts of the mine.

Although the DO is appropriately designated on the basis of the highest expected concentration of coal dust, there is inadequate provision in the sampling strategy to ensure that miners with the highest potential silica exposure would be regularly sampled. I would suggest adding Roof Bolter as a second DO in each MMU.

Although the 95% confidence limit test for noncompliance makes sense in justifying a citation, I would strong advocate removing section 5.1.5.4.2 concerning the operators test for compliance. The proposed strategy makes a significant contribution to industrial hygiene practice by requiring employers to gather exposure data in order to quantify exposure and monitor the adequacy of control measures without directly tying the activity to compliance decision-making. The inclusion of the significance test comparing individual operator-collected samples to the standard weakens this advance. Furthermore, the test cited refers to an individual sample. By requiring biweekly sampling activities, over time, the operator will have sufficient information on a particular MMU to consider the distribution of exposures and calculate the probability of a sample being greater than the standard. This type of analysis would be a great advance in the scientific interpretation of sampling data and should be promoted by NIOSH where possible.

Adequacy of the proposed standard

I support NIOSH's analysis demonstrating that there is an excess risk of significant disease at the current standard and that a lowered standard is indicated. However, I don't believe NIOSH has demonstrated that the standard chosen represents, in any rigorous fashion, an acceptable target risk level. Although the cited epidemiology and risk assessments clearly demonstrate risk, the development of an integrated "best" curve for the development of PMF, CWP and specified degrees of respiratory impairment,

would greatly enhance the recommendation. With such a set of curves, one could identify the expected benefits of each increment of exposure reduction.

Technical Feasibility

I am unconvinced by the argument set forward that the recommended standard is technically feasible. On p 216 it cites the overall means from the MSHA sampling program and notes that numerous individual mines were able to keep average dust concentrations below 1 mg/m3 at least 50% of the time. This does not suggest that the standard is feasible. In fact, given the large variability in dust concentrations and the general lognormality of the data, the mean concentration must be significantly lower than the standard to control the probability of an individual sample being higher than the standard. The >50% of samples being less than 1 mg/m3 is a reasonable expectation for controlling dust under a 2 mg/m3 standard. To control under a 1 mg/m3 standard, the average exposures will have to be significantly lower than 0.5. If NIOSH rejects the concept of a standard based on a mean exposure over time (and I support that decision) then feasibility has to be judged in terms of the probability of a single exposure being over the standard given a lognormal distribution of stated means and standard deviations. A more quantitative analysis of this issue is given in Rappaport (1984). I believe NIOSH should produce a more rigorous analysis of the feasibility of dust control to the proposed REL based on engineering solutions.

Controls

NIOSH recommends the use of respiratory protection as stated in the proposed standard (p13) and as a response to single exposures over the standard (p142,143). This recommendation appears to stem from generic NIOSH policy and is inadequately supported for the particular environment of coal mines. First, work in mines is often in crowded and difficult conditions and may require very good visibility and ability to quickly react to suddenly developing dangerous situations. The use of respiratory protection can impede the wearers' ability to see or to adequately maneuver to avoid a dangerous condition, especially in crowded or confined spaces. Second, mining often requires hard physical labor and the use of respiratory protection may put an undue added strain on individuals respiratory and cardiac systems. Finally, if respiratory protection is actually used only as an interim control while feasible engineering controls are instituted, then there is no evidence to suggest that a short term exposure near the REL would present any substantial risk to anyone.

The lack of risk for short term exposures is particularly pertinent in reference to the sampling strategy (p142-143) where NIOSH recommends respiratory protection as a response to a single sample over the REL. This is clearly an inappropriate response and may be counter-productive. Miners may see the

issuing of respirators as a punitive measure, thus making their participation in an effective sampling program unlikely. Changing the wording to suggest that respirators should be made available would not be appropriate since respiratory protection should always be available to miners who want it.