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September 13, 1993

Richard W. Niemeier, Ph.D.
Director, Division of Standards Development and Technology Transfer
Department of Health and Human Services
Centers for Disease Control
National Institute for Occupational Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati, Ohio 45226-1998

Dear Dr. Niemeier,

I am writing to provide comments on the NIOSH draft document entitled *Criteria for a Recommended Standard: Occupational Exposure to Repirable Coal Mine Dust.* Because of time constraints and the limits of my expertise, my comments will be limited to those aspects of the document related to epidemiology and medical surveillance.

Overall Comments

1. Derivation of the Recommended Exposure Limit (REL): The proposed REL is based on model estimates from epidemiologic studies. The best and most relevant evidence is used and the rationale for choice of the studies is adequately described. There is an attempt to supply a biologic basis for the choice of the model. As acknowledged, no-threshold models are used and some risk will be projected for any exposure. The use of the models would be bolstered by a more formal assessment of uncertainties. Tables 7-2 and 7-3 present only point estimates without confidence limits; ranges related to sources of uncertainty other than sampling are not addressed. Thus, Tables 7-2 and 7-3 convey an unrealistic sense of certainty. This aspect of Chapter 7 should be expanded to more clearly set out assumptions and associated qualitative and quantitative uncertainty.

2. Medical Surveillance: I do not disagree with the proposed medical monitoring strategy. I just find it to be poorly justified. Monitoring has the

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dual purpose of identifying pneumoconiosis and the early stages of obstructive airways diseases. The latter is new ground and a difficult undertaking. The document fails to consider literature on patterns of lung growth and decline and on numbers of measurements and intervals needed to estimate decline. The 15% criterion derived from ATS may prove problematic in its application to individuals with asthma or increased airways responsiveness who may have quickly varying lung function. Individual clinicians will need more guidance on the application of this screening approach.

Specific Comments

1. Page 8, paragraph 1.4.1.2: The present NIOSH training is not consistent with ATS 1987 recommendations.
2. Page 11, section 1.5: How will smoking/smokers be handled? I would anticipate that some workers who smoke will have accelerated decline, absent significant dust exposure. Will transfer be mandated?
3. Page 66, first sentence: The primary histopathological lesion...
4. Page 67, section 4.1.1.3: Are you sure that it is deposition on the alveolar walls?
5. Page 70, section 4.1.1.2.1.: This paragraph provides a confused definition of COPD; the term refers to clinically significant chronic airflow obstruction.
6. Page 72, section 4.1.1.2.2.: Confused terminology in regard to chronic bronchitis. It is only chronic sputum production.
7. Page 97, first paragraph: How long were these men not underground when studied?
8. Page 98: The concept of "effect modification" is not handled with sufficient understanding. "Interaction" is scale dependent. The analysis done by Marine was on the multiplicative scale and additivity should be considered in this context.
9. Page 102, section 4.2.1.: Can the material on overloading be better developed? Its relevance is not made sufficiently clear. Would it alter exposure-response relationships? Does it represent an uncertainty in extrapolating from higher to lower doses?
10. Page 109, last sentence: A very simplistic statement on lung dosimetry.
11. Page 171, first sentence: What is meant by "adjust"? What underlying mechanism could be involved?
12. Page 171, section 5.2.5.2.: This is a limited and poorly referenced discussion of COPD.

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I hope that these brief comments are helpful.

Sincerely,

Jonathan M. Samet, M.D.
Professor of Medicine

JMS:bvb