



COLLEGE OF MEDICINE  
DEPARTMENT OF COMMUNITY AND  
ENVIRONMENTAL MEDICINE

IRVINE, CALIFORNIA 92717

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August 16, 1993

Richard W. Niemeier, Ph.D.  
Director, Division of Standards Development  
and Technology Transfer, NIOSH  
Robert A. Taft Laboratories  
4676 Columbia Parkway  
Cincinnati, OH 45226-1998

Dear Rick:

This is my follow-up letter on the criteria document for respirable coal mine dust, following the peer review meeting in Cincinnati on July 29-30, 1993. I thought the peer review panel was very good and that Eileen Kuempel handled her role extremely well. It was a very worthwhile meeting.

I had many comments about the document which I did not think were appropriate at the meeting, but I will make them now, for whatever use you and Eileen and your staff wish to make of them. Rather than try to make a logical outline of comments, I will make them in the order of the pages on which they occur. Finally, I will respond to some of the questions which you posed to the panelists.

Pg. iv, section 5

The title of this section is "Recognition of the Hazard" - the substance of section 5 is much more than "recognition," so the title should be broader, for example "Recognition and Quantification of the Hazard."

Section 5.2

Because of the frequent confusion of medical screening and medical surveillance, I think the title of this item should be broader, for example, "Medical surveillance and screening".

Pg. v

The Black Lung Program is listed (pp 188-193). I think material on the Black Lung Program is of some general interest but I do not see any relevance to the criteria document. I think the whole portion should be omitted.

Also on pg. v is the title "Methods for Protecting Coal Miners." I think the title should be more specific. Hopefully miners will be protected from respirable dust hazards but the document says nothing about other major hazards to coal miners (as it shouldn't).

Pg. vii

I do not see why abbreviations should not include BOM, EIA, and NTIS.

Richard W. Niemeier, Ph.D.  
August 16, 1993  
Page 2

Pg. xi, line 12

I believe J~~a~~cobson should be spelled Jacobsen

Pg. 8

I note that the Goldman *et al* reference is not in the bibliography. The reference is Goldman RH, Peters JM. The Occupational and Environmental Health History, J.A.M.A. 1981; 246:2831.

Pg. 21

A figure on fatality rates for miners 1959-81 (reference in text on pg. 20). I noted that Dr. Gibbs questioned the data at the peer review meeting, and I do not believe the reference is germane to a criteria document on dust.

Pg. 22

Is reference to a newspaper article (Daykin 1991) the best reference available on the accuracy and reliability of the coal mine dust sampling program?

Pg. 25

The discussion of the transfer option is confusing. There was considerable discussion of the transfer option at the peer review meeting, so I assume this topic will benefit from rewriting.

Pg. 26

There is discussion of high risk groups of miners, but no mention is made of tobacco smoking or other factors that may increase susceptibility to coal dust (eg other lung diseases, hyper-reactive airways).

Pg. 34

The labeling of the figure seems incomplete.

Pg. 53

In Table 3.8, the labeling of the 1991 column is incorrect (should be mg/m<sup>3</sup>).

Pg. 59, line 10

Replace "is" by "are."

Pg. 66

Cotes and Steel (1987) reference is not in bibliography (also quoted on pg. 67, pg. 69 and footnote in table on pg. 70).

Pg. 67

Last paragraph - the sentence "The rate at which silicosis develops can vary." As stated, this is too obvious to require saying.

Pg. 71

The whole discussion and fig. 4.1 are in my opinion too speculative and not clearly relevant to criteria document.

Richard W. Niemeier, Ph.D.  
August 16, 1993  
Page 3

Pg. 73, line 13

The referēnces are Olofson *et al* and Silver, Hattis and Attfield (not Silver and Hattis)

Pg. 75

There are problems in the table (4.3) Medium rank H is identified with Northern West Virginia. The title of the article referenced mentions only Western Pennsylvania.

Note 4. has a misspelling - "nort" for "not". Reference C should be Lieben *et al*, not Lieken *et al*.

Pg. 78

References to Attfield and Moring 1992a and 1992b. These are not identified in the bibliography (found also on pages 80 and 81.)

Pg. 83

There is a reference to a "study commissioned by NIOSH." Why is this specified? I believe it is the only time a sponsor is mentioned in the whole document.

Line 10 - shouldn't 2 mg/m<sup>3</sup> be  $\leq$  2 mg/m<sup>3</sup>?

Pg. 84

Middle of 2nd paragraph "profusion of irregularly shaped opacities was related to coal mine dust."

Pg. 85

3rd paragraph. The Castellan . . . study may be biased toward low values . . . , while the Epstein . . . study may be biased toward high values . . .

Pg. 87, line 10

Is an NTIS reference considered equivalent to a (peer reviewed) journal publication? (Amandus 1983). In same paragraph are further references to "Silver and Hattis (1991)" and Attfield and Moring 1990b.

Pg. 95, line 24

What is meant by a "quantified pathology study?"

Pg. 96 line 3

It should be centriacinar.

It is not clear to me that the item 4.1.2.2.5 Clinical significance of dust related loss of lung function serves any useful purpose in a criteria document.

Pg. 98

(last paragraph) It is stated that the "effects of cigarette smoking and exposure to coal mine dust are similar and additive." What does "similar" mean in this context - of equal toxicity, involving the same pathophysiologic mechanisms, or what? (Essentially the same statement is made elsewhere.)

Richard W. Niemeier, Ph.D.  
August 16, 1993  
Page 4

Pg. 100

Legend of Fig. 4.7, "geographic" is misspelled.

Pgs. 102-104

I agree with Dr. Vincent that the overload hypothesis is overemphasized, to the exclusion of alternative hypotheses.

Pg. 113

Dr. Lippmann's name is misspelled three times.

Pg. 115

(first paragraph) I believe the word "magnetopneumography" is misused. Albert and others used radioactive particles to study clearance and retention, but David Cohen and others used powerful magnetic fields to study clearance and retention of non-radioactive particles, with very different measurement methods.

The Philipson *et al* and Buhning *et al* references are not in the bibliography.

In the last sentence, whatever is meant by "clearance is difficult" should be restated with words less subjective than "difficult."

Pg. 164

Reference is made to a standardized respiratory questionnaire, but this questionnaire (Appendix A) requests no information about smoking habits or history.

Pg. 165

Under reference to medical surveillance procedures is a statement about medical screening. The differences between surveillance and screening need to be kept in mind more clearly.

Pg. 169

On this page is a discussion about periodic medical examinations, the problems with voluntary participation, and the possibility of making them mandatory. Should not NIOSH make a recommendation on this, presumably involving a change in the law?

Pg. 170

line 6 - same problem I mentioned earlier about "similar" changes in smokers and non-smokers

line 10 - does item 3 refer to non-smokers only or to all miners? I think items 1-4 encompass too many different ideas to be included in one sentence.

line 21 - presumably "examiners" should be ex-miners. I think the quotation from Becklake (1985) is unclear as to its relationship to issues previously discussed.

Pg. 171

line 1 - would "adapt" be a better word than "adjust"?

The reference to Petty 1988 is not in the bibliography.

Shouldn't 5.3.5.3 include the words "medical screening and surveillance"?

Richard W. Niemeier, Ph.D.  
August 16, 1993  
Page 5

Pg. 172

line 5 - I think it would be preferable to say "PFTs are tests of specific functions."

line 15 - pleural pressure is spoken of as if it were an independent force, like the force of the lungs elastic recoil. Pleural pressure is a passive reflection of the balance of two forces - the elastic recoil of the lung tending to empty itself and the force of the thorax tending to enlarge. Pleural pressure also reflects resistive forces and the large forces that can be developed by expiratory muscles in the thorax and abdomen.

The Higgins and Keller 1973 reference is not in the bibliography (incidentally she is not the same Higgins as in the other Higgins references in the same sentence).

Pg. 175

(1st paragraph) both references to Theriault should be Theriault *et al*.

Pg. 176

A graph which is still to a large extent hypothetical. Is it relevant to this CD? If the source is Peto *et al* 1976, why not quote the original paper?

Pg. 179

Reference to Samet 1992 is not in bibliography, nor is Samet 1989 on pg. 181.

Pg. 184

(Next to last line) I think it should read "ventilation and perfusion ratios."

Pg. 187, line 2

DLCO measurement is indicated.

Pg. 205

(Next to last line) There is a reference to "recent allegations" - I think a statement like this needs to be documented with references. Also, what is "recent"?

Pg. 211

I do not think that the table is adequately described. It was discussed extensively at the peer review meeting.

Pg. 310

I have not systematically reviewed the bibliography. However, I note on this page that CHERNIAK is spelled incorrectly (CHERNACK).

Pg. 319

The Hutchinson reference includes a misspelled work (detecting, not defecting).

Richard W. Niemeier, Ph.D.  
August 16, 1993  
Page 6

With regard to the questions posed to the panelists, some are very specific and others are impossible to answer without qualifications or reservations.

Is the Recommended Exposure Limit supported by the scientific data? There is substantial evidence to support the proposed change. However, taking into account the wide variability of coal dust and the rock dust with which it is mixed, it is difficult to believe a single standard is appropriate to all underground miners or to all methods of mining. Nevertheless, multiple RELs would be very difficult to administer.

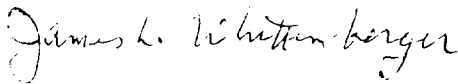
Are the proposed RELs technically feasible? There was substantial evidence at the meeting that this question needs further study.

Is the inclusion of spirometry tests in the medical surveillance program justifiable? I believe it is, and I did not hear any contrary opinions at the meeting.

Is the transfer program medically justifiable? There is so little evidence of benefit that it is not medically justifiable, but I think the program serves a useful political purpose.

As to other issues that need further consideration, I think the value of the medical surveillance programs (including the periodic examinations that are primarily for epidemiologic study purposes), is so great that serious additional efforts should be made to increase participation, including the possibility of changing the law to make periodic examinations mandatory.

Sincerely,



James L. Whittenberger, M.D.  
Professor Emeritus