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Comments, from on a draft document dated June 14, 1993 and titled:

CRITERIA FOR A RECOMMENDED STANDARD:

OCCUPATIONAL EXPOSURE TO RESPIRABLE COAL MINE DUST

1. The purpose of the draft document is "to develop strategies for preventing occupational respiratory diseases among underground and surface coalminers". The following comments are in response to a request to review the draft with a view to determining whether all relevant literature has been considered and whether the interpretation of the data and the recommendations are supported by the analyses presented. In particular, comments were solicited on seven specific aspects of the document. These matters, among others, are addressed in paragraphs 4 through 19, below.

Overview

2. The draft document refers to many published reports of effects on health of exposure to respirable coal mine dust. It concentrates particularly on quantitative estimates of risks to health implicit in current, and proposed more stringent, respirable dust exposure limits. It suggests some changes to current statutory requirements for monitoring dust levels underground and at surface coalmining operations, and it recommends modifications to current regulations regarding medical surveillance of coalminers. The effect of the latter recommendations would be to include pulmonary function testing in the medical

examinations, to extend the opportunity to participate in the medical surveillance scheme also to coal miners working above ground, and to ensure that all working coal miners are offered a medical examination once every three years.

3. The text is arranged in eight chapters and there are seven appendices.

The main recommendations are outlined in chapter 1.

An introductory chapter (2) defines the objectives of, and statutory authority for, the document.

Chapter 3 outlines information on mining methods, physico-chemical properties of coalmine dusts, the number of workers potentially exposed to those dusts in the USA and occupation-specific patterns of exposures reported during the past two decades.

Chapter 4 begins with a description of respiratory diseases associated with exposure to coal mine dust. Epidemiologic studies that demonstrate relationships between exposure to dust and effects on the health of miners are then considered in detail. A final section discusses the possible relevance of reports that differentiate between (a) miners' *exposures* to the dust in the air that they breathe and (b) the resulting effective *dose* of the inhaled dust that may damage their lungs.

Chapter 5, titled RECOGNITION OF THE HAZARD, is divided into three main sections. The first discusses dust sampling instruments and strategies and proposes modifications to current mandatory procedures for measuring, and for monitoring compliance with regulations on, coal miners' exposures to dust. The second section outlines objectives for medical surveillance and screening of workers in general and then details recommendations to modify the existing Coal Workers' X-ray Surveillance Program. The chapter concludes with a tabular resumé of 18 years' statistics relating to the Black Lung Program.

Chapter 6 recalls the background to the current US standard for respirable coal mine dust and compares that standard with those recommended and adopted in some other countries.

Chapter 7 ("ASSESSMENT OF HEALTH EFFECTS") identifies the epidemiological studies from the USA and Britain that were used as the basis for the new Recommended Exposure Limits (RELs) for (mixed) respirable coal mine dust and for any crystalline silica in such dust. The principal findings from these studies are reviewed and data are summarized as assessments of risks of (a) progressive massive fibrosis and (b) reductions in respiratory function associated with current and recommended dust exposure limits. Reasons are advanced why the RELs should apply not only to coal miners working underground but also to surface miners and other workers who may be exposed to coal dust. The technical

feasibility of achieving the RELs is considered in the context of results from mine operators' and inspectors' sampling of dust during the 1980s, and dust control technology is reviewed.

Chapter 8 records some basic occupational hygiene and administrative principles to help protect coal miners' health and Chapter 9 lists topics that would benefit from further research.

The RELs

4. The rationale for the proposed new, more stringent, RELs for respirable coal mine dust and for the silica content of such dust is presented in chapter 7. As far as coal mine dust is concerned, the argument reduces essentially to an appeal to US and British studies that demonstrate clear exposure-response relationships between respirable coal mine dust and PMF on the one hand, and loss of lung function as measured by the Forced Expiratory Volume (FEV_1) on the other.

5. The key reports cited in this connection (Attfield and Morring, 1992; Hurley and Maclaren, 1987; Marine et al, 1988; Attfield and Hodous, 1992) demonstrate convincingly that enforcement of the new REL, as distinct from the present Permitted Exposure Limit (PEL), would result in some reduction of long-term risks of PMF and of dust-induced lung function losses. However, the arrangement of data that quantify and support this conclusion, In Tables 7-1, 7-2 and 7-3 (pp 206, 208, 211), is not as clear as it might be. For instance:

(a) it is not correct to refer, in Table 7-1, to an estimated 11-year PMF attack rate in a highly selected group (men aged 50 years and with 18% prevalence of simple pneumoconiosis at the start of the period and an average prior exposure to dust already in excess of the maximum compatible with the current US PEL) as an "estimated prevalence of PMF in miners with exposures to respirable coal mine dust similar to those expected at the current MSHA PEL for a working lifetime".

(b) Neither the text, the headings or footnotes accompanying Table 7-2 explain adequately the difference between the two PMF prevalence predictions from US data that are contrasted there; and the reference cited in this context (Attfield, 1992a) is incorrect.

(c) The basis for the predictions in Table 7-3 is obscure since the paper cited in this connection (Attfield and Hodous, 1992) does not provide estimates in the form that they are quoted, and the text (p 210, paragraph 2) does not explain how the estimates were derived. However, the immediately preceding text (p 209, last paragraph) refers back to chapter 4, where results from the studies of dust-related lung function losses, by Marine et al (1988) and by Silver and Hattis (1991), are discussed. It is easy to calculate, from the equations in Table 4 of the paper by Marine et al (1988), numerical estimates of percentages of (British) miners, smokers and non-smokers, who would be expected to exhibit the lung function losses defined in Table 7-3 and under the conditions specified in

the heading to that table. Inclusion of those figures in Table 7-3 would usefully complement those apparently derived from the US study by Attfield and Hodous (1992) and would thus provide additional material for the quantitative assessment of the expected reduction in non-pneumoconiotic health risks associated with the REL. Some discussion of the magnitudes of those estimates, in contrast to those associated with abandonment of the smoking habit, would be appropriate here.

Tables 7-1 to 7-3 should be revised carefully, with more attention to clear and accurate explanation in the accompanying headings, notes and text of precisely what the figures quoted represent and how they were derived.

6. The REL for respirable crystalline silica dust is defined in section 7.1.3 (pp 202/203) but no argument is advanced in that single paragraph to support the recommendation. This omission should be repaired. Earlier in the document (pp 81/82) there is reference to results from the National Coal Workers' Autopsy Study. These indicate that significant proportions of deceased coal workers whose next-of-kin asked for autopsies in pursuit of compensation claims were found to have silicosis, thus confirming the need for some control of exposures to respirable silica dust among US coal workers. Moreover, reports from Britain, cited on page 83 (paragraph 2), show that even fairly short (4- to 10-year) exposures to respirable coal mine dust with a higher than usual (more than 10%) quartz content are associated with rapid development and progression of simple pneumoconiosis

and with an increased risk of PMF. The implications of these findings with respect to the RELs now proposed might usefully be explored, bearing in mind that one of the British mines, where the quartz-associated rapid progression of simple pneumoconiosis was demonstrated particularly clearly, had very low prevalence of pneumoconiosis prior to the period when the quartz content of the dust increased, and that the concentrations of respirable coal mine dust to which those miners were exposed were less than $2mg/m^3$ on average (Seaton et al, 1981). These results might be interpreted as suggesting that at low concentrations of mixed respirable dust (by past British standards), the free silica content of the dust assumes increasingly greater importance from the point of view of pneumoconiosis risks. It could be argued that this supports the recommendation that compliance with the RELs should be determined separately for concentrations of respirable coal mine dust and for respirable crystalline silica, since the REL for respirable coal mine dust is aimed at ensuring that in the future, concentrations of the mixed respirable dust will not exceed 1 mg/m^3 as measured by the method used in the British research.

7. Section 7.2.1 (p 214) appeals to the reports reviewed in section 4.1.2.1.6 (p 88) to justify application of the RELs, and the associated dust monitoring and medical surveillance program, also to surface miners. That argument is supported convincingly by the studies cited and is further strengthened by the hazards associated with exposures to relatively low concentrations of respirable coal mine dust with a high quartz content (see 6, above.) However, there appear to be some

numerical inconsistencies in the Tables that summarize the evidence from the US studies (pp 89 and 91), and these need to be corrected or clarified.

8. In summary, I feel that the reports and data referred to in the draft document do, in fact, support the RELs; but that presentation of the material in the tables, and the argument in the text linking the data to the recommendations, could both be improved.

Technical feasability

9. Technical feasibility of the RELs is demonstrable in principle if it can be shown that substantial proportions of past representative dust samples have yielded concentrations of respirable dusts that satisfy conditions consistent with the RELs. Tables 7-4 through 7-7 appear to provide that reassurance with respect to the REL for (mixed) respirable coal mine dust, although it is clear that achievement of the REL in some occupations, particularly at longwall faces, is likely to present formidable problems. The high proportions of samples that failed to meet the current MSHA PEL for respirable crystalline silica, particularly at surface operations (Tables 7-8 through 7-10), suggest that those problems would be even more severe in this respect. I am not qualified to judge whether or not, in practice, it is "technically feasible for most coal mines" to resolve those dust suppression and mining engineering problems even if "effective control methods are used and rigorously maintained at reasonable levels of production according to a preapproved dust control plan" (p 216).

Definition of respirable dust

10. Adoption of the ISO/CEN/ACGIH definition of respirable dust for the purpose of monitoring coal workers' exposures in the USA, as recommended, is attractive to this reviewer primarily because of the first and last of the four reasons listed on pp 123/124: consistency with an internationally accepted and biologically relevant standard. It is essential, however, to be able to relate measurements conforming to that definition at US mines to earlier US and British measurements that referred to the BMRC definition, since the latter were used to derive the health risk estimates on which the RELs are based. The studies reviewed in section 5.17 (pp 154-160) appear to have produced an acceptable approximation to such a formula.

The CMDPSU

11. Improvements in sampling instrumentation are always desirable, on general grounds. The degree of priority which should be accorded to the correction of documented deficiencies in the approved sampling device for respirable coal mine dust (the CMDPSU) should be determined on the basis of data that show the extent to which those imperfections interfere seriously, in practice, with the instrument's effectiveness as a tool for monitoring compliance with permitted exposure levels. The most important, potentially competing, priority must surely be the further development of effective dust suppression technology, as indicated by the facts referred to above in paragraph 9. In any case, any protocol for

research to develop an improved sampler intended to supplant the existing approved unit must include a requirement that results using the improved instrument under defined conditions will be relatable quantitatively to those that would have been found using the existing instrument. The reason for this requirement is the same as that indicated in the penultimate sentence of paragraph 10.

Dust sampling strategy

12. A major departure in the recommended dust sampling strategy from that operative currently is the clear distinction between what should be *dust control-oriented* sampling by mine operators and *PEL-compliance motivated* sampling by MSHA inspectors. Results from mine operators' sampling (referred to in the document as "compliance sampling") would have to be notified to the authorities, but could not be used by them as the basis for citations for non-compliance with the regulations. Only the inspectors' "non-compliance" samples could, and would, be used for that purpose. The two distinct objectives are recognized explicitly in the overall strategy. In both cases, the results reported would refer to single full-shift measurements, and in both cases those results would be classifiable into the trichotomy "compliance", "non-compliance" and "possible over-exposure" samples, as described by Leidel et al (1977) and as illustrated in Table 5-4 and Figure 5-6 (p 149). But action in response to results would differ.

13. This, it seems to me, is an excellent idea. Operators' results that fall into either the "non-compliance" or "possible over-exposure" categories would not attract sanctions as such, but would alert both the operator and MSHA to potential problems. Such results should therefore serve as a real incentive for mine operators to try to determine why they have occurred and to adjust control measures as necessary. The strategy might be expected also to reduce the temptation for mine operators to manipulate sampling schedules or tamper with samples in an effort to avoid sanctions. It should therefore encourage more useful deployment of sampling resources for their real purpose, i.e., monitoring the effectiveness of dust control measures.

14. The "possible over-exposure" category is defined in terms of arbitary but essentially sensible statistical considerations that take into account the random variability associated with the sampling instrument and analytical procedures. However, the strategy takes no account of temporal, mining method or environmentally related variability, so that results would not be suitable for estimating the kind of long-term cumulative exposures that are required for epidemiological research. That point is accepted explicitly in the document, on p 135, and wisely so in my view.

Spirometry

15. There is now abundant epidemiological evidence, reviewed in the document, that exposure to respirable coal mine dust may result in an acceleration of the normal age-related loss of lung function in smokers and

non-smokers, in those with and without bronchitic symptoms, in those with pneumoconiosis and in those with normal chest radiographs. In some cases such dust-related losses in function may be severe, even disabling if cumulative exposures have been sufficiently high, and they will be additional to any losses in function that may be present due to cigarette smoking. Inclusion of spirometry as part of mandatory periodic medical examinations of coal mine workers could therefore provide a useful medical screening procedure: to identify individuals whose levels of function are abnormally low, or whose rates of loss of function are unusually fast, for whatever reason. The aim would be to offer further clinical care and advice on how to prevent the abnormality from becoming more severe. Such advice might include suggestions on how to modify life-styles, including smoking habits, and recommending work in jobs involving little or no exposure to respirable dust, as appropriate. Such a program would be expected to help prevent some chronic obstructive lung disease among coal miners.

16. However, the multiplicity of reasons why lung function may be abnormally low in any one individual means that it is not possible, in general, to attribute such an occurrence in that individual unequivocally to any one specific cause. The discussion of this issue in section 5.2.3 (pp 166-167) is unhelpful, partly because clinical *screening* is not distinguished clearly from epidemiological *surveillance* and partly because of confusion between clinical criteria for diagnoses in individuals and criteria for assessing causality in epidemiological studies of groups. In any case, the inconclusive nature of the discussion in section 5.2.3

underlines an important difficulty with a subsequent recommendation, in section 5.2.5.3.2 (p 175), concerning the transfer option. The second sentence there states that "Miners who elect to transfer to jobs within the mine *on the basis of dust-related functional impairment of the lungs* should be entitled to the same provisions as miners who elect to transfer on the basis of radiographic evidence of simple CWP" (emphasis added.) Yet the earlier discussion, on page 167, concedes that "...the relative contribution of coal mine dust exposure to a measured decrement of lung function in an individual cannot be determined." How, then, will it be possible to distinguish miners whose lung function impairment is "dust-related" from those where it is not?

17. Apart from the primary medical screening function of the proposed periodic spirometry, data thus generated may also be used to calculate descriptive statistics of differences between groups of miners' standardized levels of lung function and rates of decline in function. However, those statistics are unlikely to be helpful as biological indicators of the effectiveness of dust control. Any dust-related losses in lung function that might occur, when averaged over groups or sub-groups of miners with varying exposures to less than the REL, are likely to be small (Tables 4-9, 4-11 and 7-2) and not distinguishable statistically from effects due to non-occupationally related factors.

18. The recommendations for expanding the NIOSH-administered medical surveillance program includes the suggestion that coal miners should be offered medical examinations, including chest X-rays, every three years

after the initial examination (p 7, last paragraph). A case can certainly be made for frequent (perhaps even annual?) spirometry, particularly for young miners during the first five or six years after they enter the industry. Such data would help to establish more statistically secure information about individuals' rates of decline in lung function and would thus facilitate more reliable and timeous identification of abnormal rates of decline. This may be particularly important for young miners because of the suggestion in some reports that the effect of exposure to coal mine dust on FEV_1 in young miners is more severe per unit of exposure than in older miners. The proposed more frequent opportunity for chest X-rays can also be justified, in view of the evident importance, from the point of view of PMF risks, of the "rapid progression" phenomenon described in the British studies (see paragraph 6, above).

The transfer option

19. A NIOSH-commissioned study, based on British data, is referred to in the first paragraph of section 5.2.5.7.1 (p 187) of the document. The authors of that report express one of their conclusions as follows.

"If a man develops category 1 simple pneumoconiosis following exposure over periods less than 40 working years to precisely 2 mg/m^3 respirable dust, then reducing his exposure to 1 mg/m^3 for

the remainder of that 40-year working life will not reduce appreciably his chances of developing further radiological changes, including the development of PMF." (Hurley and Maclaren, 1987)

It is unlikely therefore that even 100% participation in the proposed transfer program, which would enable miners who develop CWP category 1 to work subsequently in places where dust concentrations are lower than the REL, would do much to alter the pneumoconiosis prevalence picture in the USA. However, as noted on page 188 of the document, this does not necessarily imply that reducing the exposures of miners who show early signs of airways obstruction might not contribute to the prevention of subsequent obstructive lung disease. The proposal to extend the transfer option to individuals whose lung function tests show clinically significant abnormalities seems justifiable, therefore, although no data are yet available to assess the effectiveness of such intervention. Such transfer rights would then have to be made available in all cases where the clinical evidence meets the defined criteria, irrespective of the suspected cause or causes of the abnormalities found (see paragraph 16, above.)

Additional remarks

20. The scientific literature referred to in this draft includes most of that which is known to me as relevant to the task in hand: developing strategies for the prevention of occupational respiratory diseases in coal miners. As indicated above, I think that the main recommendations can be

justified from the data cited, but the tabular and textual explanations as to why this is so are not always clear and should be improved. My understanding of where the text was leading, and where conclusions had come from, was impeded, even on repeated reading, by bewildering switches, sometimes between contiguous paragraphs within a section, from restatements of well-known text-book facts, to summaries of review papers including opinions, to paraphrases of relatively recent research results, and sometimes to recommendations. These difficulties were exacerbated by ambiguity about how to interpret some of the many individual references to the literature. Is a particular bracketed citation meant to be simply an acknowledgement of a source of information? Or is it an attribution of an observation, or an inference from observations? Or does it signal endorsement by the document of the material associated with the bracketed reference?

21. My annotated copy of the typescript indicates many of the problems to which I refer, and I have some addtional notes which I will be happy to share with the authors of the document, for their consideration.

July 27, 1993