July 5th 1993

Dr. Eileen Kuempel,
National Institute for Occupational Safety and Health,
Robert A. Taft Laboratories,
4676 Columbia Parkway,
Cincinnati, OH 45226-1998.

Dear Eileen,

Re: Draft NIOSH document "Criteria for a recommended standard: occupational exposure to respirable coal mine dust"

I managed to read this draft document during my recent trip to Norway, and my comments are given in the attached report. I hope these notes will be helpful to you as you prepare for the meeting on July 29-30th. I shall now be going on vacation and will not be back in the office until July 22nd. If you have any questions, you will be able to reach me in my office after that date.

I am looking forward to an interesting meeting.

Yours sincerely,

Preliminary review of the draft NIOSH document "Criteria for a recommended standard: occupational exposure to respirable coal mine dust"

(July 5th 1993)

RESPONSES TO THE SPECIFIC QUESTIONS TO BE ADDRESSED

1. **Is the derivation of the REL supported by the scientific data?**

   I agree that the proposed REL of 0.9 mg/m^3 of respirable dust (as defined by the new ISO/CEN/ACGIH criterion) is **broadly** supported by the scientific evidence. However, I do have some queries:-

   - In my reading of the document, I was not convinced that the effect of the transition from the previous to the new respirable dust criterion on the actual measured dust concentrations has been taken fully into account. I am not aware that anyone has any practical experience in coal mines comparing dust concentrations as measured by 'old' and 'new' sampling instruments respectively. To base the new REL entirely on **calculated** estimates of the effect of the change in respirable dust criterion may be risky.

   - However, I note that the proposed new REL would be 1.0 mg/m^3 based on the 'old' method, and would fall only to 0.9 mg/m^3 based on the 'new' method. This difference is so small that I wonder whether, in actual practice, it is distinguishable (bearing in mind the known great variability in aerosol concentrations measurements in workplaces - even under so-called 'stationary' conditions). In other words, a new REL of 1 mg/m^3 would achieve virtually the same practical result. To express it as 1.0 or 0.9 suggests that we really can distinguish differences at the ±0.1 mg/m^3 level - about which I have my doubts.

2. **Are the RELs technically feasible?**

   I believe they are.

3. **Should the proposed international definition of respirable dust be recommended?**

   Definitely yes! I would add the comment that, in setting the rationale for the standard, this decision about particle size-selective criteria for the respirable fraction should be clearly stated at the outset. In fact, in a document such as the one under review, I would like to see a clear statement near the beginning about the essential ingredients required for a standard and their order of priority. Thus, an ideal aerosol standard should include:-

- A particle size-selective criterion appropriate to the health effect in question (i.e., respirable aerosol a fair index of exposure for pneumoconiosis).
- Sampling instrumentation with performance demonstrably consistent with that criterion.
- Analytical methods (i.e., for weighing, quartz determination) with sufficient sensitivity at the expected levels of collected dust.
- An appropriate sampling strategy which takes into account the variability of the exposures in question.

and <u>only</u> then

- A REL.

4. **<u>Should improvments in the proposed sampler include all-metal construction to minimise charge effects</u>?**

Although electrostatic charge effects are believed under practical conditions not to have any significant effect on the aspiration of particles into sampling devices, they are thought to influence particle losses inside such instruments (as reviewed in Vincent, 1989, Chapters 9 and 10). The latter can be minimised by manufacturing the sampling instrument from a conducting material. This could of course be metal. But it could also be a conducting plastic (as used currently, for example, in the SKC version of the IOM inhalable dust sampler). Therefore I believe it is sufficient to prescribe in the document simply the use of a "conducting material".

<u>Should performance criteria be developed for the approval of more than one type of sampling device</u>?

Definitely yes. It is highly restrictive to recommend just one specific instrument and I believe it is more appropriate to allow some flexibility in this area. A good approach would be to:-

- Recommend a 'primary' or 'reference' sampling instrument whose particle aerodynamic selectivity has already been demonstrated rigorously as matching the proposed respirable dust criterion.

- Also permit the use of other instruments where (a) basic performance either similarly matches the same criterion directly, or (b) they have been demonstrated to consistently collect the same amount of respirable dust under field conditions (by the application of appropriately-designed, side-by-side trials involving also the designated 'reference' instrument).

5. **Is the recommended sampling strategy reasonable ... in the coal mine environment?**

I think so. But I do have some queries where some clarification would be helpful:-

- Throughout the document, I note language such as "*respirable dust in the coal mine atmosphere*" and "*respirable dust exposure*". I believe that the document should be more consistent in its use of the latter, since personal sampling in order to measure individual workers' respirable dust exposure is the central objective of the standard. General respirable dust levels (e.g., as would be measured using an area or static sampler) are not relevant in the first instance. However I do accept the need for continuous area monitoring (e.g., using direct-reading instrumentation) as a quick means of assessing the effectiveness of controls - but, although this is a useful supplementary industrial hygiene tool, it is not the primary subject of the proposed standard.

- p133 "*Emphasis on sampling miners in "high-risk" jobs*" needs some clarification. How are such miners identified? Is the strategy going to concentrate on those workers where the measured personal respirable dust exposures are known (from experience) to be consistently high? If so, at the expense of measurements of the exposures of other workers?

- p134 "*..use of tamper-resistant sampler cassettes..*". I believe that this should should be qualified somewhat to include reference to samplers where the samples can be 'changed' not only by direct tampering (i.e., by deliberate human intervention) but by accident (e.g., dropping, shaking during transport, hose crimping, etc).

6. **Is the inclusion of spirometry tests in the medical surveillance program justifiable for the prevention of COLD (or COPD)?**

Although this is not within my area of expertise, this seems entirely reasonable. In the context of COLD, it might be noted that, over the years, there has been discussion about whether respirable dust is necessarily the best index of exposure relevant to airways disease, and it was suggested as early as 1968 that fractions of dust coarser than respirable might be more appropriate (WHO, 1968).

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

This is a question where the scientific evidence, to my knowledge, is not very clear. There is some evidence (reported by Professor W.T. Ulmer at the VIth Pneumoconiosis in Bochum, Germany) that progression of silicosis continues after miners have retired. This is consistent with (a) the well-known long retention times of relatively insoluble particles in the deep lung (see comments below about 'overload' and 'sequestration'), and (b) the results of an animal inhalation study reported by Vincent and Donaldson (1990) in which the potential 'harmfulness' of quartz in the lungs of rats (as measured by its ability to cause inflammation) was found to be highly persistent after exposure had ceased (in marked contrast to the less toxic titanium dioxide dust for which 'harmfulness' decayed rapidly). Further research is needed to investigate the dosimetry of retained lung dust. But based on the limited information available, it seems that removal of a worker to a less dusty area does not guarantee that there will be no further progress of disease. A possible approach worth discussing might be to relocate workers below a certain age (who might expect many more years of similar new exposures) but not to relocate older men close to retirement (where relocating them may have little or no overall effect).

8. **Additional issues not already covered**

Sampler performance characteristics in relation to the ISO/CEN/ACGIH criteria and underlying philosophy

The philosophy underlying the internationally-agreed criteria is explicitly stated in the equation (p112)

$$SR(d) = SI(d) \{ 1 - F(d) \}$$

That is, to be consistent with actual human exposure, the respirable fraction is a **subfraction** of the inhalable fraction. Strictly speaking, therefore, an instrument for the respirable fraction should first aspirate the inhalable fraction, then select the required subfraction as defined by F(d). This requirement should only be dropped if it is known that SI(d) over the particle size range of interest - and hence, also, of the chosen sampling instrument - remains close to 1 (or 100%). This has been assumed to be the case in the past. However it is known that, under wind conditions like those encountered in mines, the aspiration efficiency of samplers like those described in the document can vary greatly with windspeed, even for particles in the respirable range (e.g., Cecala *et al.*, 1983 and others as reviewed in Vincent, 1989, Chapter 14).

At present we do not have sufficient information about the inlet characteristics of samplers like the one recommended and the conditions of expected use. In order to overcome the question of windspeed dependency and to provide a consistent basis for making measurements truly consistent with the stated criteria, the ultimate goal should be to develop a sampler whose entry characteristics do match the ISO/CEN/ACGIH criteria and philosophy. I believe that much such knowledge is currently available upon which to base the development of such an instrument (see Vincent, 1989). But clearly further research is needed.

Fate of dust deposited in the lung

The document discusses in some detail in more than one part the question of the long-term fate of inhaled particles in the lung. The phenomonon of 'clearance overload' features strongly and, in my opinion, is overemphasised. The arguments can be long and complicated, and it is fair to say that there is some diversity of opinion between workers in this field. For the present purposes, I have the following brief comments relevant to these sections of the document:-

- The 'overload' phenomena was (I think) first identified in a paper by myself and colleagues in 1983 (Bolton *et al.*, 1983), based on inhalation studies with rats inhaling amosite asbestos, having already noted similar trends in previous experiments for quartz (Klosterkotter and Bunemann, 1961). It was found that clearance of dust following a period of exposure appeared to be impaired for rat lung burdens exceeding 0.5-2 mg. Later 'clearance-type' experiments indicated similar results for diesel fume.

- In subsequent experiments of the so-called 'build-up' type (i.e., chronic exposure), most of the available evidence was found (surprisingly) **not** to reflect the clearance overload phenomenon. That is, whereas we expected to see a greater relative rate of build-up of lung burden for high exposure levels, no such trend was found. Rather, even at very low lung burdens (well below that where overload had been observed in clearance-type experiments), lung burdens were observed to increase almost linearly with time of exposure and also in proportion to the level of respirable dust exposure. To explain this, a 'sequestration' hypothesis was proposed (first by Soderholm, 1981 and later by Vincent *et al.*, 1985 and 1987 and others). Under this hypothesis, even at very low lung burdens, there is no levelling off of lung burden during long-term continuous exposure as would be predicted by the old 'linear' kinetic model. To my knowledge, the only data set which deviates sharply from this consistent general trend is that for the toner particles (as described in the papers by Muhle *et al.* cited in the document), and I regard this set as a possible 'odd-man-out'.

- It is not easy to reconcile the differences between the results of clearance-type experiments (where overload is clearly demonstrated) and those of the 'build-up' experiments (where overload does not appear - except in the toner results and, perhaps, in some of the diesel data at very long exposure times as shown in the results of Wolff *et al.*, 1987). It has been suggested that different clearance kinetics may be taking place post-exposure and during ongoing exposure. However, it is fair to say that there is some disagreement about this between various workers (Vincent, 1990).

- There is little information by which to relate these findings with respect to actual human exposure. In one unpublished pilot study (Vincent *et al.*, 1988), we examined the relationship between the lung burdens of deceased mineworkers (as measured from lung tissue obtained at autopsy) and their known (measured and/or estimated) respirable dust exposure histories. Actual lung burdens were compared with those predicted from the exposure histories and a sequestration-based pharmacokinetic model derived from our previous rat inhalation studies. The results were very preliminary, but suggested that the actual miners' lung burdens increased at a rate even greater than that predicted by the sequestration model. In order to develop a full understanding of the dosimetry of dust-related lung disease such as CWP, such work needs to be followed up. In this connection, the effect of the 'shape' of the exposure may be important (i.e., uniform, intermittent, peaky).

Specific other points

ix. " Inspirable" has now been replaced by "inhalable".

x. "MRE instrument" is more correctly described as the "MRE Type 113A respirable dust sampler"

x. Respirable dust should be defined more correctly in terms of penetration, rather than actual deposition. In addition, there is no need to mention **mass** deposition since the formal definition - which in effect describes the probability of penetration to the alveolar region as a function of particle aerodynamic diameter - does not therefore specifically refer to mass. Similarly for thoracic dust.

p1. "Workplace exposures" should be "worker exposures".

p26. "High risk groups" might also have something to do with the nature of the work performed in relation to its effect on breathing parameters. For changing breathing patterns, not only does the amount of air inhaled increase, but also the regional deposition of inhaled particles changes (e.g., Vincent and Mark, 1984).

p34. Figure 3.1 needs more explanation.

p82. "..residence time of dust in the lungs..". This reinforces the need (mentioned earlier) to think dosimetrically and about the 'shape' of the long-term exposure history of a worker.

p111 and elsewhere. The so-called "MRE" convention for respirable dust should be referred to more correctly as the "British Medical Research Council (BMRC) curve". It is historically very important and goes back to 1952, long before the MRE Type 113A instrument was proposed.

p112. Should note that the expression given for the inhalable fraction is empirical. Also I am puzzled about the substitution of "x" for "d" in the equation for SR(d).

p121. Note the possible role of versatile particle size-selective sampling instruments (e.g., personal cascade impactors), especially in investigative work.

p131. Be more specific about ".. an international sampling committee..".

p147. ".. the applicable standard" should be " .. the applicable limit value" (where the standard itself is not just the REL but the whole rationale).

p153. Here the flowrate is given as 1.7 l/min, where earlier I saw 2 l/min. Check for any inconsistences between samplers, flowrates, etc.

p153. At this point it occurs to me that a desirable sampler is one where the dust is deposited very uniformly on the filter. I'm not convinced that this is so for the cyclones currently in use.

p250. Research needs (a few thoughts):-

Engineering controls: How are current methods lacking; what options are available for improvements based on current scientific knowledge; do we need new science?

Sampler development: Effects on windspeed in entry effects (which can bias respirable dust measurement); development of inhalable entries for respirable dust samplers; personal continuous monitors?

Exposure-dose-response: How better understand the relationship between exposure history, fate of inhaled particles, toxicology and so develop a better dosimetric picture; effects of uniform versus non-uniform exposure histories?

General editorial. These is excessive use of clumsy abbreviations which makes the document difficult to read. The most extreme example is CMDPSU!

References

Bolton, R.E., Vincent, J.H., Jones, A.D., Addison, J. and Beckett, S.T. (1983). An overload hypothesis for pulmonary clearance of UICC amosite fibres inhaled by rats. British Journal of Industrial Medicine, 40, 264-272.

British Medical Research Council (BMRC). (1952). Recommendations of the BMRC panels relating to selective sampling. From the Minutes of a joint meeting of Panels 1, 2 and 3, held on March 4th, 1952.

Cecala, A.B., Volkwein, J.C., Timko, R.J. and Williams, K.L. (1983). Velocity and orientation effects on the 10-mm Dorr-Oliver cyclone. US Bureau of Mines Report of Investigations, RI 8764.

Klosterkotter, W. and Bunemann, G. (1961). Animal experiments on the elimination of inhaled dust. In: *Inhaled Particles and Vapours I* (ed. C.N. Davies), pp327-341, Pergamon Press, Oxford.

Soderholm, S.C. (1981). Compartmental analysis of diesel particle kinetics in the respiratory system of exposed animals. Paper presented at the EPA Diesel Emission Symposium, October 1981, Rayleigh, N.C.

Vincent, J.H. and Mark, D. (1984). Inhalable dust spectrometers as versatile samplers for studying dust-related ehalth effects. Annals of Occupational Hygiene, 28, 117-124.

Vincent, J.H, Johnston, A.M., Jones, A.D., Bolton, R.E., Addison, J. and Beckett, S.T. (1985). Kinetics of deposition and clearance of inhaled mineral dusts during chronic exposure. British Journal of Industrial Medicine, 42, 707-715.

Vincent, J.H., Jones, A.D., Johnston, A.M., McMillan, C., Bolton, R.E. and Cowie, H. (1987). Accumulation of inhaled mineral dust in the lung and associated lymph nodes: implications for exposure and dose in occupational lung disease. Annals of Occupational Hygiene, 31, 375-393.

Vincent, J.H., Murdoch, R.M. and Hurley, J.F. (1988). Exposure-dose-response relationship for workers exposed to airborne particulates. Unpublished report on a pre-funding pilot study, Institute of Occupational Medicine, Edinburgh, U.K.

Vincent, J.H. (1989). *Aerosol Sampling: Science and Practice*, Wiley and Sons, Chichester, England.

Vincent, J.H. (1990). The fate of inhaled aerosols: a review of observed trends and some generalisations. Annals of Occupational Hygiene, 34, 623-637.

Vincent, J.H. and Donaldson, K. (1990). A dosimetric approach for relating the biological response of the lung to the accumulation of inhaled mineral dust. British Journal of Industrial Medicine, 47, 302-307.

World Health Organisation (WHO) (1968). Pneumoconiosis Report on a Symposium, Katowice, June 1967. Copenhagen, WHO Regional Office for Europe, pp17-22 (EURO 0379).