August 2nd 1993

Eileen D. 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"

Here are my final comments on this draft document. They take the form of a revised version of the comments I submitted prior to the meeting last week in Cincinnati. Please do not hesitate to contact me if you have any outstanding questions.

Kindest regards.

Yours ~~sincerely~~,

Final comments on the draft NIOSH document "Criteria for a recommended standard: occupational exposure to respirable coal mine dust"

(August 2nd 1993)

RESPONSES TO THE SPECIFIC QUESTIONS TO BE ADDRESSED

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

From the evidence given in the document and the discussion which took place at the Cincinnati meeting, it would appear 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 might be risky. I suggest that a study should be carried out under field conditions (i.e., in 'representative' mine environments) to compare the respirable masses collected by personal samplers - **used** as personal samplers - conforming to the old and new criteria respectively. In such studies, workers should be asked to wear both samplers side-by-side so that a valid comparison can be achieved. (A number of similar studies are currently taking place in other industries to determine the impact of switching from the old 'total' aerosol concept to one based on the new inhalability criterion).

- I note that, based on calculations carried out so far, 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. If this is confirmed in experiments like those mentioned above, I believe that this difference is so small as to be indistinguishable in practice (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 the REL 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. <u>**Are the RELs for respirable coal mine dust and respirable crystalline silica technically feasible?**</u>

As we discussed in Cincinnati, the answer to this question depends on the interpretation of 'feasible'. In principle, in most pollution control situations, almost any level of performance can be achieved if enough effort and resources are available. But it becomes increasingly difficult as the required levels are reduced further and further (i.e., a 'law of diminishing returns'). More useful, perhaps, is the term 'practicable'. Under this terminology, it appears that the proposed new respirable dust level might be difficult to achieve in a high proportion of mine environments. This therefore suggests that technical dust control remains an imnportant area for further research and development. Meanwhile it remains an option to deploy personal respiratory protection. However good industrial hygiene practice demands that such an option should be a last resort after all reasonable engineering control approaches have been explored.

3. <u>**Should the proposed international definition of respirable dust be recommended as the criteria for sampling respirable coal mine dust and respirable crystalline silica?**</u>

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.

By such an approach it follows that the standard is based first and foremost on the criterion. It is something of a departure from current philosophy which is primarily based on a particular sampling instrument.

Finally it should be noted that, although the proposed new criterion is based on 'typical' data from lung deposition experiments in human volunteer subjects, it does not actually reflect true lung deposition. So care should be exercised in using data gained using this approach for dosimetric purposes.

4. **Should improvments in the coal mine dust personal samplinmg unit, including all-metal construction to minimise charge effects, be recommended?**

Measurements have been made of the magnitude and distribution of electric surface charges on coal mine aerosols (Jones *et al.*, 1985). The results show that such charges can be quite high (e.g., typically of the order of the equivalent of 20 electrons on a particle of diameter 1 μm), considerably above that considered to be Boltzmann equilibrium (i.e., about 2 electrons on a 1 μm particle). Therefore it is reasonable to consider possible effects on aerosol sampling. Experience suggests that, although electrostatic charge effects are believed under practical conditions **not** to have any significant effect on the aspiration of particles into sampling devices, they might 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".

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

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. **<u>Is the recommended sampling strategy reasonable on the basis of both statistical validity and practical considerations for measuring airborne concentrations of respirable dust in the coal mine environment</u>**?

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.

- 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? 'High risk' jobs might also include workers who, by virtue of their tasks (and associated working rates), breath at higher inspiratory flowrates and so receive higher lung dose (e.g., Vincent and Mark, 1984).

- 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).

- Beyond the primary need for personal exposure monitoring for the purpose of meeting a standard, there is a also a role for other modes of sampling for research or investigative purposes. This includes continuous area monitoring (e.g., using direct-reading instrumentation) as a quick means of assessing the effectiveness of controls. It also includes the measurement of aerosol particle size distribution (e.g., using personal or area cascade impactors) for the purpose of assessing true lung doses of exposed workers (see earlier comment).

6. **<u>Is the inclusion of spirometry tests in the medical surveillance program justifiable for the prevention of chronic obstructive lung disease in underground and surface miners?</u>**

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

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 - although I cannot recall the actual reference) 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. **<u>Are there additional issues or interpretations of the in formation that need to be considered in the decvelopment of this criteria document?</u>**

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 **sub**fraction 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 - and in more than one part - the question of the long-term fate of inhaled particles in the lung. The phenomenon of 'clearance overload' features strongly and, in my opinion, is overemphasised. The arguments can be long and complicated, and sometimes contradictory - leading to some diversity of opinion between workers in this field. At this stage, therefore, I feel it is inappropriate to depend too heavily on 'overload' arguments in supporting this standard. To indicate some of the issues involved, I have the following brief comments relevant to these sections of the document:-

- The 'overload' phenomena was first identified by 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 seems to be 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).

- It is not easy at present 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 is possible 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).

- The implications of the above to the proposed standard are somewhat unclear. On the one hand, regardless of whether we accept the 'overload' or 'sequestration' hypotheses as described in the various parts of the literature, there is evidence to suggest that the lung burdens of miners will continue to increase steadily throughout ongoing exposure. However this does not necessarily lead to a 'no-threshold' argument (i.e. a respirable dust concentration below which there will be no effect). We do have evidence from rat inhalation experiments that transfer of particles to lymph nodes (Vincent *et al.*, 1987) and the onset of inflammation (Vincent and Donaldson, 1990) are dependent on having achieved a minimum lung burden. That minimum dust burden is very similar to that at which 'overload' has been observed, and that might not be coincidental.

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!

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