



CHEMICAL MANUFACTURERS ASSOCIATION

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September 13, 1993

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RE: NIOSH "Criteria for a Recommended Standard:
Occupational Exposure to Respirable Coal Mine Dust"

Dear Dr. Neimeier:

The Crystalline Silica Panel of the Chemical Manufacturers Association is submitting these comments on the June 14, 1993 draft "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust." The Panel represents, directly or through associations that are part of the Panel, about 4500 companies that produce or use products or materials containing crystalline silica.

The Panel's comments are confined to the inappropriate inclusion of a Recommended Exposure Limit (REL) for crystalline silica in the text of the coal mine dust criteria document, and the lack of scientific support for the 0.05 mg/m³ recommendation. The Panel feels that NIOSH should not introduce a crystalline silica REL into the standards process by incorporating a cursory discussion of the medical literature on crystalline silica exposure into the text of a coal mine dust criteria document.

The Panel therefore respectfully requests that NIOSH delete from the criteria document any proposed exposure level for crystalline silica.

We request that NIOSH take into consideration the specific comments attached. If you have any questions, please call Panel manager, Elizabeth Festa Watson, at 202/887-1194.

Sincerely,

Comments of the Crystalline Silica Panel
To NIOSH on the "Criteria for a Recommended Standard:
Occupational Exposure to Respirable Coal Mine Dust"

September 13, 1993

The Crystalline Silica Panel of the Chemical Manufacturers Association appreciates the opportunity to comment on the draft "Criteria for a Recommended Standard: Occupational Exposure to Respirable Coal Mine Dust." The Panel's comments are confined to the inappropriate inclusion of a Recommended Exposure Limit (REL) for crystalline silica in the text of the coal mine dust criteria document, and the lack of scientific support for the 0.05 mg/m³ recommendation. The Panel feels that NIOSH should not introduce a crystalline silica REL into the standards process by incorporating a cursory discussion of the medical literature on crystalline silica exposure into the text of a coal mine dust criteria document.

While it is possible that crystalline silica exposure plays a role in the pneumoconiotic process of coal workers' pneumoconiosis (CWP), these two agents produce distinct pathogenic lesions, and there are conflicting studies with no proven hypotheses of a coal dust-silica interaction in the lung. The work in the United Kingdom by Seaton et al.¹ suggesting that coal miners exposed to mine dust with a high quartz content develop coal workers' pneumoconiosis sooner and progress more rapidly is not supported by the exposure data. Indeed, while rapid developers and progressors were exposed to higher quartz containing coal dust than the controls, their total exposure to dust was considerably higher than controls. Other British experience reported by Hurley et al.² failed to demonstrate that quartz-containing coal dust (5 percent quartz) affected the probability of developing simple CWP. In addition, other studies in mineral mining and processing involving quartz exposure suggest that mixed dust exposures tend to reduce the fibrotic potential of quartz.

It makes no sense to request the Department of Labor to initiate rulemaking for a crystalline silica standard in coal mining without concurrent rulemaking in general industry. To do so would result in two different standards for crystalline silica. If NIOSH intends to request the Department of Labor to initiate separate rulemaking on forms of crystalline silica, it would seem logical to do so in a separate criteria document, as it did in its 1974 publication "Criteria for a Recommended Standard: Occupational Exposure to Crystalline Silica."³

Regarding the 1974 Criteria Document, it is the Panel's opinion that the NIOSH REL of 0.05 mg/m³ for all forms of crystalline silica is not supported by the scientific literature. The NIOSH recommendation relied heavily on studies of Vermont granite workers conducted in the early 1970's by Theriault and colleagues of the Harvard School of Public Health.^{4 5 6} We believe that NIOSH has failed to consider adequately the flaws and methodological problems in the work of Theriault, et al., and a 1977 Harvard study by Musk, et al.⁷ which reported pulmonary function losses occurring at two or three times the predicted normal rate.

In 1979, Dr. William Graham of the University of Vermont conducted a pulmonary function study of granite workers⁸ using the same spirometer as used by the Harvard group. Additionally, Dr. Graham obtained the spirometry tracings, performed by the Harvard group during the 1970 to 1974 studies, of workers common to his study. These spirometry data had been the basis for the Harvard publications.

The results of the Graham study⁸ showed that the losses of pulmonary function predicted in the Harvard studies did not occur in workers who continued to work in the granite industry. In fact, just the opposite of expected losses were found, with subjects showing large increases in forced vital capacity, and small increases in FEV1 when compared to previous measurements (1970-1974). This finding of increased pulmonary function runs counter to conventional wisdom, and would not be an expected observation in a dust-exposed population. After eliminating reasons for any increase in pulmonary function, Dr. Graham concluded technical flaws in the collection of the Harvard data as an explanation for the apparent improvement in pulmonary function.

From examining spirometer tracings from one of the annual surveys by Harvard, it was evident that forced expiratory efforts in many instances lasted only 2.5 to three seconds, rather than the recommended six-second expiratory effort.⁸ Another explanation that would compound the first reason is a possible existence of a spirometer leak. When Dr. Graham obtained the spirometer used in the Harvard studies, a small leak was discovered. It cannot be determined if the leak was present during the Harvard studies, but if it was, it might explain the accelerated pulmonary function loss attributed to dust exposure.

Dr. Graham and his colleagues have continued with their studies of Vermont granite workers, and at the VIIth International Labour Office (ILO) Pneumoconiosis Conference presented important roentgenographic and spirometric findings.^{9 10}

In the spirometry function study, Graham et al.⁹ reported results of pulmonary function testing on 711 workers who participated in at least three semiannual surveys over an eight-year period (1979 to 1987). The losses in both FVC and FEV1 were not correlated with years employed in the granite industry, and the losses of pulmonary function were significantly smaller than estimated previously by Harvard researchers. Dr. Graham in a submission to the OSHA Docket¹¹ noted:

"Spirometric losses were comparable to what is seen in non-dust exposed populations, suggesting that the granite dust exposure is not adding significantly to pulmonary function loss." Emphasis added.

Dr. Graham and colleagues conclude from their prospective pulmonary function studies:⁹

"...that current dust levels in the Vermont granite industry do not accelerate pulmonary function loss."

The Harvard study of x-ray changes⁶ in granite workers has been suggested by the authors and others as evidence of the need for lowering the Permissible Exposure Limit (PEL) for crystalline silica. As with the Harvard pulmonary function studies, the results of x-ray findings of the Harvard group have been the subject of considerable scientific criticism.³
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Vermont granite workers were the subject of early studies by Russell,^{14 15} and as a result of his work in 1938, the Vermont Health Department adopted a dust exposure standard of 10 million particles per cubic foot (mppcf), and began offering yearly chest radiographs to granite workers. On the basis of these yearly surveys, Ashe^{16 17} published follow-up studies in 1957 and 1964 in which he found no new cases of silicosis had developed in workers employed after 1938, a time in which exposures were drastically reduced due to installation of engineering controls. With this background, it was startling when the Harvard x-ray study found 233 of 784 workers, or some 30 percent of those examined, had some evidence of silicosis.⁶ Assuming entry into the workforce was distributed across the 1938 to 1961 period, for a population of workers to experience an increase from zero percent to 30 percent prevalence of a chronic disease such as silicosis in a seven-year period (1964-1971) is unparalleled in occupational medicine.

Two criticisms of the Harvard roentgenographic study perhaps explain these spurious findings. First, the roentgenograms were interpreted by only one physician who was not certified by NIOSH as a B Reader. The ILO responsible for the published guidelines for ILO Classification of Pneumoconioses¹⁸ strongly recommends at least two, and preferably three, independent readings be made for each radiograph because of inter- and intra-observer variability in interpretations. NIOSH certified B Readers have demonstrated proficiency in interpretation of radiograms for the pneumoconioses in accordance with ILO guidelines by successfully completing an examination requiring classification of a test set of radiograms.^{19 20}

Second, the most revealing of the flaws in this aspect of the Harvard work is the fact that among workers with no dust exposure, 30 percent were interpreted as having abnormal roentgenographic findings. NIOSH in its criteria document³ had the following to say about this study:

"...the curves drawn to fit their data suggest a significant incidence of silicosis at 0 dust-years. Based on a plot of radiographically evident silicosis against dust-years, 30% of the working population had silicosis with no exposure. Of course, this undoubtedly represents imperfections in their data or in available methods of analysis of their data, but it is not evident how to use inferences from these analyses in deriving an environmental limit." Emphasis added.

A study which concludes that no exposure to silica causes a predicted 30 percent incidence rate of silicosis is so entirely contrary to the known etiology of silicosis that it cannot be reasonably relied upon by NIOSH.

In contrast to the Harvard x-ray study,⁵ Dr. Graham and his colleagues¹⁰ reported that while over 10 percent of the workers were exposed to quartz concentrations above the OSHA PEL of 0.1 mg/m³, only seven of 972, or 0.7 percent, had x-ray changes consistent with silicosis as judged by three NIOSH certified B Readers. They conclude:¹⁰

"If exposure levels have remained approximately the same over the past 45 years, we conclude that current dust controls, which conform to OSHA standards, have essentially eliminated silicosis." Emphasis added.

It is the opinion of many in the occupational health field that Vermont granite workers are the best population for studies designed to assess the risk of developing silicosis. Based on the studies of Dr. Graham and his colleagues, as well as other studies in the medical literature, we believe that the American Conference of Governmental Industrial Hygienists' Threshold Limit Value of 0.1 mg/m^3 will adequately protect workers exposed to crystalline silica from adverse health effects.

Conclusions

The Crystalline Silica Panel respectfully requests that NIOSH delete from its proposed coal mine dust criteria document any proposed exposure level to crystalline silica, because:

1. The proposal with respect to crystalline silica is not supported within the proposed document by any scientific research.
2. The scientific research upon which NIOSH relies as the basis for its proposed crystalline silica REL in the draft coal mine dust criteria document is NIOSH's 1974 "Criteria for a Recommended Standard: Occupational Exposure to Crystalline Silica." It is inappropriate to rely on this research 19 years later without entirely revisiting the current state of the scientific literature concerning crystalline silica and pneumoconiosis.
3. As discussed above in detail, the conclusions of NIOSH's 1974 crystalline silica criteria document are seriously flawed.
4. NIOSH may be considering a new criteria document concerning crystalline silica, and any recommendation concerning crystalline silica should await publication of a new criteria document specifically focussed on crystalline silica.

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