

Investigation of the Bureau of Mines Respirator Testing Standard

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Conflicts statement: Dr. Egilman has testified in litigation involving claims against 3M respirators.

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Short title: **Respirator Standards Problem**

Investigation of the Bureau of Mines Respirator Testing Standard

From 1934 to 1995, the US Bureau of Mines and NIOSH respirator approval standard was based on a silica dust test. Respirator manufacturers used silica dust tests to certify their products as US Bureau of Mines or NIOSH approved on product packaging and advertisements. 3M ran one such approval test, exposing their respirators over a 90-minute period to 200 mg of dust that reportedly averaged 0.5 microns in diameter.¹ Regulatory certification for 3M's respirators required that they stop 99.1 percent of the dust by mass, or 198.2 mg out of 200 mg.² In 1971, 3M noticed that certain of its respirators, including its 8710 disposable, which had not yet been marketed, could pass the silica test, but failed a similar test based on sodium chloride. Tests on the 8710 that used sodium chloride as the challenging agent stopped only 72 to 82 percent of the particles by weight, therefore allowing 18 to 28 percent to pass through the respirator.³ 3M personnel noted that at 0.7 microns, sodium chloride is larger on average than silica dust, and the respirators should have stopped more sodium chloride than silica particles.⁴

This discrepancy reveals a fundamental flaw in the Bureau of Mines/NIOSH testing methodology used from 1934 to 1995. Distribution by mass is not the same as distribution by count (see Figure 1 for graphical explanation).⁵ 3M used a particle count method to calculate that the average diameter of silica particles in their respirator approval tests was 0.5 microns. Had 3M calculated the average silica particle size based on mass (the method used

for measuring efficiency), the results would reveal the actual mean was around 1.6 microns.⁶

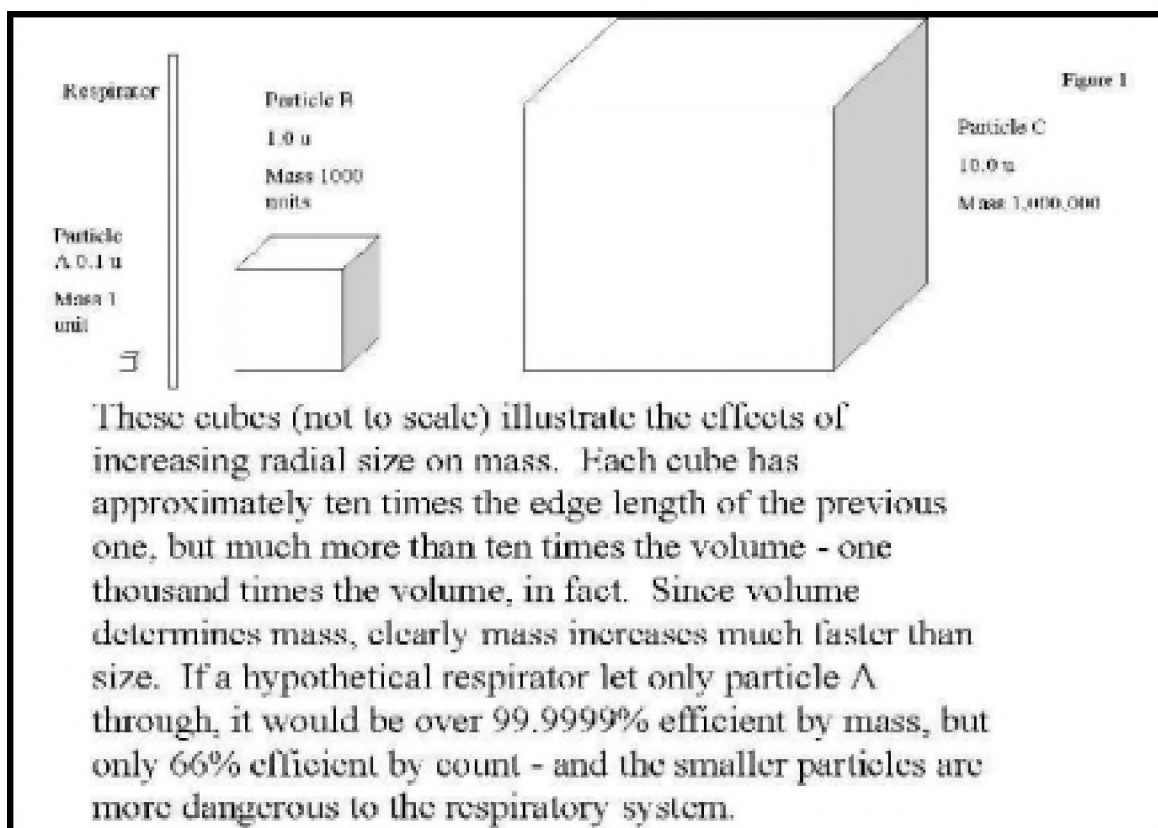
3M was aware that this test methodology resulted in gross underestimations of particle size (in this case by a factor of three).⁷ This defect in methodology in turn yielded an inflated assigned protection factor (APF) for the masks. 3M nevertheless marketed the 8710 respirator as US Bureau of Mines and NIOSH approved for use against pneumoconiosis and fibrosis producing dusts.⁸ In 1980 NIOSH notified 3M that their 8710 respirator did not give adequate protection against asbestos dust, but had no regulatory protocol for de-certifying an approved respirator.⁹ Incredibly from 1979 to 1986, 3M continued to market the 8710 for asbestos use, even adding new package language that specifically stated that the respirator was approved for asbestos and lead.¹⁰ The respirator was never approved for lead fumes, but the marketing information omitted this information.

A summary of efficiency tests conducted on the 3M 8710 disposable respirator confirms that industry scientists understood why respirators that had failed the sodium chloride test could pass the silica test.¹¹ According to internal 3M reports, had sodium chloride been sized by the same method as silica, the average diameter of sodium chloride would have been calculated at .08 to .09 microns, about one-tenth the actual estimate.¹² 3M exploited this loophole in the Bureau of Mines and NIOSH testing standards to guarantee approval of the 8710 respirator, a respirator they knew would offer scant protection against respirable poisons.

In addition, it should be noted that the 8710 – like most other disposable respirators – had no exhalation valve mechanism. Over 95% of inhaled asbestos fibers are exhaled. The 8710 trapped these fibers inside the mask. Since some workers wore these respirators at times when they were on break or were distant from continuing external exposures, the 8710 actually *increased* total fiber exposures for some workers and hastened their deaths. Thus, we feel that this and other similar respirators should be renamed 'funeral masks.'

These are not the only problems with the NIOSH/Bureau of Mines testing procedures. The tests fail to address the 'loading' factor – the fact that, as respirator filters accumulate material, they become more efficient. Los Alamos tests on the effects of loading with sodium chloride reveal that, over 90 minutes at 15 mg/m^3 , penetration could go from two percent to almost nothing – a significant change.¹³ The TLV is about 0.1 mg/m^3 , which means that the filter is being tested against 150 times the TLV. Even the worst working conditions are only ten to fifteen times the TLV, so this test at 150 times the TLV does not accurately reflect respirator performance under real working conditions. The NIOSH/Bureau of Mines tests, in using the average penetration, ignore the fact that the respirator can fail to protect when it is first used. Another flaw in the NIOSH/Bureau of Mines testing is airflow. The tests were done with airflow of 32 liters per minute, but the average worker doing moderate work inhales 77 liters of air per minute – over twice as much as in the test.¹⁴ Los Alamos tests show that at 77 liters per minute the penetration can be dramatically greater – almost tripled for one filter – than the penetration at 32 liters per minute.¹⁵

In 1995, NIOSH abandoned the silica test in favor of a sodium chloride test. We have no evidence to indicate that any previously certified respirators made by other manufacturers could pass the new test. The use of these ineffective respirators may explain why OSHA standards requiring use of these respirators failed to reduce the incidence of pneumoconiosis and cancer as much as was expected.



¹ 3M document Bates number 015734. Letter from John E. Cain to James L. Woodring. September 25, 1972

² 3M document Bates number 015734. Letter from John E. Cain to James L. Woodring. September 25, 1972

³ 3M document Bates number 22774. Field letter from John E. Cain to R. J. Barghini. January 13-14, 1971

⁴ 3M document Bates number 024302. *Summary of 8710 Efficiency Tests*. September 30, 1977

⁵ 3M document Bates number 077387. *New Respirator Development at 3M* slide show.

⁶ Based on Figure 1 of *Respirator Research and Development Related to Quality Control: Quarterly Report October 1 through December 31 1971*, call number LA-4909-PR.

⁷ 3M document Bates numbers 024302-024303. *Summary of 8710 Efficiency Tests*. September 30, 1977

⁸ 3M document Bates numbers 52827-52847

⁹ 3M document Bates number 020244. Letter from Jon R. May to Donald P. Wilmes.

¹⁰ 3M document Bates numbers 52850-52869, 91443-91445

¹¹ 3M document Bates numbers 024302-024303. *Summary of 8710 Efficiency Tests*. September 30, 1977

¹² 3M document Bates number 024303. *Summary of 8710 Efficiency Tests*. September 30, 1977

¹³ Based on figure 14 of *Respirator Studies for the National Institute for Occupational Safety and Health: July 1, 1974-June 30, 1975*, call number LA-6386-PR.

¹⁴ Based on page 13 of *Respirator Studies for the National Institute for Occupational Safety and Health: July 1, 1974-June 30, 1975*, call number LA-6386-PR.

¹⁵ Based on Figure 7 of *Respirator Studies for the National Institute for Occupational Safety and Health: July 1, 1974-June 30, 1975*, call number LA-6386-PR.