



October 5, 1994

Dr. Linda Rosenstock  
Director  
National Institute of Occupational Safety and Health  
200 Independence Avenue, NW  
Room 715-H  
Washington, DC 20201

Dear Dr. Rosenstock:

3M's Occupational Health and Environmental Safety Division has reviewed the contents of the National Institute for Occupational Safety and Health (NIOSH) docket on 42 CFR 84, the agency's proposed revision to the existing respirator certification rule. We would like to respond to a particular submission.

Specifically, 3M is responding to document #94-082. This submission, entered into the docket on June 28, 1994, consists of the minutes from a June 22, 1994 meeting you held with representatives from Mine Safety Appliances Co. (MSA). This meeting was intended to give MSA an opportunity to provide their input on the test protocols NIOSH proposed for respirator filters. During the meeting, the MSA personnel gave you a position paper stating their concerns on the proposed revision to 42 CFR 84. This position paper also is included in the 42 CFR 84 docket.

Portions of the MSA position paper were presented at the NIOSH public hearing held on June 23 and 24, 1994. 3M and others (including the Industrial Safety Equipment Association [ISEA] of which both 3M and MSA are members) have addressed the issues raised by MSA at the public hearings in separate comments previously submitted to the 42 CFR 84 docket. There are issues raised in the position paper presented at your meeting, however, that were not a part of MSA's public presentation.

It is 3M's opinion that the MSA position paper contains several fallacies, half-truths, and deceptive examples. It would not be unfair to conclude that these inaccuracies presumably are designed to mislead NIOSH into imposing regulations that would limit the abilities of MSA's competitors, other respirator manufacturers, to design and market new electrostatic filters. If successful, MSA, whose business consists mainly of sales of respirators equipped with mechanical filters, would gain a significant economic advantage.

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It is in response to these points raised by MSA, therefore, that 3M feels obligated to provide comment.

### **Specific Concerns:**

**1. "Solids" v. "Solids and Liquids"  
(94-082, Page 1, #1)**

NIOSH's proposed respirator certification rule contains a bifurcated filter classification scheme for particulate air-purifying respirators. Respirators would be classified as certified for use against either "solid" or "liquid and solid" contaminants. In their position paper, MSA objects to the "solid" only filter classification proposed by NIOSH in 42 CFR 84, alleging that this category of filter will lead to respirator misuse and misapplication. This is an erroneous assertion.

NIOSH certifies respirators, filters, and cartridges for many general and specific applications. Proper selection of these NIOSH-approved products is based on the contaminant or contaminants present. No single filter will protect against all known contaminants. Therefore, respirator selection will always require some logic and expertise. The individual in charge of respirator selection in an industrial setting must be capable of making basic technical selection decisions.

It is difficult to imagine that a person making such decisions would have more trouble differentiating a solid from a liquid contaminant than they would differentiating a dust from a fume, or an acid gas from an organic vapor. Differentiating between solids and liquids has not proven problematic in Europe where decision makers have been making such distinctions for many years under regulations CEN-143 and CEN-149.

Eliminating the "solid" only classification would require all particulate respirators to pass DOP liquid penetration and loading tests. Requiring all filters to pass the oil mist (DOP) test adds design limitations and significant cost to these filters. The additional design and cost burdens are unwarranted for most industries. The Danish study submitted earlier to the NIOSH docket (#94-289) clearly shows that 80% of the applications for particulate filters are for solid contaminants. The practical effect of eliminating the "solids" only approval classification would be to increase significantly the costs of respirators to users by limiting options available and necessitating a more expensive form of filter not needed to protect the user against solid particulates.

**2. Thermally generated (hot) v. mechanically nebulized (cold) DOP  
(94-082, page 2, #2)**

By raising the issue of "hot" versus "cold" DOP, MSA is supporting promulgation of regulations that impedes filter media advancement. MSA's position paper states "thermally generated DOP

[should] be used as the challenge aerosol since ISEA round-robin testing has shown that it better evaluates filters on their ability to inhibit the penetration of particulates of the most penetrating type." That statement is simply not true. The referenced ISEA testing, in which both 3M and MSA were participants, indicated only that the tests produce different results. There was no indication as to which method was better.

When filter loading tests are performed using both test methods, the old style, mechanical fiberglass filters exhibit little or no difference in test results. NIOSH has conducted this testing and verified these results. When the same tests are conducted on electrostatic filter media, however, the thermally generated DOP tests appear to result in higher penetrations over time than are seen under the mechanically nebulized DOP test method. The reasons for the higher penetration are not fully understood, and were partially the reason for the ISEA round-robin testing. Subsequent to this testing, serious questions have arisen as to its accuracy and validity. 3M does not believe that adequate testing and correlation has been done to date to fully explain the test result differences, if any exist.

3M has stated its position on the technical advantages of using mechanically generated DOP in position paper to the rulemaking record (found at 94-289). We encourage NIOSH to select a test method that is accurate, consistent, and more likely to ensure that workers are provided a high degree of protection.

### **3. Filter Loading Limits (94-082, Page 2, #3)**

In its position paper, MSA recommends that the DOP loading test be continued until penetration and efficiency ratings have stabilized. MSA argues that such testing will enable users to more easily discern the level of protection afforded when using particular respirators. To fully understand the motivation for this recommendation, we provide NIOSH the following background information on filtration theory.

Early electrostatic filters, used by MSA and others, were based on rosin-wool filter technology. The electrostatic charge on these filters increased the filter's efficiency by attracting fine particles to the filters, much like a comb will attract bits of paper after being rubbed on a piece of cloth. As with a "charged" comb, the charge on rosin-wool filters is not stable. Instead, the charge will degrade with time, or when the filter is subjected to high heat, humidity, moisture, and oils. When the charge degrades, the filter loses efficiency.

Modern electrostatic filters, however, use permanently imbedded charges called electrets, which are incorporated into the polymer fibers that comprise the filters. Unlike rosin-wool, electret filters are stable. The charge is not reduced by heat, humidity, time or moisture. In their position paper, MSA makes no distinction between the two types of filter technologies. Either intentionally or mistakenly, MSA assigns the weaknesses of the old rosin-wool electrostatic

technology to the modern electret technology used by 3M and other manufacturers. This serves only to confuse the reader and improperly denigrate competitive technology.

Oils (DOP in particular) do not "degrade" modern electrostatic, electret filters. When it coats the fibers, DOP acts as an electrical insulator covering the permanent charge and reducing surface resistance, effectively masking the electrostatic charge and, as a result, lowering filter efficiency. Obviously, as more DOP is loaded onto the filter, more electret charges will be covered, further reducing filter efficiency. Actual occurrences of this type of reduction in filter efficiency, however, are rarely, if ever, encountered in the workplace.

The filter loading test proposed by NIOSH in 42 CFR 84 will assure that certified filters have sufficient useful life to protect workers in every conceivable case. This test is already more severe than is necessary for the following reasons:

1. The test specifies filter DOP loading at a concentration of  $100 \text{ mg/m}^3$  to a loading level of 100 mg per filter or 200 mg per respirator. The specified test agent, particle size and concentration level are much more severe than would ever be encountered in the work place, as evidenced in a study conducted at several General Motors facilities [AIHAJ (55) Jan. 1994]. In addition, according to the Danish study cited in 3M submission #94-289, the majority (greater than 95%) of liquids encountered in industrial workplaces will be water-, acid-, or solvent-based rather than oil-based.
2. DOP is more difficult to filter and wets out on filter fibers much more than typical oils used in industry. DOP wets out at about a ten-to-one ratio as opposed to two-to-one ratio for typical cutting and lubricating oils. This means it will wet out on the fiber and cover the electret charge as much as five times faster than will most oils commonly found in the workplace. Under all known workplace conditions, electret filters will last *up to 1,000 times longer* than DOP tests predict.
3. The proposed test specifies a concentration of  $100 \text{ mg/m}^3$ . Respirators will never be used in workplaces with particulate atmospheres at this concentration. Typical oil concentrations reported in the General Motors study were in the area of  $1.0 \text{ mg/m}^3$ . At  $1.0 \text{ mg/m}^3$ , it would require nearly 20 work days to reach the loading levels proposed by NIOSH. This is far more than is needed to measure a respirator filter's useful life in typical workplace applications.
4. The particle size used in the NIOSH loading test is 0.3 micrometers which is, by definition, the most penetrating particle size. In industry, oil mists are generated mechanically and will be much larger in size. The particle size cited in the General Motors study ranged from 3.6 to 9.8 micrometers. In concentrations over  $1.0 \text{ mg/m}^3$ , the oil droplets tend to agglomerate to form very large particles, or drops.

3M addressed the proposed 42 CFR 84 loading test in comments previously submitted to the NIOSH docket (July 20, 1994, #94-289). The proposed tests assure a useful filter life, but go

well beyond the limits of the type of protection that is needed in practical industrial applications. To make these tests even more severe and, in effect, prohibit the use of electret, electrostatic media would thus serve no practical purpose and would unnecessarily remove from the market the most practical and cost-effective respirators available.

The NIOSH proposed loading test, therefore, is already far more severe than can be justified based on any workplace conditions. MSA's suggestion that NIOSH make the test even more severe seems to be designed solely for the purpose of removing successful competitive products from the marketplace and has no other valid worker-protective purpose.

#### **4. Tuberculosis Issue (94-082, Page 2, #4)**

MSA advocates a separate standard covering health care workers that may permit the use of a less expensive respirator, rather than the currently recommended high efficiency particulate air (HEPA) filter respirators. 3M agrees with MSA only to the extent that TB-exposed workers in the health care field should be covered in a separate standard, rather than in 42 CFR 84.

### **Important Considerations**

#### **1. Threshold Limit Values (94-082, Page 2, #1)**

MSA's position paper asserts that data generated in round-robin testing by the Industrial Safety Equipment Association (ISEA) indicates that, under certain conditions, particulate exposures might exceed established OSHA Threshold Limit Values (TLVs). This data was generated using the requirements proposed in 42 CFR 84.

MSA provides an example of a case in which the TLV for beryllium is exceeded. In our view, however, the example was carefully constructed and cleverly written with the result being misleading. It contains fallacies and unreal situations in an attempt to illustrate a point that is not valid. For example:

1. The selection of beryllium as a contaminant was made strictly on the basis of its extremely low TLV. The example does not work for any other contaminant.
2. The selection of a challenge concentration of  $0.098 \text{ mg/m}^3$  which is 49 times the TLV. Had the challenge concentration selected been  $0.1 \text{ mg/m}^3$  (50 times the TLV), the worker would have been overexposed in both scenarios provided.
3. Machining of beryllium with an oil coolant occurs in an enclosure that contains the contaminant. Beryllium dust then is collected in the coolant and is not dispersed freely.

In the real world, concentrations in beryllium machining operations do not reach the levels used in the example.

4. The filter leakage data referenced for the electrostatic filter (cleverly named "degradable") is from the ISEA round robin test. These were not respirator filters, however, nor were they designed or intended to meet the requirements of 42 CFR 84. These were flat filter media intended only for use in this testing by ISEA members and by NIOSH to determine test method differences. To use these data in an unrealistic hypothetical case is intentionally misleading and violates the constructive spirit of cooperation with which the filter materials were provided to participants.
5. The stated Assigned Protection Factor (APF) leakage of 2% is also incorrect. A full face respirator has an APF of 50. This represents a maximum total inward leakage of 2%. The APF leakage includes *both* face seal leakage and filter penetration. Adding filter penetration to it is redundant and incorrect. MSA surely is aware of that.
6. Even if the rest of the example was credible, an oil based coolant simply would not wet out and reduce the efficiency of an electrostatic filter to the same degree as DOP.
7. The concentration of the oil mist is not stated, but it would not be near the 100 mg/m<sup>3</sup> level used in the round robin testing. As shown in the General Motors study, typical oil concentrations in machining operations are about 1.0 mg/m<sup>3</sup>.
8. The "Note," added at the end of the example, states that these filters degrade with time and humidity is another example of MSA attempting to confuse old rosin-wool electrostatic filter performance with the modern electret electrostatic filter performance. Electret filters do not degrade with time or humidity as do old technology rosin-wool filters.

## **2. Misuse of "Solids" and "Solids/Liquids" (94-082, Page 3, #2)**

Later in its position paper, MSA states that "many of the DOE nuclear facilities have banned electrostatic filters." Regulations for nuclear facilities do not preclude the use of electrostatic filters. Contrary to MSA's assertions, 3M does have customers in the nuclear industry that are using electrostatic (electret) HEPA filters because of their ease of incineration and worker preference.

MSA further alleges that "OSHA also requires its inspectors to use only mechanical filters enclosed in cartridges or canisters. In other words, no electrostatic filters." The quote and the supporting enclosure are from OSHA Compliance Policy Letter 2- 2.54. We understand OSHA is in the process of revising CPL 2- 2.54. When the draft revision was referred to the OSHA

Technical Center in Salt Lake City, it removed the quoted language. The OSHA personnel in Salt Lake City support the use of electret filters and disposable respirators for OSHA personnel. The revised CPL still is being circulated and has not been issued as a final document to date.

The example MSA gives concerning the asbestos industry is also misleading. Asbestos is, as stated, a solid. The fact that water is present, or that the humidity is high, does not alter the situation, since moisture or humidity do not affect electret filter media. The respirable fraction of concern is solid and a "solid" approval would be sufficient. In Europe, where classifications are for "solid" or "liquid and solid", water based mists are considered solids. Requiring a more costly respirator filter certified for oil mist would not improve the protection provided to the worker.

**3. The Tuberculosis Issue  
(94-082, Page 3, #3)**

See earlier comments regarding TB.

**4. MSA Conclusion  
(94-082, Page 3, #4)**

This paragraph contains a statement with which 3M takes issue more than any other in the position paper. MSA states "...that both NIOSH and MSA have the best interest of the American worker at heart." In the preceding comments, we have attempted to support our opinion that, contrary to this statement, MSA's interest in regulations appears to be aimed at restraining new technology that will benefit the end user, but thus providing MSA with an unfair competitive and economic advantage.

**Conclusion:**

Modern electret electrostatic filters have advanced a long way since the days of rosin-wool filters. Today's electrostatics provide users with filters that are efficient, protective, user-friendly, easy to breathe through, less costly and much preferred by workers and decision makers. These factors make electrostatic filters more comfortable and easier to wear, resulting in a greater likelihood of uninterrupted use. The end result is a respirator that is more likely to be worn than an uncomfortable mechanical filter respirator that may be frequently removed by the wearer, thereby exposing the worker to significant risks.

If not stifled by unrealistic, onerous regulatory requirements, electret technology also provides the greatest potential to improve over the next few years and is most likely to provide users even

better respirator filters than are available today. This should be the ultimate goal of NIOSH as it issues its revised respirator certification standard.

Sincerely,

A handwritten signature in cursive script that reads "Katherine E. Reed".

Katherine E. Reed, Ph.D.  
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