December 15, 1994

Senior Scientist, OD, NIOSH

Subject

November 15, 1994, Meeting With 3M Representatives

To the Record

On November 15, 1994, I participated with Dr. Rosenstock in a meeting in her office with representatives of The Jefferson Group (Mr. Randy Schumacher and Mr. Rob McArver) and the 3M Occupational Health and Environmental Safety Division (Dr. Katherine E. Reed, Technical Director, and Mr. Ronald E. King, Regulatory Affairs Manager). This meeting was in response to a request by Mr. Schumacher. It began shortly after 11 am and adjourned shortly before noon.

Dr. Rosenstock made it clear at the outset that discussions bearing on the pending NIOSH revision of 30 CFR 11 would need to be documented and made available to the public record. The visitors accepted that position and assured us that their purpose was not to discuss the rulemaking but to make comments and provide information bearing on allegations made by Dr. Nelson Leidel regarding NIOSH-certified 3M respirators. Because some later comments did reflect issues raised in the NPRM, these notes are being included in the public record.

The 3M representatives provided a 1-page summary sheet (attachment A) covering their key issues. In conversation, they were anxious to make assurances that 3M had neither sought nor received preferential treatment from NIOSH staff in the certification of respirators. They also were anxious to dispute any charge that 3M respirators were improperly certified or that 3M respirators failed to perform as expected in the workplace.

With regard to the charge that the 3M "electret" filter medium is subject to degradation in the workplace, they offered a discussion of the way in which various electrostatic media function. They drew a distinction between the electret technology and other electrostatic media, saying that electret filters do not rely on a simple applied electrostatic charge. They also stated that the electrostatic charge that is carried by the electret medium is not dissipated by humidity and other environmental factors, as is the case with other electrostatic media.
They referred to workplace effectiveness testing conducted by 3M Company that they argued has demonstrated the appropriateness of the certifications issued by NIOSH for 3M products. They provided a 1-page table (Attachment B) showing results of studies conducted by 3M in a variety of workplaces and where a variety of respirators and filter types were in use. They called our attention to the fact that in every case the 5th percentile Workplace Protection Factor reported by 3M was greater than the NIOSH Assigned Protection Factor for the device in use. Their point was to refute the charge that NIOSH-certified respirators constitute a "hidden hazard" for respirator users since there was no failure to achieve the level of protection certified by NIOSH or required by OSHA/MSHA regulation.

In response to a question, they stated that these results and conclusions were based on calculations using mass penetration, not particle count penetration. However, they also argued that it would have been inappropriate to base their evaluation on particle count penetration instead of mass penetration because "fines" are not toxicologically important.

In response to questions as to the particle size distribution of aerosols in the workplaces studied, the 3M representatives indicated they did have data on particle size distributions in workplaces and offered to provide those data to NIOSH following this meeting. (Data were subsequently provided to Dr. Rosenstock in a letter dated December 8, 1994 -- Attachment C.)

With regard to Dr. Leidel's call for a "User's Notice" pertaining to perceived dangers or hidden hazards, they expressed the dual concerns that User's Notices "never go away," and that they paint all technologies with the same brush.

They discussed the training that 3M provides for respirator users. The goal of that training is to be sure 3M products are properly used, to make it easy to comply with OSHA program demands, train workers, etc. Mr. Schumacher stated that 3M spends $5 million annually on training their customers.

In closing, they briefly discussed what they regarded as the irrelevance of Dr. Leidel's charges concerning dangers to health care workers who use HEPA filters for protection against M. tuberculosis. Their central point was that there is no DOP or other severely degrading aerosol in the health care environment, aerosols all being water-borne particulates.

Bryan D. Hardin, Ph.D.
Dr. Rosenstock Meeting

November 15, 1994

3M appreciates the opportunity to meet with Dr. Rosenstock to discuss issues of mutual interest concerning regulatory standards for testing and certification of respiratory protection devices.

We support NIOSH in the 42 CFR 84 rulemaking and believe the regulations for respirator certification are due for updating. We believe the proposed standard, in general, provides the desired update. In our opinion, the proposal is somewhat over designed in some areas, and the regulation more restrictive than necessary to provide the expected protection to the respirator user. We have addressed these concerns in comments to the rulemaking docket and appreciate NIOSH’s consideration of our stated position.

The NIOSH proposal addresses the major perceived shortcoming of 30 CFR 11, in that Dust/Mist and Dust/Fume/Mist (non-HEPA) particulate filters will be tested for initial, instantaneous penetration. This will prevent certification of filters that have high initial penetration and rely on filter loading to pass current standard. The proposed standard will require all respirator manufacturers to develop and improve present filter technology.

3M has the utmost respect for the ability and integrity of NIOSH personnel involved in Testing and Certification at Morgantown, WV. 3M has never requested nor received any special treatment or deviation from the certification rules as specified in 30 CFR 11. The NIOSH personnel have administered this regulation to the best of their abilities.

3M is committed to the respiratory protection business. Our present products meet or exceed present NIOSH standards and we have validated their protective capability by conducting extensive studies in the actual workplace. 3M is the only respirator manufacturer to conduct such extensive studies. We have published our studies and made them available for others, such as NIOSH, OSHA, and ANSI committees, to use in assessing respirator performance. To assist the user and to assure that our products provide the highest level of protection through proper use, we have developed and extensive array of training materials and services. These include on-site worker training and fit testing, computerized and booklet form respirator selection guides, respirator program administration guides in paper and computer form, and a series of comprehensive training seminars for respirator program administrators.

3M will continue to develop new technologies and new products to meet new regulations, even if, in our opinion, the regulation is more stringent than practical for worker protection. We support NIOSH’s effort to update standards and hope they encourage technology advancement to the benefit of the worker.
<table>
<thead>
<tr>
<th>Industry Type</th>
<th>Application</th>
<th>Filter Type</th>
<th>respirator type</th>
<th>Date</th>
<th>Geometric Mean</th>
<th>5th % WPE</th>
<th>WPE</th>
<th>WPE</th>
<th>Variability</th>
<th>Mean WPE</th>
<th>Variability</th>
<th>Study</th>
<th>Product</th>
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<tr>
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<td>Acetylene torch/ cutting</td>
<td>Electric</td>
<td>Full Face Mask</td>
<td>Jul-90</td>
<td>Fe 139</td>
<td>Shaping</td>
<td>Welding</td>
<td>Electric</td>
<td>Full Face Mask</td>
<td>7800 Paper</td>
<td>7800 W/2325</td>
<td>8715</td>
<td></td>
</tr>
<tr>
<td>Robotic E</td>
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<td>Electric</td>
<td>Full Face Mask</td>
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<td>Fe 139</td>
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<td>8715</td>
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</tr>
</tbody>
</table>
December 8, 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:

Thank you for taking the time to meet with us on November 15. Dr. Reed and I from 3M and Randy Schumacher and Rob McArver of the Jefferson Group appreciate the opportunity to meet you and discuss mutual areas of interest concerning respiratory protection.

During our discussion, we left with you a summary sheet of Workplace Protection Factor tests conducted by 3M. This type of testing provides the clearest understanding of the actual protection being provided to the wearer during actual job performance and workplace conditions. The summary clearly shows that products certified by NIOSH under the current 30 CFR 11, whether dust/mist or HEPA, electret or fiberglass media, all provide protection in excess of the respective Assigned Protection Factors.

During this discussion, you asked if we had and could provide particle size distributions for these tests. The enclosed summary sheet and eight individual analysis sheets provides the particle size distributions in both table and graph forms. In most of the tests the largest percentage of the mass is in the larger size range, above 5.0 micrometers (μm). Several, where metal fume is generated, exhibit a bimodal distribution with a significant percent of the mass less than 1.0 μm. One test, Sheet #7, was particularly interesting. This was an operation that was cutting apart an old Navy aircraft carrier for salvage. The primary hazard was lead fume, mostly produced by torching through multiple layers of lead based paint built up over the years. In one area, 96% of the mass was around 0.4 μm. This is the most severe in terms of small particles we have seen. Nevertheless, the
electret HEPA filter provided excellent results and provided protection in excess of the Assigned Protection Factor.

We hope you find the additional information helpful. If there is any further detail needed, we would be happy to supply it. We look forward to a continuing excellent relationship with you and the NIOSH staff.

Sincerely,

Ronald E. King
Regulatory Affairs Manager
3M Occupational Health & Environmental Safety Division

REK:llj/147
Enclosure
WORKPLACE PROTECTION FACTOR STUDIES

Updated compilation 11/94 - JOB

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>RESPIRATOR TYPE</th>
<th>FILTER TYPE</th>
<th>APPLICATION</th>
<th>INDUSTRY TYPE</th>
<th>STUDY DATE</th>
<th>ELEMENT(S)</th>
<th>Geometric Mean WPF</th>
<th>5th % WPF</th>
<th>Particle Size Info Refer to:</th>
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<tr>
<td>8715</td>
<td>half mask</td>
<td>electret</td>
<td>Grind and polish</td>
<td>Aircraft parts</td>
<td>Oct-86</td>
<td>Al</td>
<td>145</td>
<td>32</td>
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<td>7800 w/7255</td>
<td>full face mask</td>
<td>fiberglass</td>
<td>Blast furnaces and casting</td>
<td>Lead smelter</td>
<td>Mar-88</td>
<td>Pb</td>
<td>3929</td>
<td>95</td>
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<td>9906</td>
<td>half mask</td>
<td>electret</td>
<td>Potroom</td>
<td>Aluminum smelter</td>
<td>Nov-88</td>
<td>Al</td>
<td>27</td>
<td>13</td>
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<td>9970</td>
<td>half mask</td>
<td>electret</td>
<td>Mold-making and pouring</td>
<td>Brass foundry</td>
<td>Apr-89</td>
<td>Zn</td>
<td>681</td>
<td>40</td>
<td>Sheet #4</td>
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<td>7800 PAPR</td>
<td>full face mask</td>
<td>fiberglass</td>
<td>Blast furnaces and casting</td>
<td>Lead smelter</td>
<td>Sep-89</td>
<td>Pb</td>
<td>4226</td>
<td>728</td>
<td>Sheet #2</td>
</tr>
<tr>
<td>9920</td>
<td>half mask</td>
<td>electret</td>
<td>Welding</td>
<td>Shipbuilding</td>
<td>Jul-90</td>
<td>Fe</td>
<td>139</td>
<td>22</td>
<td>Sheet #5</td>
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<tr>
<td>6000 w/2040</td>
<td>half mask</td>
<td>electret</td>
<td>Mixing and extruding</td>
<td>Plastic colorants</td>
<td>Mar-93</td>
<td>Cd</td>
<td>353</td>
<td>34</td>
<td>Sheet #6</td>
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<td>6000 w/2047</td>
<td>half mask</td>
<td>electret</td>
<td>Acetylene torch-cutting</td>
<td>Ship-breaking</td>
<td>Apr-93</td>
<td>Pb</td>
<td>135</td>
<td>15</td>
<td>Sheet #7</td>
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<tr>
<td>7000 w/7255 w/2040</td>
<td>half mask fiberglass electret</td>
<td>Pasting and assembly</td>
<td>Battery manufacturing</td>
<td>Apr-94</td>
<td>Pb</td>
<td>515</td>
<td>117</td>
<td>Sheet #8</td>
<td></td>
</tr>
</tbody>
</table>
Product: 8715, maintenance-free
Respirator Type: Half mask
Filter type: Electret - Dust/Mist
Application: Grind and polish
Industry Type: Aircraft parts
Study Date: October, 1986
Elements: Al, Si, Ti
Geometric Mean WPF: 145, 172, 59
5th% WPF: 32, 24, 24

Comments: This was a buffing and polishing operation. The major contaminant is aluminum. The particle size distribution is definitely bimodal. The fines (<1.0um) were generated by the buffing and make up a large part of the distribution due to the settling rate of the larger particles.

The respirator tested is an electret-filtered, disposable half-mask approved by NIOSH as a Dust/Mist per 30 CFR 11. Even though 35% of the mass had a particle size below 1.0um, the protection factors measured were well above the Assigned Protection Factor of 10 for a half-mask.
Product: 7800 Series with 7255 high efficiency filters
Respirator Type: Full face mask
Filter type: Fiberglass, HEPA
Application: Blast furnaces and casting
Industry Type: Lead smelter
Study Date: September, 1989
Elements: Pb
Geometric Mean WPF: 4226
5th% WPF: 728

Comments: As indicated, this is a smelting operation. Small size metal fume particles would normally be expected. However, the measured size shows the majority to be around 11.5μm. We suspect this is due to high ventilation carrying away fines and the tendency for lead fume to agglomerate into larger particles. The measured protection factor was very high.
SHEET #3

9906
Aluminum

GM = 0.7
45% of Mass

GM = 11
55% of Mass

Diameter (micrometers)

<table>
<thead>
<tr>
<th>Particle Size</th>
<th>0.1</th>
<th>0.52</th>
<th>0.93</th>
<th>1.6</th>
<th>3.5</th>
<th>6</th>
<th>9.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Mass</td>
<td>22.6</td>
<td>19.2</td>
<td>13.7</td>
<td>6.9</td>
<td>2.1</td>
<td>6.9</td>
<td>28.8</td>
</tr>
</tbody>
</table>

Product 9906, maintenance-free
Respirator Type Half mask
Filter type Electret, Dust/Mist
Application Potroom
Industry Type Aluminum smelter
Study Date November, 1988
Elements Al
Geometric Mean WPF 27
5th% WPF 13

Comments This is a typical aluminum smelting operation with a high percentage of small metal fume size aerosols. Even with the high percentage of submicron particles, the electret, Dust/Mist filter provided protection factors well above 10.
This test also shows a bimodal particle distribution as might be expected in a pouring operation. 55% of the mass is less than 1μm. The electret, HEPA-filtered, half-mask provided protection factors well above 10.
### Particle Size Distribution

<table>
<thead>
<tr>
<th>Material</th>
<th>GM</th>
<th>Diameter (micrometers)</th>
<th>% Mass</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manganese</strong></td>
<td>0.7</td>
<td>0.00 - 15.00</td>
<td>95% of Mass</td>
</tr>
<tr>
<td><strong>Titanium</strong></td>
<td>0.9</td>
<td>0.00 - 15.00</td>
<td>68% of Mass</td>
</tr>
<tr>
<td><strong>Zinc</strong></td>
<td>0.7</td>
<td>0.00 - 15.00</td>
<td>35% of Mass</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>0.9</td>
<td>0.00 - 15.00</td>
<td>28% of Mass</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Particle Size</th>
<th>0.1</th>
<th>0.52</th>
<th>0.93</th>
<th>1.6</th>
<th>3.5</th>
<th>6</th>
<th>9.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Mass Manganese</td>
<td>44.2</td>
<td>32.2</td>
<td>10.5</td>
<td>3.4</td>
<td>3.2</td>
<td>1.7</td>
<td>4.9</td>
</tr>
<tr>
<td>% Mass Titanium</td>
<td>14.4</td>
<td>10.6</td>
<td>7.6</td>
<td>6.8</td>
<td>14.8</td>
<td>13.1</td>
<td>32.7</td>
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<tr>
<td>% Mass Zinc</td>
<td>25.8</td>
<td>17.1</td>
<td>9.7</td>
<td>6</td>
<td>9.3</td>
<td>7.8</td>
<td>24.2</td>
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<tr>
<td>% Mass Iron</td>
<td>25.3</td>
<td>17.3</td>
<td>9.4</td>
<td>6.5</td>
<td>11.8</td>
<td>8.9</td>
<td>20.8</td>
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</tbody>
</table>

**Product**
9920, maintenance-free

**Respirator Type**
Half mask

**Filter Type**
Electret, Dust/Fume/Mist

**Application**
Welding

**Industry Type**
Shipbuilding

**Study Date**
July, 1990

**Elements**
Fe, Zn, Ti, Mn

**Geometric Mean WPF**
139, 146, 324, 104

**5th% WPF**
22, 33, 43, 16

**Comments**
A variety of elements measured exhibited bimodal distribution in this welding operation. The electret-filtered, D/F/M, half-mask, disposable respirator provided excellent protection despite the small particles in the atmosphere.
**SHEET #6**

### Graph

6000 w/2040 Cadmium

- **GM = 1.3**
- **32% of Mass**
- **GM = 9.8**
- **68% of Mass**

### Table

<table>
<thead>
<tr>
<th>Particle Size</th>
<th>0.1</th>
<th>0.52</th>
<th>0.93</th>
<th>1.6</th>
<th>3.5</th>
<th>6</th>
<th>9.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Mass</td>
<td>1.4</td>
<td>5.2</td>
<td>17</td>
<td>9.7</td>
<td>13.2</td>
<td>20.1</td>
<td>33.3</td>
</tr>
</tbody>
</table>

**Product**: 6000 Series with 2040 high efficiency filters  
**Respirator Type**: Half mask  
**Filter type**: Electret, HEPA  
**Application**: Mixing and extruding  
**Industry Type**: Plastic colorants  
**Study Date**: March, 1993  
**Elements**: Cd  
**Geometric Mean WPF**: 353  
**5th% WPF**: 34

**Comments**: As indicated, the majority of the mass of the contaminant was in the 10um range. The performance of the electret HEPA filter was excellent.
Sheet #7

<table>
<thead>
<tr>
<th>Diameter (micrometers)</th>
<th>% Mass</th>
<th>% Mass</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
<td>0.00</td>
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<tr>
<td>5.00</td>
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<td>10.00</td>
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<td>15.00</td>
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**Particle Size**

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<th>0.93</th>
<th>1.6</th>
<th>3.5</th>
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<th>9.8</th>
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<tr>
<td>% Mass #1</td>
<td>59.7</td>
<td>25.9</td>
<td>10.4</td>
<td>1.3</td>
<td>0</td>
<td>2.6</td>
<td>0</td>
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<tr>
<td>% Mass #2</td>
<td>85.5</td>
<td>4.7</td>
<td>1.8</td>
<td>0.65</td>
<td>0.84</td>
<td>0.94</td>
<td>5.6</td>
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</table>

Product: 6000 Series with 2047 high efficiency filters
Respirator Type: Half mask
Filter type: Electret, HEPA
Application: Acetylene torch-cutting
Industry Type: Ship-breaking
Study Date: April, 1993
Elements: Pb
Geometric Mean WPF: 135
5th% WPF: 15

Comments: The two graphs shown represent the different areas of a ship-breaking or salvaging operation. The particle size distributions are not significantly different; both being mainly in the submicron range. The lead in this operation comes from torch-cutting steel that has years of built-up, lead-based paint. The ship being cut up was a Navy aircraft carrier. The electret HEPA filter provided excellent results and WPF's well above 10 despite the small particle size.
7000 Series with 7255 and 2040 high efficiency filters
Half mask
Fiberglass (7255), electret (2040) - both HEPA
Pasting and assembly
Battery manufacturing
April, 1994
Pb
515, 433
117, 99
In this operation the majority of the particles are large as would be predicted in mechanical manipulation of lead material. This distribution is typical of most non-fume operations. It should be noted that 7% of the mass of the particles are below 1um. Even so, the performance of the electret HEPA filter and the typical fiberglass HEPA filter are not statistically different.