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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date December 15, 1994

From Senior Scientist, OD, NIOSH

Subject November 15, 1994, Meeting With 3M Representatives

To 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.

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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.

Attachment A

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.

Attachment B

WORKPLACE PROTECTION FACTOR STUDIES

Updated compilation 11/94 - JOB

PRODUCT	RESPIRATOR TYPE	FILTER TYPE	APPLICATION	INDUSTRY TYPE	STUDY DATE	ELEMENT(S)	Geometric Mean WPF	5th % WPF
8715	half mask	electret	Grind and polish	Aircraft parts	Oct-86	Al	145	32
						Si	172	24
						Ti	59	24
7800 w/7255	full face mask	fiberglass	Blast furnaces and casting	Lead smelter	Mar-88	Pb	3929	95
9906	half mask	electret	Potroom	Aluminum smelter	Nov-88	Al	27	13
9970	half mask	electret	Mold-making and pouring	Brass foundry	Apr-89	Zn	681	40
						Pb	310	28
7800 PAPR	full face mask	fiberglass	Blast furnaces and casting	Lead smelter	Sep-89	Pb	4226	728
9920	half mask	electret	Welding	Shipbuilding	Jul-90	Fe	139	22
						Zn	146	33
						Si		
						Ti	324	43
						Mn	104	16
6000 w/2040	half mask	electret	Mixing and extruding	Plastic colorants	Mar-93	Cd	353	34
6000 w/2047	half mask	electret	Acetylene torch-cutting	Ship-breaking	Apr-93	Pb	135	15
7000 w/7255 w/2040	half mask	fiberglass electret	Pasting and assembly	Battery manufacturing	Apr-94	Pb	515	117
							433	99

3M Occupational Health and
Environmental Safety Division

3M Center
St. Paul, MN 55144-1000
612 733 1110

Attachment C

3M 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

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

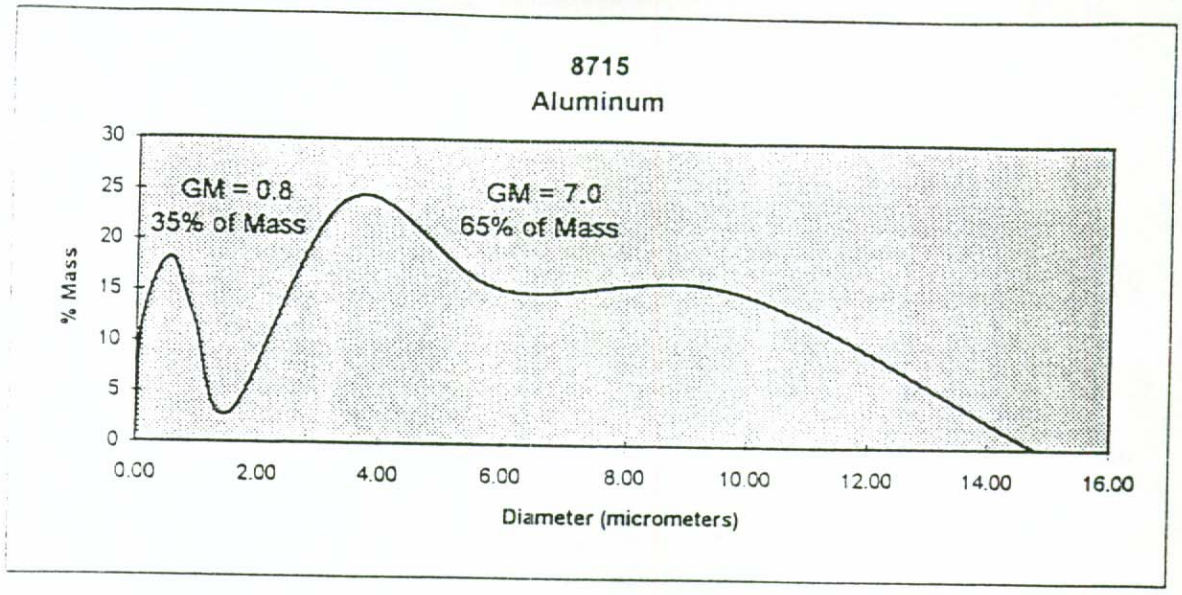
REK:llj/147
Enclosure

WORKPLACE PROTECTION FACTOR STUDIES

Updated compilation 11/94 - JOB

PRODUCT	RESPIRATOR TYPE	FILTER TYPE	APPLICATION	INDUSTRY TYPE	STUDY DATE	ELEMENT(S)	Geometric Mean WPF	5th % WPF	Particle Size Info Refer to:
8715	half mask	electret	Grind and polish	Aircraft parts	Oct-86	Al	145	32	Sheet #1
						Si	172	24	
						Ti	59	24	
7800 w/7255	full face mask	fiberglass	Blast furnaces and casting	Lead smelter	Mar-88	Pb	3929	95	Sheet #2
9906	half mask	electret	Potroom	Aluminum smelter	Nov-88	Al	27	13	Sheet #3
9970	half mask	electret	Mold-making and pouring	Brass foundry	Apr-89	Zn	681	40	Sheet #4
						Pb	310	28	
7800 PAPR	full face mask	fiberglass	Blast furnaces and casting	Lead smelter	Sep-89	Pb	4226	728	Sheet #2
9920	half mask	electret	Welding	Shipbuilding	Jul-90	Fe	139	22	Sheet #5
						Zn	146	33	
						Si			
						Ti	324	43	
						Mn	104	16	
6000 w/2040	half mask	electret	Mixing and extruding	Plastic colorants	Mar-93	Cd	353	34	Sheet #6
6000 w/2047	half mask	electret	Acetylene torch-cutting	Ship-breaking	Apr-93	Pb	135	15	Sheet #7
7000 w/7255 w/2040	half mask	fiberglass electret	Pasting and assembly	Battery manufacturing	Apr-94	Pb	515	117	Sheet #8
							433	99	

SHEET #1



Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	12.1	18.2	12.1	3	24.2	15.2	15.2

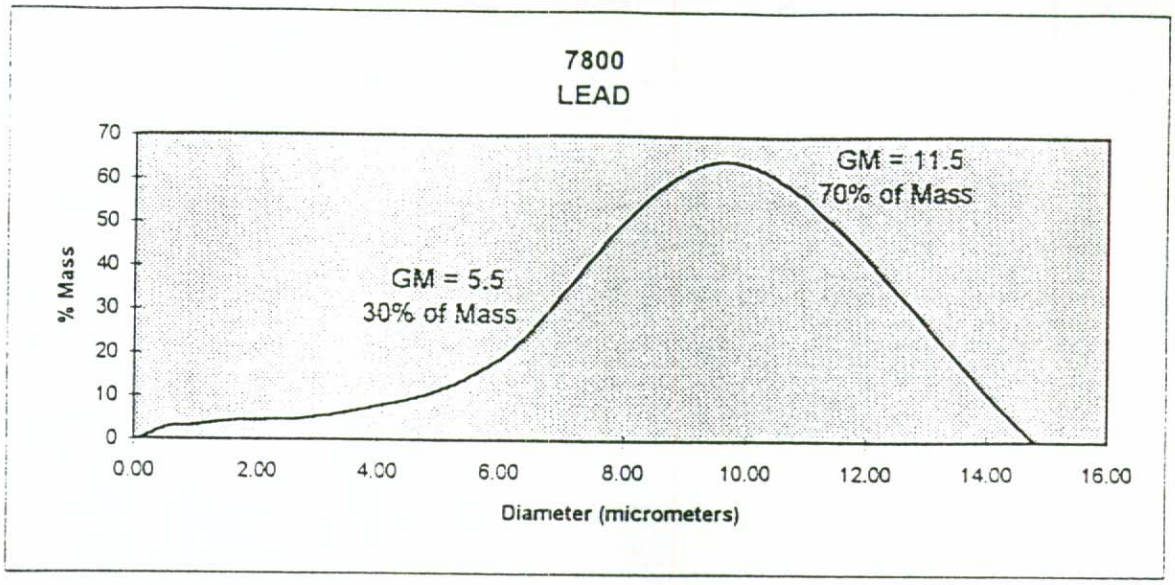
Product	8715, maintenance-free
Respirator Type	Half mask
Filter type	Electret - Dust/Mist
Application	Grind and polish
Industry Type	Aircraft parts
Study Date	October, 1986
Elements	Al, Si, Ti
Geometric Mean WPF	145, 172, 59
5th% WPF	32, 24, 24

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.

SHEET #2



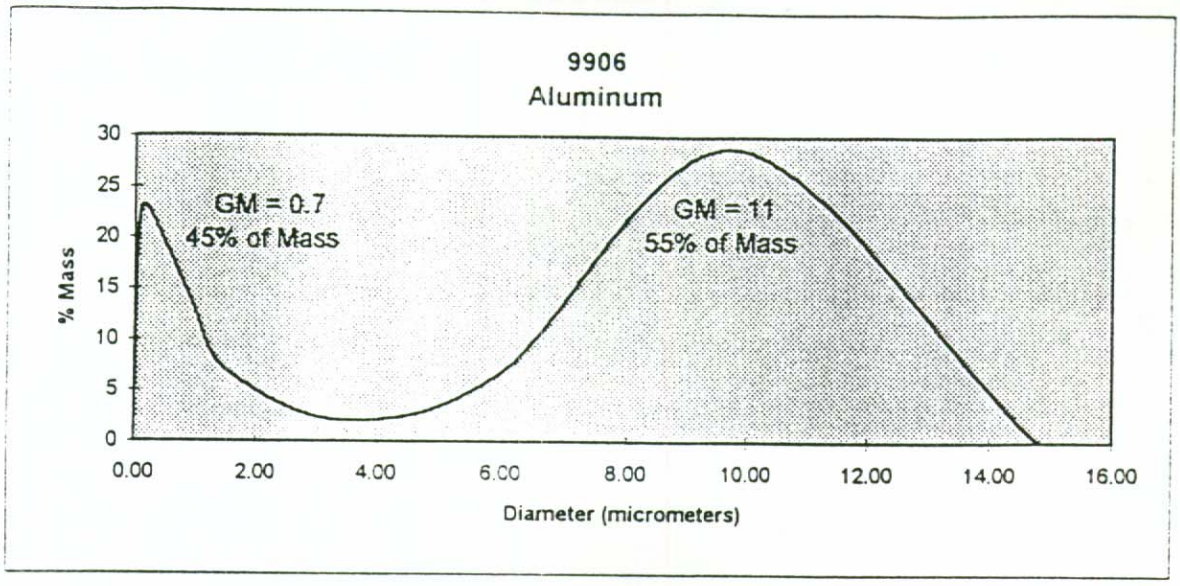
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	0.2	2.8	3.3	4.4	6.4	18.8	64.1

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 11.5um. 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



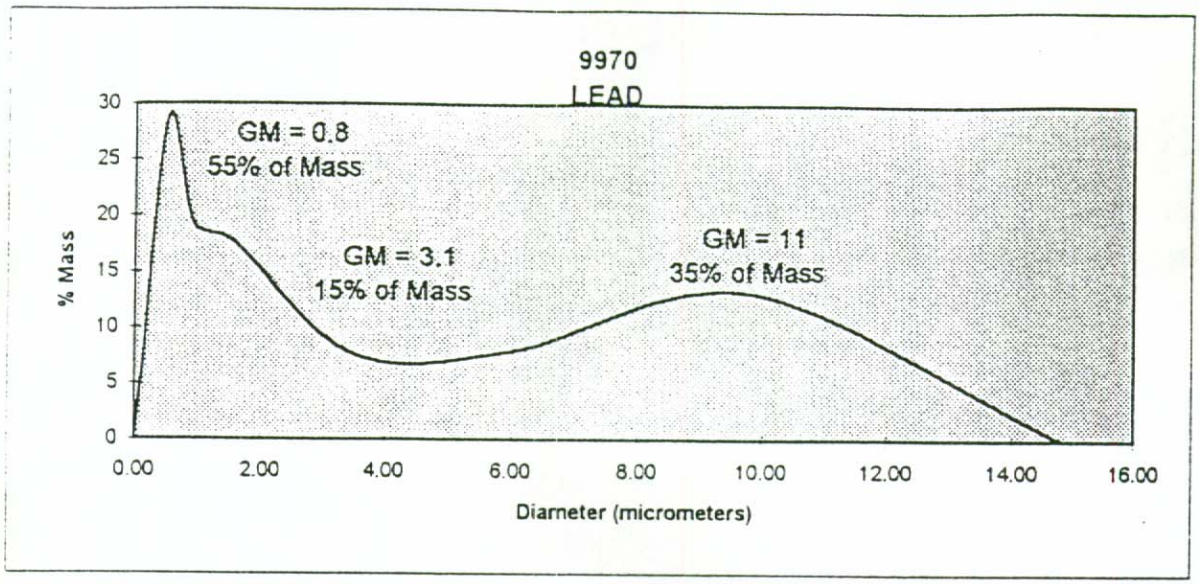
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	22.6	19.2	13.7	6.9	2.1	6.9	28.8

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.

SHEET #4



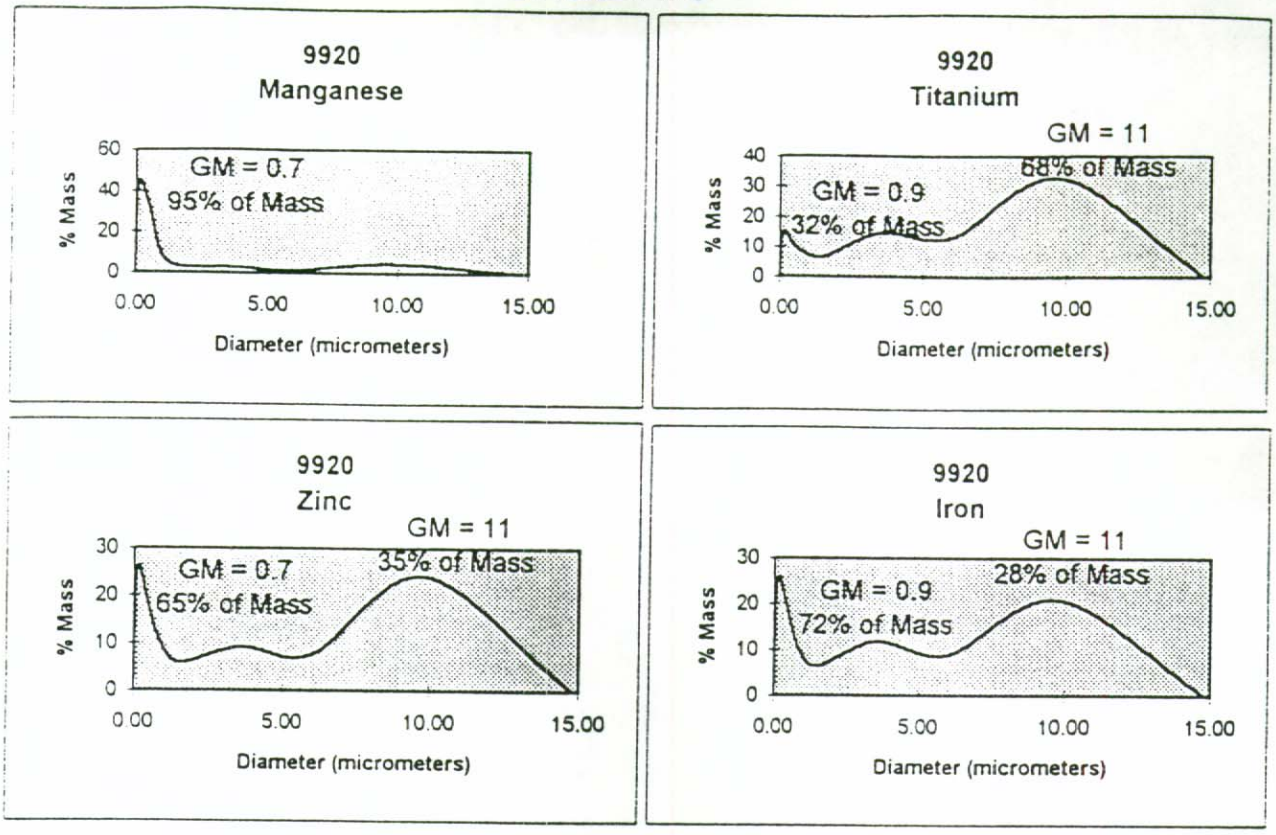
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	5.39	28.8	19.3	17.7	7.6	7.9	13.2

Product	9970 maintenance-free, high efficiency
Respirator Type	Half mask
Filter type	Electret, HEPA
Application	Mold-making and pouring
Industry Type	Brass foundry
Study Date	April, 1989
Elements	Pb, Zn
Geometric Mean WPF	310, 681
5th% WPF	28, 40

Comments

This test also shows a bimodal particle distribution as might be expected in a pouring operation. 55% of the mass is less than 1um. The electret, HEPA-filtered, half-mask provided protection factors well above 10.

SHEET #5



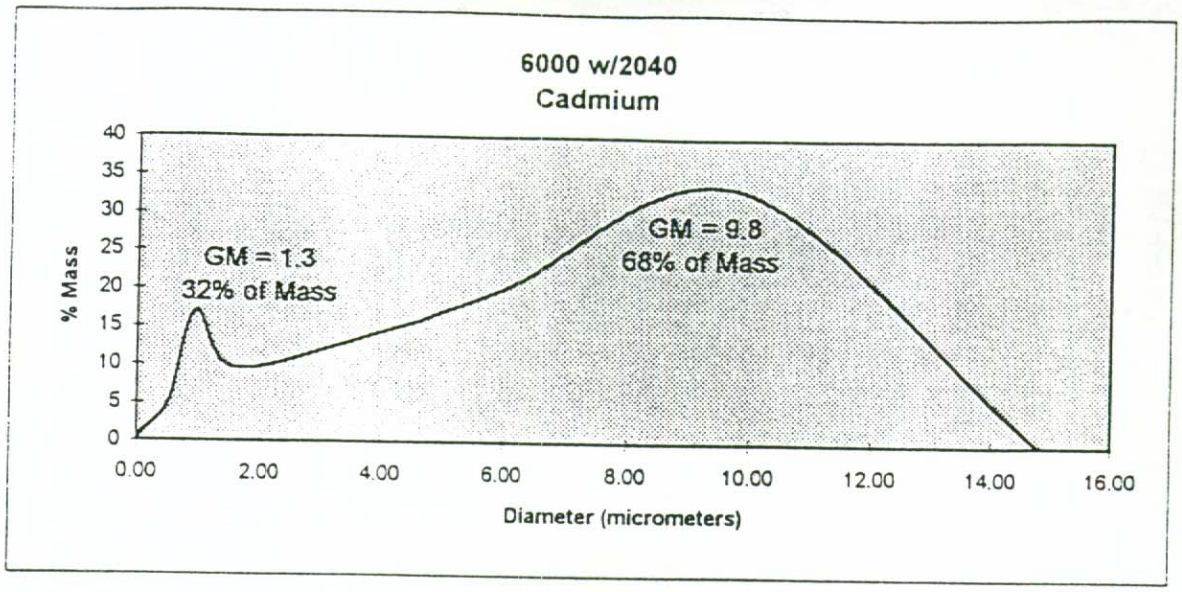
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass Manganese	44.2	32.2	10.5	3.4	3.2	1.7	4.9
% Mass Titanium	14.4	10.6	7.6	6.8	14.8	13.1	32.7
% Mass Zinc	25.8	17.1	9.7	6	9.3	7.8	24.2
% Mass Iron	25.3	17.3	9.4	6.5	11.8	8.9	20.8

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



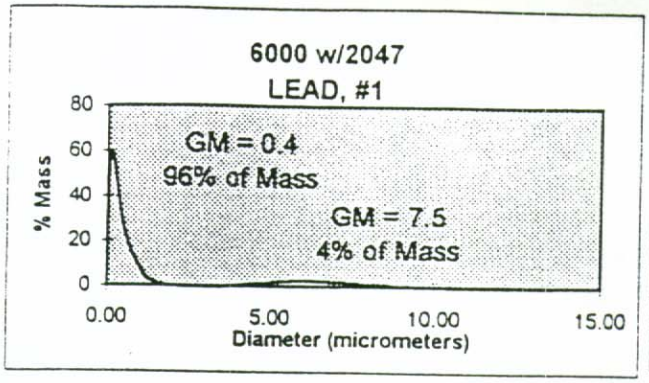
Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	1.4	5.2	17	9.7	13.2	20.1	33.3

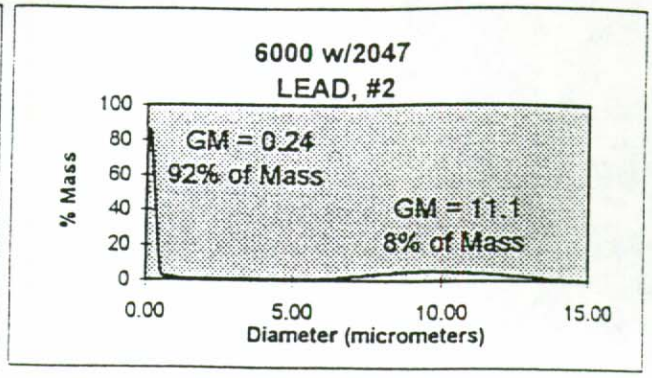
Product	6000 Series with 2040 high efficiency filters
Respirator Type	Half mask
Filter type	Electret, HEPA
Application	Mixing and extruding
Industry Type	Plastic colorants
Study Date	March, 1993
Elements	Cd
Geometric Mean WPF	353
5th% WPF	34

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





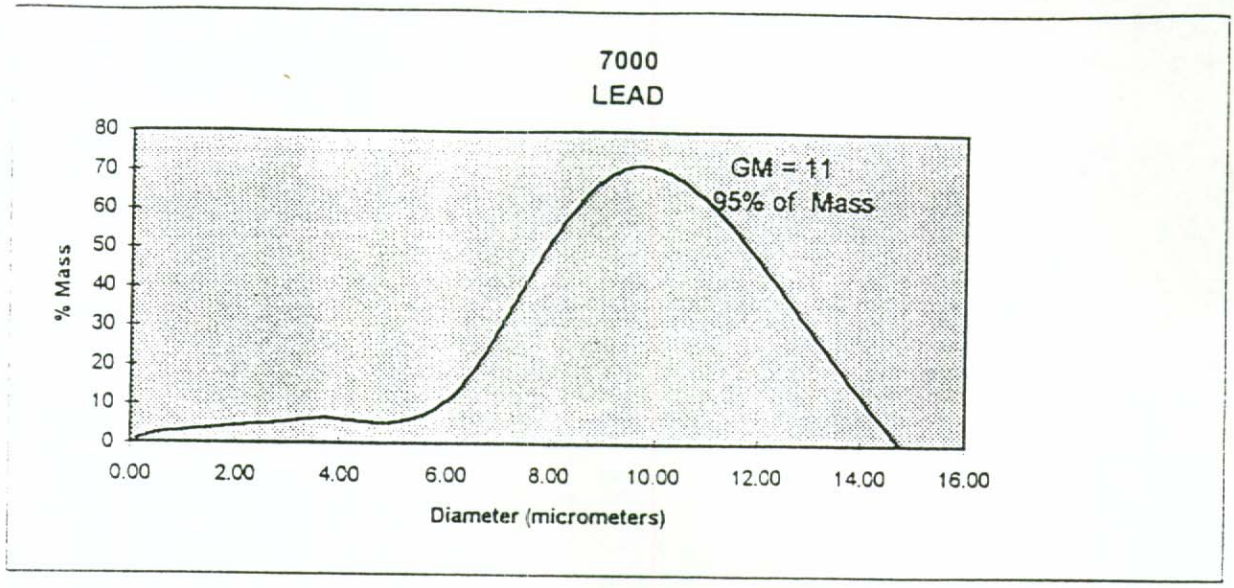
Particle Size		0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	#1	59.7	25.9	10.4	1.3	0	2.6	0
% Mass	#2	85.5	4.7	1.8	0.65	0.84	0.94	5.6

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.

SHEET #8



Particle Size	0.1	0.52	0.93	1.6	3.5	6	9.8
% Mass	1.1	2.7	3.2	4	6.4	11.1	71.5

Product	7000 Series with 7255 and 2040 high efficiency filters
Respirator Type	Half mask
Filter type	Fiberglass (7255), electret (2040) - both HEPA
Application	Pasting and assembly
Industry Type	Battery manufacturing
Study Date	April, 1994
Elements	Pb
Geometric Mean WPF	515, 433
5th% WPF	117, 99

Comments

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.