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3M

NIOSH Docket Officer
Robert A. Taft Laboratories
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RE: Comments to the proposed NIOSH Certification Standard for Chemical Biological Radiological Nuclear Air Purifying Respirator Standard per Proposed NIOSH Certification Standard for APR CBRN Federal Register Notice May 31, 2002 (Vol.67, Number 105, pg. 38127-38128)

Dear Docket Officer:

Minnesota Mining and Manufacturing Company (3M), through its Occupational Health and Environmental Safety (OH&ES) Division, is a major manufacturer and supplier of respiratory protective devices throughout the world. 3M has invented, developed, manufactured and sold approved respirators since 1972. We have developed numerous training programs, videos, computer programs and technical literature to help our customers develop and run effective respirator programs. Our sales people have trained and fit tested hundreds of thousands of respirator wearers throughout the world. Our technical staff has performed basic research on the performance of respirators and their uses, presented and published this data in numerous forums and participated in the development of the ANSI Z88 standards on respiratory protection. In sum, we have substantial experience in all phases and applications of respiratory protection. We are pleased to provide the National Institute for Occupational Health and Safety with our comments on proposed Certification Standard for APR CBRN, 67 FR 38127, dated May 31, 2002.

3M supports NIOSH in its attempt to develop a standard for evaluating the effectiveness of respirators for use in atmospheres that may contain chemical, biological, radiological, and nuclear (CBRN) war agents. We recognize that it is imperative that these types of products be available as soon as possible. However, the formal rulemaking process, which considers input from all stakeholders, is necessary for developing appropriate CBRN equipment standards. We offer the following comments and recommendations regarding a Performance Based Approach, Aerosol Filtration in CBRN Full Facepiece APR, Field of Vision, Communication and Permeation Testing.

We appreciate the opportunity to add our comments and knowledge to the rulemaking record and look forward to the promulgation of a fair, protective and useful standard.

Sincerely,

Michael L. Runge
Technical Director
3M Occupational Health & Environmental Safety Division

MLR:CEC/llb
Enclosures

Comments to the proposed NIOSH Certification Standard for Chemical Biological Radiological Nuclear Air Purifying Respirator Standard per Proposed NIOSH Certification Standard for APR CBRN Federal Register Notice May 31, 2002 (Vol.67, Number 105, pg. 38127-38128)

Performance Based Approach

The NIOSH Chemical Biological Radiological and Nuclear (CBRN) Full Facepiece Air Purifying Standard that is under development should be founded on the concepts of a performance based standard, without specific or unnecessary design constraints. In our experience, design based standards neither anticipate nor promote the development of new and improved technologies that could result in added protection, by increasing use and wear time. The standard should reflect expected use conditions (CBRN materials, concentrations, duration, etc.) based on the hazard mapping being performed in conjunction with the development of this standard so that respirators are suitable for the expected workload.

Today a number of key CBRN respiratory protection performance standards and guidelines have been established based on thorough review of available military and industry standards. They are all performance based. These documents include: Joint Service General Purpose Mask (JSGPM),[1] Joint Service Aircrew Mask (JSAM),[2] C2A1 Canister[3] and the SBCCOM Guidelines for Escape Hoods.[4]

The JSGPM is a system that will help provide 24 hours of continuous head-eye-respiratory protection against Chemical, Biological, Radiological Particulates and Toxic Industrial Material (TIM) protection (rev: DAAD13-98-R-0045).[1] The JSAM respirator is for individual aircrew "above the neck" head, eye, and respiratory protection against chemical, biological (CB) warfare agents, radiological particles and toxic industrial materials, as well as continuous protection against CB agent permeation through respiratory material (rev: 2 April 1999).[2] The scope of these two standards are very similar and outline protection against chemical, biological warfare agents, radiological particles and TIM's. Examples of performance criteria found in both JSGPM and JSAM include: weight, bulk, vision, communication, wearability such as wear time, comfort, and airflow resistance. Both JSGPM and JSAM outline the challenge conditions such as the agent, challenge airflow, relative humidity, particle size, minimum efficiency, test end point, etc. to assess a system's ability to protect against chemical warfare agents, aerosols, including radiological and biological, and toxic industrial material. They do not specify materials or operating mechanism, they simply outline the performance criteria the system must meet.

The canister that is used on today's M40 military full facepiece is the C2A1. The performance specification for this chemical, biological and radiological agent canister is outlined in MIL-PRF-51560A(EA) July, 1997.[5] This document outlines performance requirements of the C2A1 and covers such performance specifications as airflow resistance, aerosol filtration, liquid agent permeation, gas service life, rough handling,

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accelerating aging, etc.. The MIL standard does not specify materials or an operating mechanism, such as mechanical filtration or fiberglass; it simply outlines the performance criteria the system must meet.

The US Army Soldier Biological Chemical Command (SBCCOM), in Edgewood, Maryland developed Guidelines/Performance Criteria for Escape Hoods. This guideline contains performance criteria and test methods for qualifying the efficacy of hood-type respiratory protective devices (RPD) designed for self-rescue from CB incidents. The performance criteria were established based on a thorough review of available military and industry standards and accepted practices for evaluating RPD. It was intended to serve as an interim in-house standard for qualification testing of escape hoods until a National Standard could be developed and implemented by NIOSH.

These four different standards/guidelines/specifications dealing with Air Purifying Respirators are based on the latest scientific knowledge concerning respiratory protection. None of them include design restrictions on material or operating mechanisms. It is also important to note that NIOSH used a performance test approach to address the issues surrounding the evaluation of electrostatic filter media performance against oil particles. In 42 CFR 84 an oil-loading test for R and P-Series filters is included to address the concerns that existed on performance of electrets as they were being loaded with oil aerosols. By adopting this performance based approach, poor performing filter media were eliminated and incentive provided for developing the new technologies in today's filter media.

Aerosol Filtration in CBRN Full Facepiece APR

The range of CBRN agents used in a terrorist incident could likely include particulate materials (aerosols). As a consequence, filtration of these aerosols would be important in the performance of the CBRN APR. To take full advantage of new technologies in this area, aerosol filtration criteria for the NIOSH Full Facepiece CBRN standard needs to be performance based with no limitations on material (e.g. fiberglass) or mechanism (e.g. mechanical filtration). Such design restrictions could inhibit the development of new aerosol filters as the "tools" of terrorists change. Although some argue that design limitations are appropriate for electret filter material based on performance concerns with oily aerosols, exposure of filters to solvents, filtration of biological aerosols, humidity effects, ionizing radiation and thermal stability, 3M submits that for the reasons expressed below, these views are not meritorious and should not alter the goal of adopting a performance based CBRN certification standard. When these new filter technologies are evaluated under realistic exposure and use conditions, the data confirms that they can be used in ways that these environmental issues are not a factor.

Oil Loading Issue

In 42 CFR 84 the P-series test requires a 200 mg dioctyl phthalate (DOP) challenge at 85 lpm with 0.185 μm particles. The filter efficiency for P-series filters should be steady

or increasing after the 200 mg of DOP has been loaded. As shown in a typical scenario outlined below, while the 200 mg loading of DOP is an overestimate of oil aerosols found in the workplace, it is a conservative and appropriate approach. Research by Rousseau *et al.* on P-series filters presented at the 1999 American Industrial Hygiene Conference and Exposition (AIHC&E), and which has been submitted to the AIHA Journal, outlines the Performance of R and P Series Particulate Respirators with Electret Filter Media against DOP, Paraffin Oil and Metalworking Fluids[6]. Tests on the 3M 8271 P-95 respirator validated that the respirator is still greater than 95% efficient after 200 mg loading with metal working fluid (0.154 μm particles).

Oil Loading Scenario in the Workplace:

1. NIOSH estimate of mean level of exposure to metal working fluids in the workplace is 1 mg/m^3 with the highest being around 1.5 mg/m^3 ;[7]

2. At moderate work rate, a worker breathes 10-20 m^3 per 8-hr day depositing 10-20 mg of oil on the filter. Workers cannot sustain much more than a moderate work rate for an entire 8-hour work shift; and

3. 40 hrs (5 8-hour days) of use at these conditions equates to 50-150 mg loading, much less than the 200 mg test requirement.

Electrostatic filter media can be designed to meet demanding performance requirements. For example, 3M developed electret filter media that met the demanding challenge of pre-loading 200 mg of Milpro metal working fluid on media, aging it for seven days and then loading the filter media with 1360 mg DOP. Results indicated that the penetration was <0.01 percent during the Milpro loading, after the aging and after the DOP loading. Figures 1 & 2 outline the Milpro loading and DOP loading characteristics. Electret filter media can be designed to withstand extremely high oil loading as seen in figure 2.

Figure 1: Milpro 830 Aerosol at 50 LPM 200 Milligram Loading Characteristics
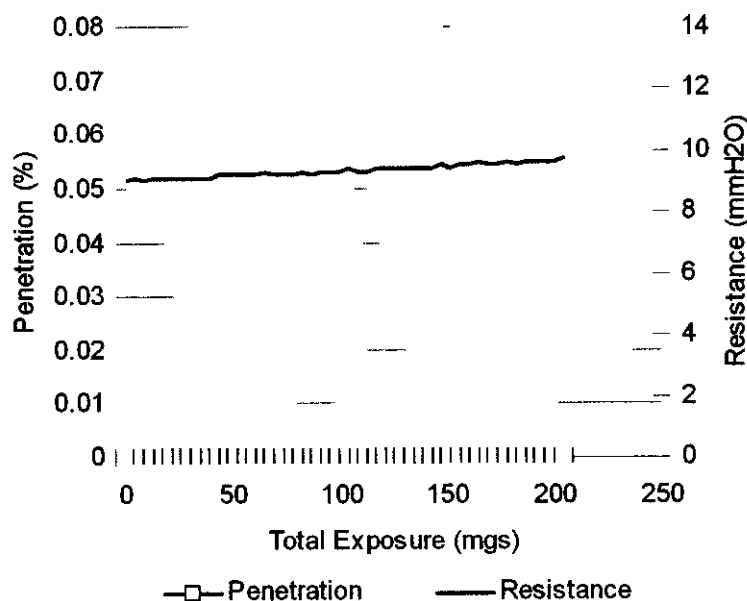
Figure 2: DOP Aerosol at 50 LPM 1360 Milligram Loading Characteristics
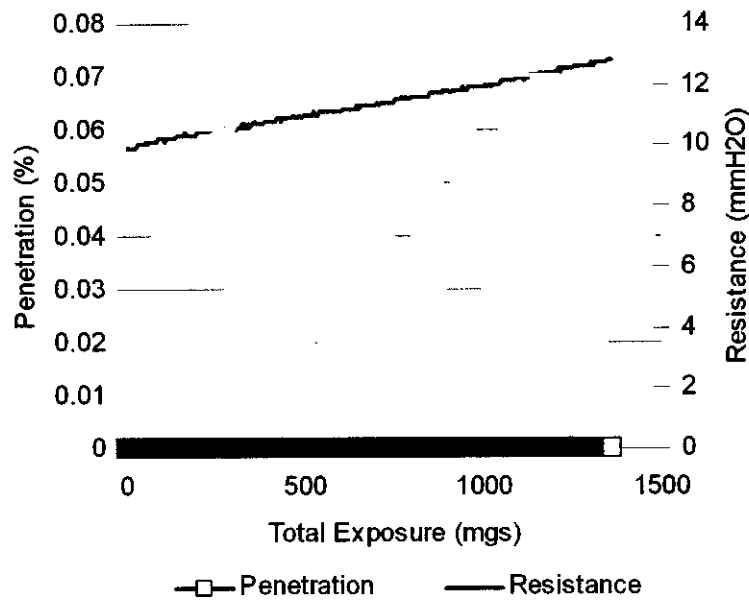
The Effect of Solvents on Electrostatic Filter Media

There are several references[8-10] in the literature to the use of a solvent treatment by which electret filters are dipped in an organic solvent. This treatment is thought to remove the electret charge so that only mechanical filtration is operating when the filter is then tested. To achieve these solvent exposure conditions in the workplace, a person would have to dip their filters into the liquid. This has nevertheless led to the concern that if liquid solvent is harmful to electret filters, then perhaps solvent vapors may also be harmful.

Recently NIOSH reported concerns regarding the performance of electret filter media that had been exposed to solvents. In a study[11] presented at the 2002 AIHC&E, NIOSH exposed N and P Series electrostatic filter media to saturation levels of isopropanol, ethyl acetate, acetone, and pentane. From the data shown, it appears it took 30 minutes to an hour before any filter efficiency effects were noticed. NIOSH states in their conclusion: "This research shows that electrostatic respirator filters can be degraded by these organic vapors at saturation levels. However this degradation is not a concern because workplace concentrations will be much lower than saturation". The experimental design that NIOSH used does not represent anticipated or legal use of these respirator systems and, therefore, any conclusions limiting their application must be done accordingly. In fact, at these levels protection from the vapor would be required. Since these filters may be used in conjunction with an organic vapor cartridge, the cartridge service life must be considered in real world applications as well. Table 1 shows the NIOSH experimental conditions compared to IDLH levels, and the service life of 3M organic vapor cartridges.

Table 1: NIOSH Experimental Conditions, IDLH and Service Life

Challenge	IDLH (ppm) NIOSH Pocket Guide	~ saturation @ 23C (ppm)	3M 6001 Organic Vapor Cartridges Service Life (min)
IPA	2000	53,000	2
Ethyl acetate	2000	111,000	1
Acetone	2500	280,000	0.5
n-pentane	1500	625,000	~0

Table 1 indicates that the challenge conditions are in extreme excess of the respirator system. First, these conditions are not permitted with an air-purifying respirator (IDLH conditions). Only an SCBA is appropriate for these conditions. Secondly, the system (organic vapor cartridge) would have failed and the cartridge would need to be changed long before any filter efficiency degradation. At the test concentrations used it is likely that liquid solvent is forming as air passes through the filter resulting in a dip test, not vapor exposure as stated. For these reasons, it is critical that experimental designs match the performance of the system. If not, the result may be an over design of a component, which could adversely effect the overall system performance.

In 2001 3M reported on the performance of electrostatic filter media against certain solvents[12]. In this study 3M 8210 N95 and 8271 P95 respirators with electrostatic filter media were exposed to methyl ethyl ketone, toluene, cyclohexane, and isopropanol (IPA) vapors. Four replicates were tested for percent penetration before solvent vapor exposure and 3 of the replicates were tested again after solvent vapor exposure. One solvent vapor exposed and one control sample were load tested to 200 mg of challenge aerosol. NaCl aerosol was the challenge for the N95 respirators and DOP aerosol was the challenge for the P95 respirators. Vapors at a concentration of 10x PEL were drawn through the media for four hours. For example, filters were exposed to IPA for four hours at 4000 ppm.

Tables 2-9 show the initial percent penetration and loading data for the two respirators and four solvents studied, and figures 3-4 graphically represent some of the data. Results of the tested N95 and P95 respirators with electret media showed that their filtration performance was not affected after being challenged with 10 times the PEL of four solvent vapors (cyclohexane, MEK, toluene, and isopropyl alcohol) for 4 hours. All filter penetration values were below the 5% penetration allowed.

Table 2: Filtration Performance of 3M 8210 N95 Respirators Under Standard NIOSH Test Conditions (NaCl aerosol at 85 liters/min) Before and After Exposure to 3000 ppm Cylohexane Vapor

| Sample | Penetration of NaCl Test Aerosol at 85 Liter/min flow [%] | | |
	Instantaneous NaCl Filter Test before Exposure to Cyclohexane Vapor	Instantaneous NaCl Filter Test after Exposure to Cyclohexane Vapor	Maximum Filter Penetration During 200 mg NaCl Filter Loading Test
1	0.334	0.448	
2	0.384	0.468	1.34
3	0.415	0.461	
	Mean = 0.378	Mean = 0.459	
	St. Dev. = 0.041	St. Dev. = 0.010	
Control	0.339	0.408	1.57

Table 3: Filtration Performance of 3M 8210 N95 Respirators Under Standard NIOSH Test Conditions (NaCl aerosol at 85 liters/min) Before and After Exposure to 2000 ppm MEK Vapor in Air

| Sample | Penetration of NaCl Test Aerosol at 85 Liter/min flow [%] | | |
	Instantaneous NaCl Filter Test before Exposure to MEK Vapor	Instantaneous NaCl Filter Test after Exposure to MEK Vapor	Maximum Filter Penetration During 200 mg NaCl Filter Loading Test
1	0.264	0.315	
2	0.340	0.425	1.61
3	0.458	0.486	
	Mean = 0.317	Mean = 0.408	
	St. Dev. = 0.046	St. Dev. = 0.086	
Control	0.585	0.668	2.20

Table 4: Filtration Performance of 3M 8210 N95 Respirators Under Standard NIOSH Test Conditions (NaCl aerosol at 85 liters/min) Before and After Exposure to 2000 ppm Toluene Vapor in Air

| Sample | Penetration of NaCl Test Aerosol at 85 Liter/min flow [%] | | |
	Instantaneous NaCl Filter Test before Exposure to Toluene Vapor	Instantaneous NaCl Filter Test after Exposure to Toluene Vapor	Maximum Filter Penetration During 200 mg NaCl Filter Loading Test
1	0.362	0.392	
2	0.271	0.340	1.28
3	0.514	0.592	
	Mean = 0.382	Mean = 0.441	
	St. Dev. = 0.123	St. Dev. = 0.133	
Control	0.390	0.474	1.69

Table 5: Filtration Performance of 3M 8210 N95 Respirators Under Standard NIOSH Test Conditions (NaCl aerosol at 85 liters/min) Before and After Exposure to 4000 ppm Isopropanol Vapor in Air

Sample	Penetration of NaCl Test Aerosol at 85 Liter/min flow [%]		
	Instantaneous NaCl Filter Test before Exposure to Isopropanol Vapor	Instantaneous NaCl Filter Test after Exposure to Isopropanol Vapor	Maximum Filter Penetration During 200 mg NaCl Filter Loading Test
1	0.472	0.577	1.91
2	0.361	0.453	
3	0.450	0.521	
	Mean = 0.478	Mean = 0.517	
	St. Dev. = 0..059	St. Dev. = 0.062	
Control	0.292	0.452	1.18

Table 6: Filtration Performance of 3M 8271 P95 Respirators Under Standard NIOSH Test Conditions (DOP aerosol at 85 liters/min) Before and After Exposure to 3000 ppm Cyclohexane Vapor in Air

Sample	Penetration of DOP Test Aerosol at 85 Liter/min flow [%]		
	Instantaneous DOP Filter Test before Exposure to Cyclohexane Vapor	Instantaneous DOP Filter Test after Exposure to Cyclohexane Vapor	Maximum Filter Penetration During 200 mg DOP Filter Loading Test
1	0.768	0.886	
2	0.767	0.879	1.28
3	0.691	0.782	
	Mean = 0.742	Mean = 0.849	
	St. Dev. = 0.044	St. Dev. = 0.058	
Control	0.697	0.856	1.20

Table 7: Filtration Performance of 3M 8271 P95 Respirators Under Standard NIOSH Test Conditions (DOP aerosol at 85 liters/min) Before and After Exposure to 2000 ppm MEK Vapor in Air

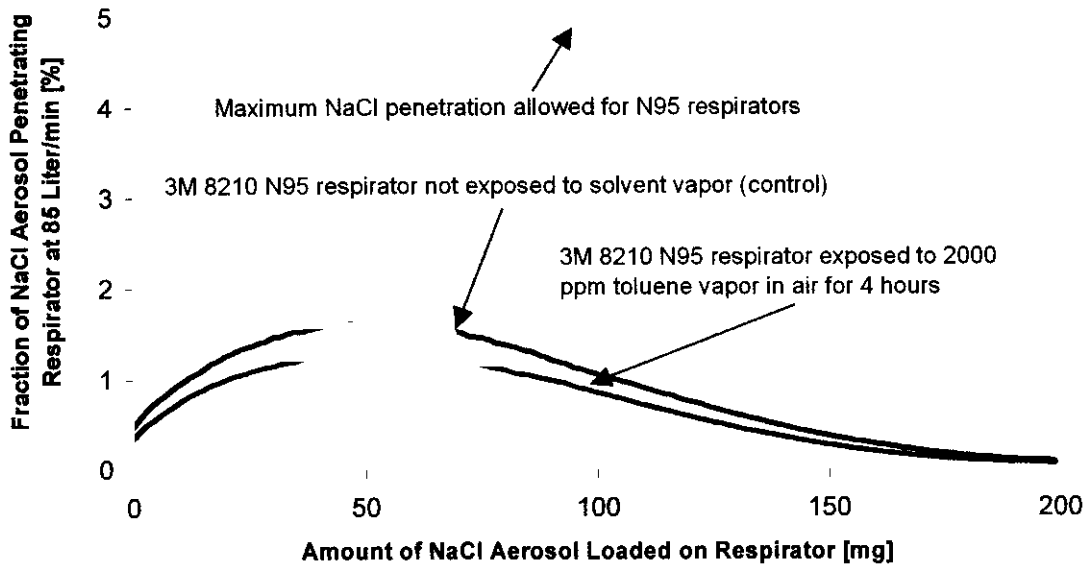| Sample	Penetration of DOP Test Aerosol at 85 Liter/min flow [%]		
	Instantaneous DOP Filter Test before Exposure to MEK Vapor	Instantaneous DOP Filter Test after Exposure to MEK Vapor	Maximum Filter Penetration During 200 mg DOP Filter Loading Test
1	0.732	0.760	
2	0.745	0.800	
3	0.767	0.815	0.914
	Mean = 0.748	Mean = 0.792	
	St. Dev. = 0.018	St. Dev. = 0.028	
Control	0.659	0.687	0.810

Table 8: Filtration Performance of 3M 8271 P95 Respirators Under Standard NIOSH Test Conditions (DOP aerosol at 85 liters/min) Before and After Exposure to 2000 ppm Toluene Vapor in Air

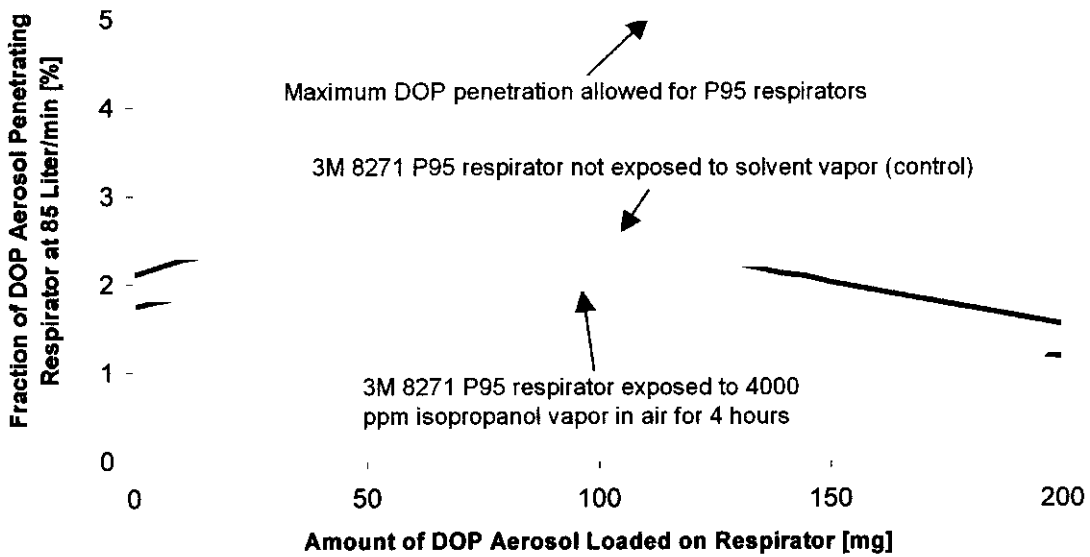| Sample	Penetration of DOP Test Aerosol at 85 Liter/min flow [%]		
	Instantaneous DOP Filter Test before Exposure to Toluene Vapor	Instantaneous DOP Filter Test after Exposure to Toluene Vapor	Maximum Filter Penetration During 200 mg DOP Filter Loading Test
1	0.705	0.795	1.11
2	0.661	0.753	
3	0.697	0.787	
	Mean = 0.688	Mean = 0.778	
	St. Dev. = 0.023	St. Dev. = 0.022	
Control	0.618	0.682	1.00

Table 9: Filtration Performance of 3M 8271 P95 Respirators Under Standard NIOSH Test Conditions (DOP aerosol at 85 liters/min) Before and After Exposure to 4000 ppm Isopropanol Vapor in Air

Sample	Penetration of DOP Test Aerosol at 85 Liter/min flow [%]		
	Instantaneous DOP Filter Test before Exposure to Isopropanol Vapor	Instantaneous DOP Filter Test after Exposure to Isopropanol Vapor	Maximum Filter Penetration During 200 mg DOP Filter Loading Test
1	2.13	2.10	
2	2.04	1.66	
3	1.72	1.75	2.01
	Mean = 1.96	Mean = 1.84	
	St. Dev. = 0.22	St. Dev. = 0.23	
Control	1.99	2.20	2.60

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Figure 3: Comparison of 3M 8210 N95 Respirator Performance in NaCl Aerosol Loading Test With and Without Exposure to 2000 ppm Toluene Vapor

Y-axis: Fraction of NaCl Aerosol Penetrating Respirator at 85 Liter/min [%]

Maximum NaCl penetration allowed for N95 respirators

3M 8210 N95 respirator not exposed to solvent vapor (control)

3M 8210 N95 respirator exposed to 2000 ppm toluene vapor in air for 4 hours

*X-axis:* Amount of NaCl Aerosol Loaded on Respirator [mg]

Figure 4: Comparison of 3M 8271 P95 Respirator Performance in DOP Aerosol Loading Test With and Without Exposure to 4000 ppm Isopropanol Vapor

Y-axis: Fraction of DOP Aerosol Penetrating Respirator at 85 Liter/min [%]

Maximum DOP penetration allowed for P95 respirators

3M 8271 P95 respirator not exposed to solvent vapor (control)

3M 8271 P95 respirator exposed to 4000 ppm isopropanol vapor in air for 4 hours

X-axis: Amount of DOP Aerosol Loaded on Respirator [mg]

In a separate unpublished 3M study, a NIOSH approved electret P100 filter was exposed to 15,000 ppm of isopropanol vapors. Results outlined in figure 5 indicate that after exposure to 15,000 ppm for 168 hours there was no filter degradation. The filter penetration for all particle sizes tested is well below the 0.03% penetration allowed.

Figure 5: Filtration Performance of a P100 Filter made with Electrostatic Filter Media Against Various Sizes of DOP Aerosol Particles During Exposure to 15000 ppm Isopropanol Vapor in Air
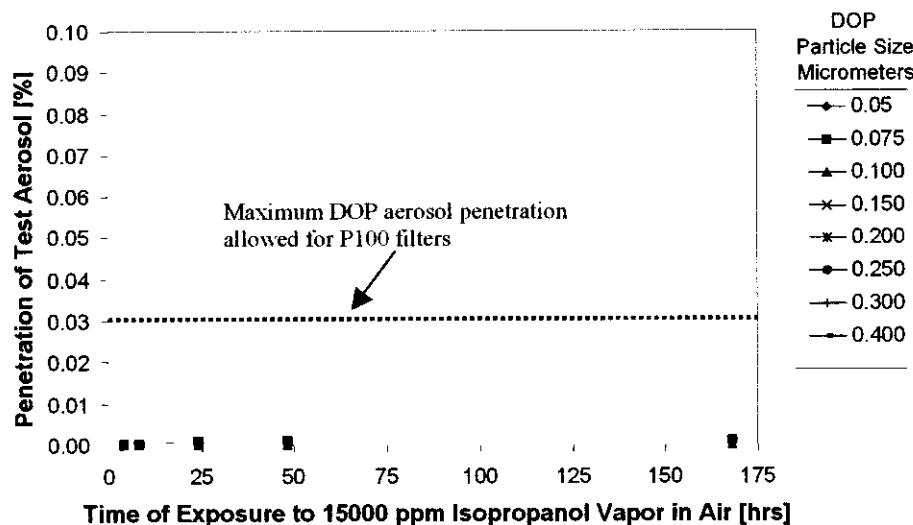
These results show that prolonged exposure of electret filter media to this extreme level of solvent vapor had no adverse effect on filter performance. The effects of liquid solvents (solvent dip) including isopropyl alcohol and saturated vapors on electret filter media should not be used to predict filter performance. The respirators should be tested at levels of solvent vapors expected to be present where a CBRN APR can be used.

The Effects of Humidity

The oldest electret filter media was produced by mixing two natural products; resin and wool. Charge was created in the filter media by a tribocharging mechanism. This filter could lose efficiency when subjected to high humidity[13], possibly due to the hygroscopic nature of the wool. This loss of efficiency in high humidity is not seen with modern electret filters made from hydrophobic synthetic polymer fibers[14].

The Effects of Ionizing Radiation

Although the effect of ionizing radiation on the performance of electret filters has not been the subject of many studies, it is known that large doses of radiation can reduce the charge on these materials, presumably by generating ions that neutralize the electrets[15]. In fact, discharging electret filters with ionizing radiation such as x-rays can be used to

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measure the charge on a filter. Using this technique, the filtration efficiency is determined and then the filter is exposed to ionizing radiation until the measured filter efficiency reaches a minimum. The difference in efficiency before and after irradiation is that which is attributed to electrostatic effects. In one study[16] the effect of exposure to x-ray radiation on a tribocharged polypropylene-modacrylic filter was determined. The penetration of a standard aerosol through the filter tested was found to increase with increasing total dose until the filter had lost all of its charge (at several thousand Roentgens, which is many times over the median lethal dose).

In a recent study[17] the effect of ionizing radiation on several types of new high performance electret filter media was quantitatively determined. Three different electret filter media were evaluated in this study. Filter media 1, which is a polyolefin electret used in commercially available respirators, was studied most extensively. Filter media 2 and 3 are also polyolefin electret filter media, which are currently under development.

In the initial studies, the various electret filter media were irradiated with two types of radiation, 1.17 and 1.33 MeV Gamma rays from a Cobalt 60 source and 60 keV X-rays from an LPX200 source. Dose rates were 5748 Roentgens/hour and 360 Roentgens/hour respectively. The initial series of exposures were made on one layer and three layers of filter media 1 using both of these sources. Filtration performance was then determined using an ATI TDA-100 Monodisperse Aerosol Penetrometer (Q127) and a nominal 0.3 micrometer DOP aerosol. Quality factors (QF) were calculated from percent penetration and pressure drop data using the following formula. The results are shown in Figures 6 and 7.

$$QF[1/mmH_2O] = -\left[\frac{Ln(DOPPenetration[\%]/100)}{PressureDrop[mmH_2O]} \right]$$
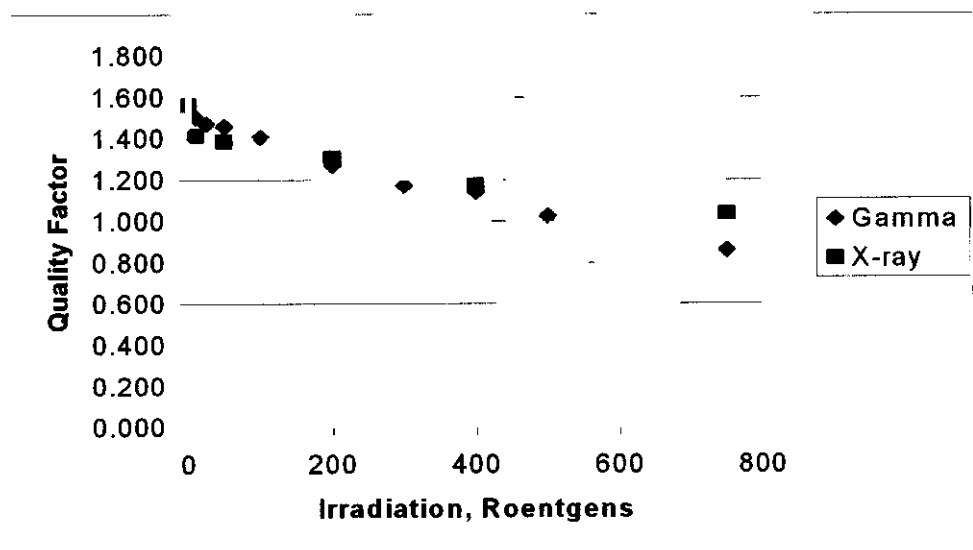

Figure 6. The Effect of Gamma and X-Ray Irradiation on the Quality Factor of Filter Media 1
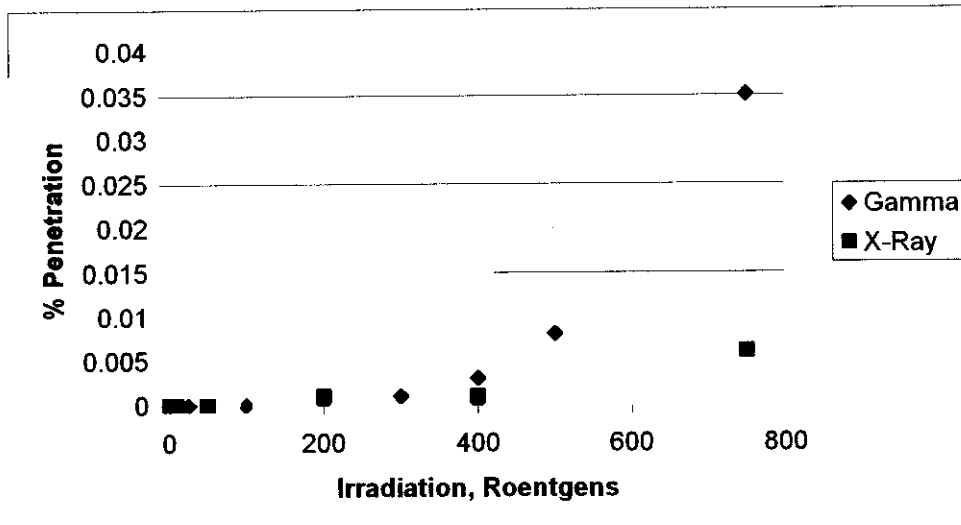
11

Figure 7. The Effect of Gamma and X-Ray Irradiation on DOP Aerosol Penetration at a Face Velocity of 6.17 cm/s for Three Layers of Filter Media 1

The two types of ionizing radiation studied appear to have a similar effect on filter media 1. The quality factor, which is related to the level of electret charge[15], decreases with increasing exposure of the filter medium. A filter with three layers of filter media 1 (figure 7) has a high enough efficiency that even at an exposure of 500 roentgens of Gamma or X-rays the percent penetration is less than 0.01. This exposure is about equal to a dose of 500 rad, which is the median lethal dose for humans.

In Table 10 the penetration and pressure drop for three layers of filter media 1, 2, and 3 after 500 Roentgens gamma irradiation are given. The percent penetration was determined using the Q127 and DOP aerosol at a face velocity of 6.17 cm/s. The penetration level after treatment is very low for all three media.

Table 10. Filter Performance of Various Electret Media after 500 Roentgens Gamma Irradiation

Filter Medium	% Penetration	Pressure Drop, mmH$_2$O
1	0.008	9.3
2	0.003	8.6
3	0.000	5.6

With filter media 3 there is no detectable penetration after this level (500 Roentgens) of radiation. The utility of these media for producing high efficiency, low profile and light weight filters with exceptionally low breathing resistance is clear. For example, using 21 in^2 (136 cm^2) of filter media 3, a flat (3 mm thick) filter can be produced weighing just 3 grams and having a pressure drop of 9.5 mmH$_2$O at a flow rate of 85 LPM.

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Although this study confirmed that ionizing radiation will reduce the charge on electret filter media, tests can be designed to ensure they still have sufficient charge after radiation exposure. Current filters have sufficient charge to withstand radiation effects based on use conditions in industrial applications. Properly constructed filters with relatively low-pressure drop can be designed to withstand more than the median lethal dose of radiation without a significant loss of filtration efficiency. Filter performance in the presence of radiation can be achieved that will outlast the human that the filter is designed to protect.

Thermal Stability

Respirators and filters with electret filter media have been successfully used for many years in industry. The electret charge on these filters is sufficiently stable to survive a wide range of storage and use conditions. Accelerated aging tests at higher than use temperatures for shorter time periods can be useful in predicting long term stability for storage and use conditions typically found where people inhabit on this planet. In formulating the CBRN standard it would be beneficial to include an accelerated aging test that would predict behavior of filters under these most severe anticipated storage and use conditions.

Respirator Filter Collection Efficiency of Biological Aerosols: A Review

An often-expressed concern about CBRN (chemical, biological, radiological, nuclear) hazards is whether biological aerosols are filtered by respirator filters the same as other aerosols. A review of recent literature of biological aerosol filtration was conducted. Most of these studies were conducted as a result of concerns on the efficacy of respirator filters for *Mycobacterium tuberculosis* (TB). This review of literature published in the last ten years demonstrates that NIOSH-approved respirator filters remove biological aerosols similarly to non-biological aerosols and that they perform as certified when challenged with biological aerosols.

Current particulate respirator filter theory is based on the single fiber filtration model. This model is based on the physical parameters (size, shape, density) of a particle and do not incorporate viability or biological nature of the particle.[18] This model is based on the principle that a "particle is a particle".

Chen et al.[19] challenged respirator filters with *Mycobacterium chelonae abscesses* (*M.c.*) as a surrogate for TB with a measured average aerodynamic diameter (d_{ae}) = 0.7 μm) and polystyrene latex (PSL) spheres (0.8 μm). The *M.c.* aerosol concentration was measured using Anderson samplers upstream and downstream of the filter. They also used an aerodynamic particle sizer for both *M. chelonae* and the PSL spheres. They evaluated four filtering facepiece respirators utilizing electrostatic media. The test respirators included two dust/mist respirators, one dust/mist/ fume respirator and a high efficiency filter respirator. All of the respirators were NIOSH-approved under 30 CFR 11. All of the respirator filters performed as expected based on this certification. They also discovered respirator filter penetration was accurately predicted by PSL spheres of a

representative size as seen in figure 8. There was good correlation between the microbiological data and solid aerosol particles of equivalent aerodynamic diameter. The PSL spheres provided more conservative estimates of filter penetration than the bio-organisms.

Figure 8. Mean efficiency of masks and respirators challenged with *M.c.* bacteria and PSL spheres (Chen et al., 1994)
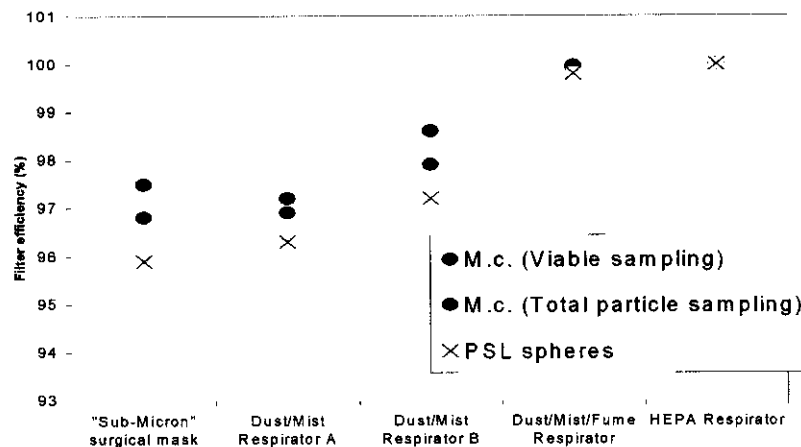
Brosseau et al.[20] challenged filters with *Mycobacterium abscesses* (*M.a.*) as a surrogate for TB (0.7 μm). *M. abscesses* used in this study is the same organism as *M. chelonae*. *M. chelonae* was renamed by the microbiologists after publication of the previous paper. The authors tested both purely mechanical filters and those incorporating electrostatic media from sixteen different NIOSH approved respirators under 30 CFR 11. The filters were tested at two flow rates, 45 and 85 liters per minute (LPM), and at two relative humidity (RH) levels, 30 and 70% RH. The respirator filters were preconditioned for 24 hr at 85% RH. When challenged with *M. abscesses* all filters performed as expected for their class.

McCullough et al.[21] challenged respirator filters with three different bacterial aerosols of different shapes and sizes: M*ycobacterium abscesses* (*M.a.*) (0.7 μm), rod shape, *Staphlococcus epidermidis* (S.e.) (0.87 μm), sphere shape, and *Bacillus subtilis* spores (B.s.) (0.88 μm), rod/sphere shape. The investigators also challenged the filters with PSL spheres (0.55 μm). They evaluated the same mix of purely mechanical and electrostatic filters as Brosseau et al.[20]. The testing was conducted at 45 and 85 LPM and 30 and 70% RH. A 6-stage Anderson Viable Sampler was used with an added 7th stage to collect aerosols down to 0.45 μm. This was needed as the investigators strived for a test aerosol composed of single cells. For NIOSH-approved filters, filtration efficiency was as expected for the certified filter performance. A change in flow affected penetration of all particles similarly as predicted by theory.

The results showed that the rod-shaped particles were less penetrating than the equivalent spherical particle when the two aerosols have the same calculated aerodynamic diameter.

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Linear regression analysis demonstrated that filter penetration of PSL spheres predicted filter penetration of the biological aerosols, $R^2 = 0.951$. The results indicated that if testing biological aerosols, total particle sampling (as opposed to viable sampling) is appropriate for determining bioaerosol penetration. This study indicates non-biological aerosols are good predictors of biological aerosol filtration behavior.

Qian et al.[22] challenged three N95 particulate filters (electrostatic) with four test aerosols. Two were bacterial aerosols. The test aerosols were:

- *Bacillus subtilis*   avg. $d_{ae} = 0.8\mu m$
- *Bacillus megatherum*   avg. $d_{ae} = 1.2\ \mu m$
- NaCl particles
- PSL

One respirator was cone shaped. The other two respirators were flat. The filters were tested at two flow rates: 32 and 85 LPM. Filter efficiency was greater than 99.5% when challenged with the biological aerosols. This was the expected result based on particle size. Respirators performed as certified when challenged with biological aerosols. Filtration efficiency determined with PSL sphere and salt particles appeared predictive for bioaerosols.

Willeke et al.[23] challenged a surgical mask and a dust/mist respirator (utilizing electrostatic media) with five test aerosols, four of which were microorganisms. They were:
- Streptococcus salvarius, *sphere, 0.8-1.0 μm*
- Pseudomonas fluorescens, *rod, 0.8 μm*
- Bacillus alcalophilus, *rod, 0.7-0.9mm x 3-4 μm*
- Bacillus megatherium, *rod, 1.2 μm*
- Corn oil aerosol, *0.1 - 10 μm*

This was done to provide a variety of different shapes and be similar to TB. The filters were tested at four flow rates of 16, 32, 50, and 80 LPM. Filter penetration of spherical corn-oil particles and equivalently sized spherical bacteria was similar. The spherical particles were consistently more penetrating than rod-shaped biological particles with equivalent aerodynamic diameter over a range of particle sizes.

In conclusion, experiments[19-23] published in peer reviewed literature have demonstrated that there is no difference in the filtration of biological aerosols and non-biological aerosols. The filter evaluations were conducted over a range of test conditions (flow, humidity), biological species, filter type and filters with varying filter media.

When aerosol generation and sampling are conducted properly, bioaerosol samplers can be replaced by direct reading aerosol monitors to increase reproducibility and ease of testing and decrease cost and variability. Further, non-biological particles with the same size, shape, and density are appropriate surrogates for biological aerosols.

Since current certification test methodologies utilize the most penetrating particles such as those currently in 42 CFR 84, they appear to be appropriate tests for predicting the filtration behavior of both biological and non-biological aerosols.

Summary on CBRN Filtration Issues

42 CFR 84 is a relevant performance test for addressing oil concerns, and subsequent research supports the P-series test as a relevant performance test. The references that have been cited regarding filter performance after solvent exposure, filtration of biological aerosols, humidity effects, ionizing radiation and thermal stability all need to be thoroughly understood before a performance standard can be promulgated. If a concern still exists regarding performance after exposure to these environmental factors, a test method should be developed that would identify the desired outcome. It is also critical that the test methods take into account the entire system. For example, challenging filters at concentrations in extreme excess of the system and outside the limitations of the device is unreasonable if another component would have failed much earlier under these conditions.

Communication and Field of View Issue

With respect to communication and field of view (FOV) requirements, we have two areas of concerns:

1) We believe that communication and field of view are product attributes not within NIOSH's scope of assessment for respiratory protection performance; and

2) The FOV requirements in the current concept CBRN standard will not meet the needs and expectations of all the users.

If you categorize potential respirator users into Fire Service, Law Enforcement, Emergency Medical Service and Federal Agencies, and look at the operational requirements of each you will find that they have vastly different expectations and requirements. For example, certain responders, including the Fire Service and medical personnel, may prefer a full facepiece with a very wide field of vision for activities such as surveys, hazard mitigation, decontamination in a warm zone, evacuation and medical treatment. Other responders, such as law enforcement, may need a full facepiece with very accurate vision (such as dual ocular lens provide) for sighting a weapon or that fits with vision-enhancing equipment such as binoculars and night vision equipment for search and rescue and tactical operations. The communication and field of view requirements will be different for each responder group and designing a standard with an expectation that it can meet the operational needs of all these user groups is not realistic or advisable.

In spite of the fact that the current CBRN concept includes a dual ocular provision, as outlined in EN136, this performance-based standard relates to industrial use; therefore it

may not meet the needs of law enforcement personnel for visual acuity when sighting a weapon or the use of accessories such as those for night vision. We do not believe that any existing dual-lens full-face mask can pass the proposed FOV standard, nor do we believe that any existing dual ocular lens mask can be quickly redesigned to do so. Attempting to design a mask to meet the standard will require substantial development time that will in the meantime leave potential users without a certified dual ocular lens facepiece choice in the marketplace.

Similarly, no one-communication system may meet the needs of all users. Certain responders may wish to incorporate additional microphones that cannot be built into all facepieces while others may need to remain silent for extended periods of time. Therefore, we feel that communication and field of view requirements should not be mandatory since users have a wide range of needs and expectations. The approach of allowing the user to select the facepiece that has the features and attributes (such as vision and communication) that best meet their needs has worked well for industrial purposes and allows a variety of products to be offered that meet all respiratory protection as well as user-specific requirements.

Physiological Effects

Physiological considerations: Air flow rate during respiration is constantly changing. In particular, the peak inhalation flow rate (PF_I) typically exceeds the ventilation rate (V_e) by three to four times. For example, an individual with a V_e of 40 Lpm (corresponding to moderate work) would be expected to have a PF_I in the range of 150-200 Lpm. Because of this, it has been argued that filters should be tested at PF_I rates attainable during maximum work.[24] Although peak inhalation flow rate may periodically exceed the flow rate that NIOSH uses in testing filters (85 Lpm), the very high flow rates and work rate are not sustainable by most individuals (Table 11).

Table 11. Time to exhaustion in averaged sized individuals (160 lbs) with similar maximal work capacities but different submaximal aerobic fitness levels as evaluated by their time to exhaustion in sustained work.

% VO₂ max	WORK Kcal/min	V_e (L/min)	Low Fitness Time to exhaustion	Average Fitness Time to exhaustion	Mod High Fitness Time to exhaustion
40%	6.3	35	1 hr	8 hrs	>8 hrs
50%	7.9	42	30 min	4 hrs	>8 hrs
55%	8.7	48	20 min	1 hr	8 hrs
60%	9.5	55	15 min	40 min	6 hrs
70%	11.0	67	10 min	35 min	2 hrs
80%	12.6	80	5 min	15 min	45 min

This table assumes that all individuals have the same maximal aerobic capacity of 42 ml/kg/min (average 20-30 year old male weighing 70 kg). For each 10 kg over or under 70 kg add or subtract 10% from the values for minute ventilation (V_e) and work

(Kcal/min) shown. Fitness is evaluated by the percentage of VO$_2$ max that the individual can sustain for different intensities of work. Note: High and low fitness are evaluated as found in the normal workplace and do not include aerobic athletes.

Filter performance modeling: A filter performance model based on single-fiber filtration mechanisms can be used to illustrate why there is no need to test filters at the suggested high flow rates.[18] The model incorporates characteristics of filter design, challenge aerosol and air flow which interact to affect filter efficiency. It allows these characteristics to be changed individually, and predicts both particle count and particle mass penetrations. Thus, it is easy to predict the effect of each individual change on the efficiency of the filter.

Table 12 summarizes the output of the model for a filter with typical design characteristics under various challenge conditions. Only the variables listed were changed in each case.

Table 12. Modeled Filter Performance as a Function of Air Flow Rate and Aerosol Characteristics.

Air Flow (Lpm)	Challenge Aerosol Size (μm MMAD)/GSD*	Count Penetration (%)	Mass Penetration (%)	Comments
85	0.3/1.8	4.55	4.34	Similar to NIOSH test conditions
30	5/3	0.9	0.03	Plausible workplace conditions
400	0.3/1.8	19.06	7.76	Performance against NIOSH aerosol at suggested higher flow rate
400	5/3	12.19	0.09	Performance against plausible workplace aerosol at suggested higher flow rate

* GSD is geometric standard deviation. It is a measure of the variability of the particle sizes in the distribution.

Discussion: The following observations can be made from Table 12:
1. The filter is much more efficient under plausible workplace conditions than it is under NIOSH test conditions. This observation is consistent with the "worst case" assumptions about the NIOSH test conditions.
2. Increasing the flow rate to 400 Lpm significantly increases count penetration of the "NIOSH" aerosol, but has a much smaller effect on mass penetration. This is expected since particle mass increases with the cube of diameter. That is, one, 1 μm particle has the same mass as 1000, 0.1 μm particles. As such, a higher number of particles penetrated the filter, but since they are small particles they have very little mass.

3. There is a _very_ small difference in mass penetration of the workplace aerosol at 400 Lpm versus 30 Lpm. Again, this is expected since workplace aerosols are much larger than laboratory test aerosols. It is also evident in this case that the small particles with very little mass are those which penetrate more readily at the higher flow rates. This is explained by the fact that removal by diffusion is less efficient at higher flow rates while impaction efficiency for larger particles (with much greater mass) is increased. This is a very significant point, since exposure limits for the great majority of particulate air contaminants are based on the mass of the contaminant inhaled, i.e., mass dose. An increase in the penetration of small particles has a minimal effect on the contaminant dose inhaled.

In addition to the fact that high flow rates have little effect on mass penetration, it is important to recognize that 400 Lpm is an unrealistically high flow rate to model filter performance in a workplace. As indicated in Table 11, 400 Lpm represents a PF_l value that is only achieved by a few individuals under extremely heavy, nonsustainable work activity. Further, the duration of the peak flow is no more than a few tenths of a second per breath.[25, 26] Since most exposure limits represent time-weighted average (TWA) exposures averaged over eight hours (or 15 minutes for short term exposure limits [STEL]), a brief increase in penetration of very small particles contributes little to overall dose.

Similar logic can be applied to biological aerosols. While the exposure risk is typically based on the number of organisms inhaled rather than mass, they behave as any other aerosol. The "worst case" conditions used in current NIOSH filter testing do not exist simultaneously in any workplace. The aerosol size typically lies above or below the "most penetrating" particle size of 0.3 μm MMAD; flow rates approaching 85 Lpm are infrequent and of very limited duration; "real world" aerosols are typically electrically charged. As a result, filters can be expected to perform much more efficiently in the workplace than they do in the laboratory testing.

Finally, it must be recognized that faceseal leakage in half and full facepiece negative pressure respirators can be estimated at 1% and 0.2%. These values correspond to fit factors of 100 and 500, respectively, i.e., OSHA's criteria for acceptable fit. The filter performance model predicts that any NIOSH approved N, R or P series filter will have far less penetration under plausible workplace conditions.

Therefore, it is clear that there is no need to conduct filter tests at flow rates above 85 Lpm or otherwise modify the current NIOSH filter test criteria.

Liquid and Vapor Permeation Testing

The requirements for vapor permeation resistance testing should be such that the protection time (in terms of minutes to reach the exposure limit) should be matched to a reasonable actual use time (i.e. one shift). The assigned protection factor of the CBRN full facepiece respirator system should be used to determine the maximum use

concentration of the system and this should provide guidance in selecting the maximum challenge concentration for vapor testing. Reasonable safety factors could be built into the test criteria. We advocate that the mask materials not be required to be orders of magnitude more protective than the system capability or than the seal around the face. Air purifying respirators are not appropriate for use in areas where liquid agents are present. Therefore, 3M supports the position that liquid agent testing is not necessary for this category of products. However, if liquid agent testing is incorporated into the standards, the test criteria should be consistent with acceptable use of a negative-pressure, air purifying respirator system.

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