December 10, 1993

Centers for Disease Control and Prevention
Attention: Guidelines Work Group
Mail Stop E07
1600 Clifton Road, NE.
Atlanta, Georgia 30333

Dear Sirs:

Introduction:

The Centers for Disease Control and Prevention (CDC) issued a notice on October 12, 1993 requesting views and comments on a draft document entitled Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, Second Edition. As a manufacturer of respiratory protection products, 3M submits the following comments regarding the sections of the guidelines that deal with respiratory protection. This includes: part II Recommendations, Section G. Respiratory Protection and Supplemental 4. Respiratory Protection.

The CDC has based its TB control program guidelines on a hierarchy of control measures which include: the use of administrative measures to reduce the risk of health care workers (HCW) exposures to persons with infectious TB; the use of engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei; and the use of respiratory protection where the first two control methods are insufficient or not feasible. 3M supports this proposed control program.

The proposed guidelines allow the use of half mask respirators equipped with high efficiency particulate air (HEPA) filters based on an analysis of respirator efficiency and practical use limitations for the various styles of respirators in a health care setting. CDC has concluded that "Although the following recommendations do not offer the maximum available protection, they probably exceed the minimum level of protection needed to prevent occupational exposure." It is 3M's view that respirator selection involves more than picking the respirator with the highest assigned protection factor. Other factors such as respirator comfort or wearability are important in the selection process. Wearability is one of the key determining factors in whether a person will actually use or wear the respirator. This is important since even short periods of time when a respirator is not worn can significantly reduce its effectiveness. As a result, 3M supports CDC's decision to look at all factors that affect respirator selection and not to rely solely on assigned protection factors.
No respirator currently available can reduce the risk of exposure to any airborne contaminant to zero. Each type of respirator has limitations on its effectiveness. The program that governs how respirators are used directly impacts respirator performance. For a respirator to function as intended, four conditions must be met:

1) the respirator filtration system must be capable of filtering the contaminant from the air with an acceptable level of efficiency;
2) the concentration level of the contaminant must be within the capabilities of the class of respirator in order to reduce the level of a contaminant to an acceptable level inside the respirator;
3) the respirator must be free of defects; and
4) the user must be trained and wearing the respirator properly during all times of exposure.

Each of these conditions must be addressed before a given respirator will be able to perform properly and provide appropriate protection to the wearer.

To achieve this goal, a respiratory protection program must be established at each site where respirators are used. 3M recommends that CDC carefully examine the requirements for a respiratory protection program contained in the ANSI Z88.2(1992) standard. It is an up to date reflection of the knowledge available regarding what is essential for maintaining a program and assuring adequate protection. The OSHA standard on respirators (29 CFR 1910.134), although a legal requirement, is severely out of date and OSHA has scheduled a proposed rule for its revision in 1994. The OSHA standard is based on the ANSI Z88.2(1969) standard. Since that standard was adopted by OSHA, many more improvements have been made in the state of the art as to what is necessary to have a functioning respirator program. Compliance with the more comprehensive ANSI Z88.2 (1992) program requirements would meet the legal requirements of 29 CFR 1910.134.

Testing of filters:

The proposed guideline states that:

"Respiratory protective devices used for M. tuberculosis should meet the following criteria: 1. The ability to filter particles 1 micron in size in the unloaded state with a filter efficiency of ≥95% (i.e., filter leakage of ≤5%), given flow rates of up to 50 liters per minute.

Note /1/ Some filters become more efficient as they become loaded with dust. Health-care settings do not have enough dust in the air to "load" a filter on a respirator. Therefore, the filter efficiency for respirators used in health-care settings must be determined in the unloaded state."
Available evidence suggests that infectious droplet nuclei are in the 1-5 micron size range, therefore respirators used in health-care settings should be able to filter the smallest particles in this range efficiently. Fifty liters per minute is a reasonable estimate of the highest flow rate a HCW is likely to achieve during breathing even with strenuous work activities."

While a beginning, 3M believes this testing protocol is inadequate to properly assess filter performance. To measure the performance of a given filter requires that exact details of the test be listed. These test parameters that effect filter performance include:

1) The type or material composition of the particle
2) Whether it is a solid or liquid aerosol
3) Whether the test particle is charged or charge neutralized
4) The exact size of the particle, whether the size measurement is a count median or mass median aerodynamic diameter (MMAD)
5) The size distribution as described by the standard deviation to specify if the test particle is monodispersed or polydispersed.
6) The measurement of the test challenge concentration
7) Test conditions including temperature, humidity and any filter preconditioning, if any
8) The exact flow rate of air through the filter. For example, both 1 liter per minute and 49 liters per minute meet the specified "up to 50 liters per minute" but would yield very different results.

Finally, the criteria for interpretation of test results must be specified, including standard deviation and confidence limits. All of these items must be specifically addressed in order to compare filter test results to a specification such as that proposed by CDC of no more than 5% leakage.

Once the test parameters are set, then the measurement technique must be specified. The current silica loading test used by NIOSH to test and certify dust/mist (DM) and dust/fume/mist (DFM) respirators measures performance by a total mass penetration throughout the test. This does not allow for the determination of changes in filter efficiency with time. A filter could leak at a high rate at the beginning of the test, but overall meet the test requirement by reduced leakage, due to filter loading, for the majority of the test time. An instantaneous measurement of filter penetration would be desirable.

Particle capture can occur through several mechanisms: interception, sedimentation, inertial impaction, diffusion, and electrostatic capture. For the types of filters used in respirators, the capture mechanisms of interception, sedimentation and inertial impaction combined are effective in removing particles above 0.6 μm. In the range below 0.1 μm, diffusion is very effective in removing these particles. In between these size ranges, there is a point where filtration is least efficient, i.e., a most penetrating particle
size. For respirator filters this is generally between 0.2 and 0.4 \(\mu m\). Above and below this size, filter efficiency is greater.

Several organizations are currently writing new procedures for testing respirator filters. An ANSI committee, Z88.8, is drafting a testing standard for air purifying respirators. NIOSH is in the process of revising the testing and certification procedures in their proposed rule 42 CFR 84. Both organizations have adopted a similar testing scheme, using the most penetrating particle size, as described above, as the test particle. The remaining parameters as identified above, are also specified. These requirements eliminate the uncertainty of comparing differing particles as allowed in the current certification process and will allow for direct comparison of filter efficiencies. Both ANSI and NIOSH are proposing to classify filters into three classes with filter efficiencies of 95, 99 and 99.97% for a solid or liquid aerosol. The filter is tested with the most penetrating particle size (count median diameter of 0.1 to 0.3 \(\mu m\), Std deviation not to exceed 1.8) with continuous measurement of penetration (one minute intervals). For the droplet nuclei, a solid aerosol would be the appropriate test aerosol as the droplet, although having a somewhat liquid center, has dried and performs aerodynamically, and interacts with the filter as a solid particle. 3M submits that the CDC should evaluate these emerging standards for applicability to respirator filter evaluations for protection against \textit{M. tuberculosis}.

Current situation:

Though various groups are working towards an improved certification process, CDC must still specify a respirator for use in today's environment. As noted in the draft guide, the current NIOSH testing and certification procedures do not specifically determine the filter efficiency of DM and DFM filters in the size range of 1 to 5 \(\mu m\). Only the NIOSH HEPA filter approval testing requirements assure that this minimum filtration performance level is satisfied by certifying protection against dusts, fumes, and mists with a time weighted average less than 0.05 mg/m\(^3\)

As already noted, the filtration efficiency of a particulate filter will vary with the size of the particles. Because of this, the ANSI Z88.2(1992) standard recommends that if the contaminant is an aerosol with a particle size less than 2 \(\mu m\) (MMAD) or has an unknown size, that a high efficiency filter be used. In reviewing the available data, the ANSI committee could not find sufficient information to justify recommending any filter other than a high efficiency filter for such cases. Since the MMAD of the droplet nuclei has not been determined and probably varies depending on relative humidity and time, the MMAD is unknown. As such, the ANSI recommendation agrees with the analysis of CDC that HEPA filters are the only currently available certified respirators that, as a class, should be selected and meet or exceed the performance criteria to filter at least 95% of particles with a size greater than or equal to 1 \(\mu m\) (assuming complete test parameter specifications).
3M is in agreement that the current NIOSH certification procedures do not adequately test filter efficacy of DM and DFM filters against low-concentration aerosols in the size range of droplet nuclei. This does not mean that all DM and DFM filters do not meet CDC's criteria. It simply means that the certification process does not determine which NIOSH-certified DM and DFM filters meet these performance criteria. Since the NIOSH certification process and OSHA's respirator selection tables group respirators in classes rather than identifying individual performance capabilities, it is not possible for a purchaser to select the better performing respirators within a class of respirators. One way to resolve this is to allow respirator manufacturers to specify test results and let the purchaser to determine which filters to use. 3M believes, however, this solution would be undesirable at this point since the user would be confronted with a variety of claims based on unreliable tests that may not be truly comparable. As a result, DM and DFM filters should not be allowed until the work by NIOSH and ANSI is complete and procedures for certification under these standards can be granted.

It should be noted that an analysis by Nelson\(^1\) showed that when data from workplace performance tests for a variety of half mask respirators are examined, HEPA filters provide, on average, a higher level of protection than either DM or DFM filters. Nelson concluded that:

> When the type of filter is examined, the mean WPF (the actual protection factor measured in a workplace setting) for HEPA filters is significantly higher than either a DM or DFM filter.

> Leakage into a respirator will be governed by several factors including filter efficiency, face seal leakage and leakage through defects such as a faulty valve. Depending on the particle size of an aerosol, a HEPA filter may be expected to perform better than either a DM or DFM filter......The performance of a DM, DFM and HEPA filters when comparing the 5th percentiles are not that different and are not inconsistent with the assigned protection factor of 10. If the assigned protection factor was based on an average level of protection, then the differences seen would be significant. Since the assigned protection factor is defined as the minimum level of protection expected, the differences seen are not important.

**Combined WPF Results for Filter Type\(^2\)**

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<tr>
<th>Dust-mist</th>
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<th>HEPA</th>
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<td>N GM 5th 95th</td>
<td>N GM 5th 95th</td>
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<tr>
<td>117 212 22 2000</td>
<td>135 121 12 1140</td>
<td>138 918 26 32000</td>
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</table>


\(^2\) Ibid.
In the case of *M. tuberculosis*, though, this difference in performance may be significant, since there is no known safe exposure limit. Therefore, it may be prudent to decrease the overall level of exposure via filter penetration as much as practical.

Once it has been determined that a particular filter is best suited to reduce the penetration of an aerosol through the filter to an acceptable level, the second decision is to specify the type of respirator. There are a number of styles which have varying levels of performance as shown by the assigned protection factor. ANSI assigns a protection factor of 10 to half mask respirators, and 100 to full facepiece respirators. Assigned protection factors (APF) are estimates of the level of exposure reduction (risk reduction) expected from each respirator type.

Normally in selecting a respirator the accepted exposure limit of the contaminant in the work environment is known as well as the concentration levels actually found. Therefore, the assigned protection factors can be used to judge whether a given model of respirator will have performance characteristics that will reduce the airborne concentration of a contaminant to an acceptable level. In the case of *M. tuberculosis*, though, CDC states:

"There are gaps in the understanding of the transmission of *M. tuberculosis* that limit the ability to conduct the appropriate studies to determine the effectiveness of respiratory protection against transmission of *M. tuberculosis*. Neither the smallest infectious dose of *M. tuberculosis* nor the highest level of exposure to *M. tuberculosis* at which transmission will not occur have been conclusively defined .... Furthermore, the size, size distribution, and number of particles containing viable *M. tuberculosis* that are generated by infectious TB patients have not been adequately studied, and it is not possible to measure the concentration of infectious droplet nuclei in a room accurately with currently available methods. Nevertheless, there are certain settings where administrative and engineering controls may not fully protect HCWs from airborne droplet nuclei, such as in TB isolation rooms, during cough-inducing or aerosol-producing procedure, and in certain other settings (e.g., transportation of an infectious TB patient in an ambulance). Respiratory protective devices used in these settings should have characteristics that are suitable for the organism they are protecting against (i.e., *M. tuberculosis*) and the settings in which they are used (i.e., health-care settings). Although the following recommendations do not offer the maximum available protection, they probably exceed the minimum level of protection needed to prevent occupational exposure."
Wearability:

In the proposed guideline, the determination of the minimum required respirator must involve an analysis of both limitations on performance and the ability to use the respirator in the health care facility. This includes an analysis of the work that must be performed by the HCW. Some respirators would interfere with a HCW's normal duties. For example, an airline respirator would limit mobility, a full face respirator would interfere with the ability to work through a microscope, etc. A further factor influencing respirator selection relates to the HCW's verbal communication needs.

One of the most important factors affecting respirator performance is based on how much of the time the user actually wears the device. Thus, a respirator that may have an assigned protection factor that is greater than a half mask respirator, will not provide a higher level of performance if it is not worn continuously. The impact that user wear time has on diminishing the achievable levels of protection afforded by a specific respirator is easily calculated.

By assuming a protection factor for the time a respirator is worn, calculating leakage with this assumed factor and adding to this the exposure for not wearing the respirator, the resulting effective protection factor can be found. As shown below for exposure times of one hour and non-wear times of one minute to 30 minutes (1.67% to 50% non-wear time), the effective protection factor is reduced for all types of respirators. For example, a calculation of the percent time in an hour a respirator is not worn shows that a half mask respirator will lose 13% of the assigned protection factor if it is not worn for 1 minute in that hour (1.67%) while a powered air purifying respirator will lose 28% of its protection factor. In other words, the level of protection as indicated by the assigned protection factor is only achieved when the respirator is worn 100% of the time during exposure.

**Effective Protection vs % Time Not Worn in One Hour**

![Graph showing effective protection factor vs percent time not worn](image)

- Half Mask, APF of 10
- Loose fitting PAPR, APF of 25
- Air Line Respirator, APF of 1000
CDC has evaluated these numerous factors that affect respirator performance and has concluded that a half mask respirator with HEPA filters is currently an acceptable respirator for use in health care facilities. 3M supports this conclusion as well as CDC's approach of looking at all factors that affect respirator selection and not to rely solely on assigned protection factors.

Issues in a hospital environment:

There are other issues that need to be examined regarding the use of respirators in a hospital environment. Respirators have been used for protection in occupational exposures for many years, and their use is accepted by the people who work in their specific occupations. In a health care setting, however, such equipment has not been used as extensively.

For respirators to gain acceptance and to be used properly in the health care setting, it will be necessary to establish respiratory protection programs, including training of the HCW in the risks of exposure to *M. Tuberculosis* and the effect of not wearing the respirators provided.

Training of a respirator wearer to use a respirator can be divided into two phases: an explanation of how and when to use the respirator, and fit testing. Both are essential if a respirator is to perform as expected.

CDC's draft guide lists a number of items that need to be included in the training phases such as an explanation of how to use a respirator and an explanation of the operation, capabilities, and limitations of the respirator. As explained above, wearability is an important factor in achieving maximum performance and therefore 3M recommends that the draft guide include an explanation of the effect of not wearing the respirator during all times of exposure. Even brief periods of non-wear time can severely degrade any respirator's performance.

The second important phase of training is fit testing, *i.e.* determining how well a particular respirator fits the individual wearer. CDC has determined that both qualitative and quantitative fit testing may be used. 3M agrees with this determination. Both types of fit tests have been used successfully in good respiratory protection programs for a number of years. Respirator workplace studies conducted on half mask respirators have been performed where part of protocol for inclusion in the study has been to successfully pass a quantitative or qualitative fit test. When these have been done properly, the workplace performance has consistently exceeded the assigned protection factor of ten.³

To ensure that proper fit test procedures are followed, specific protocols for qualitative fit tests should be included in the guide. The protocols listed in OSHA's lead standard (29 CFR 1910.1025, Appendix D) have been previously validated and should be

³Ibid.
required. OSHA has issued other fit test protocols in other standards, but these have not under gone full evaluation. Also some of the test exercises listed in these protocols are not applicable to the health care setting. For example, some require jogging in place or bending over and touching toes.

3M disagrees, however, with the decision to allow an irritant smoke fit test to be used as part of respirator training. 3M does not believe that the irritant smoke protocol has received sufficient testing. In this regard, an ANSI committee charged with developing a standard for fit test protocols (ANSI Z88.10), has thus far excluded consideration of an irritant smoke protocol since validation testing to date is not sufficient to meet validation criteria. 3M submits that only the saccharin and isoamyl acetate qualitative fit test protocols such as those listed by OSHA in the lead standard (29CFR1910.1025) have been evaluated and shown to be effective.

For a fit test to be effective, it must be capable of measuring contaminant concentrations that occur inside and outside the respirator during the fit test. In a quantitative fit test, a piece of analytical equipment is used to measure the challenge material that may be an aerosol, gas, or vapor. In a qualitative fit test, the protocol relies on a person's response to the challenge agent and a reproducible test atmosphere.

In the isoamyl acetate fit test protocol, the odor screening test has been designed to generate a concentration of approximately 1 ppm. During the fit test, the protocol has been demonstrated to produce a challenge concentration of 100 to 150 ppm. For the saccharin fit test, the taste screening and fit test challenge concentrations are based on using two solutions that have a saccharin concentration difference of 100 times. The mist for screening and fit testing is generated within a test hood with the same type of aerosol generator, producing a documented concentration difference of 100. For the irritant smoke fit test no protocol has been tested to demonstrate that either a screening or test concentration can be reliably reproduced. For these reasons, 3M recommends that an irritant smoke fit test not be allowed to be used to select respirators.

The ANSI Z88.2 standard also has recommendations for the training of the supervisor - that is, a person who has the responsibility of overseeing the work activities of one or more persons who must wear respirators. ANSI recommends that the supervisor shall be given adequate training which includes the following subjects as a minimum:

1. Basic respiratory protection practices.

2. Nature and extent of respiratory hazards to which persons under his/her supervision may be exposed.

3. Recognition and resolution of respirator use problems.

4. Principles and criteria for selecting respirators used by persons under his/her supervision.
(7) Inspection of respirators.

(8) Use of respirators, including monitoring of use.

(9) Maintenance and storage of respirators.

(10) Regulations concerning respirator use.

CDC should include these requirements for supervisor training in their guideline.

Other issues:

Reuse of Respirators: CDC anticipates that because of the low levels of any aerosol in a health care facility, disposable respirators may remain functional for weeks. This will add to the training necessary for the health care workers to make sure they understand how to properly store these respirators so they are not damaged and will continue to function properly.

In several places in the draft guide, CDC refers to the ANSI standard as Z88.2(1980). (For example, at page 52845) The correct reference for program content should be the ANSI Z88.2 (1992) standard.

In table S4-1, CDC lists the summary features of respiratory protective devices. The table contains errors that may mislead people in health care facilities and should be corrected.

Fit tests: Fit tests can be performed on surgical masks with the saccharin fit test, however, most of these tests, if not all, will probably result in test failure.
Face seal leakage: The table lists face seal leakage for disposable, negative pressure DM and DFM respirators to be 10-20% and HEPA types to be less than 10%. Face seal leakage is controlled by fit testing. Fit testing is a requirement for a respiratory protection program and will screen out inadequately fitting respirators. The qualitative fit test protocols were validated for fit factors of 100. For half mask respirators, a fit factor of 100 is generally required as the pass/fail criterion for quantitative fit tests. A properly conducted, validated fit test, will limit face seal leakage to around 1% for those who successfully pass the test. The analysis by Nelson, also examines the performance of disposable and elastomeric facepiece respirators and does not find a statistically significant difference in performance between these two types of respirators. There should be no difference between the types of respirators listed.

Table S4-2 Advantages and Disadvantages of different types of respirators: The information in this table is confusing and inaccurate. It should be deleted from the guidelines.
Type of respirator: Two basic types are listed, negative pressure and positive pressure. The positive pressure group is incorrectly named. It should be called powered air purifying respirators (PAPR). Also, there are four classes of PAPRs, the CDC is incorrectly grouping two of the loose-fitting types into a single category. In the ANSI standard the correct groups are listed as a loose-fitting facepiece style and a helmet/hood style. This distinction was made because of data supporting a performance difference between the two styles.

Negative pressure respirators are divided into disposable and replaceable filter types. Both types are available with the three classes of filters.

Disadvantages, Limitations: The table states that measuring face seal in the field may be difficult for disposable respirators. This is not a clear statement. What face seal characteristic is being measured? As previously discussed, both disposable and replaceable filter types can be successfully fit tested and can provide an acceptable minimum face fit. Both types can be successfully fit checked by the wearer following the manufacturer’s instructions as required by NIOSH for certification and OSHA for usage.

Future Considerations:

In the healthcare setting, 3M believes the concerns with using a HEPA filtered respirator will be two fold; worker acceptance and cost. Typically, a high efficiency filter has a higher pressure drop (resistance to air flow) and is therefore more difficult to breathe through and hence less comfortable than a DM respirator or the traditional surgical mask the HCW has come to accept. Also, the cost of a HEPA filter product may be several times that of DM respirators. This could be a major concern to the health care industry.

Finally, 3M suggests that CDC closely monitor the issuance of NIOSH’s revised testing and certification procedures in 42 CFR 84. It would appear that a respirator tested and certified to NIOSH 42 CFR 84, Subpart U, as a Subclass C - solids respirator, would consistently meet CDC’s requirement of >95% efficiency against a 1 micron particle (properly defined test assumed). The Subclass C respirator would be comparable to a present DM in breathing resistance and comfort for the wearer and several times less expensive than a HEPA filter product.

Respectfully submitted,

Katherine E. Reed
Katherine E. Reed, Ph.D.
Technical Director
Occupational Health and Environmental Safety Division
"Worst Case" Aerosol Testing Parameters: I. Sodium Chloride and Dioctyl Phthalate Aerosol Filter Efficiency as a Function of Particle Size and Flow Rate

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U.S. Department of Health and Human Services. Public Health Service, Centers for Disease Control, National Institute for Occupational Safety and Health, Division of Safety Research, Injury Prevention Research Branch, Laboratory Investigations Section, 944 Chestnut Ridge Road, Morgantown, WV 26505-2888

The efficiency of filter media is dependent on the characteristics of the challenge aerosol and the filter's construction. Challenge aerosol parameters, such as particle size, density, shape, electrical charge, and flow rate, are influential in determining the filter's efficiency. In this regard, a so-called "worst case" set of conditions has been proposed for testing respirator filter efficiency in order to ensure wearer protection. Data collected on various types of filters (dust and mist; dust, fume, and mist; paint, lacquer, and enamel mist; and high efficiency) challenged with a worst case--type sodium chloride (NaCl) and dioctyl phthalate (DOP) aerosol are presented. The particle size of maximum penetration varies as a function of filter type and was <0.25-μm count mean diameter (CMD) in all cases. The count efficiency for high efficiency filters was >99.97% at worst case testing conditions, but the worst case count efficiencies for dust and mist; dust, fume and mist; and paint, lacquer and enamel mist filters were not nearly as efficient as existing test methods indicate. Also, as the test flow rate is increased, the count efficiency decreases. Thus, respirator filters were found to conform to the prediction of single-fiber filtration theory.

Introduction

The National Institute for Occupational Safety and Health (NIOSH), in cooperation with the Mine Safety and Health Administration (MSHA), currently is responsible for the testing and certification of respiratory protective devices. The criteria that these devices must meet in order to be certified are found in Title 30, Code of Federal Regulations, Part 11 (30 CFR Part 11). Numerous deficiencies have been identified in this regulation with regard to particulate air-purifying respirators. Therefore, a number of years ago, NIOSH undertook the task of revising 30 CFR Part 11 to incorporate updated procedures and test requirements. These revisions were recently published in the Federal Register as 42 CFR Part 84.

Subpart V of 42 CFR Part 84 contains the requirements for particulate air-purifying respirators. Paragraph 84.273 describes the filter tests that must be met for the filters to be certified by NIOSH. Many of the requirements found in this paragraph were based on theoretical considerations of single-fiber filtration theory which predicts the existence of a most penetrating, or "worst case," size aerosol. Little respirator filter data exists to support this theory, although some studies have been conducted on commercial filtration material which have confirmed the theory.

The object of this study was to determine the optimum aerosol particle size for testing particulate respirator filters and to determine how this varies as a function of test flow rate. This so-called worst case challenge aerosol would be the test condition which gives the maximum filter penetration or the minimum filter efficiency. A method utilizing such an aerosol would differentiate between good, medium, and low efficiency filters of all types. The important safety issue involved is that filters tested against a worst case aerosol would protect wearers against smaller as well as larger particles. This is the only way of guaranteeing performance against virtually all size particles. The need for such methodology is evident, since data in the literature indicate that the filter efficiencies measured using a worst case--type aerosol are significantly lower than those obtained with the current certification tests specified in 30 CFR Part 11.

Background

The efficiency of a filter medium is dependent on the challenge aerosol's characteristics and the filter's characteristics. Challenge aerosol characteristics--such as particle size, density, shape, electrical charge, and flow rate—are influential in determining the filter's efficiency. Naturally, many filter characteristics, such as packing density and fiber diameter, which are controlled by the manufacturer, are also critical. These latter characteristics (controlled by the manufacturer) are of minimal importance to NIOSH so long as the filters perform well. NIOSH's interest is with the overall performance of commercially marketed filters as a function of testing parameters.

Single-fiber filtration theory predicts the existence of an aerosol size of minimum efficiency for fibrous filters. Stated briefly, theory predicts that an increase in particle size will cause increased filtration by the interception and inertial impaction mechanisms, whereas a decrease in particle size will enhance collection by Brownian diffusion. Thus there is an intermediate particle size region where two or more of these mechanisms are operating simultaneously. In this region, the particle penetration through the filter is a maximum, and the filter's efficiency is a minimum. This most-
penetrating size aerosol is in the range between 0.1–0.4 μm (aerodynamic) for most fibrous filters. Theory also states that most mechanisms of filtration are dependent on the aerosol flow rate, where an increase in flow rate causes a downward shift in the particle size of maximum penetration. This is particularly noticeable at high filtration velocities (100–300 cm/sec) as reported by Liu and Lee.\(^{11}\)

Although some experimental investigations\(^{10,16-17}\) have verified these facts, little work has been done on commercially available respirator filters to determine the aerosol size at which the maximum penetration occurs. Stafford and Ettinger\(^{9}\) did evaluate Whatman 41 (Whatman Inc., Clifton, N.J.) and IPC [Institute of Paper Chemistry] 1478 filter paper as a function of particle size and velocity against polystyrene latex spheres (PSL) and concluded that a reevaluation of filter testing should be considered, since a 0.3-μm aerosol does not yield minimum efficiencies for all filter media at the different velocities of concern. Also, a study\(^{18}\) of the effect of charging on electret filter behavior shows the size at which maximum filter penetration occurs is aerosol charge dependent.

The present study monitored respirator filter media penetration versus particle size and flow rate. Particles in the worst case, most penetrating aerosol size range were used for testing commercially available filters of the dust and mist (DM); paint, lacquer, and enamel mist (PLEM); dust, fume, and mist (DFM); and high efficiency (HE) types. Both solid and liquid aerosols were investigated since reports in the literature\(^{19-22}\) indicate that differences in filter penetration exist between them because of increased degradation, loading effects, and/or differences in charging.

**Experimental Design**

Air-purifying respirator filters and the filters’ holders and gaskets (where separable) were tested for the initial, instantaneous filter efficiency when mounted on the holder in the manner as used on the respirator. When the filter holders were not separable, the exhalation valve was blocked to assure that valve leakage, if present, was not included in the filter efficiency results. Also, wherever possible, all filters tested were from the same lot to eliminate lot-to-lot variability.

The filters all were initially tested at a continuous airflow rate of 64 L/min. This flow rate was chosen for two reasons. First, a study by Campbell\(^{23}\) predicted, and data (dioctyl phthalate [DOP] filter efficiency determinations as a function of flow rate) confirmed, that 66 L/min was the choice continuous flow rate for evaluating filters. Also, Fuchs\(^{24}\) showed the existence of a flow rate of maximum penetration. Secondly, this higher flow rate should allow for easier detection of changes in the filter penetration as a function of the aerosol size. Later, this study was modified to include continuous flow rates of 16, 32, 42.5, and/or 85 L/min.

All filters were tested as received from the manufacturer without any kind of pre-conditioning. Filters were challenged with a solid sodium chloride (NaCl) aerosol and/or a liquid DOP aerosol. The aerosols were passed through a Kr-85 radioactive source in order to reduce the charge on the aerosol to a Boltzman charge distribution to “neutralize” the aerosol. Room temperature was employed for all the studies. Where possible, at least five filters of each type from the same lot were tested at each particle size, and the average efficiency was determined. The efficiency determined when five filters are tested should be within 0.9% of the true value. For HE filters, when three filters are tested, the measured value should be approximately 0.001% of the true value (three or more filters were actually tested). An alpha level of 0.05 was used in determining these limits.

Filters from three different manufacturers were tested against various particle sizes in the range from 0.03 to

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<th>Filter Description</th>
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<td></td>
<td>dusts, fumes, and mists; asbestos-containing dusts and mists; radionuclides and radon daughters</td>
<td>high efficiency filter paper</td>
</tr>
<tr>
<td>B</td>
<td>dusts and mists, paint, lacquer, and enamel mists, dusts, fumes, mists, and radionuclides</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>—</td>
<td>high efficiency filter paper</td>
</tr>
<tr>
<td>C</td>
<td>dusts and mists, dusts, fumes, and mists, paint, lacquer, and enamel mists, dusts, fumes, mists, and radionuclides</td>
<td>electrostatic felt, resin, fiberglass, wool, electrostatic felt, high efficiency filter paper</td>
</tr>
<tr>
<td>D</td>
<td>dusts and mists, dusts, fumes, and mists, pesticides, paint, lacquer, and enamel mists and dusts and mists</td>
<td>impregnated wool, fiberglass</td>
</tr>
</tbody>
</table>

---

0.24-μm count mean diameter (CMD) for solid NaCl and from 0.03 to 0.30-μm CMD for DOP. Filters of the DM, DFM, PLEM, and HE types were employed in this study and are described in Table I. All filters were NIOSH certified under the current 30 CFR Part 111 regulations. In all cases the challenge concentration was maintained at less than 10⁷ particles per cm³ to avoid coagulation. The exact concentration did vary over a limited range, but by monitoring both upstream and downstream concentrations, any effect was minimized. Also, if the upstream concentration at the onset and completion of a run changed by more than approximately 3%, the tests were not considered valid runs.

**Solid NaCl Aerosol Generation**

The solid NaCl aerosol was generated by a TSI model 3076 constant output atomizer (TSI, Inc., St. Paul, Minn.) operating in the recirculating mode. Solutions of varying concentration of NaCl (0.001–0.1 gm/cm³) in double distilled, deionized water were used to generate various size ranges of NaCl particles. The resulting aerosol particles were wet and highly electrostatically charged. They were passed through a series of two diffusion driers to dry the particles. The dried particles then entered an electrostatic classifier (TSI model 3071, operated with an aerosol flow rate = 4 L/min and a sheath and excess flow rate = 20 L/min, which uses the principal of electrical mobility (28–27) to select the desired particle size for testing. By this method, particles with a CMD between 0.03–0.24 μm were produced. During the initial portion of this study, there was a problem with turbulent flow inside the electrostatic classifier. This caused the geometric standard deviation (σg) to be between 1.4 and 1.6. When the turbulent flow problem was corrected, a monodisperse aerosol was obtained. The system configuration employed throughout this study is depicted in Figure 1.

**DOP Liquid Aerosol Generation**

The liquid DOP aerosol was produced by an evaporization/condensation technique. The system employed is basically that depicted in Figure 1, except that the drier and electrostatic classifier are replaced with an evaporation/condensation conditioner. This system has been described by Liu and Lee (28) as producing a moderately monodispersed aerosol with a geometric standard deviation of 1.3 to 1.5. The system included a TSI constant output atomizer (Model 3075) which is fed by a syringe pump (0.59 cc/min) to provide for a constant flow of liquid to the pneumatic atomizer. This results in a stable and reproducible particle-size output. A TSI Model 3072 evaporation/condensation conditioner was used for producing the DOP aerosol. By changing the DOP solution concentration, the particle size changes. Various concentrations of DOP/ethanol (5 × 10⁻⁴ to 5% by volume) were employed to generate particles with a CMD between 0.03 μm and 0.30 μm and a σg between 1.6 and 1.8 as determined with a differential mobility particle sizer (DMPS). This aerosol is not monodispersed. A plot of log particle size versus log DOP concentration showed linear correlation as per the results of Liu and Lee. (28) Also, a small amount of anthracene was added to the solutions to serve as a nucleating agent.

**Aerosol Efficiency Measurements**

The efficiency and penetration was monitored and recorded by means of the TSI Filter Efficiency Test System (FETS) which has been described by Remiarz et al. (28) This instrument, which was built under contract for NIOSH, contains a continuous flow, single-particle-counting condensation nucleus counter (CNC, TSI Model 3020). The CNC (Agarwal and Sem (30)) can measure concentrations as high as 10⁷ particles/cm³ when using the photometric mode and can measure concentrations down to 10⁻² particles/cm³ using its single-particle counting ability. When used to measure the particle concentrations both upstream and downstream of a filter, the CNC can determine count filter efficiencies as high as 99.99999+%. This instrument’s sensitivity and dynamic concentration range of measurement were necessary in order to detect the differences in filter efficiency and to cover the
large range of concentrations anticipated in going from upstream to downstream concentrations. This is especially true in the case of HE filters. In addition to testing efficiencies, the system measures respirator flow rates and pressure drops. The instrument is automated by means of a dedicated microcomputer system.

**Aerosol Size Measurements**

The aerosol size (CMD) and size distribution (ug) initially were determined with a TSI Model 3030 electrical aerosol size analyzer (EAA) according to the procedure of Liu and Pui. The EAA measures the aerosol size distribution by the principle of unipolar diffusion charging and mobility analysis. First, the analyzer places a unipolar charge on the aerosol and then measures the resulting mobility distribution of the charged particles by means of a mobility analyzer. All determinations of the size and ug were accomplished by hand calculations. This procedure was used until a TSI Model 3932 differential mobility particle sizer (DMPS) became available. The DMPS measures the size distribution of submicrometer aerosols by the electrical mobility detection technique. First, the aerosols are classified with an electrostatic classifier, and then their concentration is determined with a CNC. The system is automated and microprocessor controlled. The aerosol was sampled at the point of entrance into the test chamber.

When using raw EAA data to determine aerosol size and distribution by hand calculations, the resulting size will be slightly lower than the actual size. This is due to the increments of the voltages applied to the collector rod in the EAA (the automated version of the EAA corrects for this shift). Therefore, a brief correlation study was performed so that the EAA data could be converted to an equivalent DMPS size. This was accomplished by determining sizes of a number of different size aerosols using both the EAA and DMPS in parallel. The data were plotted and a correlation equation determined for converting all EAA particle-size data.

**Results and Discussion**

The purpose of this study was to determine the worst case, most penetrating size of aerosol particulates for testing commercially available respirator filter media. The filters tested are described in Table 1. Typical results for HE filters are shown in Figure 2 and Figure 3 for NaCl and DOP, respectively. Figure 4 and Figure 5 depict results obtained for a DFM filter against NaCl and PLEM filter against DOP, respectively. It should be noted that these curves represent an average efficiency for a series of filters tested at each size, which resulted in some scatter in the data. This also is influenced by the fact that the DOP aerosol was not monodispersed. Better control of the system and uniform filters would have resulted in improved efficiency versus particle-size curves. The plots of percent filter efficiency versus challenge aerosol particle size at flow rates of 16, 42.5, 64, and 85 L/min show a minimum in the efficiency curve, as theory predicts.

In addition to the worst case penetrating particle size, the phenomenon of a shift of this region toward a smaller parti-
Figure 5—Paint, lacquer, and enamel mist filter efficiency as a function of particle size and flow rate for Manufacturer C's filters against DOP aerosol

Figure 4—Dust, fume, and mist filter efficiency as a function of particle size and flow rate for Manufacturer C's filters against NaCl aerosol

cle size as the flow rate is increased is observed also and agrees with theoretical predictions. Similarly, the magnitude of penetration increases as the flow rate increases. An additional observation at a couple of particle sizes is the crossover of the efficiency curve of lower flow rates. That is, at certain points, a lower flow rate gives more penetration than a higher flow rate. This observation is in agreement with findings of Fuch's and with the theory which predicts that as the velocity increases, collection by diffusion is reduced and collection by impaction is increased. Thus, there is a face velocity which should give a minimum efficiency for a given particle size and filter.

The NaCl and DOP results for all the filters listed in Table I are given in Table II and Table III, respectively. These data show that all the HE filters gave efficiencies greater than the 99.97% required by the DOP test in 30 CFR Part 11, but it must be noted that the FETS gives count efficiencies which are not equal to efficiencies determined with light photometers, as on the commercial 0.3-μm DOP instrument (Q 127). Further it should be noted that Filters A and C were tested at flow rates (64 and 85 L/min) which were higher than that presently required in 30 CFR Part 11 (42.5 L/min for single filter of pair-type respirator). Even at these higher flows, the filters gave count efficiencies > 99.97%. This basically confirms that the commercially available HE filters are indeed very good, even when tested at or near the worst case conditions.

The data in Tables II and III indicate that the other filter types (DM, DFM, and PLEM) are not as efficient when a worst case method that monitors initial efficiencies is employed. These filters gave minimum efficiencies which were significantly lower than the limits set forth for the silica dust test (>99% gravimetric TWA over 90 min) or the lead fume test (>99% gravimetric TWA over 312 min). It must be noted, however, that these filters were tested at a variety of flow rates, some of which were higher than those required by the present regulations (32 L/min for single filters, 16 L/min for filter pairs).

These significantly lower count efficiencies cannot be explained solely by the type of efficiency measured (count versus mass). Parameters such as particle size and charging also play an important role in determining the filter's efficiency. These results indicate that the worst case—type test is much more vigorous and is able to differentiate between good, medium, and low efficiency filters. The present tests (silica dust and lead fume) do not have the ability to discriminate between the various filter types. It must be remembered, however, that the DOP and NaCl tests run in this study do not consider or evaluate any loading effects, and it is known that mechanical filters become more efficient with loading.

Table IV and Table V show the CMD particle-size range (DMPS) at which maximum filter penetration takes place for NaCl and DOP, respectively. These data show that for the HE filters, the most penetrating particle-size region is occurring at a larger particle size than for the other filter types tested. This probably is because of the increased surface area of the HE filters. These filters are pleated and have

### TABLE II

**Range of Minimum NaCl Initial Instantaneous Filter Efficiency**

for Commercial Filters in the “Worst Case” Size Region

<table>
<thead>
<tr>
<th>Flow Rate (L/min)</th>
<th>Manufacturer</th>
<th>Dust and Mist</th>
<th>Paint, Lacquer, and Enamel Mist</th>
<th>Dust, Fume, and Mist</th>
<th>High Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>A</td>
<td>87-88</td>
<td>92-93</td>
<td>98-99</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>88-89</td>
<td>92-93</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>84-85</td>
<td>87-88</td>
<td>98-99</td>
<td>&gt;99.999</td>
</tr>
<tr>
<td>32</td>
<td>B</td>
<td>82-83</td>
<td>85-88</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>42.5</td>
<td>A</td>
<td>79-80</td>
<td>83-84</td>
<td>94-95</td>
<td>99.997-99.998</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>71-72</td>
<td>78-79</td>
<td>95-96</td>
<td>99.996-99.997</td>
</tr>
<tr>
<td>64</td>
<td>A</td>
<td>77-78</td>
<td>79-80</td>
<td>92-93</td>
<td>99.991-99.992</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>73-74</td>
<td>79-80</td>
<td>—</td>
<td>99.995-99.998</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>70-71</td>
<td>75-76</td>
<td>93-94</td>
<td>99.995-99.996</td>
</tr>
<tr>
<td>85</td>
<td>A</td>
<td>69-70</td>
<td>77-78</td>
<td>91-92</td>
<td>99.977-99.980</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>73-74</td>
<td>78-79</td>
<td>—</td>
<td>99.993-99.994</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>67-68</td>
<td>86-87</td>
<td>87-88</td>
<td>—</td>
</tr>
</tbody>
</table>

*Estimated minimum efficiency range from filter efficiency versus particle-size plots.

large surface areas, which effectively decrease the face velocity of the filters, resulting in a shift toward a large particle size of minimum efficiency.

With both NaCl and DOP aerosols, the HE filters gave a minimum efficiency at the largest particle size. For all the other filter types, the particle size of minimum efficiency was less than that observed for the HE filters. Also, the particle size at which the minimum efficiency occurred varied from one manufacturer to another within the same filter type. This suggests that the ideal method would be one which evaluates a filter versus particle size and then runs all subsequent tests at the particle size of minimum efficiency.

**Conclusions**

The results of this study show that respirator filters do indeed follow many of the predictions of single-fiber filtration theory. The following conclusions were noted. (1) A particle size at which a minimum efficiency occurs does exist and varies as a function of flow rate, filter type, and filter

### TABLE III

**Range of Minimum DOP Initial Instantaneous Filter Efficiency**

for Commercial Filters in the “Worst Case” Size Region

<table>
<thead>
<tr>
<th>Flow Rate (L/min)</th>
<th>Manufacturer</th>
<th>Dust and Mist</th>
<th>Paint, Lacquer, and Enamel Mist</th>
<th>Dust, Fume, and Mist</th>
<th>High Efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>A</td>
<td>86-89</td>
<td>88-89</td>
<td>98-99</td>
<td>&gt;99.999</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>87-88</td>
<td>91-92</td>
<td>—</td>
<td>&gt;99.999</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>84-85</td>
<td>87-88</td>
<td>98-99</td>
<td>99.998-99.999</td>
</tr>
<tr>
<td>32</td>
<td>B</td>
<td>84-85</td>
<td>86-87</td>
<td>—</td>
<td>99.998-99.999</td>
</tr>
<tr>
<td>42.5</td>
<td>A</td>
<td>79-80</td>
<td>82-83</td>
<td>94-95</td>
<td>99.997-99.998</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>80-81</td>
<td>85-86</td>
<td>—</td>
<td>99.994-99.995</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>72-73</td>
<td>73-79</td>
<td>95-96</td>
<td>99.995-99.995</td>
</tr>
<tr>
<td>64</td>
<td>A</td>
<td>73-75</td>
<td>77-78</td>
<td>92-93</td>
<td>99.987-99.988</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>74-75</td>
<td>80-82</td>
<td>—</td>
<td>99.990-99.991</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>67-68</td>
<td>72-73</td>
<td>91-93</td>
<td>99.977-99.978</td>
</tr>
<tr>
<td>85</td>
<td>A</td>
<td>74-75</td>
<td>76-77</td>
<td>87-88</td>
<td>99.978-99.979</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>70-71</td>
<td>75-76</td>
<td>—</td>
<td>99.983-99.984</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>69-70</td>
<td>70-71</td>
<td>86-87</td>
<td>99.989-99.990</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>67-68</td>
<td>84-85</td>
<td>85-86</td>
<td>—</td>
</tr>
</tbody>
</table>

*Estimated minimum efficiency range from filter efficiency versus particle-size plots.*
### TABLE IV
Particle Size* Range of Minimum NaCl Initial Instantaneous Filter Efficiency for Commercial Respirator Filters

<table>
<thead>
<tr>
<th>Flow Rate (L/min)</th>
<th>Manufacturer</th>
<th>CMD^A (μm)</th>
<th>CMD^A (μm)</th>
<th>CMD^A (μm)</th>
<th>CMD^A (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>A</td>
<td>&lt; 0.055</td>
<td>0.07-0.11</td>
<td>0.06-0.10</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>&lt; 0.055</td>
<td>ND</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&lt; 0.055</td>
<td>0.085-0.12</td>
<td>0.10-0.14</td>
<td>0.16-0.20</td>
</tr>
<tr>
<td>32</td>
<td>B</td>
<td>0.06-0.10</td>
<td>0.08-0.12</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>42.5</td>
<td>A</td>
<td>&lt; 0.06</td>
<td>0.06-0.10</td>
<td>0.045-0.085</td>
<td>0.17-0.21</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&lt; 0.05</td>
<td>0.045-0.075</td>
<td>0.08-0.12</td>
<td>0.15-0.19</td>
</tr>
<tr>
<td>64</td>
<td>A</td>
<td>&lt; 0.06</td>
<td>0.06-0.095</td>
<td>0.05-0.08</td>
<td>0.16-0.20</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>&lt; 0.06</td>
<td>0.10-0.14</td>
<td>—</td>
<td>0.14-0.18</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&lt; 0.05</td>
<td>0.05-0.09</td>
<td>0.07-0.11</td>
<td>0.14-0.18</td>
</tr>
<tr>
<td>85</td>
<td>A</td>
<td>0.06-0.10</td>
<td>0.065-0.10</td>
<td>0.05-0.08</td>
<td>0.16-0.21</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.06-0.10</td>
<td>ND</td>
<td>—</td>
<td>0.14-0.19</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>0.06-0.10</td>
<td>0.055-0.085</td>
<td>0.07-0.12</td>
<td>0.12-0.15</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>0.04-0.07</td>
<td>0.03-0.07</td>
<td>0.05-0.09</td>
<td>—</td>
</tr>
</tbody>
</table>

*Estimated particle size of minimum filter efficiency from DMPS experimental or converted from EAA data correlation.

BND = not distinguishable.

### TABLE V
Particle Size* Range of Minimum DOP Initial Instantaneous Filter Efficiency for Commercial Respirator Filters

<table>
<thead>
<tr>
<th>Flow Rate (L/min)</th>
<th>Manufacturer</th>
<th>CMD^A (μm)</th>
<th>CMD^A (μm)</th>
<th>CMD^A (μm)</th>
<th>CMD^A (μm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>A</td>
<td>0.05-0.08</td>
<td>0.08-0.12</td>
<td>0.06-0.10</td>
<td>ND</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.06-0.10</td>
<td>0.09-0.13</td>
<td>—</td>
<td>ND</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>0.04-0.08</td>
<td>0.085-0.125</td>
<td>0.11-0.15</td>
<td>0.125-0.165</td>
</tr>
<tr>
<td>32</td>
<td>B</td>
<td>0.055-0.095</td>
<td>0.09-0.13</td>
<td>—</td>
<td>0.09-0.13</td>
</tr>
<tr>
<td>42.5</td>
<td>A</td>
<td>&lt; 0.04</td>
<td>0.10-0.14</td>
<td>0.04-0.08</td>
<td>0.14-0.18</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.04-0.08</td>
<td>0.085-0.125</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&lt; 0.04</td>
<td>0.095-0.135</td>
<td>0.10-0.14</td>
<td>0.13-0.17</td>
</tr>
<tr>
<td>64</td>
<td>A</td>
<td>&lt; 0.04</td>
<td>0.08-0.12</td>
<td>0.05-0.09</td>
<td>0.11-0.15</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.03-0.06</td>
<td>0.07-0.11</td>
<td>—</td>
<td>0.12-0.16</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>&lt; 0.04</td>
<td>0.05-0.09</td>
<td>0.11-0.15</td>
<td>0.12-0.16</td>
</tr>
<tr>
<td>85</td>
<td>A</td>
<td>&lt; 0.04</td>
<td>0.06-0.09</td>
<td>0.07-0.10</td>
<td>0.095-0.135</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>0.04-0.08</td>
<td>0.04-0.08</td>
<td>—</td>
<td>0.135-0.175</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>0.03-0.07</td>
<td>0.06-0.10</td>
<td>0.08-0.12</td>
<td>0.09-0.13</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>0.03-0.06</td>
<td>0.055-0.095</td>
<td>0.07-0.10</td>
<td>—</td>
</tr>
</tbody>
</table>

*Estimated particle size of minimum filter efficiency from DMPS experimental or converted from EAA data correlation.

BND = not distinguishable.

---

manufacturer. (2) Minimum efficiencies for HE filters occur at larger particle sizes than for other filters. (3) HE filters showed excellent efficiencies at or near the worst case conditions. (4) DM, DFM, and PLEM filters are not nearly as efficient when tested by a worst case type aerosol as when tested with the present 30 CFR Part 11 test methods.
In relation to the changes found in 42 CFR Part 84, this study has shown that the proposals made in 42 CFR Part 84 are a step in the right direction in achieving a test regimen that is more capable of discerning a filter's ability to protect the wearer against most all sizes of particulate matter.

All of the filters, except the HE filters, tested in this study gave efficiencies that were below that currently required by 30 CFR Part 11. The HE filters, when tested at the most stringent conditions, gave efficiencies greater than 99.97%. It must be noted, however, that only filter efficiencies were evaluated in this study, and important factors, such as face seal leakage and valve leakage, were not considered. In some cases, especially with HE filters, these factors may overshadow the protection afforded by the filter itself.

References
"Worst Case" Aerosol Testing Parameters:  
II. Efficiency Dependence of Commercial Respirator Filters on Humidity Pretreatment  

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Previous studies have shown that relative humidity has a degrading effect on the performance of commercially available particulate air-purifying respirator filters. That degradation results from a reduction of charge within the filter. This study was done to evaluate the time-dependent effects of relative humidity pretreatment and the reduction of charge on filter penetration against a most penetrating, "worst case" aerosol challenge. Filters of the dust and mist; dust, fume, and mist; paint, lacquer, and enamel mist; and high efficiency types were tested after being pretreated in an environment of 38°C and 85% relative humidity for periods up to 42 days. After various intervals of pretreatment (1, 7, 14, 28, and 42 days), the filters were tested against neutralized worst-case sodium chloride (NaCl) and dioctyl phthalate (DOP) aerosols for percent penetration. The results showed a drop in filter efficiency of approximately 2%–6% depending on preconditioning time, except for the high efficiency filters tested which showed no detectable change.

Introduction  
This study was initiated to evaluate the filter preconditioning recommendations made to the National Institute for Occupational Safety and Health (NIOSH) by the American National Standards Institute's (ANSI) Ad Hoc Respirator Committee(1) for the testing of particulate air-purifying respirator filters. These recommendations were incorporated into the proposed revision to Code of Federal Regulations Title 30, Part 11 (30 CFR 11)(2) (published as 42 CFR 84(3) in the Federal Register, August 27, 1987). The respirator filters tested in this study were challenged with a "worst case" type aerosol, the size aerosol that is most difficult to filter. Filters tested with this worst-case aerosol and prehumidified condition should give an indication of the filter's performance under a wider range of environmental conditions.

The ANSI recommendations called for the preconditioning of the unprotected respirator filter media in an environment of 38°C and 85% relative humidity (RH) for a period of 24 hr before testing the filter media. The preliminary results of that portion of the study(4) showed that after 24 hr in this environment, most filters (with the exception of high efficiency filters) demonstrated a drop in their filter efficiencies of approximately 1.5% to 2%. Although this difference is statistically significant (at α = 0.05), practically speaking, the difference is not great. As a result the study was expanded to look at some of the same respirator filter media after longer exposure times at these same environmental conditions. The expanded exposure times used were 1, 7, 14, 28, and 42 days. Results from all the relative humidity studies are presented.

Background  
There have been a few previous studies that have looked at the effect of relative humidity pretreatment on electrostatic filters. The first two were performed under contract with NIOSH by the Los Alamos National Laboratory (LANL). The first series of tests performed by LANL(5) tested six resin-impregnated wool felt filters using a 0.6-μm mass median aerodynamic diameter (MMAD) unneutralized sodium chloride (NaCl) particle at a flow rate of 32 L/ min (16 L/ min for dual filter respirators). The filters were preconditioned in a chamber for a period of 7 days at three different humidities (50%, 75%, and 100% RH at 22.2°C [72°F]). A group of filters was taken out at the end of each day and tested. The results indicated that there was indeed an effect on the filters' performance that depended on the relative humidity level and the number of days the filter was stored at that relative humidity level: the trend being, the higher the humidity and the longer the preconditioning period, the higher the magnitude of penetration.

The second study performed by LANL(6) used a 0.6-μm MMAD unneutralized NaCl aerosol, but with flow rates of 32 and 77 L/min. The filters were preconditioned at 32°C and 90% RH and tested at 7 day intervals, up to 28 days total preconditioning. For the 77 L/ min flow rate, NaCl aerosol penetrations for unexposed filters were in the 10%–25% range, but at the end of the 28-day preconditioning period, aerosol penetrations were in the 60%–65% range. For the 32 L/min flow rate, the penetrations ranged from 5%–10% initially to 50%–60% after 28-day preconditioning.

In a study performed by Ackley(7) in 1982, four different types of electrostatic filters were tested using a monodispersed 0.3-μm diameter dioctyl phthalate (DOP) aerosol generated by an AT1 model Q127 penetrometer (Air Techniques Inc., Baltimore, Md.). Also, an NaCl aerosol with a 1.0-μm MMAD was used. Both aerosols were unneutralized. The study used filter face velocities of 5.4 cm/sec and 6.5 cm/sec.
The filters were tested against various particle sizes of NaCl and DOP aerosols in the range from 0.03 to 0.30-μm count mean diameter (CMD). In all cases the challenge concentration was maintained at less than 10^7 particles per cm^3 to avoid coagulation. The exact concentration did vary over a limited range, but this should not have affected the results since both upstream and downstream concentrations were monitored.

The charge distribution on both aerosols was reduced to a Boltzman charge equilibrium using a Kr-85 source.

**Aerosol Generation and Detection**
The solid NaCl and DOP aerosol generation system has been completely described in another paper by Stevens and Moyer. The neutralized aerosol then was fed to the test chamber of the filter efficiency test system (FETS), which measured count efficiencies. Only one of the three filter sample ports was used in this study since the initial instantaneous penetration was being measured. Thus, short testing times (1–3 min) could be employed to minimize filter loading.

**Aerosol Size Measurements**
The aerosol size (count mean diameter, CMD) and size distribution (geometric standard deviation, σg) were monitored with a TSI Model 3932 Differential Mobility Particle Sizer (DMPS/C) (TSI, Inc., St. Paul, Minn.). The aerosol was sampled at the point of entrance into the testing chamber. The DMPS measures the aerosol size distribution by the principle of mobility analysis. The DMPS uses an electrostatic classifier and a condensation nucleus counter to measure discrete particle sizes of the aerosol, allowing the instrument to measure accurately the aerosol’s distribution.

**Results and Discussion**
Initial studies showed that a region of minimum efficiency exists for the respirator filters tested. The “as received”

### TABLE 1

<table>
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<tr>
<th>Manufacturer/Filter Type</th>
<th>1 Day NaCl</th>
<th>1 Day DOP</th>
<th>7 Day NaCl</th>
<th>7 Day DOP</th>
<th>14 Day NaCl</th>
<th>14 Day DOP</th>
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<th>28 Day DOP</th>
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<tr>
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<td>B DM</td>
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<tr>
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</table>

*Filter designations and types described in earlier work.*

*X = filter tested.*
Figure 1—Filter efficiency comparison of two lots of Manufacturer A’s DFM filter against NaCl aerosol

Filter data from this study and from those previous studies are consistent (Figure 1). Both the region of minimum efficiency and the magnitude of penetration are approximately the same, with differences being attributed to lot-to-lot variability. This demonstrates the reproducibility of this test method over long time periods.

The relative humidity pretreatment generally had the same degrading effect, which resulted in increased filter penetration on all types of filters tested, except the HE filters. Figures 2 and 3 illustrate results for an HE filter against NaCl and DOP challenges before and after RH pretreatment. Note that in Figure 3, the last point seems to indicate an increase in efficiency which is in agreement with earlier results. The high efficiency filter showed no statistically detectable difference between the as-received filters, the 24-hr RH pretreated filters, and the 45-day pretreated filters (t-test at $\alpha = 0.05$). Degradation of HE filters was not expected because these filters rely purely on mechanical filtration to remove particles in the challenge atmosphere.

The other types of filters tested depend to some extent on electrostatic filtration. These types of filters, as discussed earlier, normally will exhibit some degradation when exposed to elevated temperature and humidity, resulting in a decrease in the filter’s efficiency. This decrease in efficiency is depicted in Figure 4 for a filter pretreated for 24 hr prior to testing. This decrease in filter efficiency has been reported as being caused by charge neutralization of the filter media caused by moisture.

Previous studies showed that the filters’ efficiency will continue to decline (filters will continue to degrade) if the filters are left in an elevated temperature/RH environment. In fact, the filters will degrade until only the mechanical efficiency of the filter remains. Literature studies show that filter efficiency continued to decline as exposure time increased, up to 180 days, at which time the studies were terminated. In the first 20–40 days, however, the greatest percentage change was noted.

Before comparing these data with the earlier studies, differences in the experimental design must be taken into consideration. Specifically, the aerosol used in this test is in the worst-case size region, and the aerosol was neutralized (Boltzman distribution) before the filter was challenged. The Los Alamos results, where the test parameters were closest to those used in this study, were obtained at a flow rate of 77 L/min and employed a 0.6-μm unneutralized NaCl particle. DM filters showed a penetration of 10%–25% for the as-received filters. NIOSH’s data, employing a worst-case aerosol, measured penetrations of 30%–35%. The three effects which could cause this significant difference are (1) particle size, (2) aerosol charge, and (3) differences in the types of filters tested. A comparison of the studies indicates that there was approximately a 2% drop in efficiency after 24 hr at both the worst-case aerosol size and at 0.6 μm.

Pretreatment for time periods up to 42 days did not show the continuing sharp increase in penetration the earlier studies had shown (Figures 5–7). Increased penetration of only 4% to 6% was noted after 42 days pretreatment. Also, in a preliminary set of experiments where poor control was maintained over the temperature/RH conditions, water droplets formed throughout the chamber walls and on the filter media themselves. At these conditions the PLEM fil-

Figure 2—Filter efficiency for Manufacturer A’s HE filter at 85 L/min against NaCl aerosol: control and 1-day RH pretreatment
ters showed a decrease in efficiency of approximately 10% (Figure 8) as compared to the 2% difference for the same filters tested under the controlled preconditioning environment (Figure 4). This preliminary run truly could be considered a worst case condition because the filters were basically water logged.

The data collected in this study indicated that there is a trend of increasing difference between some of the pretreated filters' efficiencies and the as-received filters' efficiencies (i.e., Figures 6 and 7) as the particle size is increased. This effect appears to be more pronounced at the longer preconditioning periods. It has been postulated that this effect is caused by the movement from the diffusion region of collection into the interception and impaction region of collection where the collection caused by the electrostatic forces is the dominant mechanism of collection. Hence, the increased difference when the charge on the filter is reduced by humidity pretreatment conceivably could account for a portion of the difference between the Los Alamos study(6) and these data, but this needs to be confirmed further experimentally.

When considering the experimental design of the earlier studies,(6-7) it can be seen that no attempt was made to isolate the two possible simultaneous effects—relative humidity and the aerosol's charge. This study has accounted for aerosol charge effects by conditioning the challenge aerosol with a Kr-85 source. Therefore, the results should reflect only the relative humidity effect. But, to better estimate the contribution from charging, a few preliminary experiments were done. Filters were tested against the DOP aerosol with and without the neutralizer (Kr-85) in line to see how substantial the charging effect was. Two filters were tested this way, and the results are shown in Table II. This DOP data suggest that the charging effect is substantial and may be more important than the relative humidity effect. Future work needs to isolate those effects and monitor their contribution.

Conclusions

The results of this study have shown that respirator filters do show some degradation following unprotected preconditioning at 38°C and 85% RH when tested with a neutralized worst-case aerosol. In general, the longer the preconditioning, the more degradation and penetration which result. It is not unreasonable to expect these filters to be stored for extended periods of time at environmental conditions quite similar to those evaluated in this study. The specific conclusions shown by this study are the following.

- The electrostatic filters tested demonstrated a drop in efficiency of approximately 2%-6% depending on the preconditioning time (from 1 to 42 days).
- High efficiency filters showed no detectable change in their efficiencies when preconditioned at 38°C and 85% RH. They maintained efficiencies of > 99.97% at the worst-case size range.
- It appears from this study, in connection with past investigation, that the effect of particle charge and size is significantly larger than the effect of RH.
Figure 5 — Filter efficiency for Manufacturer B’s PLEM filter at 85 L/min against NaCl aerosol: control and various days of RH pretreatment

Figure 7 — Filter efficiency for Manufacturer D’s PLEM filter at 85 L/min against DOP aerosol control and various days of RH pretreatment

Figure 6 — Filter efficiency for Manufacturer D’s DFM filter at 85 L/min against NaCl aerosol: control and various days of RH pretreatment

Figure 8 — Filter efficiency for Manufacturer A’s PLEM filter at 85 L/min against NaCl aerosol: control and “worst case” RH preconditioning

This study has pointed out several areas that need further research in order to better understand the filtration characteristics of particulate respirator filters. As discussed, there appears to be an influence of particle size, in relation to prehumidification time, on the efficiency of the filter in going from smaller size to larger size particles. From this
study, the data are inconclusive as to how the RH pretreatment affects the region of maximum penetration. That is, does the worst-case particle-size region shift to a larger size for the humidified filters, or is the effect of RH preconditioning of a particular filter constant over a wide range of particle sizes? Also, it is apparent from this study that particle charge, as well as size, is a significant factor in determining the filtering properties of a filter. In fact, the influence of the charge on the particle may well outweigh the effect of filter RH preconditioning. Additional studies need to be performed to separate the effects caused by aerosol charging, size, and filter RH pretreatment.

References

30 March 1988; Revised 28 October 1988
"Worst-Case" Aerosol Testing Parameters: III. Initial Penetration of Charged and Neutralized Lead Fume and Silica Dust Aerosols through Clean, Unloaded Respirator Filters

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The National Institute for Occupational Safety and Health (NIOSH) tests and certifies respirator filter media according to Title 30, Code of Federal Regulations, Part 11 (30 CFR 11). Subpart K of those regulations specifies that a silica dust test, silica mist test, and/or lead fume test will be used to test and certify dust and mist; and dust, fume, and mist particulate air-purifying respirator filter media. NIOSH studies have shown that an aerosol particle of a certain size can be identified as the most penetrating particle ("worst case") size. Commercial filter media of various types have been studied and the filter's performance against a worst-case sodium chloride (NaCl) and dioctyl phthalate (DOP) aerosol evaluated. This investigation was done to complement those previous studies by determining how one manufacturer's particulate filters performed against the existing certification aerosol challenges as compared with the worst-case size DOP and NaCl aerosols. Only initial penetration values were determined, and no loading effects were considered. Both neutralized (Boltzman charge distribution) and unneutralized aerosols were used in order to assess the contribution of charging. The results show the dramatic effect of particle size on filter efficiency, and they show that the present methods are not as sensitive as the worst-case aerosol method.

Introduction

The National Institute for Occupational Safety and Health (NIOSH) currently tests and certifies respirator filter media in accordance with the regulations set forth in Title 30, Code of Federal Regulations, part 11 (30 CFR 11). Subpart K of those regulations specifies that a silica dust, silica mist, lead fume, and/or dioctyl phthalate (DOP) aerosol be used to test respirator filter media. Presently only high efficiency (HE) filters are certified with an approximately 0.3-μm DOP aerosol, but a 0.3-μm DOP aerosol's use for other filter classes is under consideration. Alternative challenge aerosols being considered by NIOSH include a solid aerosol and a liquid aerosol. These changes have been put forth to bring respirator filter testing up to date with current technologies. Some of these changes, based on "worst-case" testing parameters have been reported earlier.

This study was undertaken to determine the initial instantaneous count efficiencies of dust and mist (DM); paint, lacquer, and enamel mist (PLEM); and dust, fume, and mist (DFM) respirator filter media against the certification silica dust and lead fume aerosols. The filter efficiency test system (FETS) was used. These data are compared with earlier count efficiency results for these respirator filters against the most penetrating worst-case size DOP and sodium chloride (NaCl) aerosols. Thus, a direct comparison of the initial count efficiency values employing the certification aerosols and the worst-case aerosol was possible. Some additional experiments with "neutralized" (Kr-85 radiation source) silica dust and lead fume aerosols were performed in order to assess filter collection effects caused by aerosol charge.

Background

An earlier study by Reed et al. compared the filter penetration of NaCl, DOP, silica dust, and lead fume on a variety of filter media. Also, some initial results on relative humidity and charging effects were presented. That study suggested that DOP and NaCl would be reliable aerosols for measuring the efficiency of respirator filter media and their degradability. The results of that study showed the following conclusions.

1. The silica dust test is not a sensitive indicator of the relative efficiency of respirator particulate filters since the penetration of all filter types ranged from 0.06% for HE filters to 0.07% for DM filters. This was attributed to the large size of the silica dust particles as specified in the regulations.

2. The lead fume test seemed to be somewhat more differentiating than the silica dust test. In this case the DM filters showed 8.8%-14.2% penetration while the DFM and HE filters gave penetrations of < 0.63%. The differences in the DFM and HE filter results were not statistically significant.

3. The lead fume and silica dust aerosols were difficult to generate and maintain at a stable mass concentration and particle size over the entire length of the test runs (90 min for silica dust and 312 min for lead fume).

4. The instantaneous penetration of the silica dust and lead fume aerosols could not be determined at any given time during the test since these efficiencies are a time-weighted average (TWA) over the total test time as determined gravimetrically.

The above study suggested that smaller, more penetrating aerosols are more vigorous, discriminating challenges for respirator filter media testing.
Experimental Materials and Methods

The silica dust and lead fume aerosols used are exactly as described in 30 CFR 11 Subpart K (11.140-4, "Silica Dust Test" and 11.140-6, "Lead Fume Test") and were not subjected to any size classification or separation. The 30 CFR 11-140-4 silica dust particle-size criteria are as follows: geometric mean of 0.4–0.6 μm and a standard geometric deviation (σg) not to exceed 2. The lead fume aerosol is generated by impinging an oxygen gas flame on molten lead (30 CFR 11-140-6 [d]) with no particle size or σg being specified. To facilitate a direct comparison to the worst-case size aerosols, both the silica dust and lead fume aerosols were sized by independent methods.

The aerosols generated in the certification test chambers were withdrawn, diluted to ≈ 2 × 10⁶ particles/cc, and employed for testing. The dilution of these aerosols with diluter air filtered through high efficiency filters should not alter the size characteristics of the aerosol. For the aerosol "neutralization" studies, the only experimental difference was that a Kr-85 radioactive source was placed in line to reduce the aerosol's charge to a Boltzman distribution.

DM, PLEM, and DFM filters from a single lot of Manufacturer A's filters were tested. Individual filters were tested "as received" at flow rates of 16 ± 0.3 L/min and 85 ± 1.4 L/min. The initial instantaneous penetration was determined 2 min after exposure to the challenge aerosol by means of the TSI, Inc., Filter Efficiency Test System (FETS) (TSI, Inc., St. Paul, Minn.) which has been described by Remiarz et al. In the present study only one respirator was tested at a time since the initial instantaneous aerosol penetration was the parameter of primary interest. A simplified schematic diagram of the FETS as used in this study is shown in Figure 1.

Results and Discussion

The initial instantaneous percent count efficiency values for the DM, PLEM, and DFM filters studied against the certification aerosols are presented in Table I. The silica dust data show that the DM filters at 16 L/min (equivalent to 30 CFR Part 11 requirement for this filter configuration) gave an initial instantaneous count efficiency of 98.12%. Presently

![Figure 1—Operating schematic of TSI Filter Efficiency Test System.](image)

DM filters are required to have a mass efficiency of > 99% when tested according to the silica dust test (30 CFR 11.140), which is a 90-min, time-averaged gravimetric test. When the test flow was increased to 85 L/min, the efficiency against the silica dust decreased to 96.03%. A similar trend was seen with the PLEM and DFM filters against the silica dust aerosol (Table I). In each case a significant decrease in efficiency was seen with increased test flow rate. It appears, however, that the magnitude of this change is less dramatic for the DFM filters than for the DM or PLEM filters. This same effect was seen with the lead fume challenge aerosol

<table>
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<tr>
<th>Filter Type</th>
<th>Flow Rate (L/min)</th>
<th># Filters Tested</th>
<th>% Efficiency (Standard Deviation)</th>
<th>% Minimum Efficiency</th>
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<td>10</td>
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<td>0.06–0.10</td>
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<tr>
<td></td>
<td>85</td>
<td>6</td>
<td>98.49 (0.18)</td>
<td>87–92</td>
<td>0.05–0.10</td>
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</table>

Silica dust size of 0.48 μm, determined by SEM.

Lead fume size of 0.15 μm, determined by DMPS.

Count mean diameter, determined by DMPS.
and was more pronounced. Against lead fume, the DM filters gave an initial efficiency of 91.64% at 16 L/min. When the test flow rate was increased to 85 L/min, the efficiency decreased to 80.11%. This significant flow rate effect likewise was seen with the PLEM and DFM.

Upon comparing these data, it can be seen that in all cases the lead fume aerosol gives lower filter efficiency values than the corresponding silica dust results. For example, the DM filters gave efficiencies of 98.12% at 16 L/min and 96.03% at 85 L/min against silica dust as compared to 91.64% at 16 L/min and 80.11% at 85 L/min against lead fume. Table 1 presents similar data for PLEM and DFM filters. These data are consistent with the earlier study by Reed et al. which show that the lead fume test aerosol is a more sensitive and differentiating indicator of the relative efficiency of particulate filters than the silica dust aerosol. It must be remembered, however, that presently DM filters are not required to be tested and pass a lead fume challenge.

The present certification program requires DFM filters to have a mass efficiency of >99% when tested according to the lead fume test, which is a 312-min, TWA gravimetric test (30 CFR 11.140-6), with no instantaneous efficiency values being obtained. Thus, the DFM filters are designed to protect against fume aerosols which are smaller than silica dust. This is why the DFM filter results gave the highest efficiencies of those tested and did not show the significant magnitude of differences in efficiency when going from silica dust to the lead aerosol challenge. The data show that the DFM filters at 16 L/min (equivalent to 30 CFR 11 requirements for this filter configuration) gave an initial instantaneous count efficiency of 98.23%. When the flow rate was increased to 85 L/min, an initial instantaneous efficiency value of 89.13% was obtained with the lead fume aerosol. As anticipated, when the smaller particle-size lead fume aerosol (0.15 μm count mean diameter [CMD], η of 1.92, determined by differential mobility particle sizer [DMPS] assuming a log-normal distribution) was used for testing, rather than the silica dust aerosol, the DM and PLEM percent efficiencies dropped considerably: 16 L/min DM filter efficiency dropped from 98.12% to 91.64%, and the DFM filter efficiency dropped from 99.36% to 91.82%. This is dramatized further when one looks at the 85 L/min data where the DM efficiency went from 96.03% to 80.11% and the PLEM efficiency dropped from 96.11% to 81.63%.

The silica dust results also can be compared with the worst-case results presented for DOP and NaCl in Part I of this series. (Table 1). It can be seen that at 16 L/min, the initial instantaneous count efficiency results with silica dust are about 9%-11% higher than those obtained using a worst-case size aerosol. The results obtained with the worst-case challenge aerosol at 85 L/min are from 21% to 27% lower than with silica dust. These results indicate (1) the worst-case aerosol is a more critical, vigorous test aerosol and (2) that the percent efficiency for worst-case aerosols decreases more rapidly with increasing flow rate than for the larger silica dust aerosol. The PLEM and DFM filters gave higher efficiency values than the DM filters. The PLEM filter gave efficiencies that were 6%-11% and 18%-20% lower than the worst-case aerosols for 16 and 85 L/min, respectively. The DFM filters, which should be the most efficient against smaller fume particles, did possess the best filter efficiency characteristics of those studied, with efficiency differences that were as low as 0.42% for 16 L/min and 6.5% for 85 L/min. These efficiency differences are caused by (1) the silica dust's particle size (0.48 μm by scanning electron microscopy [SEM]), which is significantly larger than the worst-case aerosol particle size, and (2) aerosol charge differences, remembering that the worst-case aerosols are neutralized.

Likewise, the lead fume results can be compared with the worst-case DOP and NaCl results. The lead fume data show that the DFM filters at 16 L/min gave an initial instantaneous count efficiency of 98.23%, whereas the worst-case particle-size aerosols gave 98%-99% efficiency at 16 L/min. When the flow rate was increased to 85 L/min, an initial instantaneous efficiency value of 89.13% was obtained with the lead fume aerosol and compare with worst-case efficiency values of 87%-88% for DOP and 91%-92% for NaCl.

Further, comparison of the worst-case initial instantaneous count efficiency with the results for the silica dust and lead fume aerosols reveal some interesting data trends. First, there are greater differences in the initial efficiency results when the silica dust results are compared to the worst-case aerosol results than when the lead fume results are compared to the worst-case results. This is probably because of the aerosols' size differences, with the worst-case aerosol being smaller than the lead fume aerosol (0.15 μm CMD and η of 1.92, determined by DMPS—the top region of the worst-case aerosol size), which in turn is smaller than the silica dust aerosol (0.48 μm, determined by SEM). This is exemplified by the fact that the differences in the efficiency magnitudes from the worst-case challenge aerosol are DM > PLEM > DFM, which correlate with the challenge aerosol's particle sizes: silica dust larger than lead fume larger than worst case. This is demonstrated further by the fact that a direct comparison of the two certification test aerosols versus the worst-case size aerosol revealed that for the filters tested, there is a significant difference for the silica dust, and there is not sufficient evidence to detect a difference for the lead fume aerosol (paired t-test on In transformed data at α = 0.05). Secondly, there is a significant decrease in percent efficiency for both the silica dust and lead fume aerosols as the flow rate is increased from 16 to 85 L/min. Thus, both particle size and flow rate have a significant effect on the initial instantaneous filter efficiency values determined for commercially available respirator filters.

The second part of this study examined the effect of aerosol charge on the filter's initial penetration by silica dust and lead fume aerosols. A Kr-85 radiation source was placed in line to reduce the silica dust and lead fume aerosol charge to a Boltzmann distribution. The results obtained for the charge conditioned/neutralized certification silica dust and lead fume aerosols are presented in Table II, along with the results of the "charged" aerosols from Table I. Table II also indicates the statistical significance of the differences. It can be seen that the effect of charge on these efficiency values is less than or equal to 5% for both aerosols. Also, the aerosol charge effect appears larger for the silica dust than for the lead fume and is reflected by the relative differences in the efficiency values, where the differences for the silica dust
range from -0.55% to +5% and the lead fume differences range from -1.48% to 1.87%. This probably is caused by the aerosol generation methods and/or to the aerosols' ability to retain a higher charge. The evaporation/condensation aerosol generation procedure of the lead fume aerosol would be expected to provide a smaller charge than the fluidized bed-type, generated silica dust aerosol.

To further investigate the charge effects, some preliminary tests were obtained using a neutralized and nonneutralized DOP challenge aerosol. Two separate runs were done at each particle size for each filter: one using a "charged" or nonneutralized DOP aerosol and the other using a neutralized DOP aerosol. These preliminary results revealed that aerosol charge had a large effect on the efficiency of filters when tested against a worst-case DOP aerosol at 85 L/min. The efficiencies determined for the DM filter were 85.90% efficiency for a nonneutralized DOP challenge versus 75.03% efficiency for the neutralized DOP challenge (0.045 μm) produced as per Stevens and Moyer. The difference in efficiencies was 10.87%. The difference in efficiencies determined for a slightly larger DOP aerosol (0.061 μm) was not as significant (81.39% efficiency for nonneutralized versus 76.73% efficiency for the neutralized, or a difference of 4.66%). Similar results were obtained for a PLEM filter run against the 0.045- and 0.061-μm DOP aerosols which were neutralized and nonneutralized. Those results are 87.14% efficiency for the nonneutralized versus 77.25% efficiency for the neutralized, representing a difference of 9.89% with the 0.045-μm DOP challenge. The PLEM results with the 0.061-μm DOP are as follows: 82.5% efficiency, nonneutralized, versus 78.49% efficiency, neutralized, or a difference of 4.01%. Thus, a 4%-11% increase in percent efficiency resulted when the aerosol was not neutralized with the Kr-85 source to reduce the aerosol's charge. Also, it appears that the effect of the aerosol's charge on percent penetration is related to and dependent on the aerosol's particle size.

Conclusions
This study shows that particle size has a dramatic effect on the experimentally determined initial count efficiency of respirator filter media. As the particle size is reduced in going from the silica dust to the lead fume aerosol, the filters' percent efficiencies decrease. This indicates that the lead fume is more penetrating and, thus, more of a discriminating test aerosol than silica dust. Also the worst-case particle-size aerosol gave significantly lower efficiency values for all filter types and flow rates, except for the DFM filters tested at 16 L/min. This confirms that the worst-case aerosol is more penetrating and a more discriminating test aerosol than either silica dust or lead fume. Additionally, the effect of aerosol charge on the percent filter efficiency was investigated. The effect of charge reduction on the silica dust and lead fume aerosol was not nearly as large as the charge effect observed with the worst-case particle-size aerosol. Finally, the differences seen in the percent penetration between the 16 L/min and 85 L/min data was substantial. These flow results are in agreement with earlier NIOSH(5) findings.

The findings from Reed et al. (4) when considered in conjunction with the results from this study, indicate that smaller, more penetrating aerosols would be more discriminating and would make a better test system. It should be noted, however, that these studies all relate to attempts to find respirator filter tests that are or relate to worst-case testing criteria and are not necessarily indicative of measured efficiencies against a "workplace-type" aerosol.

References