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From: deAzevedo, David [david.deazevedo@tsi.com]
Sent: Monday, March 29, 2010 12:13 PM
To: NIOSH Docket Office (CDC)
Subject: TSI Comments to RIN: 0920-AA 33, 42 CFR Part 84
Attachments: TSI comments to TIL Proposal.pdf; RFT-007.pdf

Dear Sir or Madam:

Attached please find TSI Incorporated's comments regarding RIN 0920-AA 33.

Sincerely,

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March 29, 2010

NIOSH Docket Office
Robert A. Taft Laboratories, MS-C34
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Cincinnati, OH 45226

Re: TSI Comments regarding the Centers for Disease Control and Prevention, HHS, Notice of Proposed Rulemaking, "Total Inward Leakage Requirements for Respirators," RIN 0920-AA33

As a manufacturer of aerosol test and measurement instrumentation, TSI Inc. has an interest in the TIL proposal. The ability of any instrument manufacturer to provide products that will make accurate and repeatable certification measurements in widespread locations requires an unambiguous specification. Likewise, respirator manufacturers and third-party laboratories require clear guidance on the test configuration in order to duplicate measurements that are to be made by NIOSH. The instrumentation specifications and test configuration guidance contained in the TIL Proposal do not meet these criteria.

Issue: Use of a DMA in-line with the CNC:

Paragraph (i)(11) contains the main specification for instrumentation:

> (11) The instrumentation used to measure the concentration inside and outside the facepiece will:
> (i) Utilize a condensation nuclei counter;
> (ii) Measure only the concentrations of sodium chloride challenge aerosol in the approximate size range of 0.02 to 0.06 micrometers (mass median aerodynamic diameter); and
> (iii) Respond linearly to changes in the aerosol concentration, within ±5 percent, over the ambient concentration range of 70 to 3,000 particles/cm³ and TIL ≤ 5.0 percent, within the particle size range of 0.02 to 0.06 micrometers.

TSI agrees that CNC (condensation nuclei counter) is the best instrument to use for the proposed measurement; however we are concerned about limiting the challenge aerosol size range to 0.02 to 0.06 micrometers without providing detail on exactly how this should be done. Without more detail, different instrument configurations could be used which are likely to produce different results.

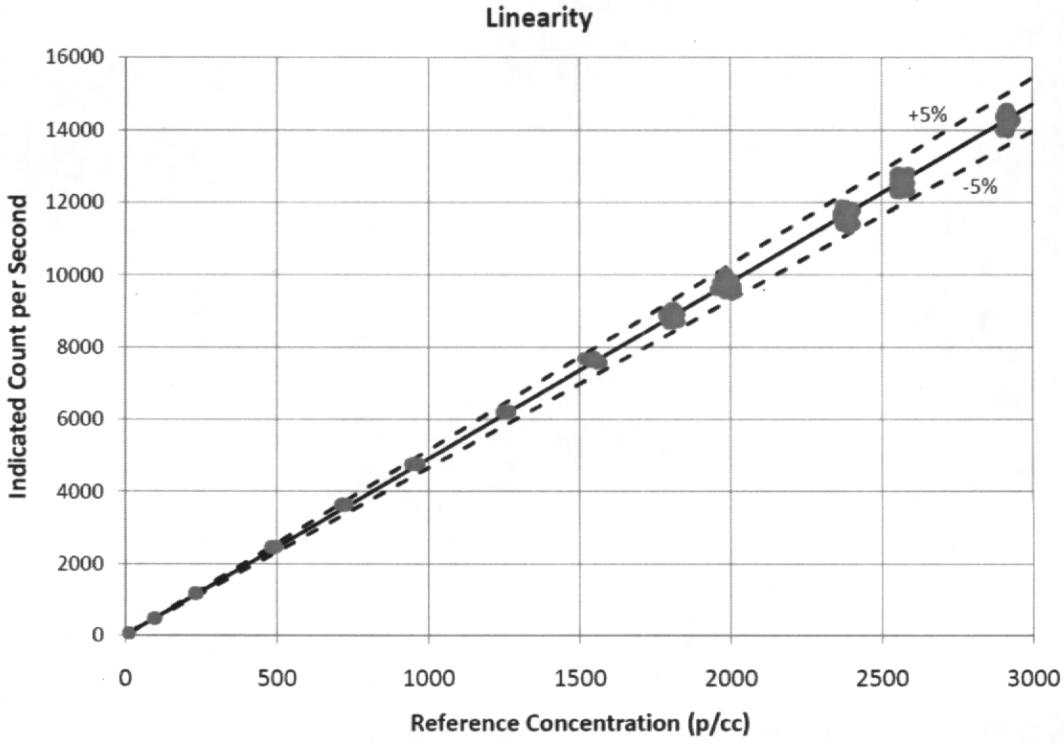
If NIOSH intends the aerosol instrumentation to select this size range using the "N95-Companion method", then the use of a DMA (differential mobility analyzer) in-line ahead of the CNC should be specified. In this case it is also necessary to specify that an aerosol neutralizer must NOT be used, because some laboratory-grade DMA's have an aerosol neutralizer built-in, which would need to be removed in order to duplicate the N95-Companion method.

Due to the way a DMA works, it would be best to specify a target particle size than to specify a size range. DMA design involves the selection of a center point, not two boundary points. DMA designers can easily select the target particle size, but have very limited control over the high and low limits. A specification such as "approximately 0.05 ± 0.03 microns" would be appropriate. Any changes to the size specification made in (i)(11) should be reflected in (i)6.

We find the linearity specification in (i)(11)(iii) to be confusing. Why is the concentration minimum stated as 70? Using the 1% TIL criterion and the minimum challenge concentration of 1,500 particles/cc from (i)(6), the in-mask concentrations must fall below 15 for a pass. Also, the manner in which the linearity requirement is stated is subject to different interpretations.

Here is an example of what we think is a better way to specify linearity for any aerosol instrument system that is intended to accurately measure both the challenge and in-mask aerosol concentrations for the purpose of calculating ratios such as TIL or fit factor:

> Respond linearly within ± 5% to aerosol concentrations in the range of 15 to 3,000 particles/cc for particles in the approximate size range of 0.05 ± 0.03 micrometers.



Issue: Challenge Aerosol Concentration:
TSI is concerned about the challenge aerosol specification in paragraph (i)(6).

> (6) The TIL will be measured in the presence of a sodium chloride challenge aerosol with a concentration of 1,500 to 3,000 particles/cm^3 within the size range of 0.02 to 0.06 micrometers.

Obtaining such a high concentration in that size range requires aerosol generation. Maintaining the aerosol concentration within 1,500 to 3,000 requires control such as a test chamber. NIOSH should require a particle generator and test chamber. Language should also be included to prevent testers from thinking that they must generate particles of *only* that size range, which would be very difficult and unnecessary. The particle generator must produce an aerosol that includes a sufficient number of particles in the target size range so that the DMA/CNC combination can "see" 1,500 to 3,000 particles/cc.

Issue: Mask Sample Duration:

In the interest of creating a test method that will produce similar results when performed at various laboratories, it will be important for NIOSH to specify the minimum length of time required to draw the sample from inside the respirator. Using the same minimum mask sample time at all locations is just as important as using the same challenge aerosol parameters. The Proposal refers to OSHA for this:

> (8) Each test exercise will be performed using the OSHA protocol as specified at 29 CFR 1910.134 Appendix A, Part I.A.14.(b).

Where OSHA specifies; "Each test exercise shall be performed for one minute…"

Contrary to OSHA; NIOSH Procedure No. RCT-APR-STP-0068 calls out 30-second exercises in paragraph 5.8. Neither document mentions minimum mask sample time. NIOSH should specify a minimum mask sample time such as 30 seconds per exercise.

Issue: TIL vs. Fit Factor

TSI is concerned that the proposed measurement is TIL, but the proposed instrumentation measures fit.

The discussion section of the NIOSH TIL Proposal (F.R. p. 56146) states;

> The particle size range represents the most penetrating particle sizes, producing an atmosphere that challenges the limits of the respirator's TIL performance.

And defines TIL as;

> TIL is the combination of contaminated air leaked through various potential sources including the facepiece-to-face seal, exhalation valves (if any), and gaskets (if any) and any contaminants that have penetrated the filter.

In addition, Procedure No. RCT-APR-STP-0068 supplied with the Proposal shows a TSI PortaCount Pro+ Model 8038 which uses a DMA in-line with a CNC (N95-Companion method).

So, as it appears that NIOSH wants to include particles that penetrate the filter media in the TIL measurement and proposes to use a DMA/CNC combination to do so. The issue of concern here is that while the DMA/CNC uses the particle size range that represents the most penetrating particle sizes, it does *not* use the most penetrating particles. That statement is confusing at first glance. Understanding how the most penetrating particle size (MPPS) could be used without using the most penetrating particles requires an understanding of how N95 electrostatic filter media, DMA's, and aerosol neutralizers work with both charged and zero-charged particles. To aid those who need to understand these issues, TSI recently completed a laboratory study and reported the results in TSI Application Note RFT-007 which is attached.

The study described in the application note demonstrates that measuring Co and Ci via the use of a DMA in-line with a CNC (and without a neutralizer) results in the measurement of face seal leakage alone. Filter penetration is nearly eliminated.

All this leads us to question the use of the term "TIL" in the Proposal. It seems that the issue compelling NIOSH to incorporate the TIL testing into the certification process is face seal leakage, not filter penetration. Filter penetration is tested elsewhere in 42CFR84. If there is concern over the MPPS moving to smaller size, this should be addressed there. Since the DMA/CNC combination being proposed is appropriate for fit testing respirators with electrostatic media and not for measuring TIL, the term "TIL" should not be used. We recommend that NIOSH change the terminology used in the Proposal from "TIL" to "fit factor".

If we are mistaken, and NIOSH truly wants to measure TIL, then the measurements should be made with a CNC alone, thereby counting particles that penetrate the filter media as well as the face seal. It should be noted that measuring True TIL instead of fit, by eliminating the DMA in line with the CNC, would significantly broaden the particle size range used for the measurement. For example, a PortaCount would see all particles in the range of 0.02 to about 1.0 micrometers regardless of charge. That measurement would include particles that penetrate the filter because they are near the MPPS, which contrary to what many thought, are not used in the current Proposal. The large increase in challenge concentration would also improve sampling accuracy. In addition, since eliminating the DMA would result in more leakage being measured for respirators with N95 electrostatic media, the1% TIL criterion would need to be increased. Otherwise, good-fitting respirators may fail the certification.

Penetration of N95 Filtering-Facepiece Respirators by Charged and Charge-Neutralized Nanoparticles

Application Note RFT-007

by Hee-Siew (Ryan) Han and Mark Prell
March 4, 2010

Introduction

Aerosol-based quantitative respirator fit testing relies on the assumption that all particles detected inside the mask arrived there through a face seal leak. This assumption is valid when respirators use high-efficiency filter media such as NIOSH series-100 or series-99 and assumes no other respirator leak paths (i.e., damage to the facepiece). However, when less efficient media such as NIOSH series-95 media is used, this assumption may no longer be valid since a significant number of particles may penetrate. During fit testing, any particles that penetrate through the filter are interpreted as face seal leakage, resulting in artificially lower fit factors, the fit test might fail even if the face seal is acceptable.

The most penetrating particle size (MPPS) for mechanical filters, which rely on diffusion, interception and impaction collection mechanisms, generally occurs at around 300 nm. However, most respirator filter media currently offered by US respirator manufacturers relies on electrostatic attraction, in addition to mechanical collection mechanisms, to capture particles. These electrostatically-charged filters media offer a significant advantage by increasing particle capture without increasing breathing resistance.

When TSI developed an accessory to the PORTACOUNT® Respirator Fit Tester—the N95-Companion™ Model 8095*—to measure the fit of N95 respirator filters, a particle size of 55 nm was selected because it was far removed from the MPPS for mechanical filters (300 nm). It was assumed that this particle size would be collected by an N95 filter with high efficiency, ensuring that any particles measured inside the facepiece would reflect leakage around the facepiece.

Recent studies have demonstrated; however, that the MPPS for commercially available N95 filters occurs in the range of 40 to 60 nm (Balazy et al., 2006a, b; Rengasamy et al., 2007; Richardson et al., 2006). This is the same size range that the N95-Companion™ technology uses, causing concerns to be raised that the N95-Companion™ method is not valid for N95 filtering facepiece respirators that use charged fibers.

It should be noted that the penetration results from the Balazy et al. and Rengasamy et al. studies may not apply to the N95-Companion™ method since the test aerosols used in these studies were charge-

*The PORTACOUNT® Plus Model 8020 and N95-Companion™ Model 8095 were discontinued in 2008 and replaced by the PORTACOUNT® PRO Model 8030 and PORTACOUNT® PRO+ Model 8038. The Model 8038 uses the N95-Companon™ technology when operated in N95-mode.

neutralized (particles with Boltzmann charge distribution), while the N95-Companion™ technology measures only negatively charged aerosols. The penetration characteristic of charged aerosols could be quite different from the charge-neutralized aerosols. Lee et al. (2005) studied the filtering efficiency of N95 and R95 respirators operating in unipolarly ionized environments. They found that the aerosol penetration through the N95 and R95 respirators was significantly lower when aerosols were charged.

Previous studies performed at TSI indicated that the MPPS of the current N95 filter media is indeed in the range of 40 to 100 nm. However, TSI also found that the particles that penetrate electrostatic N95 media are primarily zero-charge particles that are unaffected by electrostatic forces, the positively and negatively charged particles are efficiently trapped by electrostatic filter media. The nominal 55 nm particles allowed to pass through to the N95-Companion™ technology are all negatively charged (and counted), while the zero-charge and positive-charge particles are eliminated by the N95-Companion™ technology for both the ambient and mask samples. Since the N95-Companion™ method uses only the efficiently trapped negative-charge particles, the fit test assumption that all particles detected inside the respirator entered via a face seal leak, remains valid. Therefore, the N95-Companion™ method remains valid.

To further quantify the amount of aerosols penetrate through the N95 filter media and its effect on the fit factor, TSI conducted a study to measure the fractional penetration efficiencies of several commercially available N95 filtering-facepiece respirators using charge-neutralized, positively charged, and negatively charged monodisperse aerosols.

It should be understood that naturally occurring ambient aerosol particles typically used during respirator fit testing with a condensation particle counter such as the TSI PORTACOUNT® fit tester carry a mixture of electrostatic charges. Some are positively charged, some are negatively charged, and some carry no charge. Generating challenge aerosols that are entirely composed of particles that are only positive, only negative or only neutral can only be done in the laboratory.

Methods

Six different models of NIOSH-certified N95 filtering-facepiece respirators from five different manufacturers were used in this study. Each respirator was mounted on a manikin head and sealed using a silicone sealant applied to the edges to prevent face seal leakage. The manikin was then placed in the center of a 47 x 24 x 28-inch test chamber. The experimental setup is shown in Figure 1.

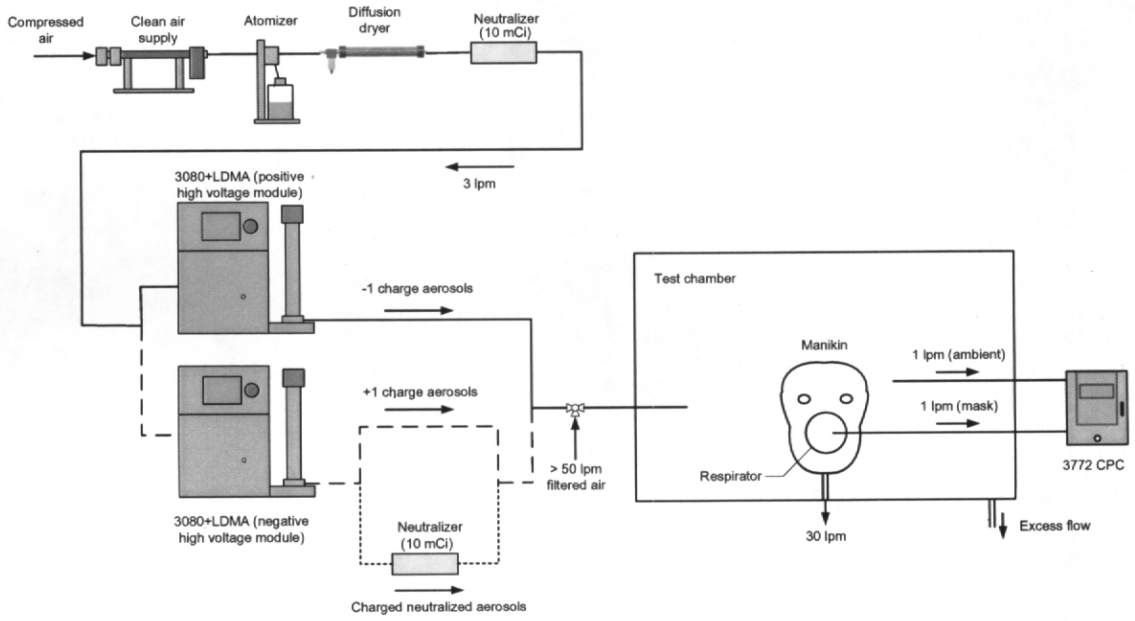


Figure 1: Experimental Setup

Sodium chloride aerosol was generated by an atomizer (TSI 3076 Constant Output Atomizer). A diffusion dryer was then used to dry the aerosols before they were introduced into a 10 mCi Kr-85 neutralizer (TSI 3012A) to remove high charges on the aerosols caused by the atomization process. Two electrostatic classifiers (TSI 3080) and two long differential mobility analyzers (LDMAs) (TSI 3081) were used to generate monodisperse positively and negatively charged aerosols. One electrostatic classifier had a negative-high-voltage module to generate positively charged aerosols while the other one had a positive-high-voltage module to generate negatively charged aerosols. To generate charge-neutralized aerosols, a 10 mCi neutralizer (TSI 3077A) was placed downstream of one of the electrostatic classifiers. Charge-neutralized, negatively-charged, and positively-charged monodisperse aerosols were introduced into the chamber one at a time in three separate experiments.

Monodisperse aerosols of 40, 50, 65, 80 and 100 nm were used in these experiments. Before entering the test chamber, the aerosol was mixed with at least 50 L/min of filtered air. Since the flow rate from the atomizer was about 3 L/min, the total flow rate entering the test chamber was at least 53 L/min. The flow rate through the N95 respirators was controlled to 30 L/min. The aerosol concentrations inside and outside the respirators were measured with a condensation particle counter (CPC) (TSI 3772). The respirators were ported with a sampling probe so that 1 L/min of sample flow could be drawn from inside the respirators. The challenge (chamber) aerosol samples were taken at about 1.5 inch away from the respirators. To avoid coincidence error, aerosol concentration inside the chamber was kept below 7000 particles/cm^3, by adjusting the volume of filtered dilution air. To ensure that the test chamber was properly purged and the aerosol concentrations inside the test chamber were stable and uniform, the following test protocol was used:

1. Before each test, the test chamber was purged for at least 20 minutes. This was done using a blower and HEPA filters installed on the test chamber.
2. Monodisperse aerosols were introduced into the test chamber for at least 30 minutes before any data was recorded.
3. Chamber aerosol concentration data was sampled every second for at least 1 minute with the 3772 CPC (at least 60 samples total).
4. Using the same CPC, mask aerosol concentration data was sampled every second for at least 1 minute (at least 60 samples total). This is mask concentration, C_{mask}.
5. Using the same CPC, chamber aerosol concentration data was sampled every second for at least 1 minute (at least 60 samples total).

The aerosol concentration of the test chamber, $C_{challenge}$, is the average of the two chamber concentrations measured before and after the mask sample.
The fractional penetration efficiency of the respirator was calculated as the ratio of C_{mask} and $C_{challenge}$: ($C_{mask}/C_{challenge}$). Percent penetration = $100*C_{mask}/C_{challenge}$

Results and Discussion

The penetration of positively-charged and negatively-charged aerosols is much lower than that of charge neutralized aerosols (Figure 2). These results are similar to the findings of Lee et al. (2005) and Balazy et al. (2006b). Lee et al. also found that the polarity of a charged aerosol had no significant effect on the filtration efficiency of a respirator filter.

The necessity of the N95-Companion™ method for fit testing N95 respirators is most clearly shown for respirators 3 and 4, with neutralized aerosol penetrations of approximately 1.5% and 2% respectively. If a particle-counting fit test using charge-neutralized aerosol (i.e., no N95-Companion™ technology) were to be performed on workers wearing these respirators, the maximum fit factors that could be achieved are 67 and 50 respectively (Fit Factor = 100/%Penetration), which are below the OSHA-required fit factor of

100 for a half-facepiece negative pressure respirator. Any face seal leakage would reduce the fit factor even further.

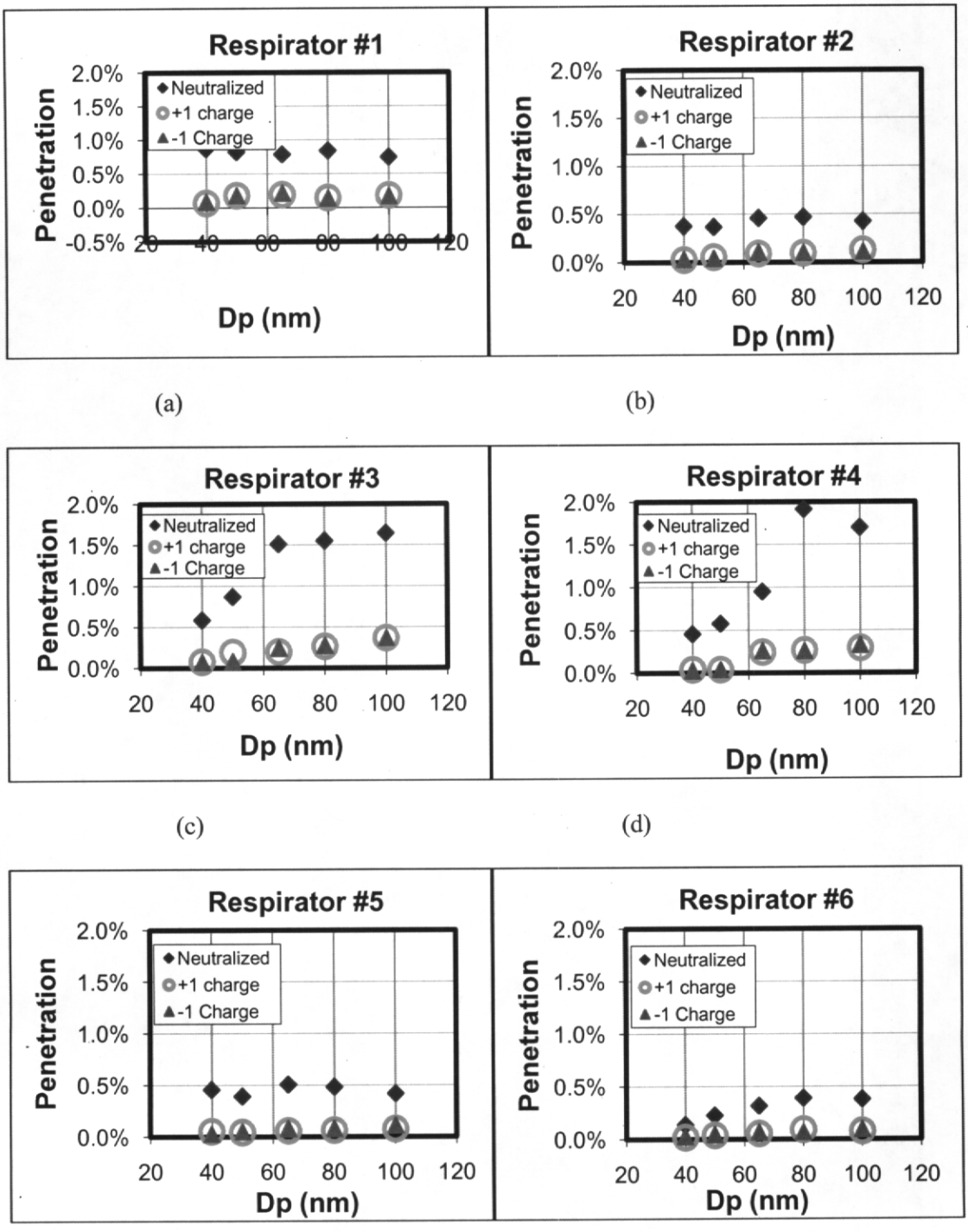


Figure 2: Percent Penetration vs. Particle Size Curves for Various N95 Filtering-Facepiece Respirators

Respirators 1, 2, 5 and 6 all showed neutralized aerosol penetrations of approximately 0.5%, indicating a maximum (zero face seal leakage) fit factor of 200. Thus, it would be possible to pass a fit test without the N95-Companion™ method if the respirator fit very, very well. However, any additional face seal leakage may cause the fit factor to drop below 100. For example, if the filter penetration is fixed at 0.5%, face seal leakage could not exceed 0.5% or the fit factor would drop below 100 (1% total leakage). This would have the affect of requiring workers to have an actual fit factor of at least 200 to achieve an indicated fit factor of at least 100.

Using a charged aerosol, as utilized in theN95-Companion™ instrument, all respirators showed penetrations below approximately 0.25% indicating a maximum (zero face seal leakage) fit factor of 400. During an actual fit test, real face seal leakage could be as high as 0.75% or an actual fit factor of 133 and still pass with an indicated fit factor of 100. Respirators 2, 5 and 6 showed extremely low charged aerosol penetrations which would greatly reduce the difference between actual and indicated fit factors. For example, if filter penetration were 0.1%, an actual fit factor of only 111 (0.9%) would be needed to achieve an indicated fit factor of 100. Thus, the use of the N95-Companion™ method significantly reduces false fit test failures.

Conclusion

The N95-Companion™ method measures respirator fit using nominal 55 nm particles that carry a negative charge. Penetration of these particles is insignificant for both mechanical and electrostatic filters. For mechanical media, this is due to impaction, interception and diffusion. For electrostatic media, this is due to those same mechanical forces, plus electrostatic forces. Thus, the N95-Companion™ method is valid for measuring the fit of any respirator using NIOSH series-95 or similar filter media.

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