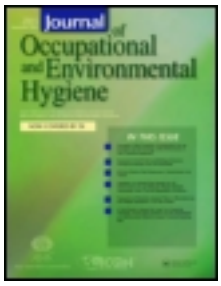

Journal of Occupational and Environmental Hygiene
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/uoeh20

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Accepted author version posted online: 03 Jul 2013.

To cite this article: Journal of Occupational and Environmental Hygiene (2013): Laboratory Faceseal Leakage Evaluation of N95 Filtering Facepiece Respirators Against Nanoparticles and "All Size" Particles, Journal of Occupational and Environmental Hygiene, DOI: 10.1080/15459624.2013.818237

To link to this article: http://dx.doi.org/10.1080/15459624.2013.818237

Laboratory Faceseal Leakage Evaluation of N95 Filtering Facepiece Respirators Against Nanoparticles and "All Size" Particles

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Word count of the exposition only = 4,320

ABSTRACT

National Institute for Occupational Safety and Health (NIOSH)-certified N95 filtering facepiece respirators (FFRs) are used for respiratory protection in some workplaces handling engineered nanomaterials. Previous NIOSH research has focused on filtration performance against nanoparticles. This paper is the first NIOSH study using human test subjects to compare N95 FFR faceseal leakage (FSL) performance against nanoparticles and "all size" particles. In this study, estimates of FSL were obtained from fit factor (FF) measurements from nine test subjects who participated in previous fit test studies. These data were analyzed to compare values obtained by: (1) using the PortaCount Plus (8020A, TSI, Inc., MN, USA) alone (measureable particle size range 20 nm to > 1,000 nm, hereby referred to as the "all size particles test"), and (2) using the PortaCount Plus with N95–Companion™ accessory (8095, TSI, Inc.,

MN, USA) accessory (negatively charged particles, size range ~40 to 60 nm, hereby referred to as the "nanoparticles test"). Log-transformed FF values were compared for the "all size particles test" and "nanoparticles test" using one-way analysis of variance tests (significant at $P < 0.05$). For individual FFR models, geometric mean (GM) FF using the "nanoparticles test" was the same or higher than the GM FFs using "all size particles test." For all three FFR models combined, GM FF using the "nanoparticles test" was significantly higher than the GM FF using "all size particles test" ($P < 0.05$). These data suggests that FSL for negatively charged ~40–60 nm nanoparticles is not greater than the FSL for the larger distribution of charged and uncharged 20 to > 1,000 nm particles.

Keywords: Nanoparticles, N95 filtering facepiece respirators, fit test, fit factors

INTRODUCTION

A nanoparticle is defined as a nano-object with all three external dimensions in the size range from ~1 to 100 nm.[1] Few risk-based occupational exposure limits (OELs) have been established specifically for nanoparticles as much remains to be understood regarding the influence of particle size on factors determining health effects.[2, 3] Workplace tasks such as opening a reaction chamber, drying a product, or the post-process handling of products present the potential for inhalation exposure to nanoparticles.[4] Because of these concerns, the National Institute for Occupational Safety and Health (NIOSH) recommends limiting worker exposures to engineered nanoparticles through standard industrial hygiene practices, including respiratory

protection, if necessary (NIOSH 2009). In general, the decision to use respiratory protection should be based on a professional workplace assessment that takes into account toxicity information and exposure measurement data. NIOSH has published guidance on respirator selection criteria.[5] These criteria apply to a variety of respiratory hazards, including particulate. NIOSH certifies different classes of respirators (e.g., disposable filtering facepiece respirators (FFRs), half-mask elastomeric, powered air-purifying, self-contained, etc.) which will provide different levels of protection when properly fit tested and used in the context of a complete respiratory protection program described in the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard 29 CFR 1910.134.[6] The N95 class of FFR is commonly used to reduce exposure to airborne particulates, including solid and non-oil liquid aerosols in industrial settings.[7]

In its strategic plan for nanotechnology research, NIOSH recommends research on respiratory protection including nanoparticle penetration through filter media as well as through faceseal leakage (FSL).[8] This research is needed to assess whether traditional respirator selection criteria apply to nanoparticles as well. Inward leakage (IL) of particles into an FFR facepiece may occur by direct filter penetration (FP) through the filter media as well as through FSL.[9] Recent research findings related to FP of various respirator types have been reviewed elsewhere.[10]

Research is needed to better understand FSL of nanoparticles. Some have speculated that nanoparticle aerosols, due to their high mobility, will have an increased likelihood of enhanced leakage compared to larger particles.[11] Some recent studies have also reported trends that suggest that some nanoparticles may be more likely to enter the facepiece than larger particles,

but additional studies using human subjects are needed to confirm or refute these trends. Leak size was found to be the most important factor affecting the IL of nanoparticles in a study incorporating an FFR sealed to a manikin headform with artificially created leaks.[12] However, at the smallest leak sizes, the IL measured for 50 nm size particles was ~2-fold higher than the values for 8 and 400 nm. Only one study reported the FSL of nanoparticles (size range of 40 nm–1,000 nm) for human test subjects.[9] Their results showed greater FSL for particles < ~200 nm than for larger size particles up to 1,000 nm. This would indicate that FFs would be lower for particles < ~200 nm than for larger size particles. Their study additionally showed that the faceseal leakage-to-filter (FLTF) ratio increased with increasing particle size indicating greater contribution of FSL compared to FP for larger size particles.[9]

NIOSH has recently conducted a series of fit test studies measuring the FSL of N95 FFR using a test method to measure negatively charged particles (size range ~40 to 60 nm), hereby referred to as the "nanoparticles test". NIOSH has also conducted a study of FSL using a test method to measure both charged and uncharged particles of the size range 20 nm to > 1,000 nm, hereby referred to as the "all size particles test." To address the knowledge gap of human subject data related to FFR FSL of nanoparticles, the goal of this study is to compare FFs measured using both methods. It was hypothesized that FFs measured by the "nanoparticles" test would be lower than the "all size particles test." This hypothesis was developed in light of the Grinshpun et al.[9] study which showed the highest levels of FSL for nanoparticles < ~200 nm.

MATERIALS AND METHODS

Study Descriptions

Nine test subjects were tested with three commercially available NIOSH-certified N95 FFR models: one N95 respirator (2200, Moldex, CA, USA) and two surgical N95 respirators (1860 and 1870, 3M, MN, USA). Surgical N95 respirators are NIOSH-certified N95 respirators that have also been cleared by the U.S. Food and Drug Administration (FDA) for sale as medical devices.[13] The individual studies in which these data were collected were approved by the NIOSH Institutional Review Board. Test subjects gave their written consent to participate and were cleared to participate through a medical screening. Subjects were recruited from the pool of experienced N95 FFR subjects who regularly participate in NIOSH respirator certification testing. Although many test subjects participated in the seven studies from which this subset of data was analyzed (*see the 'Study Descriptions' section*), only data from nine subjects met the criteria for inclusion for this analysis (i.e., each subject participated in Study 1 and 7, and also at least one of Studies 2–6). The nine subjects were four men and five women. These criteria allow for a comparison of fit test data for the same respirator model against nanoparticles and "all size particles."

Data from seven different studies of N95 FFR fit were used for this analysis. These seven studies are summarized in Table I. Studies 1–6 utilized the "nanoparticles test" configuration (i.e., PortaCount Plus (8020A, TSI, Inc., MN, USA) with N95–Companion accessory (8095, TSI, Inc., MN, USA)) while Study 7 utilized the "all size particles test" configuration (i.e., PortaCount Plus alone). Table I lists the exercises in each study along with the timings used by the instrument for each and summary descriptions of the studies are presented below. All studies were conducted within two years in the same building but in adjacent laboratories (Studies 1–6

were performed in Laboratory "A" and Study 7 was performed in Laboratory "B"). All tests for Studies 1–6 were performed using ambient room particles supplemented with sodium chloride (NaCl) aerosol from a particle generator (8026, TSI, Inc., MN, USA). The supplemental NaCl aerosol was necessary for the operation of the PortaCount Plus with N95–Companion accessory which requires a minimum of 70 particles/cm^3 to operate.[14] For Study 7, a NaCl aerosol generator (9302, TSI, Inc., MN, USA) was used when there was insufficient ambient particle concentration to operate the PortaCount Plus alone which requires a minimum of 1,000 particles/cm^3;[15] the generator was employed for only about 10% of these tests. The following is a brief summary of the seven studies. Full details can be found in the references.

Study 1: OSHA-accepted fit test.

This study served the purpose of qualifying subjects to test specific FFR models in Studies 2–6. Test subjects were required to achieve a passing result (FF $\geq$ 100) on a standard OSHA-accepted 8-exercise quantitative fit test for a given FFR model.[6, 16]

Study 2: One-cycle decontamination fit test.

This study assessed facepiece fit and test subject perceptions of smell, donning ease, and comfort for N95 FFRs which had undergone one cycle of decontamination processing using either ultraviolet germicidal irradiation (UVGI), microwave-generated steam (MGS), or moist heat incubation (MHI). Only the untreated control respirators were considered for this study's analysis.[16]

Study 3: User Seal Check (USC) Evaluation.

Test subjects performed fit testing using 20 FFR samples (10 in which a USC was performed prior to testing and 10 with no USC). For this current study's analysis, only samples tested with USC were included.[17]

Study 4: Multiple consecutive donnings (up to 20).

Subjects performed up to 20 consecutive tests on an individual FFR sample using a modified protocol. Only the first five donnings were considered in this analysis based on the previous study findings showing that there was little degradation in fit over the first five donnings.[18]

Study 5: Infrared (IR) thermography evaluation of faceseal leaks.

Test subjects performed one fit test for each FFR model. During the fit test, test subjects were simultaneously filmed with an IR camera to detect FSL as exhaled warm air.[19]

Study 6: Multiple cycle decontamination fit test.

This study assessed facepiece fit following one, two, and three cycles of decontamination processing using either UVGI, MGS, or MHI. Only the first donning for each sample which was untreated was considered for this study's analysis.[20]

Study 7: Temporal changes in facepiece fit.

Test subjects performed fit testing at six months intervals to investigate factors that affect changes in respirator fit over time (e.g., changes in weight). The study included only subjects who on their first visit both (a) passed one of the first three fit tests (FF ≥ 100), and (b) demonstrated through a series of nine donnings that they achieved adequate fit (90^{th} percentile FSL ≤ 5 %).[21] Test subjects made two to four six-month interval visits.

N95 FFRs were instrumented with a metal flush-mounted sampling probe. The probe has its inlet (4 mm diameter) flush with the interior wall of the respirator. On the exterior of the respirator, the probe tube projects from the respirator ~1 cm to accommodate the attachment of the sampling line. For all studies, subjects were trained on the proper donning and USC procedures for each model using the manufacturer's user instructions. For each fit test, subjects donned the FFR, performed the USC and made any necessary adjustments to the FFR until they felt they had achieved a good seal. Next, subjects wore the FFR for a 3-minute acclimatization period. In a standard OSHA-accepted fit test, the acclimatization period is 5 minutes; however, we shortened the time to be able to accommodate a greater number of fit tests during a subject visit. Following acclimatization, the fit test was started. A total of 594 data points (i.e., tests for subject/respirator combinations) were collected for the nine subjects over all seven studies (Table I). Of these, 205 data points were from Studies 1–6; for these data each subject had a minimum of 11 data points. For Study 7, 389 data points were collected; for these data each subject had a minimum of 18 data points.

Fit Factor Measurement for the "Nanoparticles Test": Studies 1–6

Fit tests were performed using a PortaCount Plus with an N95–Companion accessory. This instrument configuration is capable of recording FFs from 1 (poor fit) up to 200 (good fit). NIOSH certification regulations permit N95 FFRs to have up to 5% particle penetration through the filtration medium.[22] This makes it difficult for some N95 FFR models to achieve a FF of 100 using the PortaCount Plus alone. The N95–Companion accessory to the PortaCount Plus contains an electrostatic particle classifier to address this issue. The particle classifier takes advantage of the electrostatic charges on ambient particles to allow only a predetermined particle size range (~40–60 nm) of negatively charged particles to pass through to the detector for counting.[23, 24] The FP of negatively charged particles in this size range through N95 filter media has been shown to be insignificant;[25] thus, any particles detected inside the respirator are mainly attributed only to FSL.[26] Using only the ~40–60 nm size particles, the PortaCount Plus with N95–Companion accessory calculates FF as the ratio of the number of particles outside the FFR ($Concentration_{outside}$ (C_{out})) to the number inside ($Concentration_{inside}$ (C_{in})) (Equation1).

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$$FF = \frac{C_{out}}{C_{in}} \qquad \text{(Equation 1)}$$

For Study 1, the standard OSHA-accepted 8-exercise fit test protocol was used (Table I). The overall FF for the test is calculated as the harmonic mean of FFs obtained for seven of the

eight individual fit test exercises (a FF for the "grimace" exercise is not included in the calculation) (Equation 2).

$$FF = \frac{7}{\frac{1}{FF_1} + \frac{1}{FF_2} + \frac{1}{FF_3} + \frac{1}{FF_4} + \frac{1}{FF_5} + \frac{1}{FF_6} + \frac{1}{FF_7}} \quad \text{(Equation 2)}$$

where: FF_1, FF_2, FF_3, FF_4, FF_5, FF_6, FF_7 are the seven individual fit factors for each of the individual test exercises included in the calculation.

For studies 2–6, a shortened protocol of only six test exercises was used to minimize subject test time when performing multiple donning fit tests (Table I).[16-18, 20] The modified protocol calculates an integrated overall FF for the six test exercises as the ratio of (C_{out}) (sampled for 15 sec) divided by the in-facepiece concentration (C_{in}) (sampled for 81 sec) (Equation 1).

Fit Factor Measurement for the "All Size Particles Test": Study 7

This test configuration utilizes the PortaCount Plus alone to measure IL of ambient particles (i.e., particle infiltration into the respirator facepiece by both potential pathways of FP and FSL) for both charged and uncharged particles from 20 nm to > 1,000 nm. The PortaCount Plus reports—for purposes of discussion of this method—an "Uncorrected FF", meaning that the

result has not yet been corrected for FP to obtain a FF corresponding to FSL only. The "Uncorrected FF" reported by the instrument is the harmonic mean of the "Uncorrected FFs" for the five individual test exercises. The equation for calculating the "Uncorrected FF" for this method is similar to Equation 2; however, only using five exercises instead of seven.

The IL is the reciprocal of this "Uncorrected FF". The PortaCount Plus alone was chosen because measuring the full range of charged and uncharged particles allows the output of a large range of (C_{out}/C_{in}) ratios (i.e., resulting in "Uncorrected FFs" from 1 to > 10,000) compared to using the Companion accessory which restricts the FF range to an upper limit of 200. Using this larger range of "Uncorrected FFs" better facilitates comparisons of IL between six month subject visits. Additionally, the PortaCount Plus alone was shown in a previous study to result in a lower beta error (the chance of passing a fit test in error) than the PortaCount Plus with N95–Companion accessory, 4% and 9%, respectively.[27]

Because IL is composed of both FP and FSL, the FP of each FFR sample following a test subject's fit test was measured using a bench-top test similar to that used by Coffey et al.[27] For this test, melted beeswax (450, Brushy Mountain Bee Farm, NC, USA) was used to seal the periphery of the FFR to an acrylic plate having a centered circular hole (9.6 cm^2). The plate was placed into a test fixture with a vacuum line that drew air continuously at ~10.3 L/min to simulate the breathing minute volume of a person while seated.[28] Filter penetration was measured with the PortaCount Plus alone using the same exercise timings employed for the subject tests (i.e., five individual exercises were used which resulted in one overall FP value); each respirator was tested three times. Each of the three overall FP measurements was subtracted from each of the three corresponding IL measurements from the person's fit test resulting in

three FSL values. Finally, the inverse of each FSL value was taken to compute three individual "Corrected FFs" (1 / FSL = "Corrected FF"). These "Corrected FFs" (now simply referred to as FFs) corresponded to only FSL. This test methodology is capable of generating FFs in excess of 200; however, FFs results were capped at 200 for this analysis to be consistent with results using the "nanoparticles test" configuration.

A previous study showed good correlation of ratios of particle concentration outside and inside respirators (C_{out}/C_{in}) between a PortaCount Plus alone (measuring "all size particles") and an ultrafine condensation particle counter (UCPC); r-values were observed between 0.95-0.99 at both the 20 and 30 L/min flow rates.[26] The correlation suggests that the PortaCount Plus alone accurately measures IL and that FP can be subtracted to obtain FSL as we have done in our study.

Ambient Particle Distribution Analysis

The ambient particle size concentration and distribution in the two human subject fit test laboratories were measured with a scanning mobility particle sizer (SMPS; 3936, TSI Inc., MN, USA) system consisting of a classifier controller (3080, TSI Inc., MN, USA), a differential mobility analyzer (DMA; 3081, TSI Inc., USA), an ultra-fine condensation particle counter (UCPC; 3776, TSI Inc., MN, USA), and an aerosol neutralizer (3077, TSI Inc., MN, USA). One 2–minute scan was taken in the center of each laboratory. The ambient particle size data were collected after all fit tests were conducted to provide basic information on the ambient particle

concentrations and to determine if the size distributions were different between the two test laboratories. During the measurements, NaCl was being generated in each of the laboratories.

Statistical Analysis

It is important to note that every subject in this study passed (i.e., achieved a FF ≥ 100) an OSHA-accepted fit test on all three FFR models using the PortaCount Plus with N95–Companion accessory; this was the criterion for Study 1. This criterion provides a baseline for all subjects achieving a good fit on the three FFR models and provides justification for comparing the "nanoparticles" and "all size particles" test data even though the test methods differed.

Geometric mean (GM), geometric standard deviation (GSD), and 5th percentile FFs were calculated by FFR model and for all models combined. One-way analysis of variance (ANOVA) tests were performed using the PROC GLM statement (General Linear Model) in SAS Version 9.2 (© 2002-2008, SAS Institute Inc., Cary, NC) to compare log-transformed overall FFs (logFF) obtained utilizing the nano size range and the wider size range. The independent variable for all analyses was "Test Configuration" (i.e., use of the "nanoparticles test" or "all size particles test." The dependent variable was "logFF". Pair-wise comparisons of logFF means were performed using Duncan's Multiple Range Test (DMRT) following ANOVA. Results were considered statistically significant for P-values < 0.05.

Because logFFs from the "all size particles" test and "nanoparticles" test were not normally distributed, Kruskal-Wallis tests using Wilcoxon scores (i.e., the non-parametric ANOVA equivalent test) were also performed on data for each FFR model and all models

combined to compare logFFs using the two different fit test methods; a significance level of 0.05 was used.

To visualize differences in the individual FFs obtained by FFR model when using the "nanoparticles test" or "all size particles test", cumulative frequency distributions of individual FFs were created using Microsoft Excel (part of Microsoft Office Professional Plus 2010, ©2010, Microsoft Corp.).

RESULTS

Geometric mean FFs are summarized by FFR model in Table II. Two of the three N95 FFR models (3M 1860 and Moldex 2200) achieved higher GM FFs using the "nanoparticles test"; the comparison was statistically significant by DMRT ($P < 0.05$) for only the 3M 1860. For all three FFR models combined, GM FF using the "nanoparticles test" was significantly higher by DMRT ($P < 0.05$). Of the three FFR models, only the 3M 1870 had a greater GM FF and greater 5^{th} percentile FF using the "all size particles test"; however, the differences were small and well within the error of the study. Using the non-parametric test, the only difference from the DMRT results shown in Table II is that the Moldex 2200 showed statistical significance for GM FF (i.e., GM FF for the "nanoparticles" test became significantly greater than GM FF for the "all size particles" test). Because all FFs were capped at a maximum of 200 for these analyses, results may have been different if the full range of FFs were used; however, it is not possible for us to run this additional analysis as data collected using the PortaCount Plus with N95–Companion accessory were recorded using software which capped FFs at 200.

Cumulative distributions of FFs for each model using the "nanoparticles test" or "all size particles test" configurations are illustrated in Figures 1, 2, and 3. For the 3M 1860 and Moldex 2200 (Fig. 1 and 3), the distribution curves for the "nanoparticles test" appear to the right or below those for the "all size particles test." This indicates that the percentage of donnings associated with the "nanoparticles test" for the same level of FF was less than that for the "all size particles test" (i.e., FFs from the "nanoparticles test" were generally higher than the "all size particles test"). For the 3M 1870, the distributions of fit test results were similar for the two fit test methods (Fig. 2).

The ambient particle size distribution and concentration measured in both laboratories using an SMPS system are plotted in Figure 4. Both laboratories had similar count median diameters (CMD) and geometric standard deviations (GSD): Laboratory A, 75 nm CMD with 1.90 GSD; for Laboratory B, 72 nm CMD with 1.75 GSD. This indicates that the two laboratories had similar particle size distributions, suggesting that the effect of location on the data collected for the two fit test methods is likely to be minimal.

DISCUSSION

The findings from our study suggest that FSL of nanoparticles is not greater than all sizes of particles for respirator users who have passed an OSHA-accepted fit test on a NIOSH-certified N95 FFR. Thus, these results do not support our initial experimental hypothesis which predicted that FFs would be lower for the "nanoparticles" test. A possible explanation for our results differing from that of Grinshpun et al (2009) is that their group used an electrical low pressure

impactor (ELPI) to detect particles which were charge-equilibrated to a Boltzmann charge distribution, whereas our PortaCount Plus with N95–Companion accessory method only detected negatively charged particles.

The PortaCount Plus with N95–Companion accessory configuration (used in the "nanoparticles" test) detects particles from only FSL of a FFR. The N95–Companion accessory has a radial-DMA at a fixed setting which under optimum conditions allows only singly negative charged particles with diameters ~40–60 nm to travel to the counter. Modern N95 FFRs use electret media that has been reported in several studies to have a most penetrating particle size (MPPS) in this range, ~50 nm;[10] however, this value is for neutralized aerosol. For singly charged aerosol, static electric forces shift the curve to have a MPPS of ~300 nm.[25] Further, the penetration of singly charged aerosols in the 40–60 nm size range have been shown to be near zero for several N95 FFRs models.[25] This effectively eliminates the contribution of FP to the inside facepiece concentration. Thus, for singly charged particles, FSL is the primary pathway for particles to infiltrate the facepiece. For the PortaCount Plus alone (i.e., as used in the "all size particles" test), there is no such selection for size or charge. As a result, virtually all of the particles > 20 nm travel to the detector.

Our higher PortaCount Plus with N95–Companion accessory FF results ("nanoparticles" test) agree with a previous study that found this configuration generally tested higher or equal to the PortaCount Plus alone after correcting for FP.[29] A similar trend of higher FFs using the PortaCount Plus with N95–Companion accessory compared with the PortaCount Plus alone was also observed in another study on IL of a manikin headform, although their method differed from ours as they did not subtract FP from their FF.[26] These results indicate that using the PortaCount

Plus alone and subtracting FP can provide conservative FFs for nanoparticles. Although this method is not approved by OSHA nor recommended by NIOSH for fit testing of employees, the method could serve as a tool for conducting research studies.

Two recent surveys have examined the use of personal protective equipment in nanoparticle workplaces.[30, 31] Conti et al.[30] investigated 82 nanoparticle manufacturing facilities internationally and found respirator use at 22 of the facilities—P100 type respirators (half-mask elastomeric and FFR) were the most commonly reported type. Dahm et al.[31] investigated 30 workplaces, finding elastomeric half-mask respirators with either P100 or N100 filters to be the most commonly used respiratory protection followed by P100 or N95 FFRs. When elastomeric half-mask respirators are fit tested, they are usually equipped with P100 filters and the PortaCount Plus alone is used. The findings in the present study support this fit testing practice using "all size particles" resulting in a FF which is a conservative for nanosize particles.

Results of this study should be viewed in the context of a laboratory study and do not directly translate to respirator performance against nanoparticles in the workplace. However, studies like the one reported here help bridge the gap toward understanding the factors affecting respirator performance against nanoparticles. Until workplace protection factor (WPF) studies can be performed to measure respirator performance in actual workplace settings where nanoparticle exposures occur, laboratory studies such as this one will need to serve as the basis for recommendations.

There are some limitations of the study design which must be acknowledged. Data on ambient particle concentrations and size distributions were not collected before and after fit test data collection, so some minor shifts in the background could have occurred. Testing

methodology varied between studies for measuring and calculating FF (Studies 1–6 utilized the PortaCount Plus with N95–Companion accessory to directly measure FF in contrast to Study 7 which utilized the PortaCount Plus alone to initially measure IL and later subtract FP to calculate FF). The number and duration of exercises varied between studies (Table I). FFs for this study were capped at 200; results may have been different if the full range of FFs were used. Finally, due to the inclusion criteria for data in the study, only data from three N95 FFR models were analyzed; thus, the results may not be representative of all N95 FFR models. Future studies can be designed to address these weaknesses.

CONCLUSIONS

The study compared FFs measured with a “nanoparticles” fit test to FFs measured with an “all size particles” fit test. With the FP subtracted from the “all size particles test” “Uncorrected FF”, a statistical difference from the “nanoparticles test” was only found for one FFR model. N95 FFR FSL against nanoparticles by respirator model in laboratory testing was the same or lower than the FSL against “all size particles”. These data suggests that faceseal leakage for negatively charged ~40–60 nm nanoparticles is not greater than the faceseal leakage for a larger distribution of charged and uncharged 20 to >1,000 nm particles. Further research is needed to determine how respiratory protection from nanoparticles in workplace settings compares to that found in the laboratory.

ACKNOWLEDGMENTS

The authors would like to thank Andrew Palmiero, Jeffrey Powell, Stacey Benson, Dennis Viscusi, and Stephanie Lynch for their assistance with data collection.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

REFERENCES

1 **International Standards Organization (ISO):** Nanotechnologies -- Terminology and definitions for nano-objects -- Nanoparticle, nanofibre and nanoplate. ISO/TS 27687. Geneva: ISO, 2008.

2 **Schulte, P.A., V. Murashov, R. Zumwalde, E.D. Kuempel, and C.L. Geraci:** Occupational exposure limits for nanomaterials: state of the art. *J. Nanopart. Res.* 12:1971-1987 (2010).

3 **Schulte, P.A., C. Geraci, R. Zumwalde, M. Hoover, and E. Kuempel:** Occupational risk management of engineered nanoparticles. *J. Occup. Environ. Hyg. 5*(4):239-249 (2008).

4 **Luther, W.:** "Industrial Application of Nanomaterials—Chances and Risks". Dusseldorf: Future Technologies Division of VDI Technologiezentrum GmbH, 2004.

5 **National Institute for Occupational Safety and Health (NIOSH):** " NIOSH Respirator Selection Logic." Publication no. 2005-100. Cincinnati: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH), 2005.

6 **Occupational Safety and Health Administration** (**OSHA):** Respiratory Protection. 29 CFR 1910.134. Washington, DC: US Government Printing Office, Office of the Federal Register, 1998.

7 **National Institute for Occupational Safety and Health (NIOSH):** "NIOSH Guide to the Selection and Use of Particulate Respirators Certified Under 42 CFR 84." Publication no. 96-101. DHHS (NIOSH), 1996.

8 **National Institute for Occupational Safety and Health (NIOSH):** Approaches to Safe Nanotechnology: Managing the Health and Safety Concerns Associated with Engineered Nanomaterials. NIOSH Publication No. 2009-125. DHHS (NIOSH) (2009). [Online] *http://www.cdc.gov/niosh/docs/2009-125/pdfs/2009-125.pdf* (Accessed January 03, 2013).

9 **Grinshpun, S.A., H. Haruta, R.M. Eninger, T. Reponen, R.T. McKay, and S.A. Lee:** Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: two pathways for particle penetration. *J. Occup. Environ. Hyg. 6*(10):593-603 (2009).

10 **Shaffer, R.E., and S. Rengasamy:** Respiratory protection against airborne nanoparticles: a review. *J. Nanopart. Res. 11*(7):1661-1672 (2009).

11 **Aitken, R.J., K.S. Creely, and C.L. Tran:** "Nanoparticles: An occupational hygiene review". Riccarton, Edinburgh: Institute of Occupational Medicine, 2004.

12 **Rengasamy, S., and B.C. Eimer:** Total Inward Leakage of Nanoparticles Through Filtering Facepiece Respirators. *Ann. Occup. Hyg. 55*(3):253-263 (2011).

13 **Food and Drug Administration (FDA):** Masks and N95 Respirators (2009). [Online] *http://www.fda.gov* (Accessed January 03, 2013).

14 **TSI Inc.:** Model 8095 N95–Companion™ to the PORTACOUNT® Plus, Operation and Service Manual P/N 1980308, Revision H, 2005.

15 **TSI Inc.:** PORTACOUNT® Plus Model 8020 Operation and Service Manual P/N 1980092, Revision(2006).

16 **Viscusi, D.J., M.S. Bergman, D.A. Novak, K.A. Faulkner, A. Palmiero, J. Powell et al.:** Impact of three biological decontamination methods on filtering facepiece respirator fit, odor, comfort, and donning ease. *J. Occup. Environ. Hyg. 8*(7):426-436 (2011).

17 **Viscusi, D.J., M.S. Bergman, Z. Zhuang, and R.E. Shaffer:** Evaluation of the Benefit of the User Seal Check on N95 Filtering Facepiece Respirator Fit. *J. Occup.Environ. Hyg. 9*:408-416 (2012).

18 **Bergman, M.S., D.J. Viscusi, Z. Zhuang, A.J. Palmiero, J.B. Powell, and R.E. Shaffer:** Impact of multiple consecutive donnings on filtering facepiece respirator fit. *Am. J. Infect. Control. 40*:375-380 (2012).

19 **Roberge, R.J., W.D. Monaghan, A.J. Palmiero, R. Shaffer, and M.S. Bergman:** Infrared imaging for leak detection of N95 filtering facepiece respirators: a pilot study. *Am. J. Ind. Med. 54*(8):628-636 (2011).

20 **Bergman, M.S., D.J. Viscusi, A.J. Palmiero, J.B. Powell, and R.E. Shaffer:** Impact of Three Cycles of Decontamination Treatments on Filtering Facepiece Respirator Fit. *J. Int. Soc. Respir. Prot. 28*(1):48-59 (2011).

21 **Zhuang, Z., S. Benson, S. Lynch, A. Palmiero, and R. Roberge:** Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering Facepiece Respirator Fit: Part I – Pilot Study. *J. Occup.Environ. Hyg. 8*(12):729-739 (2011).

22 **National Institute for Occupational Safety and Health (NIOSH):** Respiratory Protective Devices. 42 CFR Part 84. Code of Federal Regulations. Washington, DC: US Government Printing Office, Office of the Federal Register, 1995.

23 **TSI Inc.:** N95–Companion™ Model 8095 Theory of Operation. Application Note ITI-053, Rev B., 2010.

24 **Karlsson, M.N.A., Z. Geretovszky, and K. Deppert:** The TSI N95 Companion – A Convenient Alternative in Everyday Nanoparticle Classification? In European Aerosol Conference. Abstract T09A042. Salzburg, Austria, 2007.

25 **Rengasamy, S., A. Miller, and B.C. Eimer:** Evaluation of the Filtration Performance of NIOSH-Approved N95 Filtering Facepiece Respirators by Photometric and Number-Based Test Methods. *J. Occup.Environ. Hyg. 8*(1):23-30 (2011).

26 **Rengasamy, S., B.C. Eimer, and R.E. Shaffer:** Evaluation of the performance of the N95-companion: effects of filter penetration and comparison with other aerosol instruments. *J. Occup. Environ. Hyg. 9*(7):417-426 (2012).

27 **Coffey, C.C., R.B. Lawrence, Z. Zhuang, D.L. Campbell, P.A. Jensen, and W.R. Myers:** Comparison of five methods for fit-testing N95 filtering-facepiece respirators. *Appl. Occup. Environ. Hyg. 17*(10):723-730 (2002).

28 **Silverman, L.G., L.T. Plotkin, L.A. Sawyers, and A.R. Yancey:** Airflow Measurements on Human Subjects With and Without Respiratory Resistance. *Arch. Ind. Hyg. Occup. Med. 3*:461-478 (1952).

29 **Coffey, C.C., R.B. Lawrence, D.L. Campbell, Z.Q. Zhuang, C.A. Calvert, and P.A. Jensen:** Fitting characteristics of eighteen N95 filtering-facepiece respirators. *J. Occup. Environ. Hyg. 1*(4):262-271 (2004).

30 **Conti, J.A., K. Killpack, G. Gerritzen, L. Huang, M. Mircheva, M. Delmas et al.:** Health and safety practices in the nanomaterials workplace: Results from an international survey. *Environ. Sci. Tech. 42*(9):3155-3162 (2008).

31 **Dahm, M.M., M.S. Yencken, and M.K. Schubauer-Berigan:** Exposure Control Strategies in the Carbonaceous Nanomaterial Industry. *J. Occup. Environ. Med. 53*(6):S68-S73 (2011).

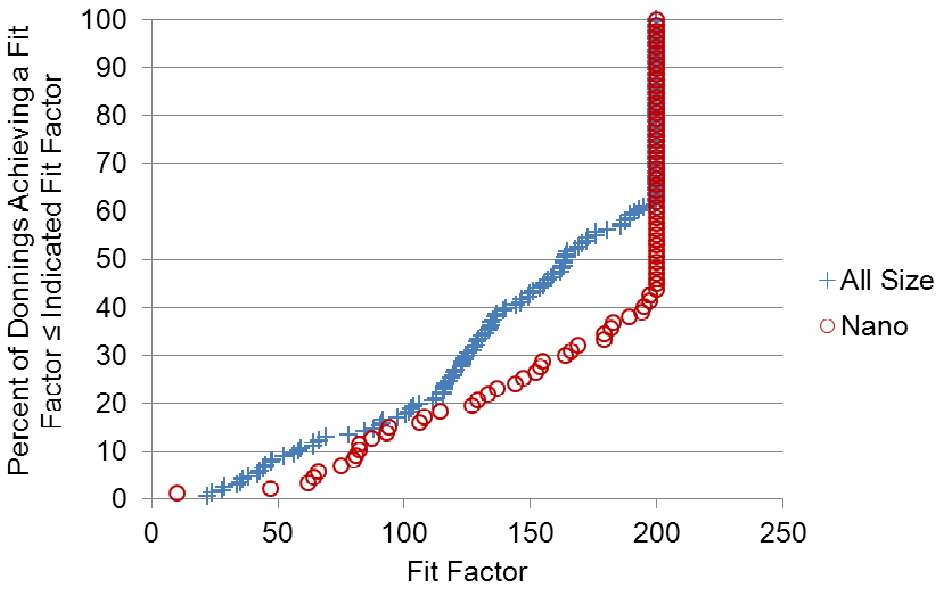

FIGURE 1. 3M 1860 fit factors measured using the PortaCount Plus only (+) and using the PortaCount Plus with N95–Companion (○)

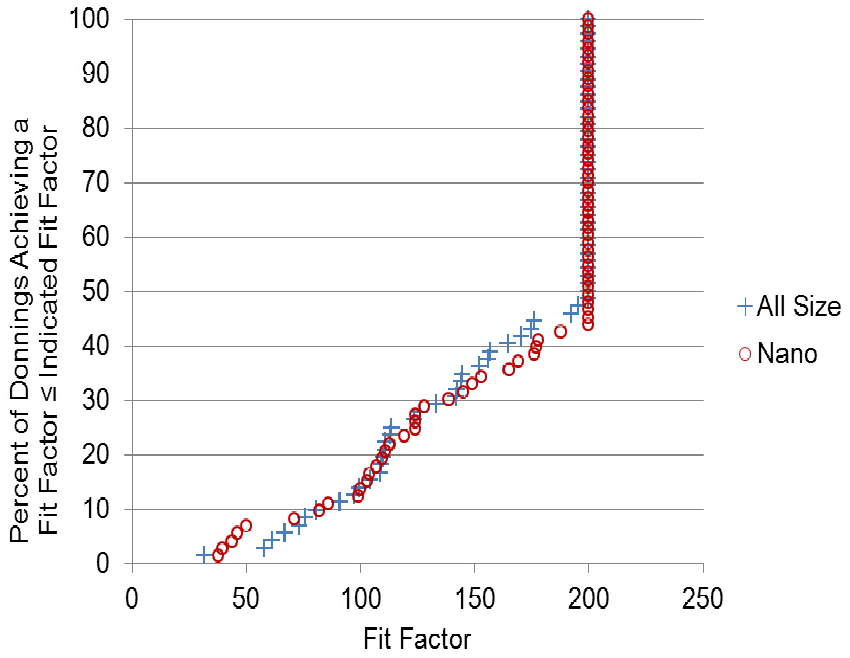

FIGURE 2. 3M 1870 fit factors measured using the PortaCount Plus only (+) and using the PortaCount Plus with N95–Companion (○)

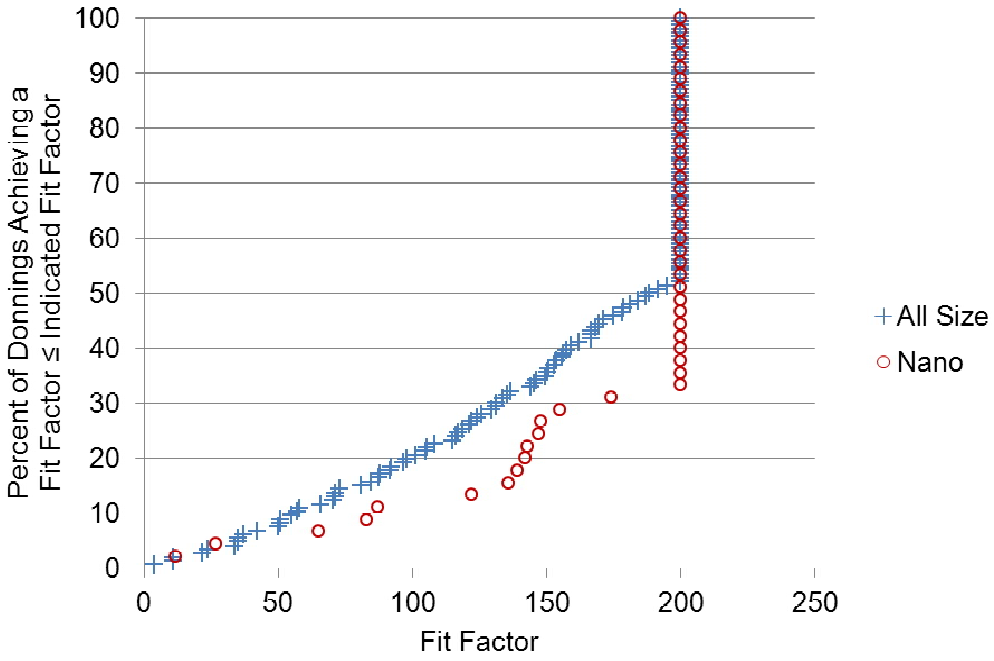

FIGURE 3. Moldex 2200 fit factors measured using the PortaCount Plus only (+) and using the PortaCount Plus with N95–Companion (○)

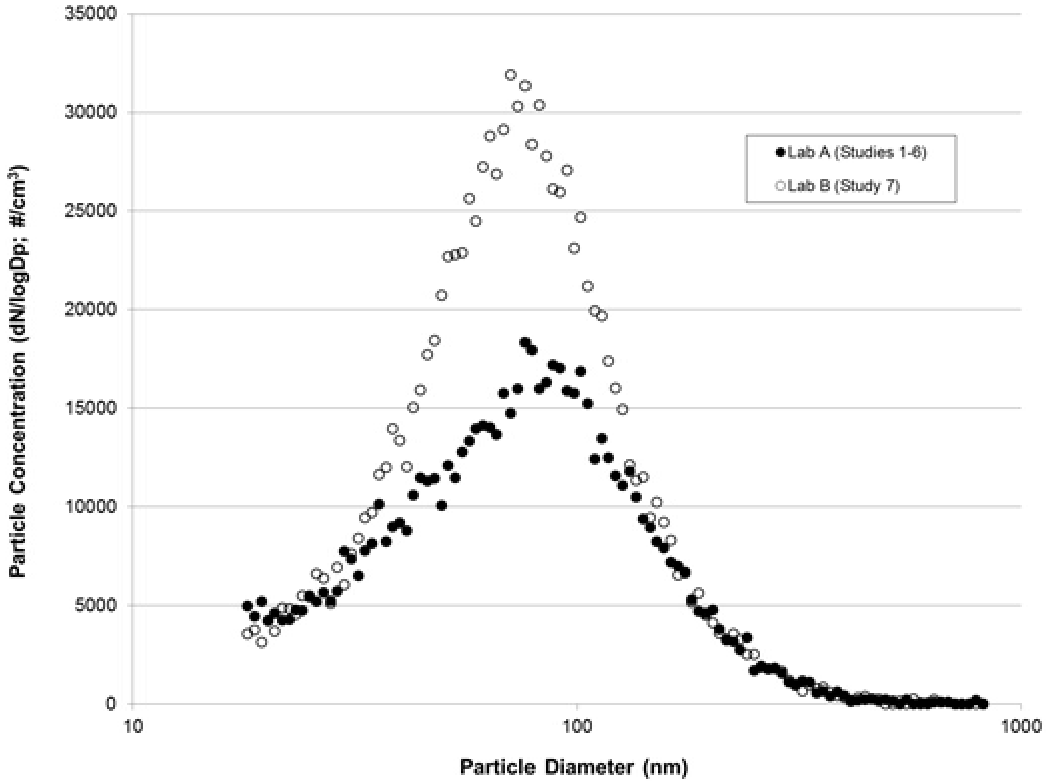

FIGURE 4. Ambient particle size distribution as measured by an SMPS in human subject testing laboratoriesNote: One scan was taken in each laboratory. NaCl aerosol was being generated in the laboratories for these ambient measurements.

TABLE I. Test study summary

Study No.	Description	Nano[A]	Exercise duration (s)								Donnings (n)
			Normal breathing	Deep breathing	Turning head side to side	Moving head up and down	Talking (rainbow passage)	Grimace	Bending over	Normal breathing	
1	OSHA fit test (29 CFR 1910.134)	Yes	86	86	86	86	86	22	86	86	9
2	One-cycle decon fit test	Yes	70	10	10	10	10	-	-	10	70
3	User Seal Check (USC)	Yes	70	10	10	10	10	-	-	10	40
4	Consecutive donnings (up to 20)	Yes	70	10	10	10	10	-	-	10	57
5	IR-camera faceseal leakage evaluation	Yes	70	10	10	10	10	-	-	10	5
6	Multi-decon fit test	Yes	70	10	10	10	10	-	-	10	24
		Subtotal									205

7	Temporal changes in facepiece fit	No	60	60	60	60	-	-	-	60	389
		Total									594

[A] Yes= PORTACOUNT Plus with N95–Companion (negatively charged particles, size range ~40 to 60 nm).

NO= Measured using the PORTACOUNT Plus only (particle size range 20 nm to > 1,000 nm).

TABLE II. Geometric mean, geometric standard deviation and 5th %tile fit factor (FF) by respirator model

FFR Model	Nano*	Donnings (n)	GM FF	GSD	5th %tile FF
3M 1860	NO	171 (67)**	137 [A]	1.7	59
	YES	87 (50)	157 [B]	1.6	74

3M 1870	NO	72 (38)	153	1.5	80
	YES	73 (42)	152	1.5	74
Moldex 2200	NO	146 (71)	136	1.9	47
	YES	45 (31)	158	1.7	64
All Models	NO	389 (176)	139 [A]	1.7	56
Combined	YES	205 (123)	156 [B]	1.6	72

* Yes= PORTACOUNT Plus with N95–Companion (negatively charged particles, size range ~40 nm to 60 nm).

NO= Measured using the PORTACOUNT Plus only (particle size range 20 nm to > 1,000 nm).

** Number in parenthesis is the portion of donnings with fit factors that were limited to 200.

Note: For each FFR model, GM value with superscript “A” is significantly different from the value with superscript “B” using the Duncan’s Multiple Range Test following ANOVA.