Miller, Diane M. (CDC/NIOSH/EID)

From: Cristine Fargo [cfargo@safetyequipment.org]
Sent: Monday, March 29, 2010 1:58 PM
To: NIOSH Docket Office (CDC)
Subject: RIN: 0920-AA33 - 42 CFR Part 84 Total Inward Requirements for Respirators
Attachments: ISEA_Comments_to_Docket-TIL-2010_March29.pdf

To NIOSH Docket Officer:

Attached please written comments on behalf of the International Safety Equipment Association (ISEA) on the subject NPRM.

Please don't hesitate to contact me if you have any questions.

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INTERNATIONAL
SAFETY EQUIPMENT
ASSOCIATION
ISEA

Via email: niocindocket@cdc.gov

March 29, 2010

NIOSH Docket Office
Robert A. Taft Laboratories, MS-C34
4676 Columbia Parkway
Cincinnati, OH 45226

ISEA Comments on 42 CFR Part 84 Notice of Proposed Rulemaking (NPRM)
Total Inward Leakage Requirements for Respirators, 42 CFR Part 84, RIN 0920-AA33

The International Safety Equipment Association (ISEA) is the trade association representing suppliers of personal protective technologies, including respiratory protective devices certified by NIOSH. ISEA welcomes the opportunity to comment on the October 30, 2009 Notice of Proposed Rulemaking (NPRM) on 42 CFR Part 84 Total Inward Leakage Requirements for Respirators and offers the following comments related to the information contained in the preamble and specific sections of the proposed rule:

General Comments

In the preamble to the proposed rule, NIOSH notes that it "conducted benchmark testing of 101 respirator models currently on the market, using a test regimen similar to that being proposed in this rulemaking, to assess their TIL performance." (74 FR 56142) NIOSH reported that this study found wide variability in the fitting characteristics of half-mask respirators, and used the results of the benchmark testing as the basis for most, if not all, of its conclusions including the number of models that would be expected to fail the proposal by not achieving a fit factor of 100.

The fact that the proposed regulation implements a *similar* but not *identical* protocol to that used in the benchmark testing calls into question the validity of the proposal. A stark example of this is the number of persons on the test panel. NIOSH benchmark testing used a 25 person panel; however, the proposal includes a 35 person panel. The NIOSH benchmark test appears not to have been evaluated for a pass in each cell of the fit panel. The NIOSH proposal indicates a pass/fail criterion for the respirator model of a fit factor of 100 instead of the fit factor of 20 used in benchmark study and presentations by NIOSH.

Following the December 3, 2009 NIOSH public meeting on the TIL proposed rule, ISEA's Respiratory Protection Group commissioned an independent study to attempt to determine the probability that available half-mask respirators will pass the proposed NIOSH tests, what percentage of the intended user population should be able to achieve adequate TIL performance for the respirator to be approved by NIOSH, the variability in subject pass rate for a given model of respirator between different panels of subjects, as well as the reproducibility of results from the proposed test.

The testing was conducted in January and February 2010, using the test protocols from the proposed rule. The researchers tested one filtering facepiece and one elastomeric half-mask respirator from different manufacturers, selected by the independent advisory panel. The data set from a second filtering facepiece respirator, previously tested using the NIOSH TIL protocol, was included in the analysis. In addition, the study panel evaluated the results of NIOSH benchmark testing of 24 respirators and compared them to the results obtained in the ISEA testing. A copy of the study report is included as part of these comments.

The study produced the following conclusions and recommendations:

1. Multiple donnings of a single respirator on each subject may be a more rigorous test than evaluating the fit of multiple respirators.

2. A panel with more than 35 subjects or multiple panels of 35 subjects would yield better information about respirator performance than a single 35-subject panel.

3. NIOSH should develop a consistent approach to selecting an appropriate respirator size, rather than relying on manufacturer instructions. ISEA recommends the method used in its study, which allowed each subject to conduct, with assistance, a preliminary qualitative evaluation of each size before making a final selection.

4. The proposed NIOSH criteria are overly stringent and likely to exclude almost all filtering facepiece and 50% of elastomeric respirators from the marketplace. Approximately 25% of filtering facepiece and 80% of elastomeric respirators would be certified at a fit factor criterion of 20. A fit factor criterion of 10 (the assigned protection factor) would exclude 45% of filtering facepiece and 10% of elastomeric respirators from the market. ISEA suggests that using a 75% pass criterion at or near a fit factor of 10, and dropping the cell criterion, would be a more reasonable approach.

5. The NIOSH benchmark dataset could have been more informative about between- and within-subject variance, and respirator pass rates, if a more realistic protocol for testing multi-sized respirators had been used. This dataset was also limited by its use of smaller panels (25 subjects) meeting the older Los Alamos criteria.

6. A bootstrap approach that draws on information from multiple panels would be the most appropriate method for assessing the probability that a respirator will fit a population of wearers, but it may not be economically feasible. ISEA suggests that NIOSH consider conducting additional tests of representative filtering facepiece and elastomeric respirators with multiple trials, donnings, and panels, following the methodology used in its study. Results would lead to a better understanding of between- and within-subject variability and may suggest methods for simulating and predicting fit performance for the population of respirator wearers.

Fit Test for Certification

In evaluating the NIOSH proposed TIL protocol, the ISEA study advisory panel assessed whether a panel fit test is appropriate to a respirator certification standard; i.e., will such a test increase the likelihood that substantial numbers of non-fit tested respirator users will be protected when they wear the respirator correctly?

This goal implies that it is acceptable that wearers may use a negative-pressure respirator without receiving initial fit testing (or, we presume, medical evaluation). The proposed TIL regulation does not assess untrained, naïve subjects. Performing the proposed TIL procedures involves assisted donning on individuals who will in most cases have donning experience either from their work or from previous TIL studies. A worker who has been trained and fit tested can expect to achieve a protection factor of 10 (the current OSHA APF).

What protection factor does NIOSH expect for a naive respirator wearer who selects a size based on a recommendation and who has not been trained or fit tested? According to the NIOSH/BLS survey cited in the preamble to the proposed rule, 40% of employers are not selecting respirators for their workers based on fit testing, and that percentage may be higher in some work settings. Nothing in the NIOSH TIL proposal addresses this issue. Is the NIOSH TIL proposal intended to protect those workers? If so, what protection level does NIOSH expect un-fit tested workers to achieve? Presumably, this level would be less than the APF of 10.

ISEA is aware of no studies that show the separate effects of training, prior fit testing or donning assistance on the level of fit. Thus, it is only conjecture that the TIL procedure will lead to better chances that non-fit tested (untrained, non-medically-cleared) users will get an adequate fit, whatever the level might be. ISEA believes the panel fit test is not appropriate to a respirator certification standard.

The ISEA expert advisory panel also asked whether it is an appropriate goal for a respirator certification standard that employees who wear a respirator without any elements of a respirator program will obtain adequate fit and protection, at some lower level than fit tested individuals.

ISEA believes it is not within NIOSH's mission to ensure that respirators should yield "adequate" protection to anyone who dons a respirator. This goal is within OSHA's purview and should be addressed by OSHA's standards and enforcement activities.

The most significant problem with this goal is the failure to quantify what an "adequate" level of protection might be. Why should some respirator wearers be expected or even allowed to receive protection less than that required for this class of respirators? This goal implies that the expectations for respirator use outlined in the OSHA regulation are neither important nor necessary. ISEA believes this goal is not appropriate to a respirator certification standard.

Effective Date

NIOSH has proposed a 3-year transition period from the effective date of the final rule that permits approval holders to continue to sell and ship devices certified under the current provisions. ISEA requests clarification on how the agency will apply this to products already approved and *manufactured* during this three-year timeframe.

It is also unclear if an existing device that fails the TIL test can be resubmitted after design adjustments under a request to modify the certification (as it relates only to TIL testing) or if the device would have to be resubmitted for full testing. This must be clarified in detail by NIOSH as it could impact a manufacturer's decision to make certain devices available, which could affect product offerings to the end-user.

NIOSH should consider a permanent exception to TIL testing for all devices holding NIOSH certification as of the effective date. These devices already in the marketplace have been working effectively for many users for a long time with no known inadequate performance. The new test protocols could drive manufacturers toward the center of panel cells, whereby they make devices that favor common and "average" facial characteristics, leaving those individuals that are outliers with fewer products available. Having existing devices remain available will help assure that the outlier individuals will continue to have access to effective respiratory protection.

ISEA also believes that the implementation schedule may prove burdensome to NIOSH itself as the agency must ensure that it has all the necessary resources in place to accommodate modifications of existing approvals to include TIL testing. As the agency seeks to consider modifications during the specified time period, we are concerned that the volume of expected applications, without adequate resources, could jeopardize the continued availability of current protectors that may languish in the queue beyond the two years, but will also hinder the approval rate of new and unrelated products.

Comments on Specific Sections

§ 84.175 Half-mask facepieces, full facepieces, hoods, helmets and mouthpieces; fit and total inward leakage (TIL); minimum requirements

The proposed requirement in §84.174(h)(1) states that "The applicant shall specify in the user instructions the face size or sizes that the respirator is intended to fit; pursuant to this requirement, one respirator may be intended to fit all face sizes."

We interpret this paragraph to require the respirator manufacturer to indicate the size of the face that a specific model or facepiece size is intended to fit. If only one model is made in a stated size, this would imply that the device is designed to fit all the sizes of the NIOSH bivariate test panel, which may not be the case.

ISEA is not aware of any published data which statistically correlates facial measurements from bivariate grid dimensions to adequate fit of a respirator. A manufacturer cannot claim with any certainty that all users within a cell will fit facepieces appropriate for that cell. Requiring a manufacturer to provide such information may subject the manufacturer to potential liability issues as an end-user may view this information as an implicit warranty.

According to this proposal and comments made at the 2007 public meeting, it appears NIOSH believes that requiring that "[a]ll test subjects shall also have facial characteristics which result in being included within the Principal Components Analysis Panel, which excludes extreme facial features"[1] will eliminate the variability between members of a cell of the NIOSH bivariate test panel. This will not account for nor control the panel-to-panel variability. This panel variability that results is another factor that contributes to variability between the manufacturer's pre-submission data and NIOSH testing and why ISEA does not support this proposed test procedure.

Related to this is the concern that users are expected to identify for themselves the size of respirator to be selected, having them rely on manufacturer's instructions and descriptions of applicable facial shapes and other pertinent characteristics.

ISEA members believe that this has the effect of creating worksite fit testing procedures that are more complicated, having an unintended consequence of *less* workplace fit testing. If they follow the TIL program, employers will have to acquire calipers, receive training on their use, measure facial dimensions of each wearer, determine the panel cells each respirator wearer fits into, and acquire respirators for those panel cells if they elect to select respirators in accordance with the information NIOSH may require manufacturers to place on packaging. Because of the complexity of these procedures and the questionable correlation of grid size to fit, employers will find it more difficult to comply with the required Respiratory Protection Program. Neither the employer nor the respirator wearers will benefit from any of these new requirements.

§ 84.175(i) Half-mask respirator TIL testing requirements:

With respect to testing and the use of the test panel, NIOSH states in the preamble that "concerns …will be considered further in the development of testing procedures to be implemented under a final rule." (74 FR 56144) Manufacturers stress the importance of having the final standard test procedure developed, corroborated and available for execution prior to its incorporation into regulatory text. ISEA shares the concerns raised by a representative from TSI at the December 3, 2009 public meeting regarding the test set-up that was used to validate the TIL test used in the proposed regulation[2], and has identified several areas of the testing procedure that are either unclear or incorrect that need to be addressed before final implementation.

In the proposed regulation NIOSH outlines its draft test procedure (No. RCT-APR-STP-0068) using Portacount Pro+. The NIOSH procedure does not use any type of chamber where the NaCl challenge concentration is developed and maintained. This is a serious flaw in the protocol as the Portacount does not do instantaneous monitoring and comparisons of outside concentration (C_o) and inside concentration (C_i) and therefore a rapid concentration change in the ambient environment could very easily give highly erroneous results.

Manufacturers also question the particle size of the challenge aerosol ranges from 0.02 to 0.06 micrometer. The most penetrating particle size range is dependent on the filter media property and flow rate. There are studies that show that the range could be from 0.03 to 0.5 microns. Since there is no

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[1] NIOSH draft specific technical procedures to be applied for TIL testing - "Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators" Procedure No. RCT-APR-STP-0068, Revision-1; 8/12/09

[2] Presentation by J Weed (TSI) entitled "Instrumentation and measurement issues in the proposed NIOSH TIL rulemaking"; NIOSH public meeting, 12/3/09; http://www.cdc.gov/niosh/docket/pdfs/NIOSH-137/0137-120309-WeedJ_Pres.pdf

way to distinguish between particles that leak through the faceseal and that penetrate the filter, the proposed particle size range could result in higher TIL values for those filters that have the most penetrating particle size in this range. It is recommended that the size range of 0.4~0.6 microns (which is similar to that used in the Laboratory Respirator Protection Level test for CBRN) is used during the TIL test.

Request for Extension of Comment Period

In light of the findings of our analysis of the NIOSH proposal, ISEA believes that additional research is called for before making a final decision on whether to include a TIL test as part of respirator certification. We therefore reiterate our request, contained in a January 10, 2010 petition to the Secretary of Health and Human Services, for a one-year extension of the comment period on this proposed regulation. That petition is attached as part of these comments.

Sincerely,

Daniel K. Shipp
President

Environmental Health & Safety, Inc.

Report of

NIOSH TIL Respirator Fit-Test Study

Prepared for

International Safety Equipment Association

Prepared by

Environmental Health & Safety, Inc.

March 26, 2010

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Section 1: Introduction and Scope of Services

Environmental Health & Safety, Inc. (EH&S) was retained by ISEA to provide the following Scope of Services:

- Meet with ISEA member companies to define the study objectives and methods.
- Retain the services of a two member expert advisory panel (Dr. Lisa Brosseau and Mr. Jeff Weed) to review study objectives and protocols, and aid in authoring a final report.
- Retain the services of a professional statistician (Mr. Christopher Pulling) to comment on study design and evaluate the data generated in the study.
- Oversee the work of a technician conducting the respirator testing (by a CIH and/or advisory panel member).
- Author a report, including the work done by the advisory panel members and statistician, that the ISEA can submit to NIOSH to present our findings.

"Benchmark Data" were made available to respirator manufacturers by NIOSH (the National Institute for Occupational Safety and Health), and these data sets were provided to EH&S by ISEA. In addition to the above services, the benchmark data sets were analyzed by the statistician and expert panel, and comments provided to ISEA.

Section 2: EXECUTIVE SUMMARY

The goals of this project were to:

1) measure the variability in subject pass rates by conducting experimental studies of fit following the "Total Inward Leakage Requirements for Respirators" (TIL) protocol proposed by NIOSH for air purifying half-facepiece particulate filter respirators, and;

2) determine the probability that subjects wearing this type of respirator will attain fit factors ranging from 20-100. These goals were satisfied using data from an experimental study conducted with 35-subject panels incorporating multiple donnings and days (trials) for one filtering facepiece and one elastomeric respirator. Comparisons were made using similar analyses with a subset of benchmark datasets obtained by manufacturers from NIOSH.

Based on our completed work, we have reached the following conclusions:

1. Multiple donnings of a single respirator on each subject may be a more rigorous test than evaluating the fit of multiple respirators.

2. A panel with more than 35 subjects or multiple panels of 35 subjects would yield better information about respirator performance than a single 35-subject panel.

3. NIOSH should develop a consistent approach to selecting an appropriate respirator size, rather than relying on manufacturer instructions. We recommend the method used in this study, which allowed each subject to conduct, with assistance, a preliminary qualitative evaluation of each size before making a final selection.

4. The proposed NIOSH criteria are overly stringent and likely to exclude almost all filtering facepiece and 50% of elastomeric respirators from the marketplace. Approximately 25% of filtering facepiece and 80% of elastomeric respirators would be certified at a fit factor criterion of 20. A fit factor criterion of 10 (the assigned protection factor) would exclude 45% of FF and 10% of elastomeric respirators from the market. We suggest using a 75% pass criterion at or near a fit factor of 10, and dropping the cell criterion, would be a more reasonable approach.

5. The NIOSH benchmark dataset could have been more informative about between- and within-subject variance, and respirator pass rates, if a more realistic protocol for testing multi-sized respirators had been used. This dataset was also limited by its use of smaller panels (25 subjects) meeting the older Los Alamos criteria.

6. A bootstrap approach that draws on information from multiple panels would be the most appropriate method for assessing the probability that a respirator will fit a population of wearers, but is may not be economically feasible. We suggest NIOSH consider conducting additional tests of representative FF and elastomeric respirators with multiple trials, donnings, and panels, following the methodology used in this study. Results would lead to a better understanding of between- and within-subject variability and may suggest methods for simulating and predicting fit performance for the population of respirator wearers.

7. Elastomeric respirators may be more adjustable than filtering facepiece respirators, and thus more likely to achieve a consistent fit when a facepiece is donned multiple times.

8. Elastomeric respirators are more likely than filtering facepiece respirators to achieve a high level of fit on a population of wearers (even when an incorrect size is worn).

Section 3: Background Information

In October 2009, the National Institute for Occupational Safety and Health (NIOSH) proposed "Total Inward Leakage Requirements for Respirators" (TIL) rulemaking to address fit assessments for air-purifying half-facepiece particulate respirators (filtering facepiece and elastomeric) missing from current respirator certification regulations (42 CFR Part 84). When the current regulations were last promulgated in 1995, methods for measuring the fit of air-purifying respirators equipped with particulate filters had been developed but required further research. Since that time, an ambient aerosol - condensation particle counter method was approved by OSHA (29 CFR 1910.134) in 1998 and has been the focus of research by NIOSH and other investigators.

As described in the NIOSH Notice of Proposed Rulemaking, the goals of the "Total Inward Leakage Requirements for Respirators" are three-fold:

1. To ensure that a substantial proportion of employees will achieve an adequate fit, so employers do not have to purchase many different models to fit their workforce.
2. Increase the likelihood that substantial numbers of non-fit tested respirator users will be protected, when the respirator is worn properly.
3. Increase the likelihood that employees who are wearing respirators without a respirator program and fit testing will obtain "adequate fit and protection," although not at the same level as for fit tested individuals.

NIOSH states that the standard has been statistically designed to identify and pass with high accuracy (greater than 90% probability) those respirators that provide adequate TIL performance to the large majority of intended users (60-90%), while failing with near certainty (greater than 99% probability) those respirators that do not provide adequate TIL performance to a majority (50% or more) of intended users. An adequate TIL level is defined as 1%, which is equivalent to a fit factor of 100 – the level of fit testing performance specified by OSHA for these types of respirators.

NIOSH states that the "leading" respirator manufacturers (not defined) are likely to pass the proposed TIL criteria, based on its benchmark tests. The agency estimates that approximately 30% of the 101 respirator models included in the benchmark tests did not perform adequately to achieve a fit factor of 100 for a substantial number of the test subjects. NIOSH also predicts that "substantial numbers of workers may receive improved protection as a result of instituting TIL testing…, increasing the likelihood that workers without fit testing or training might have adequate TIL performance."

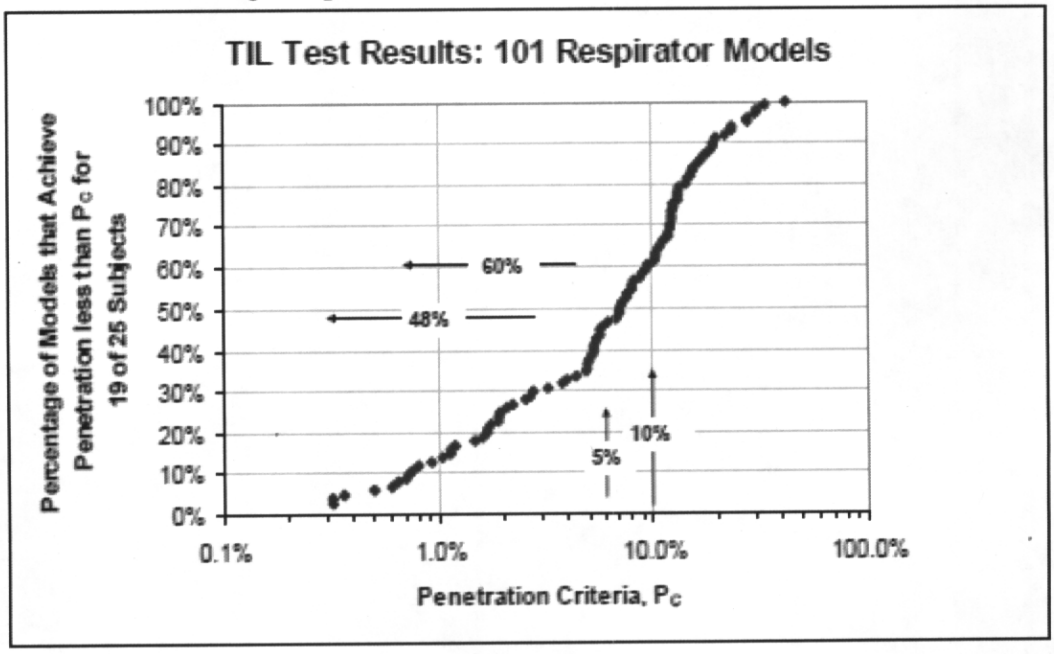
In a 2004 presentation by Roland Berry Ann, Chief of the NIOSH Respirator Branch, at a Workshop on Respiratory Protection for Infectious Agents, the TIL performance criterion was stated as not equivalent to the assigned protection factor (APF), but based on actual fit factor results. However, it was also noted that TIL certification will not be a substitute for OSHA-mandated fit testing for individuals, i.e. certification will not assure that a respirator will fit. A benchmarking study was described.

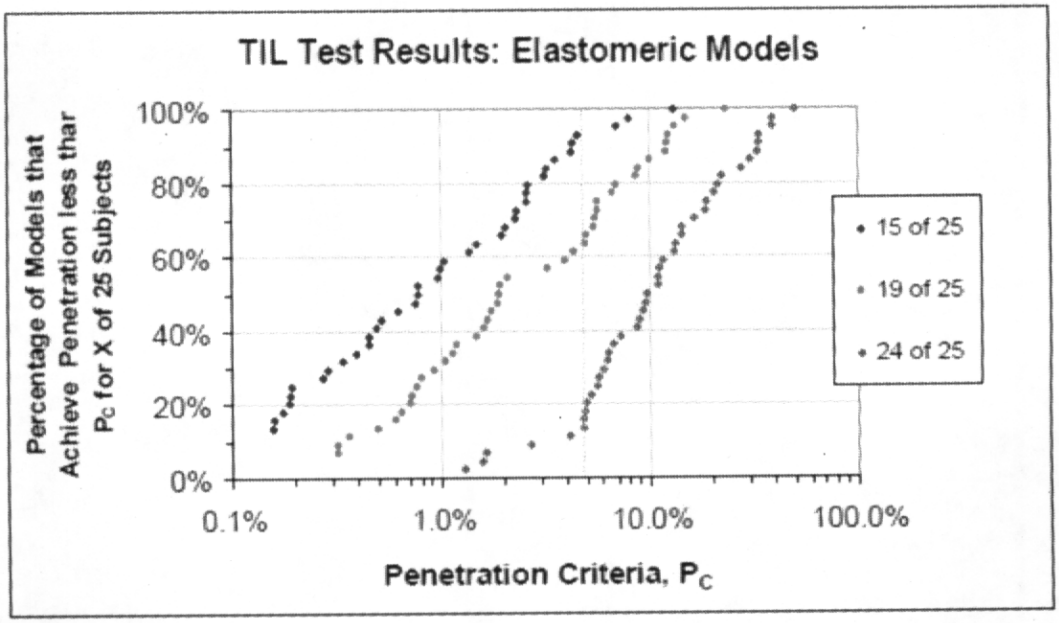
A 2007 presentation by NIOSH at the NIOSH/NPPTL Total Inward Leakage Public Meeting in Pittsburgh provides further insight into the TIL approach. Again, it was noted that the TIL would be not equivalent to the APF, but would be based on "actual fit factor results." The overall goal of the TIL criterion was described to be one that would ensure that a highly effective respirator would almost always pass and an ineffective model would almost always fail. A model that is > 80% effective should almost always pass the test and one that is less than 60% effective should almost always fail. Some variability is expected in certification testing; larger sample sizes will lead to greater certainty. NIOSH found that for a panel of 35 subjects, if the criterion requires that 25/35 (74%) of subjects achieve an acceptable fit (a TIL of 5%), a model that is 85% effective will fail 3% of tests and a model that is 55% effective will fail 98% of tests. For a panel of 50 subjects and a pass rate of 75% (37/50), a model that is 85% effective will fail 1% of tests and a model that is 55% effective will fail >99% of tests. Thus, NIOSH concludes that requiring a pass rate of 75% will yield optimal results for a TIL value of 5%. NIOSH proposed a 35-member panel with a pass rate of 26/35 (74%) with a pass criterion of $\leq 5\%$ (fit factor of 20).

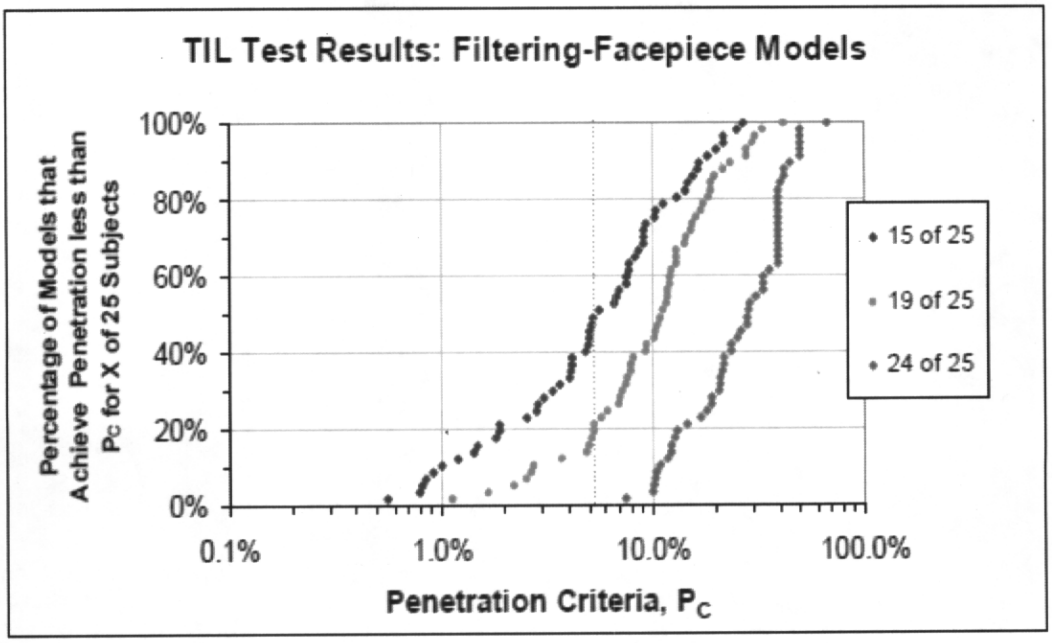
NIOSH conducted a benchmark study that included 57 filtering facepiece respirators, 43 elastomeric respirators and 1 quarter-mask respirator. They used a panel of 25 subjects; each subject performed 3 donnings for a total of 8250 fit factor points. NIOSH summarized the findings as follows:

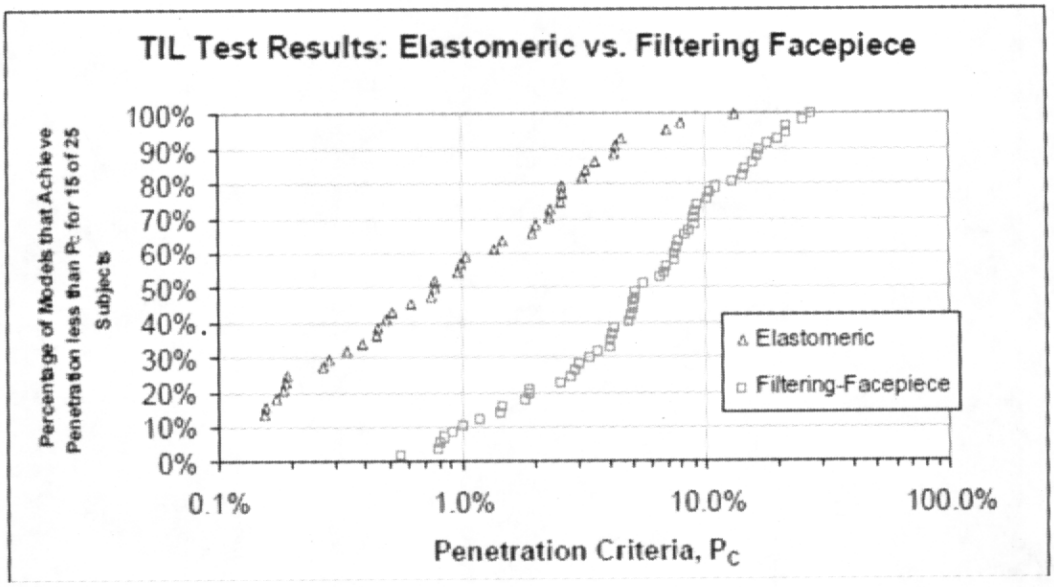
- There was wide variability in the fitting characteristics of half-mask respirators.
- Statistical differences were observed between elastomeric and filtering facepiece respirators.
- It should be easier for a potential wearer to obtain the OSHA-required fit factor wearing an elastomeric respirator.
- A TIL performance requirement is a necessary step in respirator certification.

The results are shown in the figures presented on the following two pages.






TIL Test Results: Filtering-Facepiece Models
Percentage of Models that Achieve Penetration less than Pc for X of 25 Subjects
100%
80%
60%
40%
20%
0%
0.1%
1.0%
10.0%
100.0%
Penetration Criteria, Pc
15 of 25
19 of 25
24 of 25


TIL Test Results: Elastomeric vs. Filtering Facepiece
Percentage of Models that Achieve Penetration less than Pc for 15 of 25 Subjects
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0.1%
1.0%
10.0%
100.0%
Penetration Criteria, Pc
Elastomeric
Filtering-Facepiece

Section 4: Results and Discussion:

Experimental Results

The following discussion addresses only those results most relevant to the specific goals of this project. A more detailed presentation of the experimental results can be found in Appendix B.

It should be noted that this study has some limitations. In particular, only one model of each type of respirator was included. In some cases, the transformed data did not pass the Wilk-Shapiro test for normality; however, visual examination indicated the data were not far from a normal distribution.

Goal 1: What is the variability in subject pass rate in the NIOSH TIL test for two models of half facepiece respirators (one filtering facepiece and one elastomeric) using different population panels?

(Note: One filtering-facepiece respirator and one elastomeric half-mask respirator were selected from a pool of good-fitting respirators identified in a study by Lawrence et al., Journal of Occupational and Environmental Hygiene, 3:465-474, 2006. Details of the selection process are given in Appendix A to this report.)

Respirator A (Filtering Facepiece)

This respirator was tested with one panel of 35 subjects for three different trials, which will be referred to as "Day 1", "Day 2" and "Day 3" throughout this report. Each day, the 35 subjects donned a single respirator three different times. A different respirator (for a total of 3 respirators) was used on each day. The results from Day 1 will be referred to as Panel 1. Two additional panels of 35 subjects were also tested with this respirator on only one day (Panels 2 and 3). On each day, the subject donned a single respirator three times.

Filtering Facepiece Respirator Tested on Three Days with Single Panel

The geometric mean fit factor for the data from three days combined was 30 (geometric standard deviation; GSD 2.5). The 5^{th} and 95^{th} percentile fit factors were 6 and 134. Accounting for facepiece (day) effect in an analysis of variance (ANOVA) model, there were significant differences in fit factors for the three facepieces (days) ($p=0.004$). Day 1 (GM 37; GSD 2.5) was significantly higher than Day 2 (27; 2.7) but did not significantly differ from Day 3 (30; 2.5) and Day 2 did not differ from Day 3. Accounting for multiple donnings, there was a significant difference in fit factors between the three donnings ($p<0.0001$). The first donning (36; 2) was significantly higher than the second (30; 2) and third donnings (27; 2). The second did not differ from the third. Variability was somewhat higher for the data examined by day (2.5-2.7) than by donning (2).

In all cases (all data; days and donnings considered separately), fit factors were more variable between subjects than within subjects.

On none of the three days did this group of subjects achieve all of the NIOSH TIL criteria. On Day 1 [Panel 1], 77% of subjects achieved a fit factor of 30 with at least one subject achieving this fit factor in each cell. On Day 2, 74% of subjects achieved the NIOSH criteria at a fit factor of 25. On Day 3, 74% of subjects achieved a fit factor of 25, but both subjects in Cell 1 failed to achieve this level of fit. The first point at which at least one subject in each cell passed on Day 3 was a fit factor of 15, achieved by 83% of the group.

On Day 1 [Panel 1], which had the lowest failure rate, all subjects in cells 1, 2, 5 and 10 failed all three tests at a fit factor of 100. On Day 2, subjects were most likely to fail in cells 2, 8 and 9; all subjects in these and cell 6 failed three tests at a fit factor of 100. On Day 3, which had the highest rate of failure, subjects in cells 1, 6, 9 and 10 were most likely to fail all three tests.

For the fit factor of 20 originally proposed by NIOSH, 89%, 77% and 77% of the panel achieved this level of fit on Days 1, 2 and 3 respectively. The assigned protection factor of 10 was achieved by more than 95% of the panel on all three days.

Filtering Facepiece Respirator Tested on Single Day with Three Panels

For all the data combined (Panels 1, 2 and 3), the GM fit factor was 37 (GSD 3). The 5^{th} and 95^{th} percentiles were 5 and 162. The GM (GSD) fit factors for Panels 1, 2 and 3 were 30 (2.5), 35 (3) and 40 (3), respectively. The 5^{th} and 95^{th} percentiles for Panels 1, 2 and 3 were 6, 127; 7, 199; 4, 158, respectively.

In all cases (all data combined; panels considered separately) within-subject variability was less than between-subject variability, which was highest for Panel 3. Within-subject variability did not differ much from day to day, between donnings or among panels. Between subject variability across days was slightly lower (ranging from 0.6 to 0.8) than between panels (range 0.6 to 1).

Comparing these results to the NIOSH benchmark study of filtering facepiece respirators, the same trend was observed with between-subject variability greater than within-subject variability. However, between-subject variability was higher for 15/17 of the benchmark filtering facepiece respirators (ranging from 1 to 4.4) than found in this study for panels, days or donnings. This may be due to differences in study design (number of subjects, panel distribution, methods for testing multi-size respirators), but no conclusion can be drawn without more evaluations of respirators under the proposed NIOSH protocol.

Within-subject variability for most (14/17) of the benchmark filtering facepiece respirators (range 0.2 to 1.0) was similar to that of the respirator in this study. The within-subject variability exceeded 1 for the remaining 3 benchmark respirators.

None of the three experimental panels achieved the NIOSH pass criteria with this respirator. For data from the three panels combined, the highest fit factor meeting the NIOSH criteria was 30 (76.2% of subjects). At this fit factor, subjects in cell 1 were most likely to fail (67%) and all subjects in cells 6 and 9 were successful. At a fit factor of 100 (the NIOSH criterion), no subjects in cells 1 and 2 were successful, 83% failed in cell 10, 75% failed in cell 3, and 74% failed in cell 4. The pass rate was highest in cell 6 (50%).

For Panel 1, 77% of subjects achieved a fit factor of 30 with at least one subject achieving this fit factor in each cell. The highest fit factor meeting the pass criteria achieved by Panels 2 and 3 was 25 (74.3%) and 40 (74.3%), respectively. At a fit factor of 100 (NIOSH criterion), the pass rates were 17%, 29% and 31% of subjects for panels 1, 2 and 3, respectively. For panel 1, all subjects failed in cells 1, 2, 5 and 10; for panel 2, in cells 1, 2, 3 and 9; for panel 3, in cells 1, 2 and 10.

Respirator B (Elastomeric)

The GM fit factor for the data combined across all days was 3641 (GSD 4). The 5^{th} and 95^{th} percentiles were 245 and 13,360. The GM fit factors were 3641 (4), 4023 (4) and 2981 (4) for days 1, 2 and 3, respectively. The 5^{th} and 95^{th} percentiles for days 1, 2 and 3 were 493, 14765; 148, 13360; and 245, 13360, respectively. There were no significant differences in fit factors between the three days or between the three donnings.

For the elastomeric respirator in this study, for days and donnings (except for day 1), the within-subject variability (range 0.8 to 1.6) was generally higher than between-subject variability (range 0.3 to 0.9). For Day 1, the two sources of variability were very similar (between = 0.9 and within = 0.8). Between-subject variability for the elastomeric respirator was similar among the three donnings (0.3-0.4), but less than that for the three days (0.6-0.9).

This differs from the filtering facepiece respirator, where between-subject variability was always greater than within-subject variability. Within-subject variability was higher for the elastomeric respirator (range 0.8 to 1.6) than for the filtering facepiece respirator (range 0.2 to 0.3) (for days and donnings). Perhaps there is some important difference between these two types of respirators in their design, which leads to larger differences in the way individuals don an elastomeric as compared to a filtering facepiece respirator.

For the two types of respirators, the between-subject variability across the three days (different facepieces) was very similar – ranging from 0.6 to 0.8 for the filtering facepiece and from 0.6 to 0.9 for the elastomeric. These results suggest that between-subject variability in this study is largely the result of differences among a manufacturer's facepieces.

Between-subject variability for this elastomeric respirator was much lower than for similar respirators (range 0.9 to 8) in the benchmark study. Unlike in this study, between-subject variability (range 0.5 to 8, with most greater than 1) was almost always (19/20) greater than within-subject variability in the benchmark tests of elastomeric respirators. Within-subject variability was also higher for elastomeric respirators in the benchmark tests (range 0.5 to 2.5). These differences may be the result of differences in the methods used; more tests of respirators under the proposed NIOSH protocol are needed before any conclusions can be drawn.

Respirator B met the NIOSH pass criteria on all three days; in all cases 94% of the panel achieved a fit factor of 100. At this fit factor level and combining all 3 days of data, 2 subjects failed in cell 7 and 1 subject failed in cells 3, 4, 8 and 10.

The highest fit factor achieved by 100% of subjects on Days 1, 2 and 3 was 60, 50 and 40, respectively. Single subjects in cells 3, 4, 7, 8 and 10 were most likely to fail all three repeated tests. The highest rate of failure occurred on Day 3 and the lowest on Day 1.

All subjects were able to achieve the fit factor of 20 originally proposed by NIOSH, as well as the assigned protection factor of 10.

It should be noted that this same respirator model was included in the NIOSH benchmark study, although NIOSH used a different approach by testing each size with a separate 25-member panel. In the NIOSH study, the geometric mean (GM) fit factor achieved for the three sizes ranged across an order of magnitude; the small size received a much lower GM fit factor than the medium or large sizes, which were very similar in fit performance. In our, the GM fit factor exceeded the best performance in the NIOSH benchmark study by 3 times.

The differences in performance of the elastomeric respirator between the NIOSH benchmark study and this project almost certainly result from the different approaches used for testing a respirator with multiple sizes. Because the NIOSH approach included subjects across the range of facial dimensions for each of the three sizes, many of the subjects received fit factors lower than would occur if subject had been given an opportunity to choose among the three respirator sizes, as occurred in the current study.

Many of the respirators (both filtering facepiece and elastomeric) tested in the NIOSH benchmark study were multiple sizes, each of which was evaluated with a separate panel of 25 subjects. The performance of these respirators would likely have been higher (better) and less variable if they had been evaluated with the proposed TIL protocol.

Goal 2: Which is less variable: A) three repeat donnings of a single half facepiece respirator or B) donning three different half facepiece respirators?

Respirator A (Filtering Facepiece)

A comparison of the within-subject variability for Day 1 (Facepiece 1) and Series A (Donning 1) shows that three repeat donnings of a single facepiece (0.2355) are less variable than donning three different respirator facepieces (0.3342).

Model Estimated Variability Parameters	Day 1 (Facepiece 1)	Series A (Donning 1)
Between Subject	0.6152	0.5670
Residual (Within Subject)	0.2355	0.3342

Respirator B (Elastomeric)

The results were similar for Respirator B – donning three different respirators is more variable (1.2243) than donning the same respirator three times (0.8204). Within-subject variability is higher for both of these circumstances than observed for Respirator A.

Model Estimated Variability Parameters	Day 1 (Facepiece 1)	Series A (Donning 1)
Between Subject	0.8617	0.4528
Residual (Within Subject)	0.8204	1.2243

Predicting Fit Using Bootstrap Analysis

A bootstrap analysis was performed using the experimental data from the three different panels of 35 subjects donning a Respirator A facepiece three times on a single day (Panels 1, 2 and 3; see Appendix C for more details). The results are discussed in Goal 3 (below).

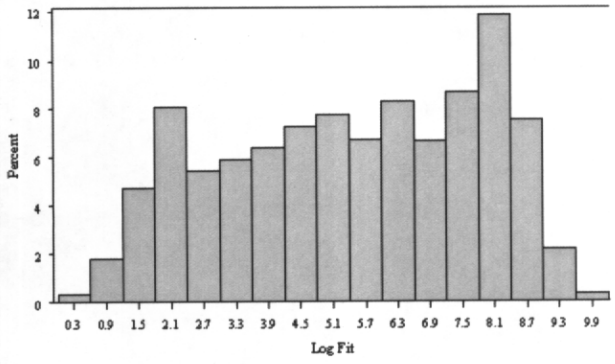
Additionally, the NIOSH benchmark data from 17 filtering facepiece models were combined, creating a dataset of 425 data points (subjects). A second dataset of 500 subjects was created by combining the NIOSH benchmark data for 20 elastomeric respirators. One-thousand datasets of 35 subjects were generated from each of these datasets, using a bootstrap technique, from which point estimates and confidence intervals were calculated using an analysis of variance model (Goals 4 and 5 below). We conducted our analyses on a subset (37 of 80) of the benchmark datasets, as provided by ISEA members to us.

It should also be kept in mind that the NIOSH study utilized 25-member panels which appear to meet the Los Alamos facial dimensions, rather than the newer NIOSH bivariate panel (see Appendix C). The number of subjects used in the NIOSH benchmark tests (25) was smaller than that required by the NIOSH protocol (35). In addition, each of the datasets includes separate panels for each size of a multiple-size respirator, which differs from the requirements of the proposed TIL protocol. The latter requires identifying a single size facepiece for each subject, following instructions provided by the manufacturer. A different size may be tried if the subject fails all three tests with their first size selection.

In many cases, the individual datasets included in the benchmark tests did not meet the Shapiro Wilk test for normality when examining the data in the original scale or after applying a lognormal transformation. The combined datasets for filtering facepiece and elastomeric respirators also did not satisfy the test for normality in either the original or transformed scales, although the histograms of the combined data appeared to be normally distributed (see graphs at top of following page). Despite the identified limitations, the bootstrap analyses were conducted (with log-transformed fit factors).

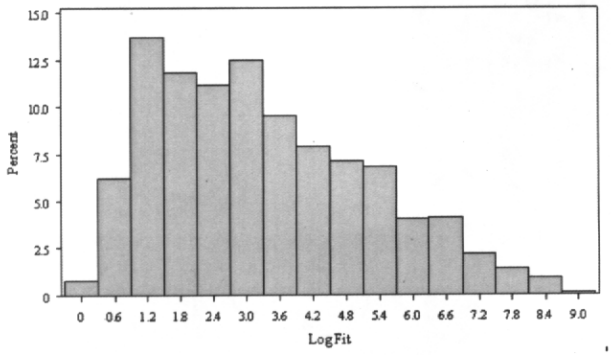
Elastomeric Respirators

Log Transformed



Filtering Facepiece Respirators

Log Transformed



Goal 3: What fraction of the experimental subjects wearing a filtering facepiece respirator could be expected to achieve, 95% of the time, fit factors ranging from 20 to 100?

The results of a bootstrap analysis of our experimental data indicate that 98.2% of users (95% confidence interval 97.7 to 98.6%) will achieve a fit factor of 10 for 95% of the times they don the respirator. Sixty-one percent (95% CI 59 to 64%) will achieve a fit factor of 15 on 95% of donnings. A very small percent (0.05%) of users (95% CI -0.05 to 0.15%) will achieve a fit factor of 100 on 95% of donnings.

Fit Factor	% of Times the Respirator is Donned	% Users	Lower 95% Confidence Limit	Upper 95% Confidence Limit
5	95	99.98	99.95	1.0002
10	**95**	**98.15**	**97.71**	**98.60**
15	95	61.47	59.36	63.57
20	95	15.69	14.18	17.20
25	95	2.53	1.95	3.10
30	95	0.14	0.14	0.41
40	95	0.05	-0.05	0.15
50	95	0.05	-0.05	0.15
60	95	0.05	-0.05	0.15
75	95	0.05	-0.05	0.15
100	95	0.05	-0.05	0.15

Goal 4: What fraction of a panel donning filtering facepiece respirators tested in the NIOSH benchmark study could be expected to achieve, 95% of the time, fit factors ranging from 20 to 100?

Results indicate that 86% of users (95% CI 85 to 87%) would achieve a fit factor of 5 for 95% of times a filtering facepiece respirator is donned. Twenty-six percent of users (95% CI 25 to 28%) would achieve a fit factor of 10 for 95% of donnings. No one would achieve a fit factor greater than 40 for this population of filtering facepiece respirators.

Bootstrap Analysis Results for Filtering Facepiece Respirator Datasets from NIOSH Benchmark Study

Fit Factor	% of Times the Respirator is Donned	% Users	Lower 95% Confidence Limit	Upper 95% Confidence Limit
5	95	86.22	84.99	87.44
10	95	26.39	24.71	28.08
15	95	5.62	4.90	6.33
20	95	1.22	0.95	1.49
25	95	0.30	0.20	0.39
30	95	0.08	0.04	0.12
40	95	0.01	0	0.01
50	95	0	-0	0
60	95	0	-0	0
75	95	0	-0	0
100	95	0	-0	0

For filtering facepiece respirators included in the benchmark study, most of the respirators were not able to pass the NIOSH goals at fit factors of 20 or 100. All three sizes of one folding respirator were able to achieve the NIOSH criteria for a fit factor of 20, but not for a fit factor of 100. Only two respirator models (one cup-shape in a single size and one unknown) were able to achieve the NIOSH criteria at fit factors of 20 and 100. One of these (single size cup-shape) was able to achieve all of the NIOSH criteria – 75% of the panel received a fit factor of 100 and at least one subject in each cell received a fit factor of 100 (see Appendix C for more details).

Note: It should be kept in mind that the NIOSH approach to testing each size of a multiple-sized respirator with a separate panel will lead to lower and more variable fit factors than would occur if the proposed TIL protocol had been followed (i.e. the "best fitting" size selected from the range of sizes available). Failure to achieve the pass rate will likely be higher in the benchmark dataset, because many subjects wore a respirator that was either too large or too small.

Goal 5: What fraction of a panel donning elastomeric respirators tested in the NIOSH benchmark study could be expected to achieve, 95% of the time, fit factors ranging from 20-100?

Results indicate that 99% of subjects (95% CI 98.8 to 99.4%) would achieve a fit factor of 10 on 95% of donnings; 94% of subjects (95% CI 93.2 to 95.2%) would achieve a fit factor of 15 for 95% of donnings. A fit factor of 25 would be achieved by 75% (95% CI 73.2 to 77.1%) of subjects for 95% of donnings. A small fraction of people – 4% (95% CI 3.5 to 4.9%) – would achieve a fit factor of 100 for 95% of the times wearing an elastomeric respirator.

Bootstrap Analysis Results for Elastomeric Respirator Datasets from NIOSH Benchmark Study

Fit Factor	% of Times Respirator is Donned	% Users	Lower 95% Confidence Limit	Upper 95% Confidence Limit
5	95	99.95	99.89	100
10	95	99.07	98.76	99.38
15	95	94.19	93.20	95.18
20	95	85.83	84.31	87.36
25	95	75.19	73.25	77.12
30	95	64.15	61.98	66.32
40	95	44.55	42.31	46.79
50	95	30.18	28.14	32.22
60	95	20.31	18.58	22.03
75	95	11.21	9.96	12.45
100	95	4.18	3.50	4.85

Nine of the twenty respirator models passed all of the NIOSH TIL criteria. For models where sizing is known, one multiple size respirator passed the criteria for both sizes (ML and S). For two multi-size respirators, 1/3 or 2/3 passed the criteria (M or S & M, respectively). One of two single-size respirators passed the TIL criteria (see Appendix C).

If the TIL pass rate were set at 5% (fit factor of 20), an additional seven respirator models would have achieved all of the NIOSH criteria. For respirators where size characteristics are known, these passing respirators include additional large- and medium-sized facepieces in the models that performed well for a TIL pass rate of 1% (see Appendix C).

Section 5: Conclusions

Filtering Facepiece Respirators

Geometric mean (GM) fit factors for the filtering facepiece respirator (FFR) in this study were slightly higher than that found by Lawrence (2006) (26.4) but similar in range for the three different days (trials) (27-37), three different donnings (27-36) and three different panels (35-40). The geometric standard deviation (GSD) was also similar for trials, donnings and panels (2-3).

These values are within the range of GM fit factors for the 17 filtering facepiece respirators for which we received NIOSH benchmark data (5 to 169); GSDs for the benchmark datasets exhibited a wider range (2-10). The latter probably occurred because NIOSH tested each size of a multi-size respirator with a separate panel.

Within- and between-subject variability

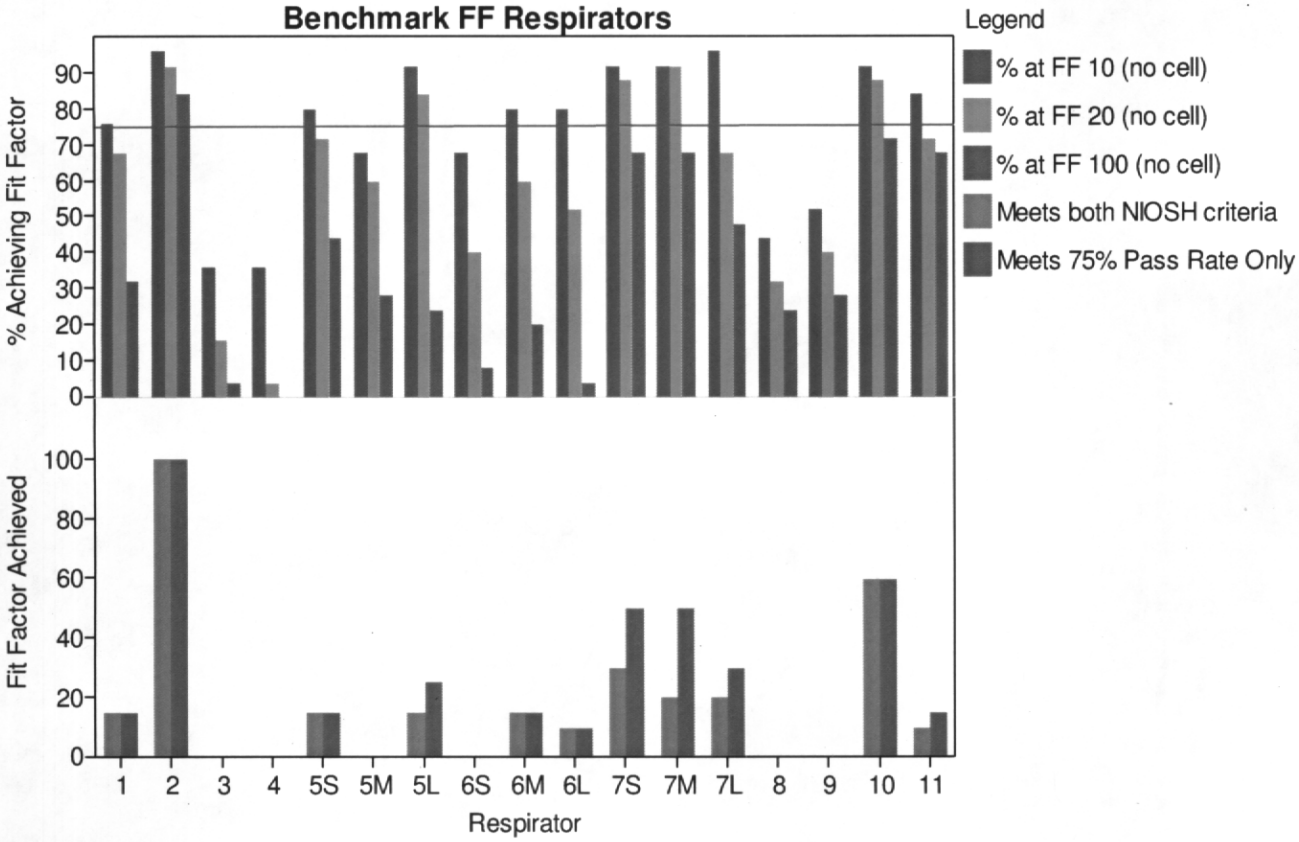
Donning a respirator three different times on a single day was slightly more variable than donning three different respirators (within-subject variance of 0.3 vs. 0.2). The variability in individual fit across three different panels ranged between these (0.2-0.3). Due to the observed within-subject variability, the most rigorous approach would involve testing the fit of a single respirator multiple times on each panel subject. The variability of fit from one subject to the next was greater across the three panels (range 0.6-1.0) than for three facepieces (0.6-0.8) or three donnings (0.6). The large between-subject variability suggests that either a larger panel of subjects or multiple panels should be used to assess a respirator's fit.

Variability in fit from subject to subject was considerably larger for all filtering facepieces evaluated by NIOSH in its benchmark study (range 4.3 – 4.4; average 2.0) than found in this study (0.6 - 1.0) This was probably due to the approach used to evaluate respirators with multiple sizes (a separate panel of subjects for each size). This suggests that NIOSH should develop a consistent approach to selecting an appropriate respirator size for each subject, rather than relying on manufacturer instructions. We recommend the method used in this study, which allowed each subject to conduct, with assistance, a preliminary qualitative evaluation of each size before making a final selection.
Variability in fit experienced by an individual across three donnings in the NIOSH benchmark study was also larger (range 0.1-1.6; average 0.6) than found in this study (0.2-0.3). Again, this may have been due to greater variability resulting from the approach used to separately evaluate each respirator size.

Pass Rates

In this study, neither the single panel of subjects tested on three different days (trials) nor the three separate panels each tested on a single day (trial) achieved the NIOSH TIL criteria for this FFR. The maximum fit factor achieved by 74% of the panel and at least one subject in each cell ranged from 15-30 on the three days (trials) and from 15-40 for the three panels. The lower fit factors (15) resulted when both subjects in cell 1 failed, although 75% of the panel passed. The pass rates would have ranged from 25-40 if the cell criterion were not part of the NIOSH protocol.

Ignoring the cell criterion, pass rates for a fit factor of 100 ranged from 11-20% on the three days and 17-31% for the three panels. Pass rates for a fit factor of 20 (originally proposed by NIOSH) ranged from 77-89% on the three days and from 80-89% for the three panels. This performance was similar to that of the better performing FFR in the benchmark study (see graph below).

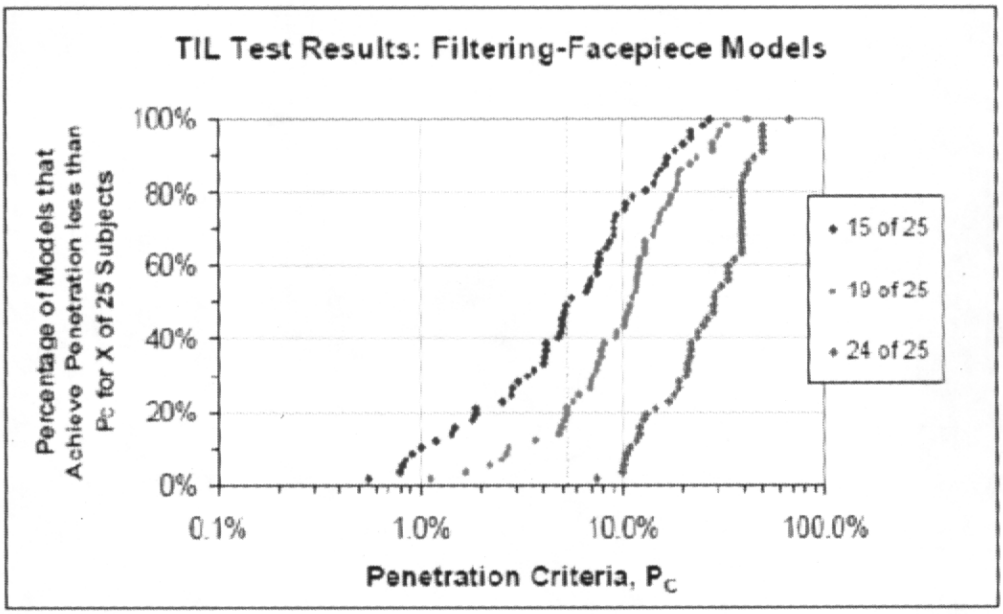


Two single-size filtering facepiece respirators in the benchmark datasets (#3 and 4) failed to fit nearly all of the subjects at all fit factors (10-100), while two additional single-size respirators (#8 and 9) had very poor performance, with fewer than 30% of subjects achieving a fit factor of 100 (see graph). Only one respirator (#2) passed both NIOSH criteria. Eleven of the seventeen respirators achieved a fit factor of 10 with more than 75% of panel subjects; five of these achieved a fit factor of 20 with more than 75% of subjects.

It is important to note that the benchmark datasets include three triple-size respirators, and thus nine single size respirators tested with presumably separate panels (we noted possible overlap in subjects from one panel to the next, but did not determine the extent of any overlap). One of these respirators (#7), however, demonstrated relatively good performance at all sizes in comparison to the other two (#5 and 6). In general, the largest size in each of the three multi-size respirators experienced the steepest drop in pass rate across the range of fit factors (10-100).

Pass Rate at Assigned Protection Factor of 10

The assigned protection factor of 10 was achieved for the experimental FFR by 97-100% of subjects on the three days and 94-97% of subjects for the three panels. The bootstrap results also indicate that almost all subjects (98.2%) will receive the level of fit expected for this respirator class 95% of the time when they don this respirator. However, the bootstrap results for the filtering facepiece respirators tested in the NIOSH benchmark study suggest a much lower level of performance – only 26% of users would achieve a fit factor of 10 for 95% of donnings. Again, it is important to note that several multi-size respirators are included in this dataset; nine of the seventeen respirators were single sizes tested with a broader range of facial sizes than if the NIOSH proposed protocol had been followed.



Experimental and benchmark results suggest that the proposed NIOSH criteria are overly stringent and likely to exclude almost all filtering facepiece respirators from the marketplace, which is supported by data presented by NIOSH (see graph above). This would be true even if the cell criterion were dropped. If NIOSH were to return to its earlier proposal that 75% of subjects must achieve a fit factor of 20, only 25% (2/8) of the single-size respirators would pass certification. This is similar to the proportion of all benchmark filtering facepiece respirators that achieved this level of fit (see graph above). A fit factor similar to the assigned protection factor, however, would exclude approximately 45% of all FFRs tested in the benchmark study. This seems a more reasonable expectation, given that this dataset includes tests for single sizes of multi-size respirators. We note that the benchmark dataset, as a whole, would have been more informative if a more realistic protocol for testing multi-sized respirators had been used.

A bootstrap approach would be the most appropriate method for assessing the probability that a respirator would fit a population of wearers, but is probably not economically feasible because multiple panels would be required. We are unable too predict between- and within-subject variability for other half-facepiece respirators, since we tested only one FFR in our experimient with multiple panels, and the NIOSH dataset has shortcomings that preclude useful conclusions. We suggest NIOSH consider conducting additional tests of representative FF and elastomeric respirators with multiple trials, donnings and panels, following the methodology used in this study. Results would lead to a better understanding of between- and within-subject variability, as well as methods for simulating fit performance across a large population of subjects.

Comparing Filtering Facepiece and Elastomeric Respirator Performance

Lawrence et al. (2006) measured a GM fit factor of 73.1 for the elastomeric respirator tested in this study. This study found GM fit factors ranging from 2981-4023 on the three days and from 3294-3641 for the three donnings, with a GSD of 4 for all days and donnings. The Lawrence data may have been artificially restricted by the TSI instrument, which reports all fit factors greater than 200 as 200, when the N95-Companion is used.

Between- and within subject variability

In contrast to the FFR, variability within subjects was greater than between subjects, with the exception of the first trial (day 1). As with the FFR, three donnings of a single respirator was more variable (within-subject variability = 1.2-1.6) than donning three different facepieces (0.8-1.1); this supports our earlier conclusion that a test protocol that includes multiple donnings would be a more stringent assessment of a respirator's fit.

Similar to the FFR, variability across subjects wearing three different elastomeric facepieces ranged from 0.6 to 0.9 and was greater than variability across subjects donning a single elastomeric facepiece three times. However, the latter variability was less (0.3-0.5) than exhibited for multiple donnings of the FFR (0.6). This suggests that there is some inherent variance encountered by any group of wearers donning multiple facepieces, while there may be some important differences in the way a group of wearers dons an FFR multiple times in comparison to multiple donnings of an elastomeric respirator. Elastomeric respirators tend to be more adjustable than filtering facepiece respirators, and thus more likely to achieve a consistent level of fit.

In contrast to the experimental elastomeric respirator, between-subject variance was generally greater than within-subject variance in the benchmark elastomeric tests. The range in within-subject variance was similar, suggesting that experienced subjects generally don any elastomeric respirator in a similar manner. The variability between subjects was much greater in the benchmark elastomerics than for the experimental respirator, probably due to differences in methods used to test different respirator sizes. The benchmark data for the elastomeric respirator evaluated in this study illustrate the important differences between the approaches (see table below). Between-subject variability for the medium-size respirator was three times higher than for the small or large sizes; variance in the latter respirators was

similar to that observed for the three different days in the experimental work (0.6-0.9). This may be simply a "panel effect", or it may reflect some important difference in the way the medium size fits a range of facial sizes.

Comparison of Variance for an Elastomeric Respirator – Experimental vs. Benchmark Data

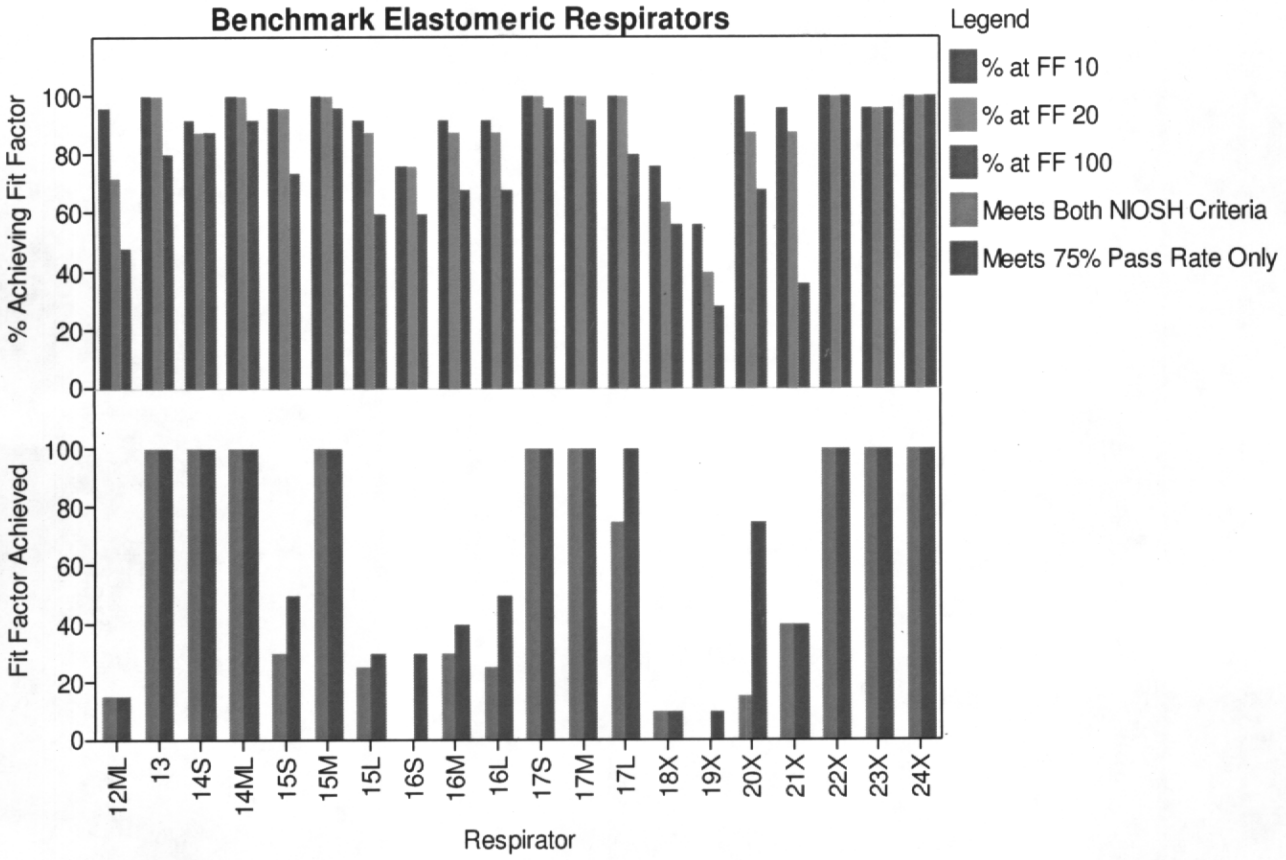
Benchmark Study	**Small**	**Medium**	**Large**
Between-subject	1.0	3.1	0.9
Within-subject	2.5	1.8	0.8
Experimental Study	**Trial 1**	**Trial 2**	**Trial 3**
Between-subject	0.9	0.7	0.6
Within-subject	0.8	1.2	1.1

The within-subject variability for the small and medium respirators was more than 2 times greater (2.5 and 1.8, respectively) than that of the large respirator (0.8). The latter was similar to the within-subject variability across days (trials) in the experimental study (0.8-1.2). It is not clear why one size of respirator would fit more consistently than other, suggesting that the differences are probably due to differences in subject populations among the three panels. Additional panel tests of this respirator using the experimental study protocol might resolve this question.

Pass Rates

Unlike the FFR, the elastomeric respirator met both of the NIOSH pass criteria on all three days, with 94% of the panel achieving a fit factor of 100. Pass rates for fit factors of 10, 20 and 100 ranged from 94-100% on all three days; at least one subject in every cell achieved the fit factor goal. The highest fit factor achieved by 100% of subjects ranged from 40-60 on the three days.

Nine of the twenty benchmark respirators passed both of the NIOSH TIL criteria; dropping the cell criterion would not have changed this outcome. Two respirators were not able to achieve the NIOSH criterion at a fit factor of 10. Performance of the experimental elastomeric respirator at the small and medium sizes was among the best observed; the large size did not meet both NIOSH criteria. Omitting the cell criterion, for all but one of these respirators more than 75% of the panel could achieve a fit factor of 10 and for all but two respirators a fit factor of 20 could be achieved. Only ten of the twenty respirators were able to achieve a fit factor of 100 by more than 75% of the panel.



NOTE: X indicates that the model and size were not known.

Without several panels, it is not possible to perform bootstrap analyses for the experimental respirator. Bootstrap results for the benchmark elastomeric respirators indicate that 99% of subjects (95% CI = 98.8-99.4%) would achieve a fit factor of 10 on 95% of donnings; 94% of subjects (CI 93.2-95.2%) would achieve a fit factor of 15 for 95% of donnings.

Our analyses of these benchmark data support the NIOSH conclusion that elastomeric respirators are more likely than FFRs to achieve a high level of fit on a population of respirator wearers (even those for which the size is incorrect). For the 11 respirators where model and size are known, it appears that two of the multi-size respirators are likely to pass the NIOSH protocol and two are likely to fail. One of the single-size respirators is likely to pass and one to fail. Dropping the cell criterion does not change this conclusion.

These analyses suggest, as with the FFRs, that a fit factor of 100 is too stringent for the elastomeric respirators and would lead to approximately 50% failure in certification. A fit factor closer to the assigned protection factor would be more appropriate and would lead to certification failure for 10-20% of applicants.

Section 6: Methods

Equipment

Fit testing was carried out in a 10x10x9-foot fit test chamber located at 3M Company's Maplewood, Minnesota campus. The chamber was large enough to permit two fit tests to be performed using two independent sets of fit test instrumentation. A salt (NaCl) challenge aerosol was generated using a Model 9306 6-Jet Atomizer (TSI Inc., Shoreview, MN) filled with a 2% salt solution. The chamber ventilation system used a HEPA filter to provide particle-free supply air and isolate the chamber from outside aerosols. Challenge aerosol concentrations were maintained between 1500 and 3000 particles/cm3 in the size range near 40 nanometers used by the fit test instrumentation.

Fit factor measurements were made using a PortaCount® Plus Model 8020 Respirator Fit Tester paired to an N95-Companion™ Model 8095 (TSI Inc.).

The instrumentation was controlled and data was collected by proprietary software version 4.0.42 created by the 3M Company running on two separate microcomputers using Windows XP.

The use of a chamber, aerosol generator and special software was necessary to allow the instrumentation to accurately measure high fit factors. Typical challenge aerosol concentrations and sizes that occur naturally in room air (< 300 particles/cc ranging from approximately 20 – 60 nm) limit fit factor measurements to a few hundred. The commercial fit test software provided by the PortaCount manufacturer has a programmed upper limit of 200 when the N95-Companion is used. Given the typical challenge concentration of 2250 particles/cc observed during this study and the 30-second mask sample, the system was capable of displaying an overall fit factor of 112,500 (equivalent to 1 particle detected during each of the seven 50cc mask samples). A fit factor that high would have a margin of error of ± 38% (100/sqrt(7)). For this study, the highest overall fit factor recorded for any FFR was 441, yielding a worst-case margin of error of ± 2.4%. For elastomeric respirators the highest overall fit factor was 17456, corresponding to a margin of error of ± 15%. The margin of error at the pass/fail fit factor of 100 was ± 1%.

All instrumentation had been serviced and calibrated within the last year per manufacturer's recommendation. Instruments were tested each morning prior to the start of fit testing by performing and passing the manufacturer-recommended daily checks.

Respirator Models

Two respirator models were selected by the advisory panel using data from a study by Lawrence et al. (Journal of Occupational and Environmental Hygiene, 3:465-474, 2006). One filtering facepiece respirator (FFR) and one elastomeric respirator model by two different respirator manufacturers were selected. Details of the selection process are included in Appendix A.

Fit tests were performed on the filtering facepiece respirators and elastomeric half mask respirators. A sampling port was installed on each FFR using sampling probes and push nuts purchased from TSI Inc. (Model 8095-N95R Refill Kit). The FFR tested did not have an exhalation valve, so the ports were installed at the center-front of the respirator such that the sample was drawn from the wearer's breathing zone. A new FFR was used for each fit test session and discarded afterwards. FFRs were randomly selected from a pool of 200 respirators purchased and probed prior to inception of the study.

New elastomeric half mask respirators were ported using the same method as the FFRs. The use of this porting method for elastomeric respirators is not mentioned by the sample port manufacturer, but works quite well for many elastomeric respirator models.

The elastomeric respirator used in this study was available in three sizes; small, medium and large. Five respirators of each size were ported and labeled S1 – S5, M1 – M5 and L1 – L5. Respirators within each size range were rotated to randomize use.

Each elastomeric respirator was equipped with a pair of N95 filters installed into a filter holder and screwed onto the facepiece per the respirator manufacturer's instruction. To make sure there were no integrity problems with the respirator such as leaks due to improperly seated filters, filter holders or faulty exhalation valves, each respirator was put through an integrity test after assembly. The test involved using a PortaCount/N95-Companion to make sure a fit factor of at least 1000 could be achieved. With the instrument in count mode displaying aerosol concentration, the inspector makes note of the chamber's challenge concentration and then attaches the sample port to the respirator. By holding the respirator tight to her/his face with both hands and breathing normally, the inspector can observe the concentration inside the respirator quickly drop. When the inside concentration drops below 1/1000 of the challenge concentration, and remains there for several seconds, it means the respirator passes the integrity test. This test takes about 60 seconds per respirator to perform. Respirators were tested prior to initial use and again if disassembled for any reason. To avoid introducing leaks, respirators were not taken apart during the study. The same pair of N95 filters remained installed throughout testing. Respirators were sanitized between fit test subjects using 3M 504/07065 Respirator Cleaning Wipes.

Fit test procedures

Procedures common to all experiments

Subjects were required to sign a consent form and have their facial dimensions recorded previous to the first fit test session. Immediately before each session, subjects completed a medical questionnaire and certified that they had not smoked or eaten for at least 30 minutes.

At the start of each session, the subject was handed a ported respirator and asked to don it according to the manufacturer's printed instruction posted on the wall. That instruction included guidance on donning the respirator and performing a user seal check. A mirror was provided. This study was designed to fit test properly donned respirators, not to test the subjects' ability to don the respirator without assistance. Thus, the researcher watched closely and provided verbal assistance as needed to make sure the subject donned the respirator properly and performed the user seal check. This part of the procedure is slightly different for the filtering facepiece respirators (FFR) vs. the elastomeric

respirators, because the FFR model was available in only one size and the elastomeric respirator model had 3 sizes. See the details described for each separate experiment below.

After the respirator was properly donned and the subject indicated a successful seal check, a 5-minute 'comfort assessment period' commenced, as measured with a digital timer. The subject was allowed to adjust the respirator during this period but instructed not to do so once the fit test began.

When the timer indicated the end of the 5-minute period, the subject was asked to enter the fit test chamber, connect the respirator to the instrument sample tube and indicate readiness. At that point the researcher initiated the fit test software program which automatically prompts the subject through the required exercise protocol via prerecorded verbal commands, and records the data.

After the first fit test was completed, the test subject exited the fit test chamber and doffed the respirator. After a period of at least one minute, the subject donned the same respirator and performed the user seal check (with researcher assistance if needed) and then re-entered the fit test chamber to begin the second fit test of that session.

After the second fit test was completed, the test subject exited the fit test chamber, doffed the respirator, and then donned the same respirator again after at least one minute, exactly as was done after the first fit test.

After the third fit test, the subject exited the chamber, doffed the respirator and handed it to the researcher. The subject was then excused and that session was complete.

The exercise protocol used was the 8-exercise protocol recommended in the NIOSH TIL Proposal.

- Normal breathing
- Deep breathing
- Head side-to-side (pausing for 2 breaths at each extreme)
- Head up and down (pausing for 2 breaths at each extreme)
- Talking out loud (reading the Rainbow Passage)
- Reaching floor to ceiling (pausing for 2 breaths at each extreme)
- Grimace (for 15 seconds, then normal breathing for balance of exercise)
- Normal Breathing

The NIOSH TIL Proposal references OSHA 29CFR1910.134 Appendix A, Part I..A.14(b) where exercises of one minute are called out. This conflicts with the NIOSH draft procedure RCT-APR-STP-0068 supplied along with the proposal, where 30-second exercises are specified (paragraph 5.8). Neither document mentions the mask sample time. In fact, an exercise as short as 30 seconds is not possible with the PortaCount/N95-Companion because of the sampling and purging sequence required. For this study a 66-second exercise was used. Each 66-second exercise consisted of a 6-second ambient purge, 15-second ambient sample, 15-second mask purge, and finally a 30-second mask sample. Fit factors were computed using the average ambient concentration measured before and after each mask sample. During the grimace exercise, subjects were required to grimace for 15 seconds and then breathe normally for the remaining 51 seconds of that exercise.

Data from the grimace exercise was not used in the TIL calculation per the NIOSH TIL Proposal. This is consistent with the OSHA aerosol QNFT fit test protocols where the special grimace exercise is intended to break the face seal in an effort to determine if the respirator can reseat itself properly before the next exercise. Any leakage measured during the grimace is ignored because it could adversely bias the overall test result.

Per the NIOSH TIL Proposal, the fit test result had to equal or exceed a fit factor of 100 ($\leq$ 1% leakage) to pass. All fit tests were carried out to completion regardless of the leakage because part of this study required analyzing the numerical leakage data from both passed and failed fit tests. The NIOSH TIL Proposal is only concerned with pass vs. fail, which would allow for early termination of fit tests that start out poorly and are certain to fail.

Experiment 1A: Filtering Facepiece Respirator A

There were a total of 35 subjects selected from a larger pool to represent the panel required by the NIOSH TIL proposal (ref). Most subjects had previous experience donning FFRs. Each subject was scheduled for 3 fit test sessions consisting of 3 fit tests each for a total of 35 x 3 x 3 = 315 fit tests.

The same manufacturer, model and size FFR was used for all subjects. That particular model is offered in only one size.

The procedure presented above under 'Procedures common to all experiments' was conducted. After each fit test session was completed, the FFR was labeled to identify which fit tests it was used for, and then stored. FFRs were discarded after the study ended and they were no longer needed.

Experiment 2A: Filtering Facepiece Respirator A

There were a total of 70 subjects selected from a larger pool to represent the panel required by the NIOSH TIL proposal. Most subjects had previous experience donning FFRs. Each subject was scheduled for 1 fit test session consisting of 3 fit tests for a total of 70 x 1 x 3 = 210 fit tests.

The same manufacturer, model and size FFR was used for all subjects. That particular model is offered in only one size. It is the identical FFR used in Experiment 1.

The procedure presented above under 'Procedures common to all experiments' was conducted. After each fit test session was completed, the FFR was labeled to identify which fit tests it was used for, and then stored. FFRs were discarded after the study ended and they were no longer needed.

Experiment 1B: Elastomeric Half Mask Respirator B

There were a total of 35 subjects selected from a larger pool to represent the panel required by the NIOSH TIL proposal (ref). Most subjects had previous experience donning respirators. Each subject was scheduled for 3 fit test sessions consisting of 3 fit tests each for a total of 35 x 3 x 3 = 315 fit tests.

The elastomeric half mask respirator was available in 3 sizes; small, medium and large. The NIOSH TIL Proposal requires the respirator manufacturer to specify the face size or sizes that the respirator is intended to fit in the user instruction. This information was not available at the time of this study so an alternative method of size selection was devised. The team decided to use the initial sizing method similar to that specified in OSHA 29CFR1910.134 Appendix A, Part I.A.4, where the subject is shown all available sizes and is instructed to hold each one up to her/his face and choose the one that seems to fit best. The choice is based on a preliminary user seal check and the subject's perception of comfort. Researchers coached subjects on how to make their choice, but did not influence the size decision.

The chosen size respirator was then used for all 9 subsequent fit tests unless a pass (FF >= 100) could not be achieved during the first 3 fit tests. If all of the first 3 fit tests failed, the subject was to be instructed to choose another size from the 2 remaining sizes. If all 3 of the fit tests were to fail for that second size, then the subject must use the last remaining size from then on. For this study, all subjects achieved at least one pass during the first 3 fit tests using the first selected size, so it was not necessary to have any subjects choose another size. This process is detailed in Figure 1 at the end of this report, "Respirator Sizing Decision Logic/Flow Chart for Multi-size Respirator Models".

After initial size selection, the subject was handed a ported respirator of the selected size and asked to don it according to the manufacturer's printed instruction posted on the wall.

The procedure presented above under 'Procedures common to all experiments' was conducted. When the subject exited the chamber between fit tests the adjustable straps of the elastomeric respirator were loosened to force readjustment during the next donning.

At the completion of each fit test session, the respirator was sanitized, the straps were loosened and the respirator was returned to the pool for later use.

Subject Pool

A pool of approximately 250 subjects were created from 3M employees who had:

- been screened to ensure their facial dimensions meet the NIOSH bivariate and PCA panel requirements;
- given written consent;
- received required medical screening;
- received initial training in respirator wear, and;
- are distributed across all ten cells of the NIOSH-NPPTL Bivariate Test Panel.

Subject Panels

For each respirator model, a panel of 35 subjects were randomly selected from the subject pool, ensuring that they meet the criteria for a NIOSH-NPPTL bivariate test panel.

Statistical Analyses

The recorded overall fit factor was compared to the harmonic mean of the seven exercise fit factors. Minor differences were observed between the two final fit factors for a small number of subjects, likely due to rounding. The recorded values were used in all analyses.

Summary statistics of fit factors including means, standard deviations, minimums, 5^{th}, 25^{th}, 50^{th} (medians), 75^{th}, and 95^{th} percentiles, and maximums are presented on both the natural log-transformed and re-transformed scales. Data outliers were determined through examination of scatter plots. No more than two data points were excluded from any one dataset. Histograms and Shapiro-Wilk normality tests were used to evaluate the distribution of the datasets.

Analysis of variance (ANOVA) models with random subject effects were used to examine the within-subject and between-subject variability. ANOVA models including fixed effects were also used to test for differences between days (trials) and donnings (series) using a Bonferroni adjustment for multiple comparisons.

A test was considered a success if any of the three repeated donnings passed the fit factor criteria. Subjects that failed all three repeated donnings were considered failures.

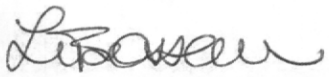
A bootstrapping method was used in which 1000 datasets of 35 subjects were randomly generated from the observed data. Point estimates and confidence intervals were calculated using an ANOVA model as described by Zhang and Kotz ("Inference and Sample Size Calculations in the Fit Assessment of Filtering Facepiece Respirators"; *Journal of Biopharmaceutical Statistics.* 18; 713-723.2008).

Data Confidentiality

Once the first experiment was begun, passwords were changed by ISEA Panel members and known only to them. This allowed the resulting data files to be transferred for analysis, and not be viewable by the host Company staff.

Section 7: Remarks and Limitations

The data interpretation, discussions, and conclusions contained in this report represent our professional opinions, and reflect the current state of practice in industrial hygiene. No warranty is implied or intended. This report was prepared by **Environmental Health & Safety, Inc.**



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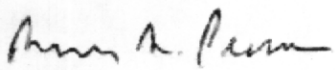

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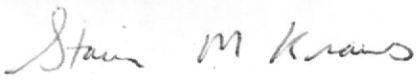

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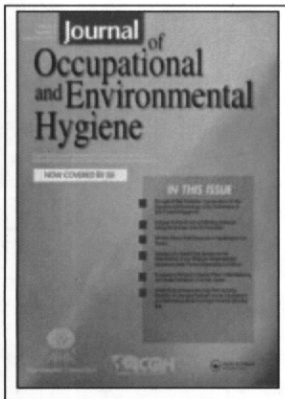
Appendix A
Respirator Selection Process

The Advisory Board used a NIOSH research paper from 2006 to establish a pool of good-fitting respirators from which to select 1 N95 filtering-facepiece and 1 N95 elastomeric half-mask:



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Comparison of Performance of Three Different Types of Respiratory Protection Devices

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Tables I, IV and V were used as our data source. Copies are included at the end of this Appendix.

Table I: List of Respiratory Protective Devices
Table IV: Summary SWPF Statistics for N95 Filtering-Facepiece Respirators by Fit-Test Method
Table V: Summary Statistics for SWPF Values Without and With Fit Testing by Fit-Test Method for N95 Elastomeric-Facepiece Respirators

Decision Process and Results:

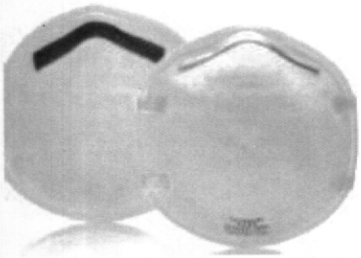
To help make a decision for the filtering facepiece, the Advisory Board used the 5th percentile Pass SWPF data from each of the 3 fit test methods and ranked the respirators (1 = highest SWPF). This yielded 3 ranks for each respirator, one for each fit test method. Then the 3 ranks were summed for each respirator yielding an overall rank. The lowest sum was the respirator with the highest overall rank. Six of the respirators in Table IV had insufficient data and were not included in the ranking. The results were:

Rank	Model	Manufacturer
1	8515	3M
1	9211	3M
3	3945	Gerson
4	TN01	San M Packaging
5	2600/2601	Moldex
6	1913	Survivair
7	1730	Gerson
8	8511	3M
9	9210	3M
10 - 15	Insufficient data	Insufficient data

For the purposes of the ISEA study, a benchmark data set from a 3M filtering facepiece previously tested by the NIOSH TIL protocol will be evaluated. Therefore, we chose not to include any other 3M respirators, to avoid over-representing a single manufacturer. We then moved down the list to obtain a filtering facepiece respirator that:

1) was still available from distributors (the Lawrence study was published in 2006);
2) was only sold in a single size.

Based on these criteria, we chose the Gerson Model 1730 to begin the testing protocol.



Gerson 1730 N95 Filtering-facepiece Respirator

The Advisory Board needed to choose one model of an elastomeric half-mask respirator. Data from Table V was used and the above ranking procedure was repeated. The results were:

Rank	Model	Manufacturer
1	3M 7000	3M
1	2000	Survivair
3	66	Scott
4	5 Star	AO Safety
5	1291	Lab Safety
6	Survivair 7000	Survivair
7	Comfo Elite	MSA
8	Comfo Classic	MSA
8	6100	Willson
10	2900	Sellstom
11	8000	Moldex
12	1200	Willson
12	6800	Willson

The 3M 7000 and Survivair 2000 were tied for rank 1. The Advisory Board chose the Survivair 2000, again, to avoid picking a 3M respirator and over-representing a single manufacturer. The Survivair 2000 is offered in 3 sizes: Small, Medium and Large.

Survivair 2000 Elastomeric Half-mask Respirator

TABLE IV. Summary SWPF Statistics for N95 Filtering-Facepiece Respirators by Fit-Test Method

Model	GM Without Fit Testing	Duncan Grouping of the GM[A]	GSD Without Fit Testing	5th Percentile Without Fit Testing	5th Percentile by Fit-Test Method					
					Bitrex		Saccharin		Companion	
					Pass	Fail	Pass	Fail	Pass	Fail
All filtering facepieces	20.4	—	3.1	3.3	7.9	3.0	11.0	3.0	20.5	2.7
9210	55.0	A	2.4	13.2	17.1	11.7	10.6	13.4	16.7	11.4
3945	43.7	B	2.2	11.8	37.6	10.5	39.7	9.6	24.8	6.5
8511	40.8	B,C	2.0	12.8	14.2	12.6	25.9	11.5	21.2	11.9
9211	37.9	B,C	2.9	6.7	39.2	6.2	26.3	5.8	34.6	5.3
8515	33.4	C,D	2.6	6.9	22.8	5.9	49.8	5.6	26.1	3.5
1913	29.0	D,E	1.9	9.9	21.6	9.5	19.3	9.7	30.9	8.7
1730	26.4	E	1.8	9.8	14.7	8.5	20.2	8.0	24.5	6.9
2600/2601	25.1	E,F	2.8	4.6	21.9	4.2	28.6	3.9	21.4	2.8
TN01	21.1	F,G	3.0	3.4	11.3	3.3	29.6	3.2	35.9	3.3
2747	19.5	G	2.8	3.6	NP[B]	3.6	13.9	3.5	12.7	3.2
910	19.5	G	1.9	6.8	5.4	7.0	NP[B]	6.8	NP[B]	6.8
Piccola	10.6	H	2.2	3.0	10.2	2.9	NP[B]	3.0	12.6	2.9
M-12	9.1	H	1.6	4.1	3.2	4.3	2.9	4.2	NP[B]	4.1
FR200 Affinity	8.8	H	2.3	2.3	NP[B]	2.3	NP[B]	2.3	NP[B]	2.3
MAS695	3.0	I	1.9	1.1	2.8	1.0	1.2	1.1	NP[B]	1.1

Note: Dash indicates fit testing not done.
[A] All means having the same Duncan Grouping letter are statistically the same.
[B] Not applicable.
[C] No subjects passed the fit test.

TABLE V. Summary Statistics for SWPF Values Without and With Fit Testing by Fit-Test Method for N95 Elastomeric-Facepiece Respirators

Model	GM Without Fit Testing	Duncan Grouping of the GM[A]	GSD Without Fit Testing	5th Percentile Without Fit Testing	5th Percentile by Fit-Test Method					
					Bitrex		Saccharin		Companion	
					Pass	Fail	Pass	Fail	Pass	Fail
All elastomeric facepieces	35.5	—	2.6	7.3	11.1	6.3	11.7	6.2	13.0	4.4
3M 7000	161.1	A	3.1	25.3	22.9	28.5	50.0	16.9	50.7	11.8
2000	73.1	B	2.0	23.4	27.3	21.8	31.1	17.3	30.7	9.6
1490/1590	49.1	C	1.7	20.8	24.6	18.9	30.7	16.8	26.0	15.8
7700	41.5	C,D	1.6	19.0	20.3	17.9	18.1	19.9	22.3	8.7
Survivair 7000	40.3	D	2.8	7.5	15.1	5.0	47.6	5.9	13.8	3.8
6800	36.7	D	2.0	11.5	9.8	13.7	11.9	12.0	10.8	18.1
66	30.3	E	2.9	5.3	19.5	4.2	27.6	4.6	27.9	2.9
5 Star	29.9	E,F	3.5	3.8	39.8	3.4	13.8	2.6	17.8	2.3
11291	26.4	E,F,G	2.2	7.3	25.3	6.0	12.9	5.6	15.8	2.0
6100	25.5	E,F,G	1.7	7.0	13.0	5.8	14.9	5.7	15.1	4.4
Comfo Classic	25.3	E,F,G	1.7	10.9	13.6	9.8	12.0	10.1	15.4	7.9
1200	24.5	E,F,G	1.7	9.8	13.2	9.3	7.7	10.0	10.2	9.7
8000	24.4	E,F,G	1.8	9.1	10.9	8.3	11.0	8.6	14.0	7.2
2900	24.2	F,G	2.7	4.7	7.8	3.6	7.1	4.0	18.5	2.3
Comfo Elite	22.2	G	1.8	8.1	17.0	7.1	15.3	7.5	13.8	7.4

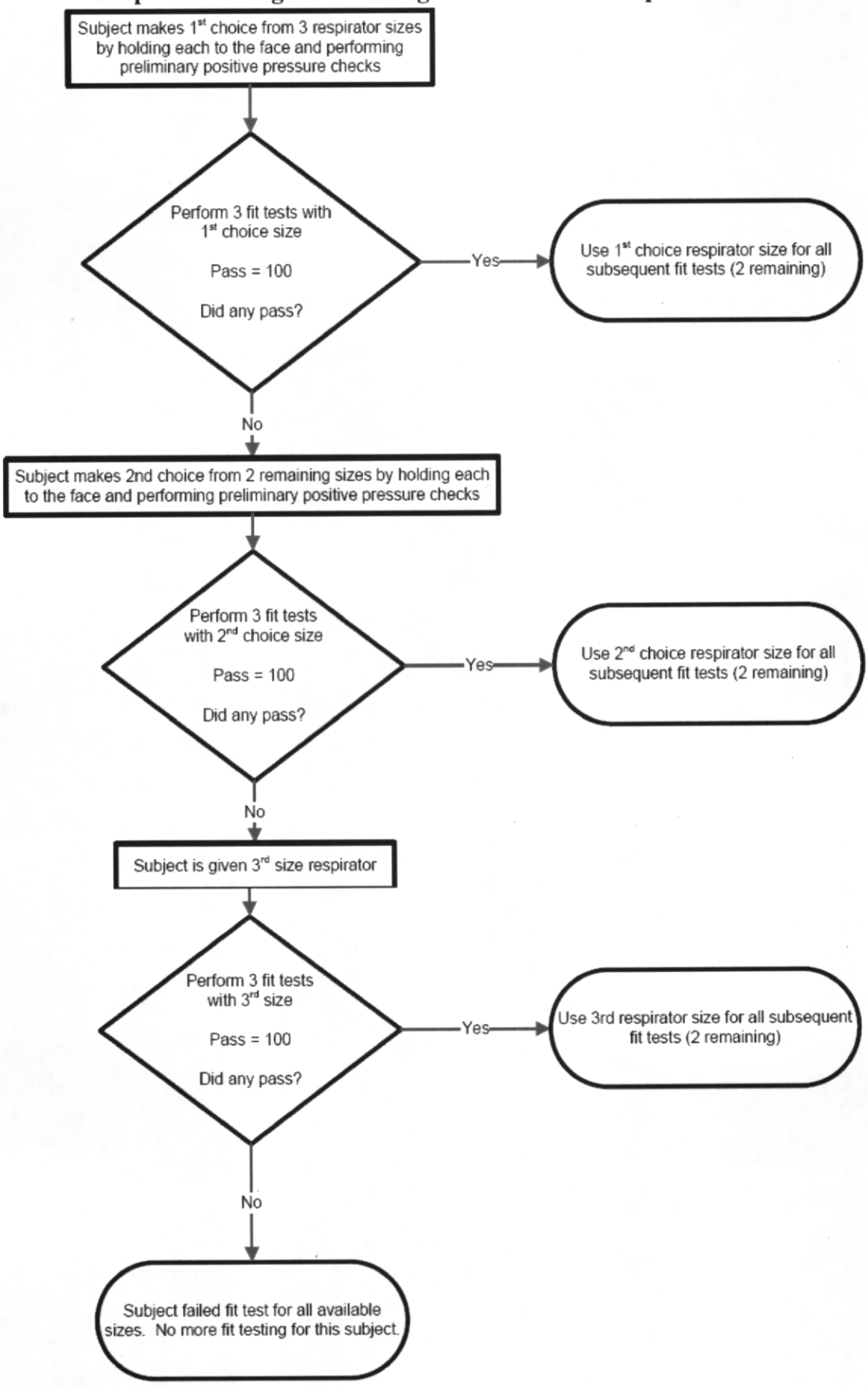
Note: Dash indicates fit testing not done.
[A] All means having the same Duncan Grouping letter are statistically the same.

TABLE I. List of Respiratory Protective Devices

Company	Model Number	Device Type	Description
3M	8511	N95 filtering-facepiece	Cup
3M	8515	N95 filtering-facepiece	Cup
3M	9210	N95 filtering-facepiece	Flat/folding
3M	9211	N95 filtering-facepiece	Flat/folding
Alpha Pro Tech	MAS695	N95 filtering-facepiece	Flat/folding
Aswan	M-12	N95 filtering-facepiece	Flat/folding
Draeger	Piccola w/o valve	N95 filtering-facepiece	Flat/folding
Gerson	1730	N95 filtering-facepiece	Cup
Gerson	2747	N95 filtering-facepiece	Cup
Gerson	3945	N95 filtering-facepiece	Cup
Makrite	910	N95 filtering-facepiece	Flat/folding
Moldex	2600/2601	N95 filtering-facepiece	Cup
MSA	FR200 Affinity	N95 filtering-facepiece	Flat/folding
San M Package	TN01	N95 filtering-facepiece	Flat/folding
Survivair	1913	N95 filtering-facepiece	Flat/folding
3M	7000	N95 elastomeric	—
AO Safety	5 Star	N95 elastomeric	—
Lab Safety	11291	N95 elastomeric	Not applicable
Moldex	8000	N95 elastomeric	Not applicable
MSA	Comfo Classic	N95 elastomeric	Not applicable
MSA	Comfo Elite	N95 elastomeric	Not applicable
North	7700	N95 elastomeric	Not applicable
Pro-Tech	1490/1590	N95 elastomeric	Not applicable
Scott	66	N95 elastomeric	Not applicable
Sellstrom	2900	N95 elastomeric	Not applicable
Survivair	2000	N95 elastomeric	Not applicable
Survivair	7000	N95 elastomeric	Not applicable
Willson	1200	N95 elastomeric	Not applicable
Willson	6100	N95 elastomeric	Not applicable
Willson	6800	N95 elastomeric	Not applicable
3M	1818	Surgical mask	Flat/folding
3M	Aseptex 1800+	Surgical mask	Flat/folding
3M	Nexcare First Aid	Surgical mask	Flat/folding
Johnson & Johnson	Surgine 4238	Surgical mask	Flat/folding
Medline	Prohibit series	Surgical mask	Cup
Tecnol	48237	Surgical mask	Flat/folding

Note: Dashes indicate fit testing not done.

Figure 1
Respirator Sizing Decision Logic for Multi-size Respirator Models



Appendix B
Detailed Results for Experiments 1 and 2

Experiment 1, Respirator A (Filtering Facepiece)

A filtering facepiece respirator was tested with 35 subjects on 3 different days (facepieces) per subject, with three replicates per day, for a total of 9 tests per subject and 315 data points. [Note: The results from Day 1 will be referred to as Panel 1 in the analyses discussed for Experiment 2.]

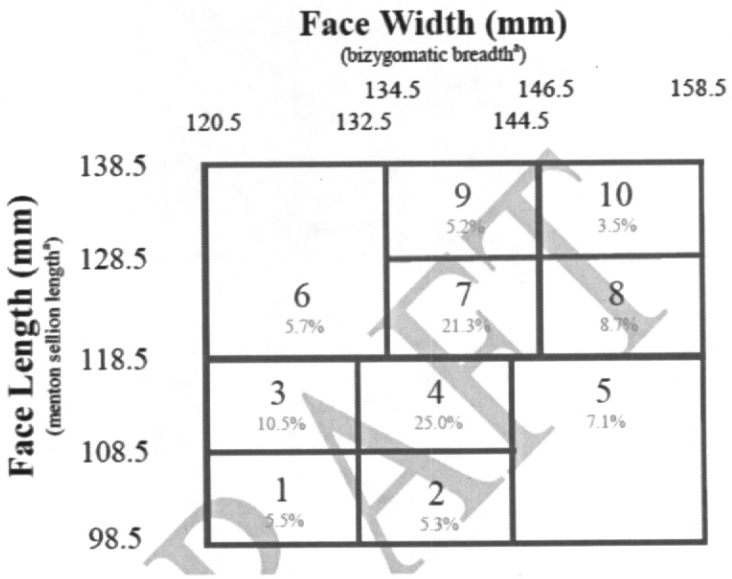
Data Cleaning

The recorded overall fit factor was compared to the harmonic mean of the seven exercise fit factors. Minor differences were observed between the two final fit factors for a small number of subjects, probably due to rounding. The recorded value was used in these analyses.

Matching Cell

Subjects in Panel 1 matched the cell distribution specified for the NIOSH bivariate panel of 35 subjects (see table below). Subjects were also checked to assure match with the PCA panel distribution.

Cell Number	NIOSH 35-Member Bivariate Panel Requirements (N, %)	Study Panel Distribution (N, %)
1	1.92 (5.5)	2 (6)
2	1.87 (5.3)	2 (6)
3	3.68 (10.5)	4 (11)
4	8.75 (25)	9 (26)
5	2.48 (7.1)	2 (6)
6	1.99 (5.7)	2 (6)
7	7.46 (21.3)	7 (20)
8	3.04 (8.7)	3 (9)
9	1.82 (5.2)	2 (6)
10	1.22 (3.5)	2 (6)



Summary Statistics

The data for Panel 1 are log-normally distributed and pass the Shapiro-Wilk test for normality (p=0.0827).[1] Analyses were performed with the natural log-transformed data.

Summary Statistics for Overall Fit Factor

(n=35 subjects tested 3 times per day; 3 days; new facepiece each day = 315 tests)

Statistic	Transformed Scale (LN (FIT))	Re-transformed to original scale (EXP(LNFIT))
Mean	3.4	30 (Geometric Mean)
Standard Deviation	0.9	2.5 (Geometric Standard Deviation)
Minimum	1.1	3.0
5th Percentile	1.8	6.0
25th Percentile	2.8	16.4
Median	3.5	33.1
75th Percentile	4.2	66.7
95th Percentile	4.9	134
Maximum	6.1	446

Accounting for facepiece (day) effect, there were significant differences in fit factors for the three facepieces (days) (p=0.004). Day 1 had significantly higher fit factors than Day 2 (Bonferroni adjusted p=0.004)[2] but did not significantly differ from Day 3 (adjusted p=0.06) and Day 2 did not differ from Day 3 (adjusted p=1.000).

Summary Statistics by Day (Facepiece)

	Day 1 (n=105) [Panel 1]		Day 2 (n=105)		Day 3 (n=105)	
Statistic	Transformed Scale LN(FIT)	Re-transformed EXP(LNFIT)	Transformed Scale LN(FIT)	Re-transformed EXP(LNFIT)	Transformed Scale LN(FIT)	Re-transformed EXP(LNFIT)
Mean	3.6	37*	3.3	27*	3.4	30*
Standard Deviation	0.9	2.5*	1.0	2.7*	0.9	2.5*
Minimum	1.4	4	1.4	4	1.1	3
5th Percentile	1.8	6	1.8	6	1.9	7
25th Percentile	2.9	18	2.6	14	2.7	15
Median	3.8	45	3.4	30	3.5	33
75th Percentile	4.3	74	4.1	60	3.9	49
95th Percentile	4.8	122	4.8	122	5.2	181
Maximum	5.6	270	5.3	200	6.1	446

* Geometric Mean and Geometric Standard Deviation

Accounting for a fixed series (donning) effect, there is a significant difference in fit factors between the three series (p<0.0001). Series A had significantly higher fit factors than Series B (adjusted p=0.027) and Series C (adjusted p<0.0001). Series B did not differ from Series C (adjusted p=0.231).

[1] A p-value greater than 0.05 indicates that the data are normally distributed.

[2] Bonferroni adjustment is used to minimize the probability of finding a difference by chance when making multiple comparisons; a more stringent alpha than 0.05, adjusted by the number of comparisons, is employed.

Summary Statistics by Series
(Series A = First Donning; Series B = Second Donning; Series C = Third Donning)

	Series A (n=105)		Series B (n=105)		Series C (n=105)	
Statistic	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**
Mean	3.6	36*	3.4	30*	3.3	27*
Standard Deviation	0.9	2*	0.9	2*	0.9	2*
Minimum	1.4	4	1.1	3	1.4	4
5th Percentile	2.1	8	1.9	7	1.8	6
25th Percentile	3	20	2.8	16	2.6	13
Median	3.7	40	3.5	33	3.4	30
75th Percentile	4.3	74	4.2	67	3.9	49
95th Percentile	5	148	4.8	122	4.8	122
Maximum	6.1	446	5.6	270	5.6	270

* Geometric Mean and Geometric Standard Deviation

Variability

In all cases, the between-subject variability is greater than the within-subject variability.

Within and Between Subject Variability

	Between subject variability	Within subject variability
All data combined*	0.5846	0.3072
All data combined (fixed day effect)	0.5875	0.2976
All data combined (fixed series effect)	0.5884	0.2890
Models fit separately by day		
Day 1 [Panel 1]	0.6152	0.2355
Day 2	0.7631	0.1713
Day 3	0.6946	0.1815
Models fit separately by series (test order)		
Series A (Donning 1)	0.5670	0.3342
Series B (Donning 2)	0.6004	0.3016
Series C (Donning 3)	0.5909	0.2380

*Ignoring correlation across repeated days for a subject

Test Pass

NIOSH criteria require that 26 out of 35 test subjects must obtain a fit factor of 100 or greater and that at least one subject in each cell must pass. In addition, subjects failing to receive a fit factor of 100 on the first try can repeat the procedure up to 2 more times.

Subjects Achieving Fit Factor by Cell – All Data

	The repeated days for a subject are considered independent for a total of 105 subjects (35 x 3) Number of Subjects that Achieve Goal by Cell										**Total**
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# Subjects in Cell	6	6	12	27	6	6	21	9	6	6	105 (100%)
10	4	6	12	27	6	6	21	9	6	6	103 (98.10%)
15	3	6	11	22	6	6	21	7	5	4	91 (86.67%)
20	2	6	10	22	5	6	21	6	4	3	85 (80.95%)
25	2	5	9	21	5	6	21	6	4	3	82 (78.10%)
30	**2**	**3**	**9**	**19**	**5**	**6**	**20**	**3**	**4**	**3**	**74 (70.48%)**
40	2	3	6	17	5	4	15	3	3	2	60 (57.14%)
50	2	3	6	14	4	4	13	2	2	2	52 (49.52%)
60	2	2	4	11	3	4	11	2	2	2	43 (40.95%)
75	1	1	4	6	2	4	10	2	1	2	33 (31.43%)
100	1	0	3	3	1	1	4	2	1	1	17 (16.19%)

Subjects Achieving Fit Factor by Cell – Day 1 [Panel 1]

	Day 1 – 35 subjects Number of Subjects that Achieve Goal by Cell										**Total**
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	1	2	4	9	2	2	7	3	2	2	34 (97%)
15	1	2	4	9	2	2	7	2	2	2	33 (94%)
20	1	2	3	9	2	2	7	2	2	1	31 (89%)
25	1	2	3	8	2	2	7	2	2	1	30 (86%)
30	**1**	**2**	**3**	**6**	**2**	**2**	**7**	**1**	**2**	**1**	**27 (77%)**
40	1	2	2	6	2	2	6	1	2	1	25 (71%)
50	1	2	2	5	2	2	5	1	2	1	23 (66%)
60	1	1	1	5	1	2	4	1	2	1	19 (54%)
75	0	1	1	2	1	2	4	1	1	1	14 (40%)
100	0	0	1	1	0	1	1	1	1	0	6 (17%)

Subjects Achieving Fit Factor by Cell – Day 2

	Day 2– 35 subjects Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	1	2	4	9	2	2	7	3	2	2	34 (97%)
15	1	2	4	6	2	2	7	3	1	1	29 (83%)
20	1	2	4	6	1	2	7	2	1	1	27 (77%)
25	**1**	**1**	**4**	**6**	**1**	**2**	**7**	**2**	**1**	**1**	**26 (74%)**
30	1	0	4	6	1	2	7	1	1	1	24 (69%)
40	1	0	2	5	1	2	4	1	0	1	17 (49%)
50	1	0	2	4	1	2	4	0	0	1	15 (43%)
60	1	0	1	3	1	2	4	0	0	1	13 (37%)
75	1	0	1	1	1	2	4	0	0	1	11 (31%)
100	1	0	1	1	1	0	2	0	0	1	7 (20%)

Subjects Achieving Fit Factor by Cell – Day 3

	Day 3– 35 subjects Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	2	2	4	9	2	2	7	3	2	2	35 (100%)
15	1	2	3	7	2	2	7	2	2	1	29 (83%)
20	0	2	3	7	2	2	7	2	1	1	27 (77%)
25	**0**	**2**	**2**	**7**	**2**	**2**	**7**	**2**	**1**	**1**	**26 (74%)**
30	0	1	2	7	2	2	6	1	1	1	23 (66%)
40	0	1	2	6	2	0	5	1	1	0	18 (51%)
50	0	1	2	5	1	0	4	1	0	0	14 (40%)
60	0	1	2	3	1	0	3	1	0	0	11 (31%)
75	0	0	2	3	0	0	2	1	0	0	8 (23%)
100	0	0	1	1	0	0	1	1	0	0	4 (11%)

Experiment 2, Respirator A (Filtering Facepiece)

The same filtering facepiece was tested with an additional 70 subjects on 1 day (facepiece) per subject with three replicates per day – for a total of 3 tests per subject and 210 data points. Subjects were selected to match the cell distribution specified for two NIOSH bivariate panels of 35 subjects. Subjects were also checked to assure match with the PCA panel distribution. These panels will be referred to as Panels 2 and 3. These data were combined with the first day of testing (3 replicates per subject) with the 35 subjects from Experiment 1 [Panel 1], for a total of 105 subjects and 315 data points.

Data Cleaning

The overall fit factor recorded by the software was used in these analyses.

Matching Cell

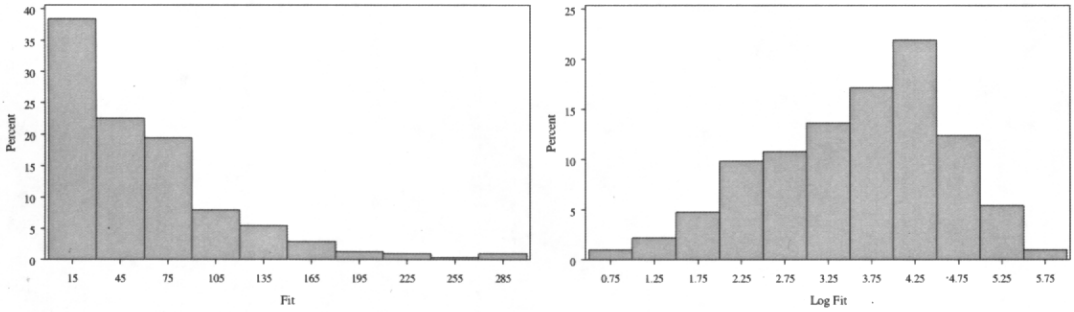
For Panels 2 and 3, the cell distribution was the same as shown for Experiment 1 (above), matching the NIOSH bivariate panel requirements for 35 subjects.

Summary Statistics

Although the transformed data failed the normality test ($p<0.0001$), the histogram of the log-transformed values looks fairly bell-shaped (see below). Analyses were performed with the log-transformed data, because the distribution appeared to be close to normal. The log-transformed data in Panels 1 and 2 were normally distributed; transformed Panel 3 data were non-normal ($p<0.0001$) (not shown).

Distribution of Combined Data for Panels 1, 2 and 3 in Original and Transformed Scales

Untransformed **Log Transformed**



Summary Statistics Overall Fit Factor for All Subjects – Panels 1, 2 and 3 Combined

Statistic n=105 subjects tested 3 times on a single day	**Transformed Scale (LN (FIT))**	**Re-transformed to original scale (EXP(LNFIT))**
Mean	3.6	37 (GM)
Standard Deviation	1.03	3 (GSD)
Minimum	0.69	2
5th Percentile	1.61	5
25th Percentile	2.89	18
Median	3.71	41
75th Percentile	4.36	78
95th Percentile	5.09	162
Maximum	5.66	287

Summary Statistics by Panel

	Panel 1 (n=35)		Panel 2 (n=35)		Panel 3 (n=35)	
Statistic	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**
Mean	3.6	37*	3.6	35*	3.7	40*
Standard Deviation	0.9	2.5*	1.1	3*	1.1	3*
Minimum	1.4	4	1.1	3	0.7	2
5th Percentile	1.8	6	2.0	7	1.4	4
25th Percentile	2.9	18	2.7	15	3.1	22
Median	3.8	44	3.5	32	3.8	45
75th Percentile	4.3	73	4.3	74	4.4	82
95th Percentile	4.8	127	5.3	199	5.1	158
Maximum	5.6	277	5.7	286	5.4	215

Variability

In all cases, the between-subject variability is greater than the within-subject variability. There were no significant differences in fit factors across panels ($p = 0.8476$).

	Between subject variability	Within subject variability
All data combined	0.8150	0.2551
Panel 1	0.6152	0.2355
Panel 2	0.8727	0.3191
Panel 3	1.0011	0.2108

Test Pass

Subjects Achieving Fit Factor by Cell – All Data – Three Panels Combined

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	6	6	12	27	6	6	21	9	6	6	105
10	4	5	11	27	6	6	21	9	6	6	101 (96.19%)
15	3	5	11	27	6	6	19	8	6	5	96 (91.43%)
20	2	5	9	26	5	6	19	7	6	4	89 (84.76%)
25	2	5	8	24	5	6	18	7	6	4	85 (80.95%)
30	**2**	**5**	**8**	**22**	**4**	**6**	**17**	**6**	**6**	**4**	**80 (76.19%)**
40	2	5	7	21	4	6	16	5	5	3	74 (70.48%)
50	1	3	6	18	4	5	12	5	3	3	60 (57.14%)
60	1	2	4	17	3	5	11	5	3	3	54 (51.43%)
75	0	2	4	11	3	4	10	4	2	3	43 (40.95%)
100	0	0	3	7	2	3	6	3	2	1	27 (25.71%)

Subjects Achieving Fit Factor by Cell – Panel 1

	Panel 1 – 35 subjects Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	1	2	4	9	2	2	7	3	2	2	34 (97%)
15	1	2	4	9	2	2	7	2	2	2	33 (94%)
20	1	2	3	9	2	2	7	2	2	1	31 (89%)
25	1	2	3	8	2	2	7	2	2	1	30 (86%)
30	**1**	**2**	**3**	**6**	**2**	**2**	**7**	**1**	**2**	**1**	**27 (77%)**
40	1	2	2	6	2	2	6	1	2	1	25 (71%)
50	1	2	2	5	2	2	5	1	2	1	23 (66%)
60	1	1	1	5	1	2	4	1	2	1	19 (54%)
75	0	1	1	2	1	2	4	1	1	1	14 (40%)
100	0	0	1	1	0	1	1	1	1	0	6 (17%)

Subjects Achieving Fit Factor by Cell – Panel 2

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	2	2	3	9	2	2	7	3	2	2	34 (97.14%)
15	1	2	3	9	2	2	5	3	2	1	30 (85.71%)
20	0	2	3	8	2	2	5	3	2	1	28 (80.00%)
25	**0**	**2**	**2**	**8**	**2**	**2**	**4**	**3**	**2**	**1**	**26 (74.29%)**
30	0	2	2	8	1	2	4	3	2	1	25 (71.43%)
40	0	2	2	7	1	2	4	3	1	1	23 (65.71%)
50	0	0	1	6	1	2	3	3	0	1	17 (48.57%)
60	0	0	1	6	1	2	3	3	0	1	17 (48.57%)
75	0	0	1	4	1	1	3	2	0	1	13 (37.14%)
100	0	0	0	4	1	1	2	1	0	1	10 (28.57%)

Subjects Achieving Fit Factor by Cell – Panel 3

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	1	1	4	9	2	2	7	3	2	2	33 (94.29%)
15	1	1	4	9	2	2	7	3	2	2	33 (94.29%)
20	1	1	3	9	1	2	7	2	2	2	30 (85.71%)
25	1	1	3	8	1	2	7	2	2	2	29 (82.86%)
30	1	1	3	8	1	2	6	2	2	2	28 (80.00%)
40	**1**	**1**	**3**	**8**	**1**	**2**	**6**	**1**	**2**	**1**	**26 (74.29%)**
50	0	1	3	7	1	1	4	1	1	1	20 (57.14%)
60	0	1	2	6	1	1	4	1	1	1	18 (51.43%)
75	0	1	2	5	1	1	3	1	1	1	16 (45.71%)
100	0	0	2	2	1	1	3	1	1	0	11 (31.43%)

Bootstrap Analysis – Experiments 1 and 2

The Day 1 data from Experiment 1 (1 panel = 35 subjects) were combined with the data from Experiment 2 (2 additional panels = 70 subjects). One thousand datasets of 35 subjects were generated using a bootstrap technique. Point estimates and confident intervals were calculated using an analysis of variance model as described by Zhang and Kotz (2008).[3] In the table below, Column 3 shows an estimate of the proportion of users who will achieve a specified level of performance (the fit factor designated in Column 1) with a probability of 95% (Column 2). As an example, row 2 can be interpreted as follows: 98.2% of users (CI: 97.7%-98.6%) are estimated to achieve a fit factor of 10 or greater 95% of the time the respirator is donned.

[3] Zhang, Z and Kotz, R (2008) Inference and Sample Size Calculations in the Fit Assessment of Filtering Facepiece Respirators. *Journal of Biopharmaceutical Statistics.* 18; 713-723.

Fit Factor	% of Times the Respirator is Donned	% Users	Lower 95% Confidence Limit	Upper 95% Confidence Limit
5	95	99.98	99.95	1.0002
10	**95**	**98.15**	**97.71**	**98.60**
15	95	61.47	59.36	63.57
20	95	15.69	14.18	17.20
25	95	2.53	1.95	3.10
30	95	0.14	0.14	0.41
40	95	0.05	-0.05	0.15
50	95	0.05	-0.05	0.15
60	95	0.05	-0.05	0.15
75	95	0.05	-0.05	0.15
100	95	0.05	-0.05	0.15

Experiment 1 – Respirator B (Elastomeric)

An elastomeric respirator was tested with 35 subjects on 3 different days (facepieces) per subject, with three replicates per day, for a total of 9 tests per subject and 315 data points. The recorded overall fit factor was used in these analyses.

Matching Cell

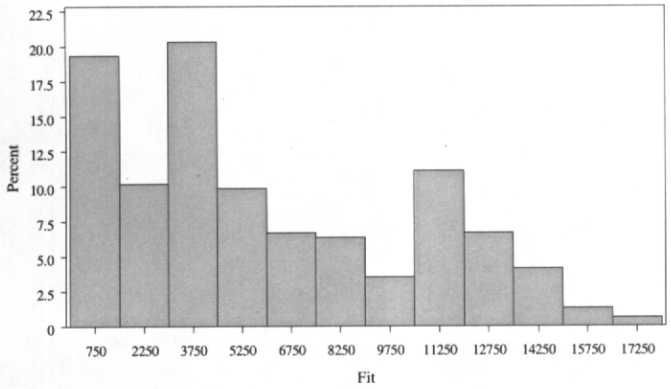
Subjects matched the cell distribution specified for the NIOSH bivariate panel of 35 subjects (see below), as well as the PCA panel distribution.

Cell Number	NIOSH 35-Member Bivariate Panel Requirements (N, %)	Study Panel Distribution (N, %)
1	1.92 (5.5)	2 (6)
2	1.87 (5.3)	2 (6)
3	3.68 (10.5)	4 (11)
4	8.75 (25)	9 (26)
5	2.48 (7.1)	2 (6)
6	1.99 (5.7)	2 (6)
7	7.46 (21.3)	7 (20)
8	3.04 (8.7)	3 (9)
9	1.82 (5.2)	2 (6)
10	1.22 (3.5)	2 (6)

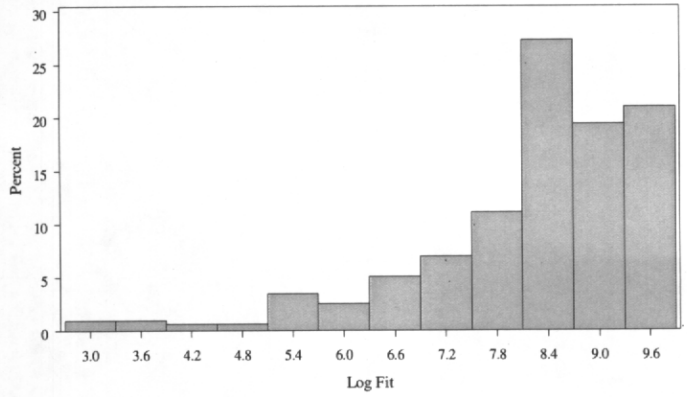
Summary Statistics

Both the untransformed and logarithmic transformed values fail the Shapiro-Wilk test for normality ($p < 0.0001$).

Untransformed



Log Transformed



Summary Statistics for Overall Fit Factor

(n=35 subjects tested 3 times per day; 3 days; new facepiece each day = 315 tests)

Statistic	Transformed Scale (LN (FIT))	Re-transformed to original scale (EXP(LNFIT))
Mean	8.2	3641 (Geometric Mean)
Standard Deviation	1.3	4 (Geometric Standard Deviation)
Minimum	2.7	15
5th Percentile	5.5	245
25th Percentile	7.8	2401
Median	8.4	4447
75th Percentile	9.2	9897
95th Percentile	9.5	13360
Maximum	9.8	18034

Summary Statistics by Day (Facepiece)

	Day 1 (n=105)		Day 2 (n=105)		Day 3 (n=105)	
Statistic	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**
Mean	8.2	3641*	8.3	4023*	8.0	2981*
Standard Deviation	1.3	4*	1.4	4*	1.3	4*
Minimum	2.9	18	3.3	27	2.7	15
5th Percentile	6.2	493	5.0	148	5.5	245
25th Percentile	7.7	2208	8.2	3641	7.4	1636
Median	8.4	4447	8.6	5431	8.2	3641
75th Percentile	9.1	8955	9.3	10938	9.0	8103
95th Percentile	9.6	14765	9.5	13360	9.5	13360
Maximum	9.8	18034	9.7	16318	9.6	14765

* GM = geometric mean; GSD = geometric standard deviation

Summary Statistics by Series
(Series A = First Donning; Series B = Second Donning; Series C = Third Donning)

	Series A (n=105)		Series B (n=105)		Series C (n=105)	
Statistic	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**	**Transformed Scale LN(FIT)**	**Re-transformed EXP(LNFIT)**
Mean	8.1	3294*	8.2	3641*	8.2	3641*
Standard Deviation	1.3	4*	1.3	4*	1.4	4*
Minimum	3.3	28	3.1	23	2.7	15
5th Percentile	5.8	334	5.5	240	5.4	224
25th Percentile	7.7	2232	7.8	2449	7.9	2647
Median	8.4	4271	8.4	4584	8.4	4664
75th Percentile	9.1	8548	9.1	9303	9.3	11124
95th Percentile	9.5	13594	9.5	13383	9.6	14406
Maximum	9.7	16625	9.6	15060	9.8	17456

* Geometric Mean and Geometric Standard Deviation

Variability

There were no significant differences in fit factors between the three days (p=0.1473), when a fixed day effect was included in the model. There were no significant differences in fit factors between the three series (p=0.8414) when a fixed series effect was included in the model. [4]

	Between subject variability	Within subject variability
All data combined*	0.5004	1.2560
All data combined (fixed day effect)	0.5013	1.2478
All data combined (fixed series effect)	0.4995	1.2635
Models fit separately by day		
Day 1	0.8617	0.8204
Day 2	0.6760	1.2580
Day 3	0.5761	1.0667
Models fit separately by series (donning)		
Series A (Donning 1)	0.4528	1.2243
Series B (Donning 2)	0.3186	1.3233
Series C (Donning 3)	0.4106	1.5534

*Ignoring correlation across repeated days for a subject

[4] NOTE: The assumptions of a mixed model are violated; the transformed fit factors are not normally distributed.

Subjects Achieving Fit Factor by Cell – All Data

	The repeated days for a subject are considered independent for a total of 105 subjects (35 x 3) Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	6	6	12	27	6	6	21	9	6	6	105 (100%)
10	6	6	12	27	6	6	21	9	6	6	105 (100%)
15	6	6	12	27	6	6	21	9	6	6	105 (100%)
20	6	6	12	27	6	6	21	9	6	6	105 (100%)
25	6	6	12	27	6	6	21	9	6	6	105 (100%)
30	6	6	12	27	6	6	21	9	6	6	105 (100%)
40	6	6	12	27	6	6	21	9	6	6	105 (100%)
50	6	6	11	27	6	6	21	9	6	6	104 (99%)
60	6	6	11	26	6	6	21	8	6	6	102 (97%)
75	6	6	11	26	6	6	19	8	6	5	99 (94%)
100	6	6	11	26	6	6	19	8	6	5	99 (94%)

Subjects Achieving Fit Factor by Cell – Day 1

	Day 1 – 35 subjects Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	2	2	4	9	2	2	7	3	2	2	35 (100%)
15	2	2	4	9	2	2	7	3	2	2	35 (100%)
20	2	2	4	9	2	2	7	3	2	2	35 (100%)
25	2	2	4	9	2	2	7	3	2	2	35 (100%)
30	2	2	4	9	2	2	7	3	2	2	35 (100%)
40	2	2	4	9	2	2	7	3	2	2	35 (100%)
50	2	2	4	9	2	2	7	3	2	2	35 (100%)
60	2	2	4	9	2	2	7	3	2	2	35 (100%)
75	2	2	4	9	2	2	6	3	2	1	33 (94%)
100	2	2	4	9	2	2	6	3	2	1	33 (94%)

Subjects Achieving Fit Factor by Cell – Day 2

	Day 2– 35 subjects Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	2	2	4	9	2	2	7	3	2	2	35 (100%)
15	2	2	4	9	2	2	7	3	2	2	35 (100%)
20	2	2	4	9	2	2	7	3	2	2	35 (100%)
25	2	2	4	9	2	2	7	3	2	2	35 (100%)
30	2	2	4	9	2	2	7	3	2	2	35 (100%)
40	2	2	4	9	2	2	7	3	2	2	35 (100%)
50	2	2	4	9	2	2	7	3	2	2	35 (100%)
60	2	2	4	8	2	2	7	3	2	2	34 (97%)
75	2	2	4	8	2	2	6	3	2	2	33 (94%)
100	2	2	4	8	2	2	6	3	2	2	33 (94%)

Subjects Achieving Fit Factor by Cell – Day 3

	Day 3– 35 subjects Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
# subjects per cell	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	2	2	4	9	2	2	7	3	2	2	35 (100%)
15	2	2	4	9	2	2	7	3	2	2	35 (100%)
20	2	2	4	9	2	2	7	3	2	2	35 (100%)
25	2	2	4	9	2	2	7	3	2	2	35 (100%)
30	2	2	4	9	2	2	7	3	2	2	35 (100%)
40	2	2	4	9	2	2	7	3	2	2	35 (100%)
50	2	2	3	9	2	2	7	3	2	2	34 (97%)
60	2	2	3	9	2	2	7	2	2	2	33 (94%)
75	2	2	3	9	2	2	7	2	2	2	33 (94%)
100	2	2	3	9	2	2	7	2	2	2	33 (94%)

Appendix C
Bootstrap Analysis of NIOSH Benchmark Datasets

Summary of NIOSH Benchmark Test Results

Respirator Description

ISEA provided data for 8 filtering facepiece and 16 elastomeric respirators from its member manufacturers. Many of the these respirators were available in multiple (2 or 3) sizes; a separate panel was conducted for each of the different sizes.

Model	Type	Style	Sizes
Respirator No. 1	Filtering facepiece	Cup shape with exhalation valve	Single
Respirator No. 2	Filtering facepiece	Cup shape with exhalation valve	Single
Respirator No. 3	Filtering facepiece	Vertical fold with exhalation valve	Single
Respirator No. 4	Filtering facepiece	Vertical fold	Single
Respirator No. 5 L	Filtering facepiece	Cup shape	3 sizes
Respirator No. 5 M	Filtering facepiece	Cup shape	3 sizes
Respirator No. 5 S	Filtering facepiece	Cup shape	3 sizes
Respirator No. 6 L	Filtering facepiece	Cup shape	3 sizes
Respirator No. 6 M	Filtering facepiece	Cup shape	3 sizes
Respirator No. 6 S	Filtering facepiece	Cup shape	3 sizes
Respirator No. 7 L	Filtering facepiece	Flat fold	3 sizes
Respirator No. 7 M	Filtering facepiece	Flat fold	3 sizes
Respirator No. 7 S	Filtering facepiece	Flat fold	3 sizes
Respirator No. 8	Filtering facepiece	Not available	Not available
Respirator No. 9	Filtering facepiece	Not available	Not available
Respirator No. 10	Filtering facepiece	Not available	Not available
Respirator No. 11	Filtering facepiece	Not available	Not available
Respirator No. 12 ML	Elastomeric	Silicone, single filter	Info not available
Respirator No. 13	Elastomeric	Single filter	Info not available
Respirator No. 14 ML	Elastomeric	2 filters	2 sizes
Respirator No. 14 S	Elastomeric	2 filters	2 sizes
Respirator No. 15 L	Elastomeric	2 filters	3 sizes
Respirator No. 15 M	Elastomeric	2 filters	3 sizes
Respirator No. 15 S	Elastomeric	2 filters	3 sizes
Respirator No. 16 L	Elastomeric	2 filters	3 sizes
Respirator No. 16 M	Elastomeric	2 filters	3 sizes
Respirator No. 16 S	Elastomeric	2 filters	3 sizes
Respirator No. 17 L	Elastomeric	2 filters	3 sizes
Respirator No. 17 M	Elastomeric	2 filters	3 sizes
Respirator No. 17 S	Elastomeric	2 filters	3 sizes
Respirator No. 18	Elastomeric	Not available	Not available
Respirator No. 19	Elastomeric	Not available	Not available
Respirator No. 20	Elastomeric	Not available	Not available
Respirator No. 21	Elastomeric	Not available	Not available
Respirator No. 22	Elastomeric	Not available	Not available
Respirator No. 23	Elastomeric	Not available	Not available
Respirator No. 24	Elastomeric	Not available	Not available

Cell Match

The NIOSH subjects appear to have been selected to match the distribution of the Los Alamos panel for full facepiece respirators.

Cell	Subjects Required by Los Alamos (N)	Subjects in NIOSH benchmark tests (N)	Percent Subjects in Cell
1	2	2	8
2	2	2	8
3	2	2	8
4	5	5	20
5	2	2	8
6	2	2	8
7	4	4	16
8	2	2	8
9	2	2	8
10	2	2	8

Descriptive Statistics

Model	GM	Median	GSD	5th %ile	Are log transformed data normally distributed? (p-value; Shapiro Wilk test)
FILTERING FACEPIECE RESPIRATORS					
Respirator No. 1	24	26	5	2	Yes (0.1985)
Respirator No. 2	169	204	5	8	No (0.0263)
Respirator No. 3*	6	5	3	2	No (<0.0001)
Respirator No. 3	6	5	2	2	No (<0.0001)
Respirator No. 4	5	5	2	2	No (0.0147)
Respirator No. 5 L*	30	27	3	4	Yes (0.3718)
Respirator No. 5 M	20	16	5	3	No (0.0001)
Respirator No. 5 S	33	41	5	3	No (0.0102)
Respirator No. 6 L	13	14	3	3	Yes (0.0658)
Respirator No. 6 M	16	18	3	2	Yes (0.2294)
Respirator No. 6 S	10	9	3	2	Yes (0.1646)
Respirator No. 7 L*	56	45	5	4	No (0.0239)
Respirator No. 7 M	81	60	7	3	Yes (0.1180)
Respirator No. 7 S	71	65	7	3	Yes (0.1823)
Respirator No. 8*	10	7	5	2	No (<0.0001)
Respirator No. 9	16	7	8	1	No (<0.0001)
Respirator No. 10	107	143	8	3	Yes (0.0615)
Respirator No. 11	60	70	10	2	Yes (0.0901)
ELASTOMERIC RESPIRATORS					
Respirator No. 12	84	41	9	7	No (<0.0001)
Respirator No. 13	194	200	4	16	Yes (0.4805)
Respirator No. 14 ML*	639	992	6	17	No (0.006)
Respirator No. 14 S	424	1636	13	5	No (<0.0001)
Respirator No. 15 L	126	153	11	2	No (0.0077)
Respirator No. 15 M	550	1326	8	7	No (<0.0001)
Respirator No. 15 S	134	69	10	6	No (0.0005)
Respirator No. 16 L	100	124	5	6	No (0.0109)
Respirator No. 16 M	150	133	10	6	No (0.0009)
Respirator No. 16 S	56	56	9	2	No (0.0025)
Respirator No. 17 l	123	148	4	7	No (<0.0001)
Respirator No. 17 M	1033	2101	9	12	No (<0.0001)
Respirator No. 17 S	1022	2231	7	13	No (<0.0001)
Respirator No. 18	192	151	19	5	No (<0.0001)
Respirator No. 19	20	8	7	2	No (<0.0001)
Respirator No. 20*	81	100	5	6	Yes (0.0085)
Respirator No. 21	51	46	4	7	No (0.0086)
Respirator No. 22 [A]	3407 (2122)	3427 (3429)	2038 (4)	38 (38)	Yes, p=0.0564 for original scale data No, p < 0.0001 for log-transformed data
Respirator No. 23	907	2080	8	9	No (<0.0001)
Respirator No. 24	1353	2566	7	18	No (<0.0001)

* Outliers removed; [A] Statistics are presented for data in original scale (log-transformed scale). Data in original scale were normally distributed; log-transformed data were not normally distributed.

Variability

Model	Between-subject	Within-subject	Normal Distribution?
FILTERING FACEPIECE			
Respirator No. 1	2.6888	0.2663	Yes
Respirator No. 2	1.9669	0.6038	No
Respirator No. 3	1.1707	0.3297	No
Respirator No. 3*	0.9620	0.1272	No
Respirator No. 4	0.3785	0.2395	No
Respirator No. 5 L*	1.2109	0.3580	Yes
Respirator No. 5 M	2.5835	0.3364	No
Respirator No. 5 S	1.9747	0.5414	No
Respirator No. 6 L	0.7397	0.3511	Yes
Respirator No. 6 M	1.1441	0.3022	Yes
Respirator No. 6 S	0.7428	0.2335	Yes
Respirator No. 7 L*	2.0106	0.8532	No
Respirator No. 7 M	2.6319	1.4450	Yes
Respirator No. 7 S	1.9842	1.6111	Yes
Respirator No. 8*	2.7702	0.2453	No
Respirator No. 9	4.0785	0.2585	No
Respirator No. 10	3.4413	1.0271	Yes
Respirator No. 11	4.4351	0.9925	Yes
ELASTOMERIC			
Respirator No. 12	4.2541	0.5261	No
Respirator No. 13	1.0541	0.7916	Yes
Respirator No. 14 ML	1.9520	1.2538	No
Respirator No. 14 S	4.9640	1.6691	No
Respirator No. 15 L	4.1545	1.8322	No
Respirator No. 15 M	2.5150	1.7574	No
Respirator No. 15 S	3.4074	2.1487	No
Respirator No. 16 L	2.3887	0.5795	No
Respirator No. 16 M	3.9753	1.4893	No
Respirator No. 16 S	4.0223	1.0532	No
Respirator No. 17 L	0.9100	0.7528	No
Respirator No. 17 M	3.1336	1.8397	No
Respirator No. 17 S	1.0278	2.5484	No
Respirator No. 18	7.9550	0.9868	No
Respirator No. 19	3.5330	0.3947	No
Respirator No. 20*	1.6219	1.0913	No
Respirator No. 21	1.0160	0.5943	No
Respirator No. 22	1.6228	0.9436	No
Respirator No. 23	2.8357	1.4471	No
Respirator No. 24	2.2064	1.6507	No

* Outliers removed

Test Pass Results for Each Respirator Model

FILTERING FACEPIECE RESPIRATORS

Respirator No. 1

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	1	1	2	2	1	2	4	2	2	2	19 (76.00%)
15	1	1	2	2	1	2	4	2	2	2	19 (76.00%)
20	1	0	2	2	1	2	3	2	2	2	17 (68.00%)
25	1	0	2	2	1	2	3	2	2	2	17 (68.00%)
30	1	0	2	2	1	2	3	2	2	2	17 (68.00%)
40	1	0	2	2	1	1	3	1	2	1	14 (56.00%)
50	1	0	2	2	1	1	3	0	2	1	13 (52.00%)
60	1	0	1	2	1	0	2	0	2	1	10 (40.00%)
75	1	0	1	2	1	0	2	0	1	1	9 (36.00%)
100	1	0	1	2	1	0	1	0	1	1	8 (32.00%)

Respirator No. 2

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	1	2	2	5	2	2	4	2	2	2	24 (96.00%)
15	1	2	2	5	2	2	4	2	2	2	24 (96.00%)
20	1	2	2	5	2	2	4	1	2	2	23 (92.00%)
25	1	1	2	5	2	2	4	1	2	2	22 (88.00%)
30	1	1	2	5	2	2	4	1	2	2	22 (88.00%)
40	1	1	2	5	2	2	4	1	2	2	22 (88.00%)
50	1	1	2	5	2	2	4	1	2	2	22 (88.00%)
60	1	1	2	5	2	2	4	1	2	2	22 (88.00%)
75	1	1	2	5	2	2	4	1	2	2	22 (88.00%)
100	1	1	2	5	1	2	4	1	2	2	21 (84.00%)

Respirator No. 3 (outliers removed)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	0	1	0	1	0	0	3	1	1	2	9 (36.00%)
15	0	0	0	1	0	0	2	0	1	2	6 (24.00%)
20	0	0	0	0	0	0	1	0	1	2	4 (16.00%)
25	0	0	0	0	0	0	1	0	0	2	3 (12.00%)
30	0	0	0	0	0	0	1	0	0	2	3 (12.00%)
40	0	0	0	0	0	0	1	0	0	2	3 (12.00%)
50	0	0	0	0	0	0	0	0	0	1	1 (4.00%)
60	0	0	0	0	0	0	0	0	0	1	1 (4.00%)
75	0	0	0	0	0	0	0	0	0	1	1 (4.00%)
100	0	0	0	0	0	0	0	0	0	1	1 (4.00%)

Respirator No. 4 (outliers removed)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	0	2	1	1	0	0	2	2	0	1	9 (36.00%)
15	0	0	1	0	0	0	1	0	0	0	2 (8.00%)
20	0	0	1	0	0	0	0	0	0	0	1 (4.00%)
25	0	0	1	0	0	0	0	0	0	0	1 (4.00%)
30	0	0	1	0	0	0	0	0	0	0	1 (4.00%)
40	0	0	0	0	0	0	0	0	0	0	0 (0%)
50	0	0	0	0	0	0	0	0	0	0	0 (0%)
60	0	0	0	0	0	0	0	0	0	0	0 (0%)
75	0	0	0	0	0	0	0	0	0	0	0 (0%)
100	0	0	0	0	0	0	0	0	0	0	0 (0%)

Respirator No. 5 (size L)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	5	1	2	4	2	2	2	23 (92.00%)
15	2	1	2	5	1	2	4	2	2	2	23 (92.00%)
20	2	0	2	5	1	2	4	1	2	2	21 (84.00%)
25	2	0	2	4	1	2	4	0	2	2	19 (76.00%)
30	1	0	2	3	1	1	3	0	2	2	15 (60.00%)
40	1	0	2	3	0	0	3	0	2	2	13 (52.00%)
50	1	0	2	3	0	0	2	0	2	2	12 (48.00%)
60	1	0	2	3	0	0	2	0	1	2	11 (44.00%)
75	1	0	1	2	0	0	1	0	1	2	8 (32.00%)
100	1	0	1	2	0	0	1	0	0	2	7 (28.00%)

Respirator No. 5 (Size L, Outliers Removed)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	5	1	2	4	2	2	2	23 (92.00%)
15	2	1	2	5	1	2	4	2	2	2	23 (92.00%)
20	2	0	2	5	1	2	4	1	2	2	21 (84.00%)
25	2	0	2	4	1	2	4	0	2	2	19 (76.00%)
30	1	0	2	3	1	1	3	0	2	2	15 (60.00%)
40	1	0	2	3	0	0	3	0	2	2	13 (52.00%)
50	1	0	2	3	0	0	2	0	2	2	12 (48.00%)
60	1	0	2	3	0	0	2	0	1	2	11 (44.00%)
75	1	0	1	2	0	0	1	0	1	2	8 (32.00%)
100	1	0	1	2	0	0	1	0	0	1	6 (24.00%)

Respirator No. 5 (size M)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	4	1	0	3	0	2	2	17 (68.00%)
15	2	1	2	4	1	0	3	0	2	2	17 (68.00%)
20	2	1	2	2	1	0	3	0	2	2	15 (60.00%)
25	2	1	2	2	1	0	3	0	2	2	15 (60.00%)
30	1	1	2	2	0	0	2	0	2	2	12 (48.00%)
40	1	1	2	2	0	0	1	0	1	2	10 (40.00%)
50	1	1	2	2	0	0	1	0	0	2	9 (36.00%)
60	0	1	2	2	0	0	1	0	0	2	8 (32.00%)
75	0	1	2	2	0	0	1	0	0	2	8 (32.00%)
100	0	0	2	2	0	0	1	0	0	2	7 (28.00%)

Respirator No. 5 (size S)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	5	1	2	2	1	2	2	20 (80.00%)
15	2	1	2	5	1	1	2	1	2	2	19 (76.00%)
20	2	1	2	5	1	0	2	1	2	2	18 (72.00%)
25	2	1	2	5	1	0	2	1	2	2	18 (72.00%)
30	2	1	2	5	1	0	2	1	2	2	18 (72.00%)
40	2	1	2	5	1	0	2	1	2	2	18 (72.00%)
50	2	1	2	4	1	0	2	1	2	1	16 (64.00%)
60	2	1	2	3	1	0	1	1	2	1	14 (56.00%)
75	2	1	1	3	0	0	1	1	2	1	12 (48.00%)
100	2	0	1	3	0	0	1	1	2	1	11 (44.00%)

Respirator No. 6 (size L)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	3	1	2	4	1	2	2	20 (80.00%)
15	1	1	2	3	0	1	4	0	2	2	16 (64.00%)
20	1	0	2	3	0	0	3	0	2	2	13 (52.00%)
25	0	0	2	1	0	0	3	0	2	2	10 (40.00%)
30	0	0	1	1	0	0	3	0	2	2	9 (36.00%)
40	0	0	1	1	0	0	2	0	2	1	7 (28.00%)
50	0	0	1	1	0	0	2	0	0	1	5 (20.00%)
60	0	0	1	1	0	0	2	0	0	1	5 (20.00%)
75	0	0	0	1	0	0	1	0	0	0	2 (8.00%)
100	0	0	0	1	0	0	0	0	0	0	1 (4.00%)

Respirator No. 6 (size M)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	4	1	2	3	1	2	2	20 (80.00%)
15	2	1	2	3	1	2	3	1	2	2	19 (76.00%)
20	1	1	2	2	1	1	3	0	2	2	15 (60.00%)
25	1	1	2	2	0	1	3	0	2	2	14 (56.00%)
30	1	1	0	2	0	1	3	0	0	2	10 (40.00%)
40	0	0	0	2	0	1	2	0	0	2	7 (28.00%)
50	0	0	0	2	0	1	2	0	0	2	7 (28.00%)
60	0	0	0	2	0	0	2	0	0	2	6 (24.00%)
75	0	0	0	2	0	0	2	0	0	2	6 (24.00%)
100	0	0	0	2	0	0	1	0	0	2	5 (20.00%)

Respirator No. 6 (size S)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	4	0	1	2	1	2	2	17 (68.00%)
15	1	0	2	3	0	0	2	1	1	2	12 (48.00%)
20	1	0	2	2	0	0	2	0	1	2	10 (40.00%)
25	1	0	2	2	0	0	1	0	1	1	8 (32.00%)
30	1	0	1	2	0	0	1	0	1	1	7 (28.00%)
40	0	0	1	1	0	0	1	0	1	0	4 (16.00%)
50	0	0	1	1	0	0	1	0	1	0	4 (16.00%)
60	0	0	1	1	0	0	1	0	0	0	3 (12.00%)
75	0	0	1	1	0	0	0	0	0	0	2 (8.00%)
100	0	0	1	1	0	0	0	0	0	0	2 (8.00%)

Respirator No. 7 (size L, Outliers Removed)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	1	2	2	24 (96.00%)
15	2	2	2	5	2	2	3	1	2	2	23 (92.00%)
20	2	2	2	4	2	2	3	1	2	2	22 (88.00%)
25	1	2	2	4	2	2	3	0	2	2	20 (80.00%)
30	1	2	2	4	1	2	3	0	2	2	19 (76.00%)
40	1	1	2	4	1	1	3	0	2	2	17 (68.00%)
50	1	1	2	4	1	1	3	0	2	2	17 (68.00%)
60	1	1	2	4	1	0	3	0	1	2	15 (60.00%)
75	1	0	2	4	1	0	2	0	1	2	13 (52.00%)
100	1	0	2	3	1	0	2	0	1	2	12 (48.00%)

Respirator No. 7 (size M)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	1	2	4	1	2	2	23 (92.00%)
15	2	2	2	5	1	2	4	1	2	2	23 (92.00%)
20	2	2	2	5	1	2	4	1	2	2	23 (92.00%)
25	2	2	2	5	1	2	4	0	2	2	22 (88.00%)
30	2	2	2	5	0	2	4	0	2	2	21 (84.00%)
40	2	1	2	5	0	2	4	0	2	2	20 (80.00%)
50	2	1	2	5	0	2	4	0	2	2	20 (80.00%)
60	2	1	2	3	0	2	3	0	2	2	17 (68.00%)
75	2	1	2	3	0	2	3	0	2	2	17 (68.00%)
100	2	1	2	3	0	2	3	0	2	2	17 (68.00%)

Respirator No. 7 (size S)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	1	2	4	1	2	2	23 (92.00%)
15	2	2	2	5	1	2	3	1	2	2	22 (88.00%)
20	2	2	2	5	1	2	3	1	2	2	22 (88.00%)
25	2	2	2	5	1	2	3	1	2	2	22 (88.00%)
30	2	2	2	5	1	2	3	1	2	1	21 (84.00%)
40	2	2	2	5	1	2	3	0	2	1	20 (80.00%)
50	2	2	2	4	1	2	3	0	2	1	19 (76.00%)
60	2	2	2	3	1	2	3	0	2	1	18 (72.00%)
75	2	2	2	3	1	2	3	0	2	0	17 (68.00%)
100	2	2	2	3	1	2	3	0	2	0	17 (68.00%)

Respirator No. 8

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	0	0	1	3	0	0	3	1	2	1	11 (44.00%)
15	0	0	1	1	0	0	3	0	2	1	8 (32.00%)
20	0	0	1	1	0	0	3	0	2	1	8 (32.00%)
25	0	0	1	1	0	0	3	0	2	1	8 (32.00%)
30	0	0	1	1	0	0	3	0	2	1	8 (32.00%)
40	0	0	0	1	0	0	3	0	2	1	7 (28.00%)
50	0	0	0	1	0	0	2	0	2	1	6 (24.00%)
60	0	0	0	1	0	0	2	0	2	1	6 (24.00%)
75	0	0	0	1	0	0	2	0	2	1	6 (24.00%)
100	0	0	0	1	0	0	2	0	2	1	6 (24.00%)

Respirator No. 9

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	1	0	1	2	1	0	3	1	2	2	13 (52.00%)
15	1	0	1	2	1	0	3	1	2	2	13 (52.00%)
20	1	0	0	0	1	0	3	1	2	2	10 (40.00%)
25	1	0	0	0	1	0	3	1	2	2	10 (40.00%)
30	1	0	0	0	0	0	3	1	2	2	9 (36.00%)
40	1	0	0	0	0	0	3	1	2	2	9 (36.00%)
50	1	0	0	0	0	0	3	1	2	2	9 (36.00%)
60	1	0	0	0	0	0	2	0	2	2	7 (28.00%)
75	1	0	0	0	0	0	2	0	2	2	7 (28.00%)
100	1	0	0	0	0	0	2	0	2	2	7 (28.00%)

Respirator No. 10

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	1	1	4	2	2	2	23 (92.00%)
15	2	2	2	5	1	1	4	2	2	2	23 (92.00%)
20	2	1	2	5	1	1	4	2	2	2	22 (88.00%)
25	2	1	2	5	1	1	4	2	2	2	22 (88.00%)
30	1	1	1	5	1	1	4	2	2	2	20 (80.00%)
40	1	1	1	5	1	1	4	2	2	2	20 (80.00%)
50	1	1	1	5	1	1	4	2	2	2	20 (80.00%)
60	1	1	1	4	1	1	4	2	2	2	19 (76.00%)
75	1	1	1	4	1	1	3	2	2	2	18 (72.00%)
100	1	1	1	4	1	1	3	2	2	2	18 (72.00%)

Respirator No. 11

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	4	1	1	4	2	2	2	21 (84.00%)
15	2	1	2	4	1	0	4	2	2	2	20 (80.00%)
20	1	1	1	4	1	0	4	2	2	2	18 (72.00%)
25	1	1	1	4	1	0	4	2	2	2	18 (72.00%)
30	1	0	1	4	1	0	4	2	2	2	17 (68.00%)
40	1	0	1	4	1	0	4	2	2	2	17 (68.00%)
50	1	0	1	4	1	0	4	2	2	2	17 (68.00%)
60	1	0	1	4	1	0	4	2	2	2	17 (68.00%)
75	1	0	1	4	1	0	4	2	2	2	17 (68.00%)
100	1	0	1	4	1	0	4	2	2	2	17 (68.00%)

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Respirator No. 12

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	5	2	2	4	2	2	2	24 (96.00%)
15	2	1	1	4	2	2	2	2	1	2	19 (76.00%)
20	2	1	1	4	2	1	2	2	1	2	18 (72.00%)
25	2	1	1	4	2	1	2	2	1	1	17 (68.00%)
30	2	1	1	4	2	0	2	2	1	1	16 (64.00%)
40	2	1	1	4	2	0	2	2	0	1	15 (60.00%)
50	1	1	1	4	2	0	2	2	0	1	14 (56.00%)
60	1	1	1	4	2	0	2	2	0	1	14 (56.00%)
75	1	1	1	4	2	0	2	2	0	1	14 (56.00%)
100	1	1	0	4	1	0	2	2	0	1	12 (48.00%)

Respirator No. 13

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
40	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
50	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
60	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
75	2	2	2	3	2	2	4	2	2	2	23 (92.00%)
100	2	1	2	3	1	2	4	2	2	1	20 (80.00%)

Respirator No. 14 (size M/L)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
40	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
50	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
60	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
75	2	2	2	5	2	2	3	1	2	2	23 (92.00%)
100	2	2	2	5	2	2	3	1	2	2	23 (92.00%)

Respirator No. 14 (size S)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	1	2	2	4	2	2	4	2	2	2	23 (92.00%)
15	1	2	2	4	2	2	4	2	2	2	23 (92.00%)
20	1	2	2	4	2	2	4	2	2	1	22 (88.00%)
25	1	2	2	4	2	2	4	2	2	1	22 (88.00%)
30	1	2	2	4	2	2	4	2	2	1	22 (88.00%)
40	1	2	2	4	2	2	4	2	2	1	22 (88.00%)
50	1	2	2	4	2	2	4	2	2	1	22 (88.00%)
60	1	2	2	4	2	2	4	2	2	1	22 (88.00%)
75	1	2	2	4	2	2	4	2	2	1	22 (88.00%)
100	1	2	2	4	2	2	4	2	2	1	22 (88.00%)

Respirator No. 15 (size L)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	1	5	2	2	4	2	2	2	23 (92.00%)
15	2	1	1	5	2	2	4	2	2	2	23 (92.00%)
20	2	1	1	5	1	2	4	2	2	2	22 (88.00%)
25	2	1	1	5	1	2	4	2	2	2	22 (88.00%)
30	2	1	0	5	1	2	3	2	2	2	20 (80.00%)
40	2	0	0	4	1	2	3	2	2	2	18 (72.00%)
50	2	0	0	4	1	2	3	2	1	2	17 (68.00%)
60	2	0	0	4	1	2	3	2	1	2	17 (68.00%)
75	2	0	0	4	1	2	3	2	0	2	16 (64.00%)
100	2	0	0	4	0	2	3	2	0	2	15 (60.00%)

Respirator No. 15 (size M)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
40	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
50	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
60	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
75	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
100	2	2	2	4	2	2	4	2	2	2	24 (96.00%)

Respirator No. 15 (size S)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
15	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
20	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
25	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
30	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
40	2	2	1	5	1	0	4	2	2	2	21 (84.00%)
50	2	2	1	4	1	0	4	2	2	2	20 (80.00%)
60	2	2	1	4	1	0	3	2	2	1	18 (72.00%)
75	2	2	1	4	1	0	2	2	2	1	17 (68.00%)
100	2	2	1	4	0	0	2	2	2	1	16 (64.00%)

Respirator No. 16 (size L)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	1	2	5	1	2	4	2	2	2	23 (92.00%)
15	2	1	2	5	1	2	4	2	2	2	23 (92.00%)
20	2	1	2	4	1	2	4	2	2	2	22 (88.00%)
25	2	1	2	4	1	2	4	2	2	2	22 (88.00%)
30	2	0	1	4	1	2	4	2	2	2	20 (80.00%)
40	2	0	1	4	1	2	4	2	2	2	20 (80.00%)
50	1	0	1	4	1	2	4	2	2	2	19 (76.00%)
60	1	0	1	4	1	2	4	2	2	2	19 (76.00%)
75	1	0	1	4	1	2	4	2	2	2	19 (76.00%)
100	1	0	0	4	1	2	3	2	2	2	17 (68.00%)

Respirator No. 16 (size M)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	1	2	4	2	2	2	24 (96.00%)
15	2	2	2	5	1	1	4	2	2	2	23 (92.00%)
20	2	2	2	4	1	1	4	2	2	2	22 (88.00%)
25	2	2	2	4	1	1	3	2	2	2	21 (84.00%)
30	2	1	2	4	1	1	3	2	2	2	20 (80.00%)
40	2	1	2	4	0	1	3	2	2	2	19 (76.00%)
50	2	1	2	4	0	1	3	1	2	2	18 (72.00%)
60	2	1	2	4	0	1	3	1	2	2	18 (72.00%)
75	2	1	2	3	0	1	3	1	2	2	17 (68.00%)
100	2	1	2	3	0	1	3	1	2	2	17 (68.00%)

Respirator No. 16 (size S)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	2	1	1	0	19 (76.00%)
15	2	2	2	5	2	2	2	1	1	0	19 (76.00%)
20	2	2	2	5	2	2	2	1	1	0	19 (76.00%)
25	2	2	2	5	2	2	2	1	1	0	19 (76.00%)
30	2	2	2	5	2	2	2	1	1	0	19 (76.00%)
40	2	2	2	5	2	2	2	0	1	0	18 (72.00%)
50	2	2	2	5	1	2	1	0	1	0	16 (64.00%)
60	2	2	2	5	1	1	1	0	1	0	15 (60.00%)
75	2	2	2	5	1	1	1	0	1	0	15 (60.00%)
100	2	2	2	5	1	1	1	0	1	0	15 (60.00%)

Respirator No. 17 (size L)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
40	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
50	2	1	2	4	2	2	4	2	2	2	23 (92.00%)
60	2	1	2	4	2	2	4	2	2	2	23 (92.00%)
75	2	1	2	4	2	2	4	2	2	2	23 (92.00%)
100	2	0	2	4	1	2	3	2	2	2	20 (80.00%)

Respirator No. 17 (size M)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	1	2	5	2	2	4	2	2	2	24 (96.00%)
40	2	1	2	5	2	2	4	2	2	2	24 (96.00%)
50	2	1	2	5	2	2	4	2	2	2	24 (96.00%)
60	2	1	2	5	2	2	3	2	2	2	23 (92.00%)
75	2	1	2	5	2	2	3	2	2	2	23 (92.00%)
100	2	1	2	5	2	2	3	2	2	2	23 (92.00%)

Respirator No. 17 (size S)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
40	2	2	1	5	2	2	4	2	2	2	24 (96.00%)
50	2	2	1	5	2	2	4	2	2	2	24 (96.00%)
60	2	2	1	5	2	2	4	2	2	2	24 (96.00%)
75	2	2	1	5	2	2	4	2	2	2	24 (96.00%)
100	2	2	1	5	2	2	4	2	2	2	24 (96.00%)

Respirator No. 18

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	1	1	2	2	2	2	4	1	2	2	19 (76.00%)
15	0	1	2	1	2	2	4	0	2	2	16 (64.00%)
20	0	1	2	1	2	2	4	0	2	2	16 (64.00%)
25	0	1	2	1	2	2	4	0	2	2	16 (64.00%)
30	0	1	2	1	2	2	4	0	2	2	16 (64.00%)
40	0	1	2	1	2	2	4	0	2	1	15 (60.00%)
50	0	1	2	1	2	2	4	0	2	1	15 (60.00%)
60	0	1	2	1	2	2	4	0	2	1	15 (60.00%)
75	0	1	2	1	2	2	4	0	2	1	15 (60.00%)
100	0	1	2	1	2	2	3	0	2	1	14 (56.00%)

Respirator No. 19

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	1	2	2	2	2	2	1	0	1	1	14 (56.00%)
15	0	1	2	1	2	2	1	0	0	1	10 (40.00%)
20	0	1	2	1	2	2	1	0	0	1	10 (40.00%)
25	0	1	2	1	2	2	1	0	0	0	9 (36.00%)
30	0	1	2	1	2	2	1	0	0	0	9 (36.00%)
40	0	1	2	1	2	2	1	0	0	0	9 (36.00%)
50	0	1	2	1	2	2	0	0	0	0	8 (32.00%)
60	0	1	2	1	2	2	0	0	0	0	8 (32.00%)
75	0	1	2	1	2	2	0	0	0	0	8 (32.00%)
100	0	1	1	1	2	2	0	0	0	0	7 (28.00%)

Respirator No. 20 (outliers removed)

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	1	2	2	5	2	2	4	2	2	2	24 (96.00%)
20	0	2	2	5	2	2	3	2	2	2	22 (88.00%)
25	0	2	1	5	2	2	3	2	2	2	21 (84.00%)
30	0	2	1	4	2	2	2	2	2	2	19 (76.00%)
40	0	2	1	4	2	2	2	2	2	2	19 (76.00%)
50	0	2	1	4	2	2	2	2	2	2	19 (76.00%)
60	0	2	1	4	2	2	2	2	2	2	19 (76.00%)
75	0	2	1	4	2	2	2	2	2	2	19 (76.00%)
100	0	1	1	4	1	2	2	2	2	2	17 (68.00%)

Respirator No. 21

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	1	2	2	24 (96.00%)
15	1	2	2	5	2	1	4	1	2	2	22 (88.00%)
20	1	2	2	5	2	1	4	1	2	2	22 (88.00%)
25	1	2	2	5	2	1	4	1	2	2	22 (88.00%)
30	1	2	2	5	2	1	3	1	2	2	21 (84.00%)
40	1	2	2	5	2	1	3	1	2	2	21 (84.00%)
50	1	2	2	4	2	0	3	1	2	1	18 (72.00%)
60	1	0	2	4	2	0	3	1	2	1	16 (64.00%)
75	1	0	2	3	0	0	2	0	2	0	10 (40.00%)
100	1	0	1	3	0	0	2	0	2	0	9 (36.00%)

Respirator No. 22

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
40	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
50	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
60	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
75	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
100	2	2	2	5	2	2	4	2	2	2	25 (100.00%)

Respirator No. 23

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	Cell 1	Cell 2	Cell 3	Cell 4	Cell 5	Cell 6	Cell 7	Cell 8	Cell 9	Cell 10	N (%)
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
15	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
20	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
25	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
30	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
40	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
50	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
60	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
75	2	2	2	5	2	1	4	2	2	2	24 (96.00%)
100	2	2	2	5	2	1	4	2	2	2	24 (96.00%)

Respirator No. 24

	Number of Subjects that Achieve Goal by Cell										Total
Fit Factor Goal	**Cell 1**	**Cell 2**	**Cell 3**	**Cell 4**	**Cell 5**	**Cell 6**	**Cell 7**	**Cell 8**	**Cell 9**	**Cell 10**	**N (%)**
Subjects in cell	2	2	2	5	2	2	4	2	2	2	25
10	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
15	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
20	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
25	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
30	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
40	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
50	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
60	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
75	2	2	2	5	2	2	4	2	2	2	25 (100.00%)
100	2	2	2	5	2	2	4	2	2	2	25 (100.00%)

INTERNATIONAL
SAFETY EQUIPMENT
ASSOCIATION
ISEA

January 19, 2010

The Hon. Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: Petition on NIOSH Administrative/Quality Assurance Proposed Regulation and NIOSH Total Inward Leakage of Respirators Proposed Regulation

Dear Secretary Sebelius:

The International Safety Equipment Association (ISEA) fully supports the need to have high quality and reliable respiratory protective devices available to a wide range of US workers. Recent proposed regulations by NIOSH state this intended purpose. However ISEA believes strongly that the proposed regulations not only fall short of their intended purpose, but may in fact stifle the development and introduction of new and innovative products that would result in increased worker protection.

ISEA, pursuant to subsection 553(e) of the Administrative Procedure Act, 5 U.S.C. §551, *et seq.*, petitions HHS and NIOSH to defer work and re-open the record on the proposed NIOSH Administrative/Quality Assurance (QA) (73 FR 75045) rulemaking until HHS and NIOSH conduct a more complete regulatory flexibility analysis and economic analysis of the proposed QA rule, and to receive and consider additional comments and analyze additional data regarding the need for and effect of that proposed regulation in light of the more recently proposed NIOSH Total Inward Leakage (TIL) rule (74 FR 56141). Specifically, the need for and effect of the proposed QA rule now needs to be analyzed in combination with the proposed TIL rule.

Together, these proposed rules have the potential to very significantly alter the manner in which respirators are made and tested and to negatively affect both the availability of respirators for the community of respirator users as well as the costs incurred by respirator manufacturers and the employers and individuals who purchase respirators. Moreover, the need for these rules has not been established in the record thus far, and is highly suspect.

NIOSH's QA Preamble Questions the Need for the QA Rule

As NIOSH recognized in its proposed QA rule preamble, "most respirator manufacturers maintain effective quality management systems," and the number of times NIOSH has had to take action "cover a small number of the 7,100 respirators approved by NIOSH . . ." By NIOSH's own admission, any problem with respirator quality assurance is small. Nor is there any evidence in the record of either of the proposed rules that performance issues exist with respiratory protection products currently on the market that should require respiratory protection manufacturers to conduct the cumbersome and unreliable procedures outlined under these two proposed rules. In fact, NIOSH's proposed testing regime would likely prevent some respirators from entering the marketplace which are needed to fit facial configurations that differ from the panel norms that NIOSH is attempting to establish. The reduced availability of respirators that could result from the proposed rules would make it more difficult and costly in many cases for employers to comply with the OSHA fit testing requirements for respirators. After all, it is the OSHA fit testing requirement that ensures that the end-user is properly protected.

Discussion of QA and TIL Rules

As pointed out above, and admitted by NIOSH, the justification for these proposals are difficult to evaluate. First, with respect to QA, NIOSH already requires that respiratory protection manufacturers have "quality plans" and comply with other QA-related regulations at 42 C.F.R. §84.40. Nevertheless, the core of the proposed QA rule would require that respirator manufacturers adopt one of four specific

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quality control plans, none of which is presently widely used by the community of respiratory protection manufacturers. The QA rule also imposes a number of requirements for reporting to NIOSH, and would require NIOSH certification holders to conform to ISO9001.

These requirements of the proposed QA rule would unnecessarily change the current quality assurance practices of respiratory protection manufacturers. Currently, sampling of components and finished goods is conducted in accordance with ANSI/ASQ Z1.4-2008, the American National Standard for Sampling Procedures and Tables for Inspection by Attributes, a widely accepted industry consensus standard. The proposed four QA specification standards would greatly increase the number of products that must be tested and the level to which they are tested, and for no apparent reason.

Moreover, the proposed QA rule's overall approach does not comport with current QA practices. The QA rule would require manufacturers to assess quality at the end of a production run, rather than the current practice of assessing the quality of incoming parts and components and training employees to manage quality during a production run. There is no evidence in the record or otherwise that the current practice does not effectively ensure that finished products meet manufacturer specifications for form, fit, function and appearance. In fact, CDC, NIOSH, OSHA and the Institute of Medicine (IOM) have recently underscored and approved the use of fit-tested N95-rated respirators for use to protect wearers from H1N1 exposure. In a recent exhaustive literature survey on respiratory protection, the IOM made no mention of concerns about these devices. As mentioned above, NIOSH has acknowledged that "most respirator manufacturers maintain effective quality management systems."

Rather than unnecessarily changing the current overall approach to QA, an alternate rule could be proposed that includes general updates to quality assurance plans, such as third-party compliance with ISO 9001:2008. This internationally accepted standard assures quality manufacturing processes. In addition, NIOSH should use its current authority under 42 C.F.R. §84.34 and 42 C.F.R. §84.43(c) to audit and penalize respirator manufacturing companies whose respiratory protection products are found to be out of compliance.

The TIL rule seeks to require respirator manufacturers to test and mark respirators based on a new testing regime meant to simulate the face sizes and shapes of respirator wearers. Under the proposed testing regime, a group of 35 test subjects would represent a certain sector of wearers. But there is great variability even in grouping types of wearers, and 35 subjects do not represent the universe of wearers. The proposed testing regime may prevent some respirators from entering the marketplace which are needed to fit facial configurations that differ from the panel norms that NIOSH is attempting to establish.

While the goal of the proposed regulation is to have in the market respirators that fit a range of users, which ISEA supports, the benchmark testing on which NIOSH based its proposed regulation and the assumptions made based on the data both appear to be flawed. Additionally, the primary manufacturer of the test equipment (TSI, Inc.) does not support the manner in which NIOSH proposes to use their equipment as outlined in their comments to the NIOSH docket. ISEA supports the need for respiratory protective devices to show evidence that they have the capability to fit a range of facial characteristics; however the methodology currently being proposed lacks reproducibility and is overly cumbersome.

Finally, there is no crisis in respiratory protection that demands either of these burdensome proposed rules. Quality respiratory protection products are currently available, and OSHA requires that these respirators fit each wearer properly.

Effect of QA and TIL Rules

The combined regulations will disrupt the market place for respirators when they are needed most – during a flu pandemic – with no real measurable benefit to users. As pointed out the proposed testing regime would unnecessarily prevent some respirators from entering the marketplace which are needed to fit faces with facial configurations that differ from the panel norms that NIOSH is attempting to establish. The proposed QA rule, which unnecessarily adds a layer of requirements over what manufacturers are already doing to ensure respirator quality, would also have the effect of preventing some number of

quality respirators from entering the marketplace. Yet, ISEA is not aware of any workplace performance failures or crisis in products that necessitate either the QA or TIL rules. Nor has the extent of this effect been analyzed by NIOSH.

Regulatory Flexibility Act Concerns

Proposed QA Rule Regulatory Flexibility Act Concerns

In addition to the potentially dangerous disruption of respirator supply at a time when respiratory protection is more necessary than ever, the proposed rules combined would have a significant economic impact on both the respiratory protection industry and the employers and individuals who use respirators. Compliance costs of the QA rule alone are likely to be more than $100 million based on a survey of ISEA members and the number of NIOSH respirator certification holders. Specifically, the five ISEA member companies that were surveyed each estimated the cost to change QA plans in accordance to the proposed rule and to comply with other parts of the measure to be $5 million per company, and possibly more for those companies with multiple product lines. NIOSH recognizes that the majority of respirator manufacturers are small businesses (73 FR 75051). Since there are more than 100 listed respiratory protection approval holders on NIOSH's website, the overall economic impact of this rule could easily exceed $100 million, mainly to small businesses. (*See attached estimates*).

Yet, in the proposed QA rule, NIOSH did not conduct an economic impact analysis. NIOSH instead stated that "it does not have access to information to estimate costs and cost savings associated with changes some manufacturers might make in response to the proposed sampling plan requirements." NIOSH requested information from manufacturers that might be useful in establishing such an estimate, but the agency says it "expects that any company that would be required to make changes would have difficulty estimating *ex ante* the potential economic impact of the changes." (73 FR 75051)

ISEA did submit cost estimates. Based on this limited sampling of manufacturers, it spears that the cost of compliance would be substantial and therefore, ISEA believes that NIOSH can and must develop a comprehensive cost estimate before moving forward with any rulemaking activity.

NIOSH also stated in the QA proposal that there "are substantial difficulties in making such estimates for a company that lacks well-controlled production processes: First, the causes of quality problems must be identified; and second, once such cause or causes are identified, there are likely to be multiple alternatives for solving the problems identified." (73 FR 75052)

ISEA believes, however, that NIOSH could estimate the cost of compliance even for a company that lacks a well-controlled production process. NIOSH could hire a management systems contractor to construct such cost estimates.

NIOSH also says that a company with a high-quality QA plan would be in a position to estimate some of the possible cost savings associated with quality improvements, "such as (1) reduced inspection costs; (2) avoided losses associated with nonconforming materials, components, and final assembled products; and (3) reduced losses." (73 FR 75052)

ISEA members have not identified any cost savings in the proposed QA regulation in any way, and they do not see how the proposed rule offers the three benefits NIOSH suggests. Moreover, current quality control systems work well.

NIOSH ends its regulatory analysis of the QA proposal by stating that "for the reasons provided, a regulatory flexibility analysis, as provided for under the RFA, is not required." (73 FR 75052)

ISEA disagrees. NIOSH did not estimate the baseline compliance costs with the costs to comply with the new proposed rule. In addition, NIOSH did not comply with various sections of the Regulatory Flexibility Act, such as Sec. 603(b)(3) which requires an estimate of the number of entities likely to be impacted; Sec.603(c), which requires a description of alternatives to the proposed rule which accomplish the stated

objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities; Sec. 603(c)(3) which encourages the use of performance rather than design standards; and Sec. 607, which encourages the preparation of quantitative and numerical analyses.

Proposed QA Regulatory Flexibility Act Certification Must Be Reversed; No Factual Basis for Claims

HHS certified the proposed QA rule Regulatory Flexibility Act analysis, stating that the proposed QA "would not have a significant economic impact on a substantial number of small entities" (73 FR 75051). ISEA asks how this can be if NIOSH states it "does not have access to information to estimate costs" of the proposed rule (73 FR 75052) and the number of small entities was not mentioned. In fact, NIOSH asks the regulated community for cost information. NIOSH states multiple times throughout its "Regulatory Assessment Requirements" section that there will likely be no costs associated with this proposed rule. ISEA submits there is no factual basis for the claim that there is no significant economic impact. Furthermore, baseline compliance costs and new compliance costs were not discussed.

Proposed TIL Rule Regulatory Flexibility Act Concerns

While the proposed QA rule alone raises significant cost issues for the regulated community, ISEA's concerns are compounded by the recently published proposed TIL rule.

In the proposed TIL rule NIOSH did not comply with Regulatory Flexibility Act Sec. 603(b)(3) which requires an estimate of the number of entities likely to be impacted; Sec.603(c), which requires a description of alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities; Sec. 603(c)(3) which encourages the use of performance rather than design standards; and ISEA questions the validity of the quantitative analysis. The proposed TIL rule's true costs are unknown. Although NIOSH did conduct a TIL cost estimate for the Regulatory Flexibility Act requirements, ISEA members have not yet been able to verify it or conduct their own cost estimates.

Proposed TIL Regulatory Flexibility Act Certification Must Be Reversed

HHS certifies that the proposed TIL rule "would not have a significant impact on a substantial number of small entities" (74 FR 56148), but as noted above, NIOSH did not estimate the number of small businesses that might be impacted. NIOSH even states it "cannot estimate the total costs associated with this rulemaking…" (74 FR 56147). But later in the proposed TIL rule, NIOSH estimates costs to be $3.1 million for the first two years and $825,000 annually after that. ISEA is concerned about the factual basis upon which these estimates were created and the factual basis of the certification that the proposed TIL rule "would not have a significant impact on substantial number of small entities." In the "Relief Requested" section, the Association asks for a one-year extension of the TIL comment period to develop these cost estimates in conjunction with testing the validity and reproducibility of NIOSH's proposed test methods.

Summary

In sum, the proposed TIL rule, with its potential to alter the manner in which respirators are made and tested, combined with the proposed QA rule, would impose significant costs on respiratory protection manufacturers and end-users that far outweigh speculative benefits. More importantly, the combined regulations will disrupt the supply of respirators in the marketplace when they are needed most – during a flu pandemic – with no real benefit to users. And yet ISEA is not aware of any market failures or crisis in products that necessitate the costs and disruption of supply that would be the combined effect of the QA and TIL rules.

Relief Requested

ISEA submits that the requirements of both the Regulatory Flexibility Act and Executive Order 12866 apply to these proposed rules and require NIOSH to complete and support with evidence in the record an assessment of the true costs of the proposed rules, which have a combined effect, as well as an examination of less costly regulatory alternatives. This has not been completed for either proposed rule. ISEA thus respectfully requests that NIOSH keep the record open on both proposed rules until such a cost assessment and examination of alternatives have been completed for the combined effect of the QA and TIL proposals on the community of respirator manufacturers and users.

Specifically, we request that NIOSH defer work on the proposed QA and TIL rules until the following are completed:

NIOSH prepares and publishes a true cost estimate for the proposed QA rule and supports that estimate on a factual basis in the rulemaking record;

NIOSH must assess the combined costs and economic impact of the two proposed rules on the regulated community, including those that are small businesses, and support that assessment in the rulemaking record;

ISEA members have commissioned independent testing of respirators using NIOSH's proposed TIL metrics to obtain data on the validity of NIOSH's TIL assumptions. Following ISEA's independent testing, we ask that NIOSH conduct designed experiments that would enable a statistical evaluation of the impact that subjects, time, and products have upon the output of the proposed TIL rule. For example: What is the variability in subject pass rate in the NIOSH TIL test for a given model of a half facepiece respirator between different panels of subjects? Are three repeat donnings of a single half facepiece respirator in the NIOSH TIL test equivalent to donning three half facepiece respirators? Are the three repeat donnings less variable? The regulated community is open to two-way dialogue with NIOSH about our concerns on the lack of reliability of the TIL method. ISEA asks for a one-year extension of the comment period on the proposed TIL rule so that this data and the cost of the proposed rule can be fully analyzed.

Examine and discuss with the regulated community any performance-based, less burdensome, and/or less costly alternatives to the proposed rules (as required by the Regulatory Flexibility Act and Executive Order 12866). ISEA understands this may mean the proposed rules are withdrawn and republished as performance-based, less burdensome and less costly proposed rules.

Finally, ISEA respectfully requests that NIOSH carefully evaluate the combined effect of both proposed rules on the availability and cost of respirators for the community of respirator users.

Respectfully Submitted,

Daniel K. Shipp
President

Attachment

Estimated Additional Hours and Cost for Compliance

	Filtering Facepiece Respirators			Facepiece Respirators - Facepiece			Facepiece Respirators - Filter Cartridge		
Initial Compliance	Technician	Engineer	Total	Technician	Engineer	Total	Technician	Engineer	Total
1a	918	5849		1388	4068		9300	16036	
2a	256	102		70	670		68	1370	
3a	200	506		160	255		1760	1869	
Total hours	1374	6457		1618	4993		11128	19275	
Estimated cost	$ 34,350	$ 484,275	$ 518,625	$ 40,450	$ 374,475	$ 414,925	$ 278,200	$ 1,445,625	$ 1,723,825
Ongoing Compliance									
1b	113005.5	1350		7120	500		44010	5908	
2b	1604	2810		3024	3430		21280	28645	
3b	4768	1410		1950	565		15315	4181	
Total hours	119377.5	5570		12094	4495		80605	38734	
Estimated cost	$ 2,984,438	$ 417,750	$ 3,402,188	$ 302,350	$ 337,125	$ 639,475	$ 2,015,125	$ 2,905,050	$ 4,920,175

	Supplied Air Respirators			PAPRs			SCBA		
Initial Compliance	Technician	Engineer	Total	Technician	Engineer	Total	Technician	Engineer	Total
1a	3750	5617		925	2870		7350	12600	
2a	68	170		68	370		0	0	
irators, October 9, 2009	800	834		160	299		125	160	
Total hours	4618	6621		1153	3539		7475	12760	
Estimated cost	$ 115,450	$ 496,575	$ 612,025	$ 28,825	$ 265,425	$ 294,250	$ 186,875	$ 957,000	$ 1,143,875
Ongoing Compliance									
1b	1750	2500		2486	500		86875	5250	
2b	9166	13588		7266	7796		1575	3150	
3b	6856	1814		3212	482		1680	5376	
Total hours	$ 17,772	$ 17,902		$ 12,964	$ 8,778		90130	13776	
Estimated cost	$ 444,300	$ 1,342,650	$ 1,786,950	$ 324,100	$ 658,350	$ 982,450	$ 2,253,250	$ 1,033,200	$ 3,286,450

KEY

1a. Quality Plans: Plan Updates and Documentation Changes, includes updates to drawings, product standards, work instructions, PQPs, etc.
2a. Annual Respirator System Product Quality Audit Testing: Setting up the system
3a. Complaint Handling and Reporting to NIOSH: Setting up the system
1b. Quality Plans: Inspection Testing for Production each year
2b. Annual Respirator System Product Quality Audit Testing: Carrying out the requirements each year
3b. Complaint Handling and Reporting to NIOSH: Carrying out the requirements each year

Estimates $25/hour for a techician and $75/hour for an engineer

Estimated Additional Hours and Costs for Compliance
Summary of All Categories

Additonal one-time compliance cost

	Technician Hours	Engineer Hours	Total
1a. Quality Plans: Plan Updates and Documentation Changes, includes updates to drawings, product standards, work instructions, PQPs, etc.	23,631	47,040	70,671
2a. Annual Respirator System Product Quality Audit Testing: Setting up the system	530	2,682	3,212
3a. Complaint Handling and Reporting to NIOSH: Setting up the system	3,205	3,923	7,128
Total hours	**27,366**	**53,645**	**81,011**
Estimated cost	**$684,150**	**$4,023,375**	**$4,707,525**

Additonal ongoing compliance cost

	Technician Hours	Engineer Hours	Total
1b. Quality Plans: Inspection Testing for Production each year	255,246.5	16,008	271,254.5
2b. Annual Respirator System Product Quality Audit Testing: Carrying out the requirements each year	43,915	59,419	103,334
3b. Complaint Handling and Reporting to NIOSH: Carrying out the requirements each year	33,781	13,828	47,609
Total hours	**332,942.5**	**89,255**	**422,197.5**
Estimated cost	**$16,647,125**	**$4,462,750**	**$21,109,875**

Notes:
1. Salary for technician ($25/hr) and engineer ($75/hr) is based upon National Salary Trend for area and includes overhead.
2. Resource requirements will be adjusted yearly and may increase or decrease depending upon the business opportunities.

This table was submitted as part of ISEA's comments to NIOSH on proposed Quality Assurance Requirements for Respirators, October 9, 2009