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Appendix A. Study Protocol

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STUDY PROTOCOL

Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering-Facepiece Respirator Fit

By

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September 4, 2007

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1. Project Overview

1.1 Title

"Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering-Facepiece Respirator Fit".

1.2 Protocol Summary

The goals of this study are to (a) assess the rate at which respirator fit changes as a function of time for a representative sample of subjects wearing filtering-facepiece respirators and (b) investigate the factors that affect such change. The specific arms of this study are to (1) determine – for time intervals of 6, 12, 18, 24, 30, and 36 months – the number of instances when a subject's respirator penetration increases more than 25%, (2) determine – for the same time periods – the number of instances when a subject's fit becomes unacceptable, (3) determine the corresponding percentages of test subjects whose respirator penetration increases more than 25% and whose fit becomes unacceptable during the these time intervals, (4) assess the extent to which changes in fit are associated with recognizable changes in the subject characteristics, and (5) investigate the correlation between respirator fit and subject characteristics at every six month interval.

A sample of 220 subjects will be recruited for this study. They will be recruited according to the frequency of the respirator user population in each face size category of the new National Personal Protective Technology Laboratory bivariate respirator fit test panel based on face width and face length. Each subject will be trained to don and wear a filtering-facepiece respirator model in accordance with the instructions of the respirator manufacturer. The metric for respirator fit will be the respirator penetration (1/fit factor) measured with the TSI Portacount instrument coupled with the TSI Companion accessory. The Occupational Safety and Health Administration (OSHA) fit test protocol and exercises will be used. The study will include only subjects who (a) pass a fit test as required by OSHA and (b) demonstrate, through a series of nine donnings, that they can achieve adequate protection with high consistency. A subject will be considered to have demonstrated adequate protection with high consistency when, after nine trial donnings, the 90th percentile penetration is 0.05 or less.

Following the respirator fit tests, a set of 13 traditional face measurements, in addition to height and weight, will be obtained. After the traditional measurements, subjects will also be scanned using a Cyberware Model 3030 head scanner.

After approximately 6 months, each subject will be retested and penetrations measured for 9 donnings of the respirator. Again, the test technician will (a) instruct the subject in

the proper donning procedure and (b) observe each donning to assure that each donning is in accordance with the manufacturer's instructions. The 90th percentile of the nine 6-month penetration values, $P_{90}(t=6)$, will be computed. Each subject will again be measured using traditional tools and scanned using the Cyberware head scanner.

The above routine will be repeated until seven testing cycles (spanning 3 years) are completed for each subject – regardless of the changes in fit that may occur during the course of the study. A subject's fit will be considered to have become unacceptable if the 90th percentile penetration becomes greater than 0.05 (i.e., if 10% or more of the subject's donnings have a penetration greater than 0.05). Physical changes (weight, facial dimensions, dental status, etc.) will also be assessed every 6 months. The rate at which respirator fit changes as a function of time will be determined. Possible relationships between such physical changes and changes in respirator fit will also be investigated.

This study will be the first of this kind. Its aims, unique design, and application of the state-of-the-art technologies will provide a basis for quantifying the benefit of periodic fit testing and determining the appropriate periodicity. Percentage of subjects whose fit become unacceptable is the best estimate of the true percentage of workers who will benefit from the annual fit testing. The results of this study will provide the scientific basis for regulatory agencies to enforce the annual fit testing requirement. The results will also help convince users to be in compliance with the standards. Correlating changes in physical appearance and facial anthropometrics with changes in respirator fit could result in improved guidelines for respirator program administrators and improved respirator designs.

1.3 Investigators/Collaborator

Ziqing Zhuang, Ph.D., NPPTL/NIOSH
Donald L. Campbell, Ph.D., EG&G Technical Services, Inc.
Ronald Shaffer, Ph.D., NPPTL/NIOSH
Dennis Viscusi, NPPTL/NIOSH
Douglas Landsittel, Ph.D., NPPTL/NIOSH

Ziqing Zhuang, Ph.D. Dr. Zhuang provides technical guidance for this study and is responsible for high quality data collection, data analyses, and dissemination of study results. His major areas of expertise are occupational health and safety engineering and industrial engineering. Dr. Zhuang joined NIOSH in 1996 and joined NPPTL since NPPTL was established. He has more than 15 years of research experience in respiratory protection. Dr. Zhuang conducted a series of workplace protection factor studies at foundry, paint-spraying, and steel-manufacturing operations. He was involved in various studies to compare fit factors of six quantitative fit test methods with exposure

dose of Freon-113, to measure laboratory performance of N95 respirators, and to determine the adequacy of Bitrex, Saccharin, ambient aerosol (PortaCount), PortaCount with N95 Companion, and generated aerosol fit test methods. His recent work included head-and-face anthropometric survey of U.S. respirator users, development of respirator fit test panels representative of today's U.S. workforce, and development of standard headforms for testing respirators, safety glass, and helmets. He serves on the ISO TC94 SC15 respiratory protective device standards, WG1 (working group 1) and WG2. He is the Editor for the Journal of the International Society for Respiratory Protection. Two of his papers were selected as the NIOSH nominees for the CDC Charles Shepard Science Award and the Institute outstanding scientific papers in 2004 and 2006. He also received the AIHA John White Best Paper Award in 1996, 1999, and 2000.

Donald L. Campbell, Ph.D. Dr. Campbell, formerly a senior scientist with NIOSH, has 30 years of research experience related to respiratory protection. He has several recent publications relating specifically to face fit testing. Currently a senior scientist for EG&G Technical Services, Inc., he will provide technical assistance with this project.

Ronald Shaffer, Ph.D. Dr. Shaffer will provide technical guidance for this study. He joined NIOSH/NPPTL as a Supervisory Physical Scientist and Chief of the Technology Research Branch in June 2003. Dr. Shaffer is a recognized expert on the performance of personal protective equipment (PPE) against potential and emerging threats such as nanotechnology, pandemic influenza, and chemical/biological warfare agents and the application of chemical micro-sensors to PPE. He served as the primary author of a "white paper" on the Efficacy and Utility of Filtering Facepiece Respirators for an internal NIOSH working group on Occupational Safety and Health Issues Associated with Influenza: Highly Pathogenic Avian, Seasonal, and Possible Occurrence of Pandemic. He initiated a new project on "Reusability of Filtering Facepiece Respirators (FFR)". This project will address fundamental knowledge gaps necessary to develop appropriate mitigation strategies if an influenza pandemic occurs and the nation's supply of respirators becomes limited.

Dennis Viscusi. Mr. Viscusi joined NIOSH in 2001 and has been focusing on project methods development and data collection associated with a project entitled "Reusability of Filtering Facepiece Respirators (FFR)". He has had nearly 30 years of experience as an analytical chemist with a major emphasis on gas chromatography and computer related electronic systems. For the last six years he has been trained for and conducted many quantitative fit tests for various respirator systems and ensembles using various fit test from methods in conjunction with multiple NPPTL projects.

Douglas Landsittel, Ph.D. Dr. Landsittel will provide statistical assistance for this study. He is currently an assistant professor of statistics at Duquesne University and

works part-time for NIOSH/NPPTL. He has previously worked at the University of Pittsburgh as the Associate Director for Biostatistics at the Cancer Institute and NIOSH/HELD&DSR in Morgantown, WV.

Raymond J. Roberge, MD, MPH. Dr. Roberge will review the questionnaires completed by potential subjects, exam them if he deems necessary, and make a determination on the subjects if they can participate in this study. Dr. Roberge joined NIOSH in 2005 as a Research Medical Officer and is currently involved in human subject physiologic testing and providing medical perspective and oversight on various NPPTL projects. He is a co-author on a recent published manuscript that evaluated the effects of increased body weight upon respirator fit-test panels. He is board-certified in Emergency Medicine and Medical Toxicology with 25 years of clinical experience and is board-eligible in Occupational Medicine.

2. Introduction

Respiratory protection is critically dependent upon the fit of the respirator to the user's face. Therefore, OSHA regulations (29 CFR 1910.134) require respirator users to pass a standard fit test before using a respirator. Thereafter fit testing and training are required to be conducted annually. During rulemaking by OSHA, data from four commenters were considered in establishing the OSHA annual fit test requirement. The Texas Chemical Council indicated that "virtually no individuals fail fit tests a year after initial testing." The Exxon Company reported less than 1% annual fit test failure rate. A third (Lord Corporation) conducted fit testing annually and found less than 1-3% of employees switching to different sizes and/or models. The fourth commenter (Hoffmann-La Roche) conducted fit testing every two years and found that 7% of the employees switched to different sizes and/or models. OSHA considered 7% to be too high and unacceptable. Thus, the annual fit testing and training requirement was adopted in 1998 OSHA standard, i.e. 29 CFR 1910.134.

So far, there is no scientific study to investigate the benefit of annual fit testing and the appropriate periodicity. The healthcare industry challenged this requirement at a Workshop on Respiratory Protection for Airborne Infectious Agents held on November 30 – December 1, 2004 in Atlanta, Georgia (CDC, 2004). The research gaps and needs were also documented in the breakout summary report as follows:

- Quantify the benefit of annual respirator fit testing.
- Gather data to determine whether annual fit testing must be performed in the same entirety and manner as initial fit testing.
- Conduct respirator studies in the field to rigorously validate initial and annual fit testing rules that were theoretically derived.
- Redesign annual fit testing to only verify individuals can properly don the

- respirator fit. Such conditions include, but are not limited to, facial scarring, dental changes, cosmetic surgery, or an obvious change in body weight.*
- (4) If after passing a QLFT or QNFT, the employee subsequently notifies the employer, program administrator, supervisor, or PLHCP that the fit of the respirator is unacceptable, the employee shall be given a reasonable opportunity to select a different respirator facepiece and to be retested.*
 - (5) The fit test shall be administered using an OSHA-accepted QLFT or QNFT protocol. The OSHA-accepted QLFT and QNFT protocols and procedures are contained in Appendix A of this section.*
 - (6) QLFT may only be used to fit test negative pressure air-purifying respirators that must achieve a fit factor of 100 or less.*
 - (7) If the fit factor, as determined through an OSHA-accepted QNFT protocol, is equal to or greater than 100 for tight-fitting half facepieces, or equal to or greater than 500 for tight-fitting full facepieces, the QNFT has been passed with that respirator.*
 - (8) Fit testing of tight-fitting atmosphere-supplying respirators and tight-fitting powered air-purifying respirators shall be accomplished by performing quantitative or qualitative fit testing in the negative pressure mode, regardless of the mode of operation (negative or positive pressure) that is used for respiratory protection.
 - (i) Qualitative fit testing of these respirators shall be accomplished by temporarily converting the respirator user's actual facepiece into a negative pressure respirator with appropriate filters, or by using an identical negative pressure air-purifying respirator facepiece with the same sealing surfaces as a surrogate for the atmosphere-supplying or powered air-purifying respirator facepiece.*
 - (ii) Quantitative fit testing of these respirators shall be accomplished by modifying the facepiece to allow sampling inside the facepiece in the breathing zone of the user, midway between the nose and mouth. This requirement shall be accomplished by installing a permanent sampling probe onto a surrogate facepiece, or by using a sampling adapter designed to temporarily provide a means of sampling air from inside the facepiece.*
 - (iii) Any modifications to the respirator facepiece for fit testing shall be completely removed, and the facepiece restored to NIOSH-approved configuration, before that facepiece can be used in the workplace."**

During the OSHA rulemaking, the only fit testing requirement of paragraph (2) above questioned was the annual retesting requirement. That issue and the reasons for retaining that provision were presented by OSHA in Federal Register announcement of the final rule.

"Only the requirement to conduct fit testing annually was disputed in the rulemaking. Commenters generally agreed that some additional fit testing beyond an initial test was necessary, but opinions varied widely on the appropriate intervals at which such tests should be performed. A few participants, including the UAW (Ex. 54-387), urged that fit testing be required every six months, since changes in weight, facial hair and scarring, dental work, and cosmetic surgery may alter respirator fit. The UAW also stated that visual observation was not a reliable way to identify the presence of these changes.

*A number of commenters suggested that longer intervals, generally two to three years would be appropriate. For example, Allied Signal (Ex. 54-175) recommended "periodic" or "every two years" as the fit testing interval. Public Service Electric and Gas Co. (Ex. 54-196) stated that a "two year time frame strikes a good balance between safety concerns and practicality." The Texas Chemical Council (Ex. 54-232) stated that, in its members' experience, " * * *virtually no individuals fail fit tests a year after initial testing for a given chemical exposure using the same manufacturer's respirator." The Exxon Company (Ex. 183), in response to questions asked at the June hearings, reported that of the 230 employees at their Baton Rouge refinery given an annual QNFT in 1995, a year after their initial respirator selection in 1994, less than one percent (two employees) changed their respirator size because of failing the annual QNFT. Exxon stated that few employees change the size of their respirator from year to year, and that "the data suggest that annual quantitative fit-testing should not be necessary and such testing may be done on a less frequent basis than once per year." The Peco Energy Company (Ex. 54-292) stated that its experience showed that a three year interval is sufficient to ensure a proper fit, provided that mandatory refitting is conducted if there are changes in the respirator user's physical condition. The Eastman Chemical Co. (Ex. 54-245) recommended that the time limit be not less than two years. The International Paper Co. (Ex. 54-290) stated that "biannual (sic) [every two years] fit-testing with proper training should be adequate" and that proper training would require that employees report to the employer facial feature changes that have occurred or failure to get an adequate seal during the positive/negative pressure seal check.*

Other participants believed that fit testing beyond initial fit testing should be required only when an employee switches to a different respirator, or when a significant change occurs in an employee's physical condition that may interfere with obtaining an adequate facepiece seal (Exs. 54-177, 54-187, 54-190, 54-193, 54-197, 54-214, 54-286, 54-297, 54-396, 54-397, 54-435, 54-323, 54-422, Ex. 123). The American Iron and Steel Institute (Ex. 54-307, Ex. 175) stated that annual fit testing was unnecessary, and that the steel industry experience shows that once a wearer has been fit tested and has an acceptable fit, subsequent fit tests demonstrate consistent fit factors. Mallinckrodt Chemical (Ex. 54-289) questioned the need for annual fit testing for those employees who may use a respirator infrequently, such as once or twice a year.

However, a large number of rulemaking participants supported OSHA's proposal to require the testing of respirator fit on an annual basis (Exs. However, a large number of 54-5, 54-6, 54-20, 54-153, 54-167, 54-172, 54-179, 54-219, 54-273, 54-289, 54-293, 54-309, 54-348, 54-363, 54-410, 54-428, 54-455, Ex. 177; Tr. 1573, 1610, 1653, 1674). The comments of these participants and other evidence in the rulemaking record convince OSHA that the annual testing requirement is appropriate to protect employee health.

Annual retesting of respirator fit detects those respirator users whose respirators no longer fit them properly. The Lord Corporation, which already performs annual fit tests, reported that of its 154 employees who wear respirators, one to three (two percent or less) are identified each year as needing changes in model or size of mask (Ex. 54-156).

Hoffman-LaRoche only performs fit tests at two-year intervals, and it reported a much higher incidence of fit test failures. Sixteen of the 233 people tested in a recent two year cycle of fit testing (6.86%) needed a change in their assigned respirators (Ex. 54-106).

The Lord experience (Ex. 54-156) indicates that annual retesting of facepiece fit detects poorly fitting facepieces, while the Hoffman-LaRoche evidence demonstrates that waiting two years for retesting can result in the discovery that quite a high percentage of workers have been relying on poorly fitting respirators. Extending the retest interval to more than one year would allow those individuals with poor fits that could have been detected by annual fit testing to wear their respirator for a second year before the poor fit is detected.

This evidence also supports OSHA's view that triggering the requirement to retest only by certain events, such as a change in the worker's condition, and not including a required retest interval, would allow poor fits to continue. Changes in a worker's physical condition, such as significant weight gain or loss, new dentures or other conditions, can cause alterations in facial structure and thus respirator fit. Physiological changes that affect facepiece fit can occur gradually over time and are easily overlooked by observers, and by the users themselves. Individuals with poorly fitting respirators were often detected only through fit testing, and not by other methods such as observation of changes in facepiece fit, failure to pass a user seal check, or an employee reporting problems with the fit of the respirator. Retesting facepiece fit solely on the basis of physical changes in individual respirator users would not be a reliable substitute for fit testing on an annual basis. These changes in an individual's physical condition do, however, indicate the need for retesting that individual's facepiece, and paragraph (f)(3) requires additional fit testing whenever any of these changes are detected.

Moreover, fit testing not only determines whether a facepiece seal is adequate, it also provides an opportunity to check that fit is acceptable, permits the employee to reduce unnecessary discomfort and irritation by selecting a more comfortable respirator, and reinforces respirator training by providing users with a hands-on review of the proper methods of donning and wearing the respirator. Therefore, as well as providing the opportunity to detect poorly fitting respirator facepieces, the annual fit testing requirement complements OSHA's requirement for, and may partially fulfill, annual training under final paragraphs (k) (1), (k)(3) and (k)(5). For the reasons presented above, and based on a thorough review of the record, OSHA has included an annual fit test requirement in the final rule."

A broader literature review related to health and safety organizations' recommendations for periodic fit testing was also conducted to include guidance documents from other health and safety organizations (ANSI, NFPA, NIOSH, etc.). There is referenced background information that professional opinion had been to recommend periodic fit testing prior to OSHA rulemaking. Periodicity (specific time frames) has not always been identified and data has been lacking, but periodic fit testing (at least every 12 months) had been a recommendation as specified in ANSI Z88.2 Respiratory Protection

Standards. NIOSH had a policy statement that NIOSH agreed with the OSHA 29 CFR 1910.134 regulations, with 2 exceptions. Those were medical credentials for evaluation of fitness of users and use of irritant smoke fit test. NIOSH policy is, therefore, annual fit testing just as the OSHA standard.

2.2.2 Manual Facial Anthropometry for Respirator Fit Purposes

Facial measurements have long been a subject of investigation for purposes of respirator fit testing. The American Industrial Hygiene Association (AIHA) and American Conference of Governmental Industrial Hygienists (ACGIH) described the theory of a relationship between facial measurements and respirator fit in 1963 (AIHA and ACGIH, 1963).

Hughes and Lomaev (1972) conducted an anthropometric survey of males in Australia, for the purpose of half-mask respirator design. This study measured faces of 538 Australian males, and recommended a panel of 10 individuals falling within dimensional criteria described by two dimensions - face length and face width.

McConville et al. (1972) reported that studies of military populations, including a 1967 Air Force study, provided the most useful data relevant to respirator fit, but noted that the military population studies are not necessarily representative of the civilian workforce. Nonetheless, McConville et al. concluded the military data could be used for the design and sizing of respirators.

Subsequently, Hack et al. (1973) developed facial size specifications for a panel of subjects that could be used by NIOSH for respirator fit testing. That work selected subjects using face length and face width as the criteria for wearing full face masks. For half masks, face length and lip length were used. Hack et al. measured 200 faces of U.S. male civilians, and compared those dimensions to those obtained in a prior survey of 2420 U.S. Air Force males. They found agreement in six of the nine measurements common to the civilian and military studies. Hack et al. also compared the measurements of their Spanish-American subjects to others in their sample of 200, and found no significant differences based on the ethnicity.

Having demonstrated the applicability of the military data to the civilian workforce, Hack et al. selected from their set of twenty-one measurements those measurements which were felt to be (a) relative to facepiece fit, (b) capable of being measured with reproducibility, and (c) independent of other measurements. Using the previously mentioned 1967 data for Air Force men and a subsequent 1972 study of Air Force women (Clauser, 1972), Hack et al. identified the combinations of facial length and width which would include 95% of the U.S. population. The upper limits were set as the mean of male measurements plus two standard deviations. The lower limits were set

as the mean of the female measurements minus two standard deviations.

Hack et al. decided that face length would best be characterized by the menton-sellion length. Face width was to be characterized by the bi-zygomatic breadth in the case of full face respirators. The selection of those two measurements for full face respirators over other measurements appears to have been strongly influenced by previous selections made by the Australian investigators.

For the half mask respirators, Hack et al. selected the menton-sellion length and lip length as the defining dimensions for facial length and width. In addition to measuring lip length in a normal position, the investigators measured lip length in the longer smiling position. They decided against using the "smiling" length because respirators could easily be designed to cover the longer length presented with smiling lips.

Leigh (1975) reported the results of anthropometric and quantitative respirator fit tests of workers. Although he had both facial dimensions and respirator fit data, Leigh only reported the "best-fit mask" for each worker. He did not determine the extent of correlation between the facial dimensions and respirator fit. Leigh also reported the menton-sellion length and lip length as the key dimensions for half mask respirators. Leigh suggested some adjustments in the 95th percentile boundaries for the test panel proposed by Hack et al.

Liau et al. collected facial dimensions of 243 subjects, using direct measurements and measurements from photographs (Liau et al., 1982). They "normalized" the facial dimensions by dividing each dimension by a comparable measurement of a respirator. The normalized data were "correlated" with quantitative fit test data via linear regression; the quantitative fit testing method was not described. These investigators acknowledged two assumptions inherent in their work: (1) differences in facial seals did not contribute significantly to variance of protection factors; and (2) differences in headband tension could be ignored for protection factors greater than 20.

Liau et al. found that the correlations with the normalized dimensions were rather low: mouth width produced an r -value = 0.22, and face width produced an r -value = 0.30. The authors noted that the use of polynomial regression models did not improve the correlations when compared to the linear regression model. The authors suggested that the low correlation coefficients were possibly the result of the assumptions regarding the facial seals and headband tension. They concluded that both of those factors might have influenced the variability of the protection factors.

Oestenstad et al. (1990) studied the location and shape of faceseal leak sites for a single brand of half mask respirator worn by 73 subjects, and compared those observations to facial measurements, subject gender, and quantitative fit factor. They

determined that 89% of the leak sites were near the nose or chin; 79% of the leaks included the nose as at least a contributing or sole leak site; 73% of the leaks were judged to be more diffuse than point-like in shape. Males were more likely to have the diffusely shaped leaks. Fit factors for chin-related leaks were significantly lower than other categories, indicating that chin leaks are generally larger in terms of amount of leakage. Significant correlations were found for three facial dimensions (menton-subnasale; biocular breadth; nasal root breadth), none of which are used to define the traditional fit test panels described by Hack et al. Oestenstad et al. found evidence of "streamlining" of leak sites toward the nose and mouth area, and noted that Myers et al. (1986) had found this to lead to a bias in fit test measurements. Oestenstad et al. noted the importance of limiting the number of investigators making facial measurements, and the variability of the investigator's measurements.

Gross and Horstman (1990) compared facial measurements for 121 (60 female and 61 male) civilian workers to quantitative fit test data for three different brands of respirators. They found no significant correlations between the facial measurements and respirator fit. However, when the fit test data were dichotomized to passing or failing (greater or less than 10), the investigators found the men who failed the fit test generally had larger facial dimensions than those who passed the fit test. Women who failed, on the other hand, generally had smaller noses and face lengths and longer lips than those who passed the fit test.

Oestenstad and Perkins (1992) reported on another set of comparisons of facial measurements to quantitative fit test data. They found the highest correlations for: menton-subnasale length; biocular breadth; nasal root breadth; and nose width. However, even those correlation coefficients were in the range of 0.26-0.37. This finding was similar to that described above for Liao et al. In an attempt to determine the predictive potential of facial measurements, Oestenstad and Perkins conducted a stepwise multiple linear regression for twelve facial measurements as the independent variables and the natural log of fit factor as the dependent variable. They found that the facial measurements were predictive when the model was gender-specific (r-square values at least 0.85). For all subjects combined, however, the r-square was reduced to 0.28. The menton-subnasale measurement was found to be the most consistent predictor of respirator fit.

In a subsequent report attempting to relate facial dimensions to respirator fit however, Oestenstad concluded that facial dimensions were poor predictors of fit, as judged by both linear and logistic regression methods (Oestenstad, 1994). A number of findings from this work seem contrary to previous work (as described above) led by Oestenstad. Gender was a significant influence on the correlation: seven facial measurements were correlated to fit for females, whereas only one measurement was correlated for males. Neither of the dimensions used by Hack et al. to define the respirator fit test panel was

found by Oestenstad to predict respirator fit. Oestenstad's abstract ends as follows: "Facial dimensions were found to be poor predictors of respirator fit, and that (sic) dimensions other than those currently used may be more appropriate to define test panels whose fit is intended to be representative of worker populations."

Brazile et al. (1998) reported on fourteen facial dimensions and respirator fit among three ethnic groups - white, African-American, and Mexican-American. Significant differences were found in the facial measurements between the ethnic groups. The only facial dimension found to be somewhat correlated with fit was nose protrusion (r value = 0.1596, p = 0.0296). The authors carried out a backward-elimination stepwise regression, and found that nose width and nose protrusion had significance, but they could only account for 4.45 percent of the variation found in the fit test data. The authors concluded that racially-influenced nose width and nose protrusion are not good predictors of respirator fit.

Anthrotech, Inc. has, under contract to NIOSH, conducted a field study of civilians who either wear respirators or could wear respirators for occupational purposes. Anthrotech has recommended (Bradtmiller, 2003) certain allowable inter-observer error in facial measurements. The allowable error was determined based on error data in the literature and analysis of results of observer error test conducted specifically before the field study. The U.S. Army conducted an anthropometric survey of their personnel, with a final report (Gordon, et al., 1989) that included a list of "allowable errors" for facial measurements. Table I compares the "allowable errors" recommended by Anthrotech and the Army.

Shea and Gomez (1988) have indicated that, "...a marked change in body weight may result in little or no alteration in facial size." Evidence to this effect can be seen in the pubertal growth spurt, during which males become significantly larger than females in height and weight, but metric aspects of facial size are still largely indistinguishable.

Table I. Comparison of allowable errors associated with head dimensions

Quantity	Anthrotech allowable error (values in mm)	Army allowable error (values in mm)
Head Circumference	5	5
Bitracion-Coronal Arc	6	7

Bitragion-Frontal Arc	5	5
Bitragion-Subnasale Arc	6	6
Bitragion-Chin Arc	6	8
Head Breadth	2	2
Head Length	2	2
Minimum Frontal Breadth	3	
Maximum Frontal Breadth	3	
Bizygomatic Breadth	2	2
Bigonial Breadth	3	
Nasal Root Breadth	3	
Nose Breadth	3	
Lip Length	4	
Subnasale-Sellion Length	3	
Menton-Sellion Length	3	3
Nose Protrusion	3	
Interpupillary Breadth	2	2

A recent study was conducted to investigate the effect of subject characteristics (gender and face dimensions) and respirator features on respirator fit (Zhuang et al., 2005). Thirty-three subjects participated in this study. Each was measured for 12 face dimensions using traditional calipers and tape. From this group, 25 subjects with face size categories 1 to 10 (based on the Los Alamos half-facepiece respirator fit-test panel) tested 18 respirator models. The SWPF test protocol entailed using the PortaCount[®] Plus to determine a SWPF based on total penetration (face-seal leakage plus filter penetration) while the subject performed six simulated workplace movements. Subsets of one to six face dimensions were found to be significantly correlated with SWPFs ($p < 0.05$) in 16 of the 33 respirator model/respirator size combinations. Bigonial breadth, face width, face length, and nose protrusion appeared the most in subsets (5 or 6) of face dimensions and their multiple linear regression coefficients were significantly different from zero ($p < 0.05$). Lip length was found in only one subset. The use of face length and lip length as the criteria to define the current half-facepiece respirator fit test panel may need to be reconsidered when revising the panel.

In 2003, a nationwide anthropometric survey of respirator users was conducted to develop an anthropometric database (Zhuang and Bradtmiller, 2004; Zhuang and Bradtmiller, 2005). The database included 3,997 subjects (2,543 male, 1,454 female) recruited from various industries, including manufacturing, construction, health care, law enforcement, and firefighting. Height, weight, neck circumference and 18 facial dimensions were measured. A stratified sampling plan was used with an equal sample size of 166 in each cell. The survey consisted of three age strata (18-29, 30-44, 45-65), two gender strata (male and female) and four racial/ethnic group strata (White, African American, Hispanic, Others). The new anthropometric database was also used to develop new respirator fit test panels (Zhuang et al., 2007). In November 2006, NIOSH contracted with the Institute of Medicine (IOM) to establish an *ad hoc* committee to review these two NIOSH studies. A report which contains the findings, conclusions, and recommendations of that IOM committee was recently published (Bailar et al., 2007). Since there is not currently a good understanding of the relationship between various facial dimensions and fit, the committee makes the following recommendations:

- Recommendation 4-5: Determine Key Features Related to Fit Using Quantitative Fit Measures. NIOSH should perform research to determine which facial features have the greatest impact on the respiratory protection of facemasks in the workplace, using quantitative measures. These research findings should be utilized in the design of future anthropometric face panel studies.
- Recommendation 4-6: Perform Facial Dimension Analyses for Half-Face Respirators. NIOSH should perform additional facial dimension analysis when developing anthropometric face panels for half-facepiece respirators, including at least one nasal dimension.
- Recommendation 4-7: Utilize Multiple Features in the Development of Face Panels. NIOSH should examine the potential effects of a nonlinear relationship between respirator fit and facial dimensions.

In summary, no studies have ever looked at respirator fit as a function of time and if changes in fit are associated with any physical changes in the subjects such as facial size. More studies are needed to investigate the relationship between respirator fit and facial dimensions.

2.2.3 Automated Facial Anthropometry for Respirator Fit

Automated facial anthropometry has been used for a variety of purposes, including treatment of facial burn victims (Whitestone, et al., 1998), tracking size/shape changes during pregnancy (Perkins, 1999), and garment applications (Bradtmiller and Gross,

1999). No previous applications of automated facial anthropometry directly related to industrial respirator fit testing have been located, although some investigators are reported to have interest (Kim and Kim, 2006). This section summarizes the literature which is most pertinent to the proposed evaluations of industrial respirators.

Kline and Whitestone have reported on work done for the Air Force to evaluate the potential for automated 3-D scanning to aid in the issuance of full face military masks (Kline and Whitestone, 1994). The authors concluded that the 3-D scanner was not reliable at predicting "wearability", and warned that 3-D techniques could be foiled by irregular skin surfaces. "Wearability" in this context refers to encumbrance or comfort, primarily associated with nosecup-related discomforts, rather than respirator fit.

Piccione and Moyer (1997) have reported on attempts to model the interface between military full face respirators and the human face. Their work employed the finite element analysis method to model mask and facial characteristics. Their model allowed them to match the respirator scan to a face scan and estimate the degree of "registration", fit, and discomfort. This work apparently did not employ any human subjects or other means of checking actual fit.

In 2003, a nationwide anthropometric survey of respirator users was conducted to develop an anthropometric database (Zhuang and Bradtmiller, 2004; Zhuang and Bradtmiller, 2005). About 1,000 of the 3,997 subjects were scanned using a head scanner.

Three-dimensional surface data were obtained using a 3-D laser scanner from a group of 102 volunteers (70 males and 32 females) and surface data from the two foreign and two domestic models (Kim and Kim, 2006). The collected data was digitized and used for shape analysis utilizing the Procrustes algorithm. The results of 3-D facial analysis showed that the facepieces of the commercial half-facepiece respirators tested, both imported and domestic, did not match with the facial shapes of Koreans. Significant gaps were found around the nose and chin areas. The authors concluded that these design deficiencies, as well as shape information of Korean faces, should be taken into consideration for the design of future half-facepiece respirators.

An anthropometric survey of Chinese respirator users was conducted in 2006 (Chen et al., 2007). A total of 2,999 subjects from 29 provinces were measured using traditional methods, while 350 of them were also scanned using a 3-D head scanner. These mean values are significantly different from the values for U.S. respirator users from a study by NIOSH (Zhuang and Bradtmiller, 2005). Fit test panels for the Chinese workers may need to be developed using the data from the Chinese survey.

Another NIOSH study is underway to determine if a relationship exists between half-mask respirator fit and three-dimensional (3-D) anthropometric measurements of a

panel of human subjects (Dr. Zhuang serves as the principal investigator). Data collection was completed. Thirty subjects were recruited from the vicinity of NIOSH laboratories in Pittsburgh, Pennsylvania. Data collected include: (1) respirator fit data for twelve half-mask respirators (four models in three sizes each); and (2) head measurements via traditional methods and a 3-D head scanner (Cyberware Model 3030/RGB). In addition to the data obtained for each subject, each respirator was also scanned using the 3-D scanner to obtain the respirators' shape and dimensional characteristics. Preliminary data analyses indicated significant correlation between principal component analysis scores and respirator fit. Three-dimensional parameters such as nose area and angles were also found to be significantly correlated to respirator fit.

Cyberware, Inc. manufactures the scanners to be used in this study. For the scanning head to be employed (3030 RGB), Cyberware provides the following data (Cyberware, 2003) regarding the sampling pitch, or scanning resolution:

Theta (X, horizontal): 0.25 - 1.0 mm

Y (vertical): 0.7 mm

Z (radial from central axis of rotation): minimum 0.1 mm

When combined for a three-dimensional measurement, these specifications produce an error of less than 2 mm. The scanner will be calibrated weekly with a calibration cylinder of precisely known diameter. Past calibrations have indicated accuracy to within 1.0 mm.

2.2.4 Comparison of Respirator Fit by Gender, Race, Age, and BMI

Brazile et al. (1998) reported on fourteen facial dimensions and respirator fit among three ethnic groups - white, African-American, and Mexican-American. Significant differences were found in the facial measurements between the ethnic groups. The only facial dimension found to be somewhat correlated with fit was nose protrusion (r value = 0.1596, p = 0.0296). The authors carried out a backward-elimination stepwise regression, and found that nose width and nose protrusion had significance, but they could only account for 4.45 percent of the variation found in the fit test data. Brazile et al. concluded that respirator fit was not associated with face dimensions based on race/ethnicity or gender and seemed to be associated with individual facial characteristics.

A recent study was conducted by Zhuang et al. (2005) to investigate the effect of subject characteristics (gender and face dimensions) and respirator features on respirator fit. Thirty-three subjects participated in this study. From this group, 25 subjects with face size categories 1 to 10 (based on the Los Alamos half-facepiece respirator fit-test panel) tested 18 respirator models. The SWPF test protocol entailed

using the PortaCount[®] Plus to determine a SWPF based on total penetration (face-seal leakage plus filter penetration) while the subject performed six simulated workplace movements. There was no significant difference in the geometric mean fit factor between male and female subjects for 16 of the 18 respirator models.

The current prevalence of overweight and obesity in the U.S. and other developed nations has reached epidemic proportions, but little work has been done addressing the impact of increasing body weight upon personal protective equipment. Utilizing the newly developed National Personal Protective Technology Laboratory respirator fit panel that was derived from anthropometric data collected from civilian respirator users in a 2003 National Institute for Occupational Safety and Health survey, a recent study was undertaken to investigate any possible effect of overweight or obese states upon facial dimensions, and to compare prior anthropometric surveys for the purpose of analyzing study population differences that might affect facial dimensions (Roberge et al., 2006). The database consisted of three previously published anthropometric studies (two military, one civilian) that were analyzed for homogeneity of study populations and for the impact of variables thought to influence facial dimensions (i.e., age, gender, body mass index). The mean age, body mass index (BMI), and face width were greater for the civilian survey subjects than either of the military surveys ($p < .01$ for each variable). Face width and face length were statistically associated with BMI in both genders of civilian subjects ($p < .01$), as was the interaction of race/ethnicity, age, and BMI for civilian females ($p = 0.03$) and the interaction of race/ethnicity and BMI for civilian males ($p = 0.02$). Increasing BMI impacted face width more than face length ($p < .05$). Further research is needed to determine quantitative weight changes that signal the need for repeat respirator fit testing and to ascertain if fit test data from more physically-fit subjects are applicable to overweight or obese subjects.

Civilian BMI's have consistently increased over the past four decades. The Third National Health And Nutrition Examination Survey (NHANES III), a continuous survey of the health and nutritional status of the U.S. civilian, non-institutionalized population, demonstrated that U.S. men and women gained, on average, more than 11 kilograms between 1960 – 2002 (Ogden et al., 2004).

So far, there are no studies investigating the differences in respirator fit among different age groups.

2.3 Locale

All testing will be conducted in NIOSH/NPPTL on Cochran's Mill Road, Pittsburgh, PA. All equipment and software needed for this study are available in the Anthropometrics Lab in Building 13.

2.4 Intended/Potential Use of Study Findings

This study will quantify the extent that respirator fit changes over time and will identify those causal factors associated with those changes. The findings of factors that most affect the fit of respirator will help in determining appropriate sizing information for respirator users. The study results will also be used as design criteria and help respirator manufacturers design better respirators. This information can be used by those groups who develop respirator regulation and recommendations (OSHA, NIOSH, CDC, MSHA, ANSI, AIHA, ISO, etc.) to judge the appropriateness of the current practice of annually fit testing all wearers of tight-fitting respirators.

2.5 Significance and Impact

Over three million American workers are required to wear respirators (BLS/NIOSH, 2003). Of the 282,000 establishments using respirators for required purposes, at least 225,100 of them use tight-fitting respirators that require fit-testing – prior to initial use and annually thereafter. The annual fit test requirement is an economic burden; however, the benefits for such testing have not been studied since OSHA promulgated this requirement in the standards on respiratory protection (29 CFR 1910.134) in 1998. This study will be the first of this kind. Its aims, unique design, and application of the state-of-the-art technologies will provide a basis for quantifying the benefit of periodic fit testing and determining the appropriate periodicity. Percentage of subjects whose fit become unacceptable is the best estimate of the true percentage of workers who will benefit from the annual fit testing.

The results of this study will provide the scientific basis for regulatory agencies to enforce the annual fit testing requirement. The results will also help convince users to be in compliance with the standards. The findings from a national survey of respirator programs were recently published by the Bureau of Labor Statistics and the National Institute for Occupational Safety and Health (NIOSH) (BLS/NIOSH, 2003). A follow-up study was conducted to analyze and interpret those published findings related to respirator fit testing in establishments with required respirator use (i.e., use on a non-voluntarily basis) (Campbell et al., 2005). That study found that fit testing was not done in approximately half of the establishments where tight-fitting respirators are used.

Correlating changes in physical appearance and facial anthropometrics with changes in respirator fit could result in improved guidelines for respirator program administrators and improved respirator designs. The long-term impact and contributions from this study are improved air-purifying respirator quality and performance and increased worker protection.

3. Methods and Materials

3.1 Study Design

This laboratory study will simulate a group of subjects who are initially trained and fit-test-qualified to wear a filtering facepiece model, but who continue to *properly* wear that respirator for several years without further fit testing.

The study is intended to assess the extent that face fit changes as a result of changes in the physical features of the subject. This study will not assess the need for periodic training of respirator wearers in the proper donning and use. Accordingly, subjects will be retrained in the proper respirator donning procedures prior to every 6-month testing session in order to eliminate changes in fit that occur because the respirator is not donned properly. Test technicians will assure that the subject dons the respirator in accordance with the respirator manufacturer's instructions and will assist the subjects in assuring that the respirator is properly positioned and free of obvious face seal gaps. This "assisted donning" is appropriate because the intention is to assess changes in fit that result from changes in the subjects, not in changes in respirator positioning or adjustment. This approach recognizes that, in spite of precisely following the manufacturers donning instructions, a subject may position or adjust the respirator differently at different times. Further, assisted donning will tend to minimize the donning-to-donning variation and thereby increase the statistical power of the study.

The study will be conducted on subjects who are generally representative of workers in the United States. They will be recruited according to the frequency of respirator user population in each face size category of the new National Personal Protective Technology Laboratory respirator fit test panel based on face width and face length (Zhuang et al., 2007). Each subject will be trained to don and wear a single respirator model in accordance with the instructions of the respirator manufacturer. The study will include only subjects who (a) pass a fit test as required by OSHA and (b) demonstrate, through a series of nine donnings, that they can achieve adequate protection with high consistency. A subject will be considered to have demonstrated adequate protection with high consistency when, after nine trial donnings, the 90th percentile penetration is 0.05 or less.

For the purpose of this study, the donning-to-donning variation in the standard OSHA fit test is too great to allow the use of the standard fit test to monitor temporal changes in fit (Coffey et al., 2005; Coffey et al., 2006). For example, a subject could pass the standard fit test today and fail tomorrow – simply as a matter of chance. Thus, if we were to use the standard fit test in this study, a subject could fail the 6-month fit test (after passing the initial fit test) and we would not know if the failure resulted from changes in the subject or simply as a matter of chance. The 95th percentile has been

used to define the adequacy of respirator performance and assigned protection factors in workplaces (29 CFR 1910.134). Since this is a laboratory study and only nine donnings are collected, 90th percentile is selected. It is a more reliable statistic than 95th percentile.

Subjects who normally wear prescription spectacles will be fit tested while wearing those spectacles. Those who do not will be tested without spectacles.

Following the respirator fit tests, a set of 13 traditional face measurements, in addition to height and weight, will be obtained. After the traditional measurements, subjects will be scanned using a Cyberware Model 3030 head scanner.

After approximately 6 months, each subject will be retested and penetrations measured for 9 donnings of the respirator. Again, the test technician will (a) instruct the subject in the proper donning procedure and (b) observe each donning to assure that each donning is in accordance with the manufacturer's instructions. The 90th percentile of the nine 6-month penetration values, $P_{90}(t=6)$, will be computed. Each subject will again be measured using traditional tools and scanned using the Cyberware head scanner.

The above routine will be repeated until seven testing cycles (spanning 3 years) are completed for each subject – regardless of the changes in fit that may occur during the course of the study. A subject's fit will be considered to have become unacceptable if the 90th percentile penetration becomes greater than 0.05 (i.e., if 10% or more of the subject's donnings have a penetration greater than 0.05). Physical changes (weight, facial dimensions, dental status, etc.) will also be assessed every 6 months. The rate at which respirator fit changes as a function of time will be determined. Possible relationships between such physical changes and changes in respirator fit will also be investigated.

3.2. Pilot Study

Because this study will extend over a period of three years, there is concern that the test environment may, for reasons beyond the control of researchers, change during the course of the study. That is, the test technician and/or the laboratory room may change during the three years. To address that concern, an inter-laboratory study will be conducted at the start of the study to assure that the test results are reproducible from one laboratory setting to another. Ten subjects will, within a period of 14 days or less, repeat the initial nine-donning test in a different laboratory with a different laboratory technician. Variation in the average of the nine penetration values will be noted and used to interpret the final test results if a change in laboratory room or technician occurs during the three year study.

3.3. Respirators

This study only includes filtering-facepiece respirators. The reasons for focusing on filtering-facepieces are as follows: (1) many more workers use filtering-facepieces than use elastomeric half-masks; (2) the requirement for annual fit testing has been questioned by the health care industry – users of predominately filtering-facepieces; and (3) resources and budget are limited.

The intention is that the study results apply to filtering-facepieces in general. So, the study will include a variety of filtering-facepiece models. To that end, approximately 15 models will be selected from the better performing models previously tested in the NIOSH study titled "Total Inward Leakage." This helps to assure that the results of this study will be representative of the better performing respirator models that will be NIOSH certified in the near future when new certification regulations require all models to have good fitting characteristics. The respirator for a given subject will be randomly selected from the available 15. If the subject fails to qualify with that model, another model will be randomly selected from the 15 available.

All respirators to be used in this study will be purchased at one time prior to the study to assure that the respirator model and size will be available throughout the study. This is necessary because of the possibility that models will be discontinued or redesigned (by manufacturer) during the three year testing program. It is under the belief that the variation in respirator performance due to respirator age would be less than the variation due to changes in the manufacturing process over time. The NIOSH monitored quality assurance programs do not monitor fitting characteristics and therefore cannot assure that the fitting characteristics do not change from month to month, or year to year. If new respirators were purchased every six months, there would be no way to know if changes in fit were due to changes in the subject or changes in the respirator. However, when respirators are purchased at one point in time (as in the current protocol) there is also no way to know if changes in fit are due to changes in the subject or due to respirator aging. So, the choice between the two methods is a judgment call. All respirators will be stored in a storage room under normal conditions or per manufacturers' instructions and remain packed until they are used.

3.4. Study Population

A sample of 220 subjects will be recruited for this study. They will be recruited according to the frequency of respirator user population in each face size category of the new National Personal Protective Technology Laboratory (NPPTL) respirator fit test panel based on face width and face length (Figure 1 and Table II) (Zhuang et al., 2007). The subjects for this study will be recruited from the NPPTL subject pool for certification testing and physiology study. Additional subjects will be recruited from the general

public in South Pittsburgh areas regardless of employment status using the information sheet in Appendix A.

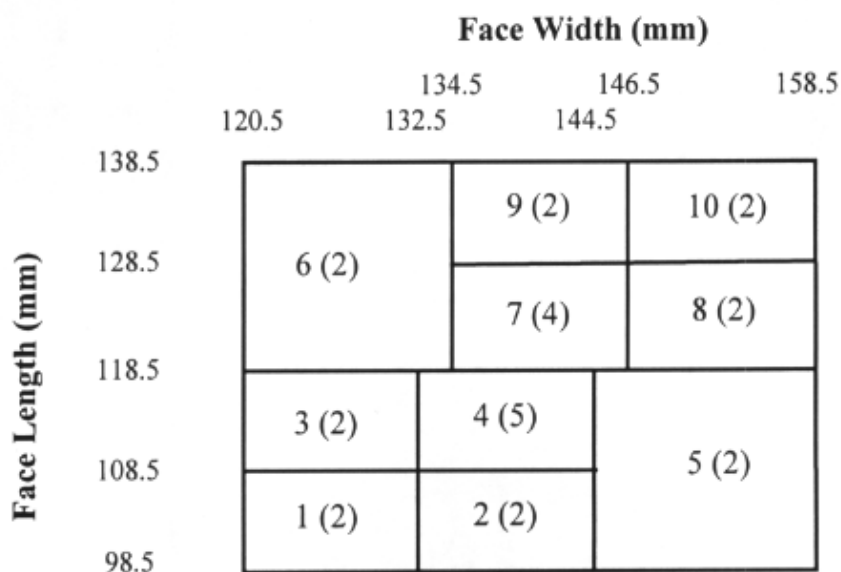


Figure 1. NPPTL panel based on face length and face width is shown. The numbers in each cell represent cell number and the numbers in parentheses indicate the number of subjects to be sampled from each cell for a panel of 25 subjects. When the subject's face length or face width fall on the boundaries, the subject is classified into the higher number cells with greater face dimensions.

Table II. Percentage of Respirator User Population and Number of Subjects Recruited for This Study by Cell of the NPPTL Panel Based on Face Length and Face Width

Cell	Respirator User Population (%)	No. of Subjects
1	5.5	11
2	5.3	11
3	10.5	21
4	25.0	51
5	7.1	15
6	5.7	11
7	21.3	44

8	8.7	18
9	5.2	11
10	3.5	7
<hr/>		
Total	97.7	200
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No one will be excluded from this study because of race, gender, or facial characteristics unless the sampling goal in each size category is exceeded by more than 25%. We will accept any subject meeting our sampling criteria and who meet the criteria specified in Title 29, Code of Federal Regulations, 1910.134 for respirator wearers, such as exclusion of beards, sideburns, etc. We will try to recruit equal male and female subjects and in case that cannot be met, subjects for either gender should not exceed 70% of total subjects. Subjects of ages 18 to 60 are allowed to participate in this study. The subjects may include experienced and inexperienced respirator users since they will be trained and assisted in donning the respirator properly. The subject pool at NPPTL is usually medically cleared to conduct certification tests and physiology study. Additional subjects recruited from the general public will only be evaluated using the OSHA medical questionnaires (Appendix B). A medical doctor will review the answers and determine if the subjects are allowed to participate in this study. Pregnant women are allowed to participate in this study and women who get pregnant during the study are allowed to continue as long as they pass the medical evaluation.

In determining the sample size for this project, we can view the problem as requiring a sufficient sample size for estimating a proportion (with clinically significant anthropometric changes) within some precision.

Let p represents the population proportion whose fit will become unacceptable after six months, while \hat{p} represents the sample proportion. We can then use the binomial distribution, under different assumptions for p , and different sample sizes, to estimate the precision of our estimate. To do so, we can approximately specify the 95% confidence interval (CI) for p as $p \pm E$, where E is sampling error. The following table gives sample sizes needed to obtain a given precision, i.e. obtain a 95% confidence interval for p within $\pm E$, under different assumptions about the true value of p . Since the binomial distribution is discrete, the CI may not be exactly symmetrical; therefore, the exact CI (to 3 decimal places) is listed by each sample size.

If, for instance, p is assumed to be 0.01 and the maximum error of the estimate of p is set to be 1%, the required sample size is equal to 400. For a maximum error of 2%, the sample size will be 100. If the maximum error is further increased to 3%, the sample size will be decreased to 50 (Table III).

Table III. Sample Sizes as a Function of Estimated Failure Rate and Error

Estimated Failure Rate (p)	Sample Size (n) [Exact Confidence Interval for p]		
	Maximum Error = 1%	Maximum Error = 2%	Maximum Error = 3%
.01	400 [0.003, 0.02]	100 [0.00, 0.03]	50 [0.00, 0.04]
.03	1105 [0.021, 0.041]	275 [0.011, 0.051]	122 [0.008, 0.066]
.05	1826 [0.04, 0.06]	450 [0.031, 0.071]	200 [0.02, 0.08]
.10	3450 [0.09, 0.11]	863 [0.080, 0.121]	384 [0.070, 0.131]
.20	6150 [0.19, 0.21]	1525 [0.18, 0.22]	683 [0.17, 0.23]

To choose the sample size for our study, we chose 0.05 as an estimate of the failure rate and 3% maximum error of the estimate; these result in a sample size of 200. The reasons the expected failure rate of 0.05 was chosen are that (1) Lord Corporation conducted fit testing annually and found less than 1-3% of employees switching to different sizes and/or models; and (2) Hoffmann-La Roche conducted fit testing every two years and found that 7% of the employees switching to different sizes and/or models. Since some subjects may drop out of the study, 220 subjects will be recruited at the beginning of the study.

3.5 Data Collection Instruments

3.5.1 Study Instruments, Including Questionnaires, Laboratory Instruments, and Analytical Software

Data Collection Forms: The data collection uses 2 forms, found in Appendices C and D.

Fit Test Device and Software: The Portacount Plus Model 8020A (with Companion accessory), manufactured by TSI, Inc., of St. Paul, MN, will provide quantitative measurements of respirator fit. The TSI PortaCount instrument will be a version that records all fit factors – no matter how low. FitPlus for Windows, developed by TSI, Inc., will automate the fit test data collection and data recording processes.

Anthropometric Instruments: The traditional anthropometric measuring instruments consist of the anthropometer, spreading caliper, and beam caliper, as well as a steel tape. The anthropometer, spreading caliper, and beam caliper are manufactured by GPM in Switzerland, and are used to measure the distance between head features as well as overall stature. The tape is manufactured by Lufkin in the United States, and is used to measure surface arc distance on the head, including head circumference. In addition, interpupillary breadth will be measured with a Hoya RC810 pupilometer.

Marking pencils: Commercially available makeup pencils will be used to place landmarks and respirator outlines on subjects' faces.

3-D Head Scanner: The 3-D head scanner device, Model 3030/RGB, is manufactured

by Cyberware, Inc., of Monterey CA. This scanning device will be used for scanning subject faces. This is a red light laser scanner whose lasers are about the same intensity as a supermarket checkout scanner. This model scanner has been safely used on several studies of U.S. military and civilian subjects (Robinette et al., 2002; Zhuang and Bradtmiller, 2004). Cyberware's Head & Face Color 3D Scanner is registered with the FDA as a Class I device (no known hazards). The equipment is considered so safe that no warning label is required. The system is comparable to a supermarket price or library book scanner. The low level of light used allows the subject being scanned to leave their eyes open and will not even create an after image as one gets from a typical photo flash. Each subject will be scanned in his or her normal street clothes. We will identify a number of bony and other landmarks on the subject, and mark these using a makeup pencil and adhesive dots.

If the subject's face has shininess due to facial oils, the glare will be reduced using Johnson's Baby Powder. The manufacturer's literature for the baby powder states: "Clinically proven to be gentle and mild ...Made with the highest quality cornstarch so it's especially mild ...Allergy- and dermatologist-tested ...". Subjects will be asked if they are aware of allergies to any of the ingredients (corn starch, tricalcium phosphate, aloe barbadensis, vitamin E, fragrance). If allergies are reported, substitute products will be sought.

The following software will also be used in collecting data and analyzing the 3-D data:

- Cyberware Software:
 - CyScanNT is software used to control the head scanner;
 - CyDir is a graphical interface system for scanning objects, assembling and editing multiple scans, measuring scanned objects, merging multiple polygonal files, and converting file formats.
 - CySlice is used to create surfaces and draw curves on polygonal models.
 - Digisize is used to measure distances, angles, surface areas, and volumes.
- Morpheus et al. is public domain software for the morphometric analysis of landmark data, available through <http://life.bio.sunysb.edu/morph/morpheus/>.
- EFA3D is public domain software for the computation of elliptic fourier coefficients from 3D curves, available through <http://life.bio.sunysb.edu/morph/soft-outlines.html>.
- Rhinoceros is modeling software available through www.rhino3d.com.
- PolyWorks is software developed by Innovmetric Software Inc., Quebec, Canada. PolyWorks allows for measurement, modification, and matching of scanned surfaces.
- VPSculpt, a PC-based commercial software package developed by researchers at the University of Colorado for editing and measuring high resolution surface

data.

- NTSYS-pc, a PC-based commercial software package developed by researchers at the State University of New York, allows the classification and analysis of patterns and shapes.

3.5.2 Training for All Study Personnel

The laboratory investigators and technicians will practice the traditional measurements as well as the scanning procedures. Traditional measurements will be practiced until pre-established observer error limits are reached. This will help assure the quality of the final data set.

3.6 Data Collection Procedures

During each of the seven testing cycles, four types of data will be collected: (1) demographic data and questionnaire; (2) respirator facepiece fit testing on human subjects; (3) traditional anthropometric measurements of the subjects' faces; and (4) scanning of human subjects' faces.

3.6.1 Questionnaire

Each subject will be asked to fill out a demographic data form (Appendix C) containing certain demographic information. Each subject will also be asked to fill out a short medical screening questionnaire (Appendix E). If the subject answers yes to any of questions 2 through 5 in Appendix E, the subject will not be allowed to participate further.

Each subject will be photographed without the respirator and while wearing the respirator as tested (including spectacles, if worn). Any obvious changes in weight or facial characteristics will be noted.

This portion of data collection is expected to take approximately 10 minutes per subject.

3.6.2 Respirator Fit Tests

At the beginning of the study, each subject will be trained and fit-test-qualified to wear a respirator model. It may take several tries with different models before a subject is able to meet the qualifying criteria. The qualifying fit tests will be conducted with the TSI Portacount (with Companion accessory) following the procedure defined in OSHA's respirator regulation 1910.134. The TSI PortaCount instrument will be a version that records all fit factors – no matter how low. Fit factor is the ratio of the ambient particle concentration outside the respirator to the ambient particle concentration inside the

respirator.

Fit test will be conducted using the following procedures.

1. The test subject will be randomly assigned a model from a sufficient number of respirator models and sizes. The subject shall agree that the respirator is acceptable to, and correctly fits, him/her.
2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.
3. The test subject shall be informed that he/she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.
4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.
5. The more acceptable facepieces are noted in case the one selected proves unacceptable; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the following item 6. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the respirator several times and to adjust the straps each time to become adept at setting proper tension on the straps.
6. Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:
 - (a) Position of the respirator on the nose
 - (b) Room for eye protection
 - (c) Room to talk
 - (d) Position of respirator on face and cheeks
7. The following criteria shall be used to help determine the adequacy of the respirator fit:
 - (a) Chin properly placed;
 - (b) Adequate strap tension, not overly tightened;
 - (c) Fit across nose bridge;
 - (d) Respirator of proper size to span distance from nose to chin;

- (e) Tendency of respirator to slip;
- (f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct a user seal check, either the negative and positive pressure seal checks described in Appendix F or those recommended by the respirator manufacturer which provide equivalent protection to the procedures in Appendix F. Before conducting the negative and positive pressure checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the user seal check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can continue to participate in the study.

11. If the test subject finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. The fit test shall be performed while the test subject is wearing any prescription spectacles if the subject normally wears them. Those who do not will be tested without spectacles.

14. Test Exercises.

For this study, subjects perform the test exercises in the appropriate test environment in the following manner:

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning.

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes.

(8) Normal breathing. Same as exercise (1).

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment voids the test, and the fit test must be repeated. The subject shall use hands to hold the sampling line to prevent it from interfering with the facepiece fit.

15. Test operator should follow the Portacount Fit Test Procedures.

(1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece.

(2) Instruct the subject to be tested to don the respirator for five minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual shall already

have been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendency of the respirator to slip; Self-observation in a mirror to evaluate fit and respirator position.

(4) Have the subject wearing the respirator do a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same model respirator, or another model of respirator.

(5) Follow the manufacturer's instructions for operating the Portacount and proceed with the test.

(6) The test subject shall be instructed to perform the exercises above.

(7) After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

A subject will be considered to have passed the OSHA fit test when a fit factor of at least 100 has been achieved in any of the first three donnings. After passing the OSHA fit test, the subject will continue testing until a total of 9 trials (including the OSHA trials) have been completed. Between each trial the respirator will be removed, returned to its unadjusted configuration before redonning for the next trial. For each of the 9 trials, as monitored by the test technician, the respirator will be donned in accordance with the manufacturer's instructions. For each trial, the respirator will be worn for at least 5 minutes before measurement begins. For each of 9 trials, the fit factor will be recorded, the corresponding penetration determined, and the 90th percentile of the nine penetration values, $P_{90}(t=0)$, computed. Although appropriate in the workplace setting, the OSHA pass/fail fit test is not the most appropriate for this study because it can yield different results from day-to-day because of the donning-to-donning variation in respirator fit. The effect of that variation can be reduced by using a parameter based on a number of donnings so that the variation tends to "average out."

The study will include only subjects who (a) pass a fit test as required by OSHA and (b) demonstrate, through a series of nine donnings, that they can achieve adequate protection with high consistency. A subject will be considered to have demonstrated adequate protection with high consistency when, after nine trial donnings, the 90th percentile penetration is 0.05 or less. If the subject fails the OSHA fit test or the 90th percentile penetration is greater than 0.05, another respirator model will be assigned and retested.

The nine penetration values for each donning are used to determine the mean and the standard deviation, then calculate the 90th percentile from those two values. This involves one issue: i.e., the measurement error for a single person at a single time point (which, in this case, is primarily attributable to donning-to-donning variability). The issue of measurement error at a single time point is common to almost any exposure-related study, and is often ignored in calculating estimates of variability, and making subsequent inferences. For this study, the issue is complicated by the fact that we are interested in the 90th percentile over multiple measurements, not the average measurement. It is not currently feasible to evaluate the error or confidence limit in the 90th percentile. We can however reassess the power estimates at the conclusion of the study to better assess the degree of variability in the estimates of the 90th percentile, and the possible effect of that variability on chance variations into unacceptable ranges of respirator fit. Using the proportion who reaches unacceptable changes in the penetration value provides a reasonable approach for minimum sample size estimation (admitting there is some additional variability in the estimate of a given 90th percentile), but that approach can be supplemented with other analyses after the data are collected. For instance, we could use repeated measure models to model the actual changes while accounting for the different sources of variability and measurement error.

Although there may be a measurement error with nine donnings, this study design is much better than the study design of only one donning as used in the current fit testing practice in the workplaces. With this study design, the estimate of the percentages of subjects whose respirator penetration increase more than 25% and whose fit becomes unacceptable during each time interval is closer to the true percentage. Simulation runs showed that increasing the number of donnings from 9 to 15 increases our ability to see significant increases in the penetration over time by about 10-20% (assuming a true 2-fold increase) for most of the 10 models that were tested in a pilot study during the bench marking testing for the NPPTL total inward leakage program. Therefore, the number of donnings for this study is nine.

This portion of data collection is expected to take approximately 2 hours and 20 minutes per subject.

After approximately 6 months, each subject will be retested and penetrations measured for 9 donnings of the respirator. Again, the test technician will (a) instruct the subject in the proper donning procedure and (b) observe each donning to assure that each donning is in accordance with the manufacturer's instructions. The 90th percentile of the nine 6-month penetration values, $P_{90}(t=6)$, will be computed.

The above routine will be repeated until seven testing cycles (spanning 3 years) are completed for each subject – regardless of the changes in fit that may occur during the

course of the study.

3.6.3 Traditional Anthropometry

Following the respirator fit tests, a set of 13 traditional face measurements, in addition to height and weight, will be obtained. This portion of the study involves taking measurements on the test subjects using traditional measuring devices. These measuring devices are: anthropometer, spreading caliper, beam caliper (rearranged pieces of the anthropometer), tape measure and scale. The anthropometer and calipers are manufactured by GPM in Switzerland, the tape by Lufkin in the United States, and the scale by Health-O-Meter in the U.S. Each of these instruments has a long history of clinical and research use and has been proven to be very safe. The instruments are not attached to the head, but are held by the investigator so as to be momentarily in contact with the subject's head. The investigators will be trained in anthropometric techniques by professional anthropometrists at Anthrotech, Inc., of Yellow Springs, Ohio. Subjects will be asked to close their eyes while the calipers and tape measure are in close proximity to their faces. The combination of training, attention to appropriate laboratory practice, and instrument design will prevent injury to subjects during the measurement of the head and face.

Each subject will be measured in his or her normal work clothes. We will identify the following landmarks on the subject: alare (right and left), cheilion (right and left), chin, frontotemporale (right and left), glabella, gonion (right and left), infraorbitale (right and left), menton, pronasale, sellion, subnasale, top of head, tragion (right and left), and zygofrontale (right and left). We will mark these landmarks using marking pencils and place adhesive dots on the skin. The landmarks and their descriptions are listed in Appendix G.

After landmarking, 13 anthropometric dimensions will be measured using traditional methods and entered into a laptop computer running the data entry and editing software. This proprietary software checks entered values for reasonableness, allowing measurements to be repeated if an error is suspected. This portion of data collection is expected to take approximately 15 minutes per subject. A complete listing of these measurements accompanied by descriptions is provided in Appendix H.

3.6.4 3-D Scanning

Following the traditional measurements, subjects will be scanned using a Cyberware Model 3030 head scanner. Each subject will be scanned in his or her normal street clothes. We will identify a number of bony and other landmarks on the subject, and mark these using a makeup pencil and adhesive dots. If the subject's face has shininess due to facial oils, the glare will be reduced using Johnson's Baby Powder. Each subject will require two scans for two different head positions. The subject will

also be asked to wear a wig cap during the scanning. This portion of data collection is expected to take approximately 10 minutes.

3.7 Data Analyses

For each subject, in order to display temporal trends, the average of the nine penetrations for each of the seven six-month tests will be plotted as a function of time, as shown in the following fictitious example (Figure 2).

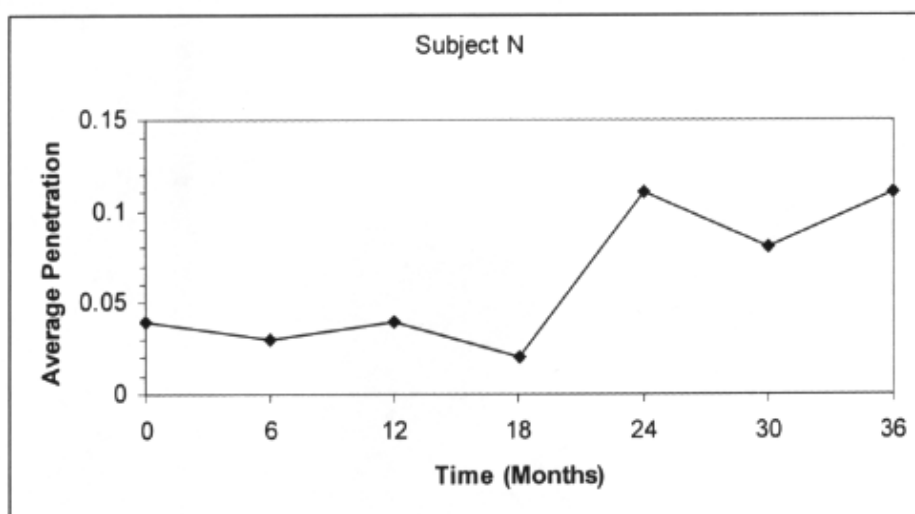


Figure 2. Average penetration is plotted as a function of time.

In all cases where a change of significance is observed in respirator fit, a comparison will be made with changes in the 3-D scans, caliper measurements of facial dimensions, weight, spectacles, dental status, of other changes in medical status. Such comparisons will be for the purpose of identifying those changes that can be associated with changes in face fit.

For each subject, the number of instances where the average penetration increases more than 25% (i.e., penetration increases by more than a factor of 1.25) will be tabulated for all of the (6) six-month periods, for all of the (5) 12-month periods, for all of the (4) 18-month periods, for all of the (3) 24-month periods, for all of the (2) 30-month periods, and for the 36-month period. Such determinations will be made at the 90% confidence level. The data for all subjects will be combined and tabulated as Table IV. (Increases in penetration other than 25% may also be investigated.)

Table IV. Expected Results when Subjects Experience Significant Increase in Penetration

Time Interval	Number (and percentage) of instances where a subject experience a 25% increase in penetration during the indicated time interval / Number of subject trials for each time intervals		
	Without changes in the subject that could be obvious to a respirator program administrator.	With changes in the subject that could be obvious to a respirator program administrator	Total
6 months	2/1200 (0.16%) †	3/1200 (0.25%) †	5/1200 (0.42%) †
12 months	2/1000 (0.2%) †	2/1000 (0.2%) †	4/1000 (0.4%) †
18 months			
24 months			
30 months			
36 months			

† Fictitious data used as example. If there were 200 subjects completing all three years, there would be 1200 subject trials: 200 from month 0 to month 6, 200 from month 6 to 12, 200 from month 12 to 18, etc.

In cases where the 90th percentile penetration exceeds 0.05, the fit will be considered to have become unacceptable. In such cases, a need for fit testing is predicted in the workplace. As explained earlier, this estimate is close to the true percentage of workers needing to switch to a different respirator size or model. The results for all subjects will be tabulated as Table V. In the workplace, could a respirator program administrator be expected to reliably identify when a worker should redo the fit test because of an observed change? So it is important to tabulate the number (and percentage) of instances for subjects with and without obvious changes that would allow a respirator program administrator to identify the need to redo fit test. Observable obvious changes are generally those changes in physical conditions of the subject such as facial scarring, dental changes or wearing of new dentures, cosmetic surgery, or an obvious change in body weight. OSHA standards require an additional fit test when these obvious changes that could affect respirator fit are observed in the workplace.

Table V. Expected Results when Subjects' Fit Become Unacceptable

Time Interval	Number (and Percentage) of instances where a subject's fit become unacceptable during indicated time interval / Number of subject trial for each time intervals		
	Without obvious changes in subject characteristics that would allow a respirator program administrator to identify the need to redo the fit test	With obvious changes in subject characteristics that would allow a respirator program administrator to identify the need to redo the fit test	Total
6 months	2/1200 (0.16%) †	3/1200 (0.25%) †	5/1200 (0.42%) †
12 months	2/1000 (0.2%) †	2/1000 (0.2%) †	4/1000 (0.4%) †
18 months			
24 months			
30 months			
36 months			

† Fictitious data used as example. If there were 200 subjects completing all three years, there would be 1200 subject trials: 200 from month 0 to month 6, 200 from month 6 to 12, 200 from month 12 to 18, etc.

Changes in a respirator wearer that would not be obvious to a respirator program administrator would be more serious because the need for a new fit test would not be recognized. Thus, it is important to distinguish between the two kinds of change.

The 3-D data will be analyzed using "Polyworks" (InnovMetric Software Inc., Quebec, Canada). Different scan data are superimposed and compared to determine differences between scans. Face size changes over time as small as less than 1 mm can be accurately determined. Figure 3 shows a plot of two scans showing gaps of 0 mm to less than 2 mm between the two faces.

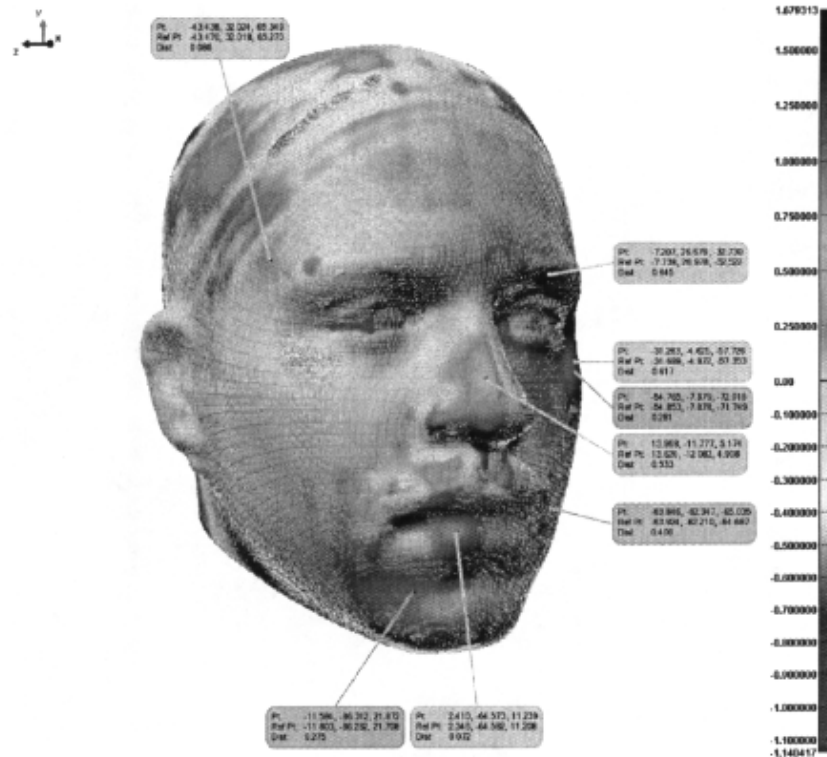


Figure 3. Comparison of two faces showing the gaps of 0 mm to less than 2 mm between the two faces.

3.8 Study Time Line

The following schedule is proposed. FY2007: (a) develop the study protocol, (b) peer review the protocol, (c) obtain HSRB approval, and (d) recruit subjects. FY2008 - 2011: Complete testing at a rate of two test cycles per year. FY2012: analyze the generated data and develop recommendations for the appropriate time for periodic fit testing. The study time line is illustrated as follows.

PROJECT TIME LINE

	Start Date	End Date
Study Protocol Development	Oct 2006	Dec 2006
Peer Review	Jan 2007	Jun 2007
HSRB Review	Jul 2007	Sep 2007
Data Collection	Oct 2007	Sep 2010
Data Analyses	Oct 2010	Mar 2011
Final Report, Slides	Apr 2011	Sep 2011
Peer Review	Oct 2011	Jan 2012
Respond to Review	Feb 2012	Mar 2012
Final Brief	Apr 2012	

3.9 Safety Precautions/Emergency Procedures

The exertion from the movements used in this study will not be strenuous. They can be classified as sedentary to light.

The study will be carried out in a controlled laboratory environment.

The respirators used are NIOSH certified and available commercially. In addition, they are light and have fairly low breathing resistance (less than 30 millimeters of water-column height). At least one person trained in cardio-pulmonary resuscitation will be present at all times during testing.

In the event an emergency develops during testing of study participants, the protocol for decision making in an emergency will be followed (Appendix I). Before every test, the subject will fill out a short screening questionnaire (Appendix E). If the subject answers yes to questions 2 through 5 they will not be allowed to participate further.

4. Informed Consent Procedures

Written informed consent will be obtained from volunteers prior to inclusion in this research project (Appendix J). The subjects will be given adequate time to read the document and ask questions before signing it. Subjects will be given a copy of the consent document. Subjects will be informed that they may voluntarily withdraw from the study at any point without prejudice to themselves.

5. Records Management

Confidentiality of human subject data will be assured in the final data set. During data collection, the participant's name is recorded on the data sheet. A subject number is also used on the data sheet. After data collection is completed, names will be removed. The data field containing participant names will be eliminated from the Excel files. At that point, it will no longer be possible to identify any individual in the data set. The original subject data sheets will be kept in a locked file cabinet at NIOSH. Confidentiality is also enhanced through controlled access to the NIOSH facility and to the office/laboratory where the files will be stored.

6. Confidentiality Provisions

The identity of the subjects and their specific information derived from their participation in this study will be kept confidential and will not be disclosed to others without written consent except as required by law. This information will be used for statistical and research purposes in such a manner that no one can be personally identified.

7. Notification of Results

The individual results will be available to the subjects if they request them. The results will be confidential, as provided under the Privacy Act. The study findings will be provided to each participant in summary form if they desire. The method of disseminating the results of this study to the public will be to submit the results to peer-reviewed journals, as well as presenting oral reports at scientific meetings.

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APPENDIX A. INFORMATION SHEET FOR POTENTIAL SUBJECTS

WANTED VOLUNTEERS FOR RESPIRATOR PROJECT

Changes in Filtering-Facepiece Respirator Fit over Time

The National Institute of Occupational Safety and Health (NIOSH) is asking for volunteers to be in a study. Many workers rely on respirators to protect their health. The level of protection provided by most respirator types depends on how well the respirator fits the wearer (seals to the face). Therefore, before a respirator can be relied upon to protect the wearer, a test (the so-called "fit test") must be conducted to assure the respirator adequately fits the wearer. And, because facial characteristics can change over time, the fit test is required to be repeated once every year.

The purpose of this project is to determine if one year is an appropriate time. That is, should the fit test be repeated more frequently or less frequently? To that end, you will be fit tested once every six months for a period of three years. Changes in the fit of the respirator will be monitored throughout a period of three years.

This study consists of three parts: In Part 1, a respirator model and size that adequately fits you will be determined with a standard respirator fit test. During that process you will be shown how to properly don (put on and adjust) the respirator. Then you will repeat the standard fit test eight times with that respirator. Between each test you will remove the respirator, wait 5 minutes, and then redon the respirator. Subjects will be measured for 18 head and face measurements, plus height and weight. The researchers will use a tape measure and calipers. Subjects will also be scanned with a digital head scanner. This uses a beam of light that is like a supermarket checkout scanner. The light does not go inside the body. *It is not like an X-ray or MRI.* The scan produces a picture of the head on a computer screen. This part will be completed in your first visit to the NIOSH facility and will take about 4 hours.

Part 2 is a repeat of Part 1 within 14 days or less of Part 1. Part 3 is a repeat of Part 1 every six months after Part 1 for three years. Each testing session will take approximately 3 hours. The total number of testing sessions is seven or eight if you also participate in Part 2. You will receive reimbursement for your time at a rate of \$30 per hour.

Anyone who is interested might be able to participate in the study. Before you participate in this study, NIOSH scientists will explain the study to you and ask if you want to participate in the study. For more information, call Dennis Viscusi at 412-386-4050 or Ziqing Zhuang at 412-386-4055.

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APPENDIX B. MEDICAL EVALUATION FORMS

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY

RESPIRATOR SCREENING CLINICAL HISTORY AND EXAMINATION FORM and OSHA Respirator Medical Evaluation Questionnaire

Revised: June 02, 2004

Note to physician: In accordance with standard good clinical practice and as required by HSRB, all positive answers to clinical signs or symptoms in the clinical history form should be followed up with additional questions to clearly document the clinical significance of the reported condition. While in many cases adequate information may be obtained with simple follow-up probes, in other cases (such as any chest pain) a rather detailed history may be necessary. The physician is expected to use good clinical judgment in this process. A special section is included in the form for this purpose.

Obviously, the findings on history should be integrated with information obtained by the physical examination and ECG to arrive at an overall evaluation of the subject.

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY

**RESPIRATOR SCREENING
CLINICAL HISTORY AND EXAMINATION FORM
and OSHA Respirator Medical Evaluation Questionnaire**

TO PARTICIPANT: PLEASE FILL OUT THIS MEDICAL QUESTIONNAIRE TO THE BEST OF YOUR ABILITY, AS EXPLAINED TO YOU BY THE NURSE OR OTHER NIOSH REPRESENTATIVE. PLEASE ASK THE DOCTOR IF YOU HAVE ANY QUESTIONS ABOUT ANY PART OF THE QUESTIONNAIRE. THANK YOU.

1. Today's date: _____
2. Your name: _____
3. Your age (to nearest year): _____
4. Sex (circle one): Male/Female
5. Your height: _____ ft. _____ in.
6. Your weight: _____ lbs.
7. Your job title: _____
8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code): _____
9. The best time to phone you at this number: _____
10. Current Address (Number, Street, or Rural Route, City or Town, County, State, Zip Code)

11. Social Security Number

Part A. Questions below must be answered by everyone.

1. Do you currently smoke tobacco, or have you smoked tobacco in the last month:

Yes/No

If yes:

How many packs/day of cigarettes do you usually smoke?

How many years have you smoked?

Any past smoking? Years _____ Packs per day

Cigar/pipe smoking? ___ Yes ___ No

2. Have you ever had any of the following conditions?

- a. Seizures (fits): Yes/No
- b. Diabetes (sugar disease): Yes/No
- c. Allergic reactions that interfere with your breathing: Yes/No
- d. Claustrophobia (fear of closed-in places): Yes/No
- e. Trouble smelling odors: Yes/No

3. Have you ever had any of the following pulmonary or lung problems?

- a. Asbestosis: Yes/No
- b. Asthma: Yes/No
- c. Chronic bronchitis: Yes/No
- d. Emphysema: Yes/No
- e. Pneumonia: Yes/No
- f. Tuberculosis: Yes/No
- g. Silicosis: Yes/No
- h. Pneumothorax (collapsed lung): Yes/No
- i. Lung cancer: Yes/No
- j. Broken ribs: Yes/No
- k. Any chest injuries or surgeries: Yes/No
- l. Any other lung problem that you've been told about: Yes/No

4. Do you currently have any of the following symptoms of pulmonary or lung illness?

- a. Shortness of breath: Yes/No
- b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No

- c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No
- d. Have to stop for breath when walking at your own pace on level ground: Yes/No
- e. Shortness of breath when washing or dressing yourself: Yes/No
- f. Shortness of breath that interferes with your job: Yes/No
- g. Coughing that produces phlegm (thick sputum): Yes/No

- h. Coughing that wakes you early in the morning: Yes/No
- i. Coughing that occurs mostly when you are lying down: Yes/No
- j. Coughing up blood in the last month: Yes/No
- k. Wheezing: Yes/No
- l. Wheezing that interferes with your job: Yes/No
- m. Chest pain when you breathe deeply: Yes/No
- n. Any other symptoms that you think may be related to lung problems: Yes/No

5. Have you ever had any of the following cardiovascular or heart problems?

- a. Heart attack: Yes/No
- b. Stroke: Yes/No
- c. Angina: Yes/No
- d. Heart failure: Yes/No
- e. Swelling in your legs or feet (not caused by walking): Yes/No
- f. Heart arrhythmia (heart beating irregularly): Yes/No
- g. High blood pressure: Yes/No
- h. Any other heart problem that you've been told about: Yes/No

6. Have you ever had any of the following cardiovascular or heart symptoms?

- a. Frequent pain or tightness in your chest: Yes/No
- b. Pain or tightness in your chest during physical activity: Yes/No
- c. Pain or tightness in your chest that interferes with your job: Yes/No
- d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No
- e. Heartburn or indigestion that is not related to eating: Yes/ No
- f. Any other symptoms that you think may be related to heart or circulation problems: Yes/No

7. Do you currently take medication for any of the following problems?

- a. Breathing or lung problems: Yes/No
- b. Heart trouble: Yes/No
- c. Blood pressure: Yes/No
- d. Seizures (fits): Yes/No

8. If you've used a respirator, have you ever had any of the following problems? (If you've never used a respirator, check the following space and go to question 9:)

- a. Eye irritation: Yes/No
- b. Skin allergies or rashes: Yes/No
- c. Anxiety: Yes/No
- d. General weakness or fatigue: Yes/No
- e. Any other problem that interferes with your use of a respirator: Yes/No

9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No

10. Have you ever lost vision in either eye (temporarily or permanently): Yes/No

11. Do you currently have any of the following vision problems?

- a. Wear contact lenses: Yes/No
- b. Wear glasses: Yes/No
- c. Color blind: Yes/No
- d. Any other eye or vision problem: Yes/No

12. Have you ever had an injury to your ears, including a broken ear drum: Yes/No

13. Do you currently have any of the following hearing problems?

- a. Difficulty hearing: Yes/No
- b. Wear a hearing aid: Yes/No
- c. Any other hearing or ear problem: Yes/No

14. Have you ever had a back injury: Yes/No

15. Do you currently have any of the following musculoskeletal problems?

- a. Weakness in any of your arms, hands, legs, or feet: Yes/No
- b. Back pain: Yes/No
- c. Difficulty fully moving your arms and legs: Yes/No
- d. Pain or stiffness when you lean forward or backward at the waist: Yes/No
- e. Difficulty fully moving your head up or down: Yes/No
- f. Difficulty fully moving your head side to side: Yes/No
- g. Difficulty bending at your knees: Yes/No
- h. Difficulty squatting to the ground: Yes/No
- i. Difficulty climbing a flight of stairs or a ladder carrying more than 25 lbs: Yes/No

j. Any other muscle or skeletal problem that interferes with using a respirator: Yes/No

16. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals: Yes/No

If "yes," name the chemicals if you know them: _____

—

17. Have you ever worked with any of the materials, or under any of the conditions, listed below:

- a. Asbestos: Yes/No
- b. Silica (e.g., in sandblasting): Yes/No
- c. Tungsten/cobalt (e.g., grinding or welding this material): Yes/No
- d. Beryllium: Yes/No
- e. Aluminum: Yes/No
- f. Coal (for example, mining): Yes/No
- g. Iron: Yes/No
- h. Tin: Yes/No
- i. Dusty environments: Yes/No
- j. Any other hazardous exposures: Yes/No

If "yes," describe these exposures: _____

—

18. Have you been in the military services? Yes/No

If "yes," were you exposed to biological or chemical agents (either in training or combat): Yes/No

19. Have you ever worked on a HAZMAT team? Yes/No

20. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications): Yes/No

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If "yes," name the medications if you know them: _____

Part B. GENERAL

1. Have you had any surgery in the past 12 months?

Yes No

If yes specify type and date

2. Have you had any symptoms or discomfort in the past few weeks which you feel may indicate a change in the state of your health?

Yes No

Specify

3. Do you see a doctor for any reason aside from mild colds or flu?

Yes No

Explain

4. How often do you exercise a week on an average?

Number of times

Activities

Part C. Heart Related

1. Are you now or have you in the past been seen by a doctor for the following conditions?
 - Angina
 - Heart attack or coronary
 - Heart murmurs
 - Rheumatic fever or rheumatic hearth disease
 - Irregular heart beat (Including flutter or fibrillation)
 - Claudication (extremity muscle pains due to inadequate circulation which commonly occurs only, or worsening with exercise)
 - Phlebitis or blood clots
 - Bad circulation
 - Heart failure
 - Fluid or congestion of the lungs
 - Any heart condition, heart medicine
 - Heart surgery
 - Diabetes
 - High-blood pressure

2. Do you at times get an uncomfortable feeling, pressure, or pain in the chest, when hurrying, going up a hill or doing extra work?
 - Yes No

3. Does your heart at times skip a beat or race too fast for no apparent reason?
 - Yes No

4. Do you get pain or cramps in the leg muscles when walking or hurrying?
 - Yes No

5. Do you find you must keep your head elevated or propped up on several pillows to breathe correctly when sleeping?
 - Yes No

6. In the past month, have you had to awaken from sleep to catch your breath?
 - Yes No

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Part D. ALLERGIES/ASTHMA

1. Do you have any allergies? Yes No
2. Are you allergic to any substances? Yes No
3. If "yes" to 2, name the substance(s)

4. Do you have asthma? Yes No
5. Do you have any other respiratory problems? Yes No
6. If "yes" to 5, describe the problem(s)

Part E. MUSCULOSKELETAL

1. Do you have arthritis or bursitis, or other joint problems which keeps you from doing the normal activities of a person your age and conditions?
 Yes No
2. Have you had any problem or injuries to your bones or muscles which keep you from the normal activities of a person your age and condition?
 Yes No
3. Do you have any back problem or condition of the spine (such as disc, pinched nerve) which keeps you from normal activities?
 Yes No

Part F. HEMATOLOGIC

1. Have you, in the past 12 months, had any blood conditions such as anemia or a low blood count?
 Yes No

2. Do you bleed or bruise more easily than usual?

Yes No

Part G. STROKE

1. Do you now or have you ever had a condition which resulted in spasticity, seizures, and convulsion, fit or epilepsy?

Yes No

2. Do you have any difficulty with your coordination which may make it difficult for you to do the usual activities of a person your age and condition?

Yes No

3. Have you ever had a stroke?
(Include a small stroke, incomplete or partial stroke, or told by a doctor "almost had a stroke")

Yes No

4. Have you ever been in a hospital or treatment center for nervous condition?

Yes No

Part H. PAST MEDICAL HISTORY

1. Medical Illnesses: (Please list any illness other than a minor "cold" or upset stomach.)

2. Date of last physical examination.

Results

Was exercise performed?

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FOR DOCTOR'S USE ONLY

(Space for expanded history. Please clearly indicate item addressed.)

PHYSICAL EXAM

NAME

DATE

MEASUREMENTS

1. Height ____ (State units)
2. Weight ____ (State units)
3. Blood Pressure:
R _____
L _____
4. Pulse
5. Respiration

GENERAL APPEARANCE

1. Skin/coloration
2. Nutrition/development
3. Dyspnea/cough

HEAD & NECK

1. Eyes/fundi
2. ENT (deformity, obstruction)

RESPIRATORY

1. Chest wall (ap diameter, deformities, excursion)

2. Percussion and diaphragm movement
3. Auscultation (tidal, forced expiration)

CARDIOVASCULAR

1. Apex beat/palpation
2. Rhythm
3. Heart sounds (P, \geq , A₂)?
4. Murmurs/gallops
5. Neck veins at
6. Peripheral pulses

ABDOMEN

1. Inspection/scars
2. Palpation/tenderness/hernia
3. Auscultation/bruits
4. Hernia check

EXTREMITIES

1. Clubbing/cyanosis/edema
2. Arthritis/deformity

NEUROLOGIC

1. Mental status
2. Motor/movement disorders

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3. Reflexes/other

ELECTROCARDIOGRAM

1. Rate/rhythm
2. Axis
3. Abnormalities

SUMMARY:

Medical Criteria for Disqualifying Potential NPPTL Respirator Exercise Subjects Based on History, Exam, and resting ECG

Note: These lists are not in any way meant to be all-inclusive, but rather are included to assist the physician in his evaluation.

By History:

1. All definite or probable angina.
2. History of myocardial infarction.
3. Asthma or any pulmonary/respiratory disease
4. Claustrophobia
5. Irregular Heartbeat
6. Shortness of breath at rest or mild exertion
7. Dizziness or syncope
8. Orthopnea or paroxysmal nocturnal dyspnea
9. Ankle edema
10. Palpitations or tachycardia
11. Intermittent claudication
12. Known heart murmur
13. Unusual fatigue or shortness of breath with usual activities

By Physical Examination:

1. Significant aortic stenosis; any diastolic murmur.
2. Blood pressure Systolic ≥ 150 ; Diastolic ≥ 95 .
3. Resting pulse ≥ 105
4. Irregular Heartbeat
5. Wheezing

By ECG:

1. ≥ 3 PVC's/minute.
2. Any coupled PVC's.
3. Multifocal PVC's.
4. PVC's which occur within .04 seconds (1 block) of T wave peak.
5. Paroxysmal ventricular tachycardia.
6. Paroxysmal atrial tachycardia; atrial fibrillation or flutter.
7. Any second or third degree heart block.
8. ≥ 1 mv ST depression with horizontal or downward slope of ST segment.

Other:

Any medical finding or condition, or combination of these which in the opinion of the physician in charge would subject the person if exercised to undue stress or risk.

NOTIFICATION OF RESULTS OF PHYSICAL EXAMINATION

An immediate debriefing regarding abnormalities on the physical exam, and ECG will be given. Participants will also receive a letter with the results of their exam and ECG. A sample letter is attached as follows.

(Date)

Dear (participant):

Thank you for your recent participation in the screening evaluation for the National Protective Technology Laboratory, National Institute for Occupational Safety and Health (NIOSH) in Pittsburgh, Pennsylvania. The results of your screening evaluation are given below.

Physical Exam

Your physical exam revealed:

Resting ECG As you may know, the ECG measures the electrical currents produced by the heart as it pumps blood through the body. While it is a useful test, it can be normal when there is serious heart disease, and it can be abnormal sometimes when the heart appears perfectly healthy. Thus you should discuss the ECG interpretation with your personal physician if you have any questions.

Your ECG reading:

If you have any questions regarding this medical information or the respirator test project, please contact:

Raymond Roberge, M.D.
NIOSH/NPPTL
PO Box 18070
Cochrans Mill Road
Pittsburgh, PA 15236
(412) 386-5241

Sincerely yours,

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Raymond Roberge, M.D.
Medical Officer

APPENDIX C. DEMOGRAPHIC DATA FORM

Date _____

Name _____

Subject No. _____

Gender (circle one): Male Female

Race (circle one):

White (non-Hispanic)

Black (non-Hispanic)

Asian

Hispanic

Other (specify): _____

Age on last birthday: _____

Do you currently smoke tobacco products? Yes _____ No _____

If "Yes", are you willing to refrain from smoking for at least one hour prior to and during a two hour lab test session?

Yes _____ No _____

(Males only) Are you willing to appear for lab tests with a cleanly shaved face?

Yes _____ No _____

Are you aware that you are allergic to any of the following substances found in baby powder (e.g., corn starch, tricalcium phosphate, aloe barbadensis, vitamin E, fragrances)?

Yes _____ No _____

Has there been any change in your overall health since your last series fit tests (approximately 6 months ago)?

Yes _____ No _____

If yes, please explain.

Has there been any change in your facial appearance since your last fit test series (e.g., cosmetic surgery, broken nose, facial piecing, scaring, etc.)?

Yes _____ No _____

If yes, please explain.

Have you had dental work since your last series of fit tests?

Yes _____ No _____

If yes, please explain.

APPENDIX D. TRADITIONAL ANTHROPOMETRIC DATA FORM

Subject No. _____

Dimension	Measurement (mm)
Bigonial Breadth	
Bizygomatic Breadth (face width)	
Interpupillary Breadth	
Lip Length	
Menton-Sellion Length (face length)	
Menton-Subnasale Length	
Nasal Root Breadth	
Nose Breadth	
Nose Protrusion	
Sellion-Subnasale Length (nose length)	
Minimum Frontal Breadth	
Head Breadth	
Head Circumference	
Stature (height)	
Weight (kg)	

APPENDIX E. SHORT MEDICAL SCREENING QUESTIONNAIRE

SHORT MEDICAL SCREENING QUESTIONNAIRE IMMEDIATELY PRIOR TO EACH RESPIRATOR FIT TEST

1. Are you in good general health?

Yes _____ No _____

2. Have you experienced pain during activities such as nodding and turning your head, twisting and bending at the waist, walking, lifting light objects (less than 25 pounds), reaching, or moving your arms for one or two minutes at a time?

Yes _____ No _____

3. Do you have any condition which might make it unwise or unsafe for you to perform the activities mentioned in question 2?

Yes _____ No _____

4. Do you have any debilitating illnesses or injuries?

Yes _____ No _____

5. Have there been any significant changes in your health since you last filled out this form or since your last physical examination by the NIOSH contractor physician?

Yes _____ No _____

If Yes, please explain:

6. Have you smoked any tobacco products within the past 60 minutes?

Yes _____ No _____

Signature:

Date:

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APPENDIX F. OSHA MANDATORY USER SEAL CHECK PROCEDURES

The individual who uses a tight-fitting respirator is to perform a user seal check to ensure that an adequate seal is achieved each time the respirator is put on. Either the positive and negative pressure checks listed in this appendix or the respirator manufacturer's recommended user seal check method shall be used. User seal checks are not substitutes for qualitative or quantitative fit tests. The OSHA user seal check procedures were modified to be applied for filtering facepiece respirators.

I. Facepiece Positive and/or Negative Pressure Checks






A. Positive pressure check. Close off the exhalation valve (if there is one), cover the filtering facepiece with both hands, and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal.







B. Negative pressure check. Cover the filtering facepiece with both hands, inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.






II. Manufacturer's Recommended User Seal Check Procedures

The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and/or negative pressure check procedures provided that the manufacturer's procedures are equally effective.






APPENDIX G. DESCRIPTION, DEFINITION AND DIAGRAM OF LANDMARKS







Description	Definition	Diagram
Alare, right and left	The lateral point on the flare or wing of the nose.	
Cheilion, right and left	The lateral point of the juncture of the fleshy tissue of the lips with the facial skin at the corner of the mouth.	
Chin	The most protruding point on the bottom edge of the chin, along the jawline.	
Frontotemporale, right and left	The point of deepest indentation of the temporal crest of the frontal bone above the browridges.	
Glabella	The anterior point on the frontal bone midway between the bony browridges.	



Gonion, right and left	The lateral point on the posterior angle of the mandible (jawbone).	
Infraorbitale, right and left	The lowest point on the anterior border of the bony eye socket.	
Nasal Root Point, right and left	The point on the right side of the nasal root at a depth equal to one-half the distance from the bridge of the nose to the eyes.	
Menton	The inferior point of the mandible in the midsagittal plane (bottom of the chin).	
Pronasale	The point of the anterior projection of the tip of the nose.	
Sellion	The point of the deepest depression of the nasal bones at the top of the nose.	

<p>Subnasale</p>	<p>The point of intersection of the philtrum (groove of the upper lip) with the inferior surface of the nose, in the midsagittal plane.</p>	
<p>Top of head</p>	<p>The highest point on the head when the head is in the Frankfort plane.</p>	
<p>Tragion, right and left</p>	<p>The superior point on the juncture of the cartilaginous flap (tragus) of the ear with the head.</p>	
<p>Zygion, right and left</p>	<p>The most lateral point on the zygomatic arch. (unmarked). When unmarked, this is located by movement of the tips of the spreading caliper during measurement.</p>	
<p>Zygofrontale, right and left</p>	<p>The lateral point of the frontal bone on its zygomatic process.</p>	

APPENDIX H. DESCRIPTION, DEFINITION AND DIAGRAM OF MEASUREMENTS

Description	Definition	Diagram
Bigonial Breadth	Straight-line distance measured with a spreading caliper between the right and left gonion landmarks on the corners of the jaw.	 <p>A line drawing of a person's face from the front. A horizontal line with arrows at both ends is drawn across the lower part of the face, passing through the corners of the jaw (gonions).</p>
Bizygomatic Breadth	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches.	 <p>A line drawing of a person's face from the front. A horizontal line with arrows at both ends is drawn across the widest part of the face, passing through the zygomatic arches.</p>
Head Breadth	Maximum horizontal breadth of the head as measured with a spreading caliper above the level of the ears.	 <p>A line drawing of a person's face from the front. A horizontal line with arrows at both ends is drawn across the top of the head, above the level of the ears.</p>
Head Circumference	Maximum circumference of the head just above the ridges of the eyebrows (supraorbital ridges) and the attachment of the ears.	 <p>A line drawing of a person's head in profile. A horizontal line with arrows at both ends is drawn around the head, passing just above the eyebrows and the ears.</p>
Interpupillary Distance	Distance as measured with a pupillometer at the center of the right and the center of the left pupil.	 <p>A line drawing of a person's face from the front. A horizontal line with arrows at both ends is drawn across the eyes, passing through the centers of the pupils.</p>

<p>Lip Length</p>	<p>Distance between the right and left Chelion landmarks at the corners of the closed mouth.</p>	
<p>Menton-Sellion Length</p>	<p>Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark.</p>	
<p>Minimum Frontal Breadth</p>	<p>Straight-line distance as measured with a spreading caliper between the right and left frontotemporale landmarks.</p>	
<p>Nasal Root Breadth</p>	<p>Horizontal breadth of nose as measured with a sliding caliper at the sellion landmark and a depth equal to one-half the distance from the bridge of the nose to the eyes.</p>	
<p>Neck Circumference</p>	<p>Circumference of the neck at the level of the infrathyroid landmark (Adam's apple).</p>	
<p>Nose Breadth</p>	<p>Straight-line distance as measured with a sliding caliper between the right and left alare landmarks.</p>	

Nose Protrusion	Straight-line distance as measured with a sliding caliper between the pronasale landmark and the subnasale landmark.	
Subnasale- Sellion Length	Straight-line distance as measured with a sliding caliper between the subnasale landmark and the sellion landmark.	

APPENDIX I. EMERGENCY DECISION MAKING PROTOCOL

Station Emergency Procedures for NIOSH Pittsburgh

- 1) Dial 11 - Employee calls, all calls will be received by the Telephone Operator/Security Guard (B-100).
- 2) The Telephone Operator/Security Guard will answer "What is the Emergency?"
- 3) Caller - Stay on the line to answer these questions:
 - a) The location of the emergency (Building, Floor, and Room)
 - b) Number of persons who are injured and the nature of injury
 - c) Your name and telephone number
- 4) **Do not attempt to move or assist an injured person unless you have had the proper training.** If possible, provide comfort by talking to the injured person until further help arrives.
- 5) At this point, Telephone Operator/Security Guard will activate the NIOSH-Pittsburgh Emergency Response Team, with an announcement over the NIOSH-Pittsburgh 2-way radio system.
- 6) Telephone Operator/Security Guard will call for the outside emergency response assistance (i.e., Fire, Police, and Ambulance Services) and forward all information to the NIOSH-Pittsburgh Emergency Response Team.
- 7) During an incident involving a subject in the lab, the lab staff will provide the first line of emergency care to the subject. In addition, we require all lab staff to be at least CPR/AED certified. The on-site clinic can no longer treat anyone other than federal employees. The lab staff will continue to support the subject until further outside assistance (ambulance) arrives to transport to outside medical facility (Hospital). The emergency numbers are prominently displayed in the lab so that any of the lab staff can activate the emergency system. We have not assigned a specific person to activate the system as we believe that all of the participating lab staff assumes responsibility for the subject and, therefore, all are empowered to activate the system in the event of an emergency.

APPENDIX J. CONSENT FORM

**NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
(NIOSH)
CENTERS FOR DISEASE CONTROL AND PREVENTION
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

I. DESCRIPTION

1. Title: Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering-Facepiece Respirator Fit
2. Sponsor and/or Project Officer: Ziqing Zhuang, Ph.D.
3. Purpose and Benefits: Many workers rely on respirators to protect their health. The level of protection provided by most respirator types depends on how well the respirator fits the wearer (seals to the face). Therefore, before a respirator can be relied upon to protect the wearer, a test (the so-called "fit test") must be conducted to assure the respirator adequately fits the wearer. And, because facial characteristics can change over time, the fit test is required to be repeated once every year. That one-year period is, however, not based on scientific studies.

The purpose of this project is to determine if one year is an appropriate time. That is, should the fit test be repeated more frequently or less frequently? To that end, you will be fit tested once every six months for a period of three years. Changes in the fit of the respirator will be monitored throughout a period of three years.

Results of the project will be published and will be made available to anyone upon request. Information gathered by this research will benefit:

- a. You, the participant, by determining how well your respirators fit you;
- b. Those involved in developing respirator regulation and recommendations (OSHA, MSHA, ANSI, AIHA, etc.) by helping them judge the appropriateness of the current practice of annually fit testing all wearers of tight-fitting respirators. The long-term potential benefits are improved standards for the use of respirators.
- c. Because you complete this 3 year study, workers who depend on respirators to protect them from toxic and hazardous environments can be more reliably protected.

II. CONDITIONS OF THE STUDY

1. This study consists of three parts: In Part 1, a respirator model and size that adequately fits you will be determined with a standard respirator fit test. During that process you will be shown how to properly don (put on and adjust) the respirator. Then you will repeat the standard fit test nine times with that respirator. Between each test you will remove the respirator, wait 5 minutes, and then redon the respirator. Repeating the fit test is necessary because respirator fit can change every time the respirator is removed and redonned and it is important to determine how consistently the respirator fits you. You will be measured for 18 head and face measurements, plus height and weight. The researchers will use a tape measure and calipers. You will also be scanned with a digital head scanner. This uses a beam of light that is like a supermarket checkout scanner. The light does not go inside the body. *It is not like an X-ray or MRI.* The scan produces a picture of the head on a computer screen. This part will be completed in your first visit to the NIOSH facility and will take about 4 hours.

In Part 2, you will be retested with the same respirator (model and size, not the same sample) that you used in Part 1. You will review the proper donning procedure with the NIOSH researcher. You will be fit tested with the respirator 9 times. Again the respirator will be removed and redonned between each test. The Part 2 testing sessions will be conducted in the NIOSH facility approximately within 14 days or less after Part 1. You will be asked about changes (weight, dental work cosmetic surgery, etc.) that might affect the fit of the respirator. This testing session will take approximately 4 hours. Only 10 of the subjects are randomly selected to participate in Part 2. You will be notified if you are in this group.

In Part 3, you will be retested with the same respirator (model and size, not the same sample) that you used in Part 1. You will review the proper donning procedure with the NIOSH researcher. You will be fit tested with the respirator 9 times. Again the respirator will be removed and redonned between each test. You will be measured for 18 head and face measurements, plus height and weight. The researchers will use a tape measure and calipers. You will also be scanned with a digital head scanner. The Part 3 testing sessions will be conducted in the NIOSH facility approximately 6 months after Part 1 and every 6 months thereafter for three years. You will be asked about changes (weight, dental work cosmetic surgery, etc.) that might affect the fit of the respirator. Each testing session will take approximately 4 hours. The total number of testing sessions is seven or eight if you also participate in Part 2.

2. The risk of injury is very low since you only need to stand and carry out simple head and face movements while wearing a respirator.

If you have any reaction to the tests/procedures, you should contact Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (412) 386-4055.

3. Injury from this project is unlikely. There is an emergency protocol to be followed if the need should arise. If injury results, medical care is not provided, other than emergency treatment. If you are injured through negligence of a NIOSH employee, you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Public Health Service Claims Office (301) 443-1904. If you are injured through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If an injury should occur to you as the result of your participation, you should also contact: Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (412) 386-4055, or Dr. Cherie Estill, Chairperson, NIOSH Human Subjects Review Board, (513) 841-4476.
4. There are no alternative test procedures.
5. If you have questions about this research contact, Ziqing Zhuang, Ph.D., General Engineer, at the NIOSH National Personal Protective Technology Laboratory, (412) 384-4055. If you have any questions about your rights as a member of this study, contact Dr. Cherie Estill, Chairperson of the NIOSH Human Subjects Review Board at (513) 841-4476.

6. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

You will receive reimbursement of \$90 for each testing session. If a testing session takes longer than four hours, you will receive \$7.50 for each additional 15 minutes of your time.

7. The overall results of the study will be documented in a journal article or a National Personal Protective Technology Laboratory research report. Copies will be provided to you, upon publication, at your request.

III. USE OF INFORMATION

This study is being performed by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control (CDC), a government agency in the Department of Health and Human Services. NIOSH is allowed to collect and keep information about you, including the results from your physical examination, because of three laws passed by Congress. These laws are:

- The Public Health Service Act (42 U.S.C 241)
- The Occupational Safety and Health Act (29 U.S.C. 669)
- The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. It is up to you. If the information we are collecting is maintained and retrieved by personal identifiers, such as your name and social security number, it will become part of the CDC record system and we will protect it to extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources such as the following:

- Private contractors assisting NIOSH;
- Collaborating researchers under certain circumstances to conduct further investigations;
- The Department of Justice or the Department of Labor in the event of litigation.

You may request an accounting of the disclosures made by NIOSH. Except for these and other permissible disclosures authorized by the Privacy Act, or in limited

circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.

IV. SIGNATURES

I have read this consent form and I agree to participate in this study.

PARTICIPANT

_____ DATE _____ AGE _____
(signature)

_____ DATE _____
(Guardian signature, if required)

I, the NIOSH representative, have accurately described this study to the participant.

NIOSH REPRESENTATIVE

_____ DATE _____
(signature)

- 1 copy to participant
- 1 copy to project officer

DETAILED PERSONNEL PLAN

Name and Degree	Role on Project	FY06	FY07	FY08 - FY10	FY11	FY12
<i>Federal:</i>						
1 Zhuang	Project Officer	50%	50%	50%	50%	50%
2 Shaffer	Technical assistance		10%		10%	10%
3 Viscusi	Technical support	20%	20%	20%	20%	20%
4 Landsittel	Statistical support		10%		10%	10%
5 Roberge	Medical support		5%	10%	10%	5%
Onboard Subtotals:		0.7	1.05	0.8	1.0	0.95
<i>Contract (EG&G)</i>						
1 Campbell	Technical assistance		10%	10%	10%	10%
2 Technician 1	Test operator			100%	10%	
3 Technician 2	Test operator			100%	10%	
Contractor Subtotal:			0.1	2.1	0.3	0.1
Totals		0.7	1.15	2.9	1.3	1.05

PROJECT BUDGET SPREADSHEET

Category	FY06(\$)	FY07 (\$)	FY08-FY10(\$)	FY11(\$)	FY12(\$)	Total(\$)
Contracts ^a	260,000 ^b	6,500	615,120 ^c	20,000	20,000	912,620
Equipment	0	0	0	0	0	
Supplies ^d	0	13,000	20,000	2,000	2,000	37,000
Travel ^e	0	2,020	6,000	2,000	2,000	12,020
Misc.	0	0	0	0	0	
Total	260,000	21,520	574,790	24,000	24,000	970,640

Notes:

^a contract for this project are EG&G for on-site technical support, fees for test subjects, and equipment and software maintenance services.

- Two EG&G Technicians: \$600,000 (FY 08 \$95k x 2=\$190k; FY 09 \$100k x 2=\$200k; FY 10 \$105k x 2=\$210k)

- Campbell of EG&G: \$20k for each year from FY07 to FY12
- Subject fees: \$186,120 ($200 \times \$120 \times 7 = \$168k$; $10 \times \$120 = \1200 for the pilot study in FY08; add 10% to EG&G for making payments to the subjects \$16,920). Since 220 subjects will be recruited at the beginning of the study and 200 of them are expected to complete the study, subject fees were estimated for only 200 subjects.
- PortaCount (4 units) calibration services for FY08 to FY10: $\$750 \times 4 \times 3 = \$9,000$

^b Received \$260k of supplemental funding from CDC in FY 06 to initiate this study.

^c This amount is obtained by subtracting \$260k (the supplemental funding from CDC in FY 06) from the total budget for EG&G technicians for FY08-FY10, Campbell for FY07-FY10, and PortaCount calibration services (\$875,120), i.e., $(875,120 - 260,000) = \$615,120$.

^d Supplies for this project include: respirators, scan data storage media, landmark materials, wig cap, etc.

^e Travel: one trip each year for project officer to present study results, gather inputs from stakeholders, etc.