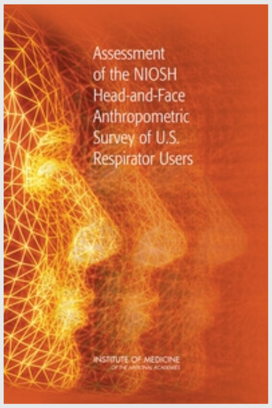


Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users

DETAILS

122 pages | 6 x 9 | PAPERBACK
ISBN 978-0-309-10398-5 | DOI 10.17226/11815

AUTHORS

Committee for the Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users, John C. Bailar III, Emily Ann Meyer, and Robert Pool, Editors

Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users

Committee for the Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users

Board on Health Sciences Policy

John C. Bailar III, Emily Ann Meyer, and Robert Pool, *Editors*

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

THE NATIONAL ACADEMIES PRESS • 500 Fifth Street, N.W. • Washington, DC 20001

This study was supported by Award No. HHSH200-2005-10881 between the National Academy of Sciences and the U.S. Department of Health and Human Services. Any opinions, findings, or conclusions expressed in this publication are those of the author(s) and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

International Standard Book Number -13: 978-0-309-10398-5
International Standard Book Number -10: 0-309-10398-3

Additional copies of this report are available from the National Academies Press, 500 Fifth Street, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); Internet, http://www.nap.edu.

For more information about the Institute of Medicine, visit the IOM home page at: **www.iom.edu.**

Printed in the United States of America.

The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

Suggested citation: Institute of Medicine (IOM). 2007. *Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. respirator users.* Washington, DC: The National Academies Press.

"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Advising the Nation. Improving Health.

THE NATIONAL ACADEMIES

Advisers to the Nation on Science, Engineering, and Medicine

The **National Academy of Sciences** is a private, nonprofit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research, dedicated to the furtherance of science and technology and to their use for the general welfare. Upon the authority of the charter granted to it by the Congress in 1863, the Academy has a mandate that requires it to advise the federal government on scientific and technical matters. Dr. Ralph J. Cicerone is president of the National Academy of Sciences.

The **National Academy of Engineering** was established in 1964, under the charter of the National Academy of Sciences, as a parallel organization of outstanding engineers. It is autonomous in its administration and in the selection of its members, sharing with the National Academy of Sciences the responsibility for advising the federal government. The National Academy of Engineering also sponsors engineering programs aimed at meeting national needs, encourages education and research, and recognizes the superior achievements of engineers. Dr. Wm. A. Wulf is president of the National Academy of Engineering.

The **Institute of Medicine** was established in 1970 by the National Academy of Sciences to secure the services of eminent members of appropriate professions in the examination of policy matters pertaining to the health of the public. The Institute acts under the responsibility given to the National Academy of Sciences by its congressional charter to be an adviser to the federal government and, upon its own initiative, to identify issues of medical care, research, and education Dr. Harvey V. Fineberg is president of the Institute of Medicine.

The **National Research Council** was organized by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government. Functioning in accordance with general policies determined by the Academy, the Council has become the principal operating agency of both the National Academy of Sciences and the National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities. The Council is administered jointly by both Academies and the Institute of Medicine. Dr. Ralph J. Cicerone and Dr. Wm. A. Wulf are chair and vice chair, respectively, of the National Research Council.

www.national-academies.org

COMMITTEE FOR THE ASSESSMENT OF THE NIOSH HEAD-AND-FACE ANTHROPOMETRIC SURVEY OF U.S. RESPIRATOR USERS

JOHN C. BAILAR III, (*Chair*), University of Chicago, Illinois
LISA M. BROSSEAU, University of Minnesota, Minneapolis
HOWARD J. COHEN, University of New Haven, West Haven, Connecticut
ALAN L. HACK, Los Alamos, New Mexico
SUBHASH R. LELE, University of Alberta, Edmonton, Canada
YOUCHENG LIU, Yale University School of Medicine, New Haven, Connecticut
JOAN T. RICHTSMEIER, Pennsylvania State University, University Park
KNUT RINGEN, Seattle, Washington
JAVIER ROJO, Rice University, Houston, Texas
ALBERT A. SCIARRETTA, CNS Technologies, Inc., Springfield, Virginia

IOM Staff
BRUCE M. ALTEVOGT, Study Director (since December 2006)
EMILY ANN MEYER, Study Director (until November 2006)
SARAH L. HANSON, Research Associate (since December 2006)
LORA K. TAYLOR, Senior Project Assistant
VILIJA TEEL, Senior Project Assistant

BOARD ON HEALTH SCIENCES POLICY*

*IOM boards do not review or approve individual reports and are not asked to endorse conclusions and recommendations. The responsibility for the content of the report rests with the authoring committee and the institution.

Independent Report Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the NRC's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

David Abrams, ARS Environmental Health, Inc., Minnetonka, Minnesota
Jeffrey S. Birkner, Moldex-Metric, Inc., Simi Valley, California
Fred L. Bookstein, Department of Statistics and Department of Psychology and Behavioral Sciences, Fetal Alcohol and Drug Unit, University of Washington, Seattle
Craig E. Colton, Regulatory Affairs & Training, 3M Occupational Health & Environmental Safety Division, St. Paul, Minnesota
Harry Ettinger, Los Alamos National Laboratories, New Mexico, Retired
David C. Hoaglin, Abt Associates Inc., Cambridge, Massachusetts
James Melius, New York State Laborers' Union, Albany, New York
James Platner, Center to Protect Workers' Rights, Silver Spring, Maryland
Aaron Richardson, Applied Biology and Aerosol Technology, Battelle Memorial Institute, Columbus, Ohio

Tim D. White, Department of Integrative Biology and Human Evolution Research Center, University of California, Berkeley
M. Donald Whorton, WorkCare, Inc., Alameda, California

Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Dr. Enriqueta C. Bond**, Burroughs Wellcome Fund. Appointed by the National Research Council and the Institute of Medicine, she was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

Acknowledgments

The committee acknowledges with appreciation the individuals who provided information to the committee. These individuals include Heinz Ahlers, NIOSH; Roland Berry Ann, NIOSH; Jeffrey Birkner, Moldex; Les Boord, NIOSH; Bill Hoffman, NIOSH; Roy McKay, University of Cincinnati; William Newcomb, NIOSH; Alex Pappas, Edgewood Chemical Biological Center; Jim Platner, Center to Protect Workers' Rights; Ron Shaffer, NIOSH; Julie Tremblay, Aearo; and Robert Weber, 3M. The committee is especially grateful to Bruce Bradtmiller from Anthrotech, Inc.

The National Personal Protective Technology Laboratory at NIOSH sponsored this study. We appreciate their support and especially thank Maryann D'Alessandro and Ziqing Zhuang for their efforts on behalf of this study.

We finally would like to thank the IOM staff, including Bruce Altevogt, Judy Estep, Sarah Hanson, Amy Haas, Emily Ann Meyer, Andrew Pope, and Vilija Teel.

Preface

This Committee's task—to examine and assess the adequacy and validity of the National Institute for Occupational Safety and Health (NIOSH)-sponsored Anthrotech Survey of U.S. Respirator Users—was as challenging as it was important. Having effective respiratory protection can be, and often is, a matter of life and death. Yet the scientific bases for developing and fitting effective respiratory protection remain more art than science.

A Los Alamos National Laboratory (LANL) respirator fit-test panel, performed in the 1970s and based on a survey of Air Force personnel, has been the basis for testing and certifying respirators for the past 30 years. It is not clear, however, that the Air Force population adequately represented the range of workers even then, and more recent changes in the composition and diversity of the U.S. workforce may make it even less suitable. Developing new test panels for respirators that will fit the changing "face" of the U.S. workforce became an obvious need that NIOSH sought to address in contracting with Anthrotech to conduct a new survey of the U.S. workforce in 2001. NIOSH is to be commended for taking that initiative and also for seeking an independent review of the study's outcome by the Institute of Medicine (IOM) (as presented in this report).

The conduct of our work was interrupted after our second meeting in order to accommodate an urgent request from the DHHS Office of the Secretary for advice on the potential reusability of disposable face masks in protecting against pandemic flu. Some of our committee members served on that committee, and then returned 6 months later to reconvene in addressing this committee's charge.

It is always easier to critique someone else's work than it is to develop and conduct new work. And it is with this awareness that our committee offers our evaluation and assessment. We found many weaknesses in the collection and analysis of the data that were used to develop the proposed face panels. The Anthrotech survey, rather than using novel methodology, served more as an update of a 30-year-old strategy with a larger sample population. The study would have been improved greatly by assuring that the sample was representative of workers who should be using respirators, by validating and incorporating three dimensional measures, and by measuring quantitative fit. There was also a surprising lack of detailed information about the methods that were used in its conduct. Nonetheless, the proposed NIOSH face panel represents an improvement over the existing LANL face panel, and its application is likely to improve the availability of respirators that fit a broader segment of the workforce.

The committee was not charged to comment on whether or not the survey should be redone. However, the Anthrotech research plan, survey, and data analysis had weaknesses that will limit their reliability for NIOSH purposes. As resources and time become available, NIOSH might undertake a new study with a different strategy and research plan.

The committee acknowledges and thanks the IOM staff who supported its efforts, the numerous NIOSH staff who provided detailed information and briefings, and others who provided information in open meetings, and otherwise during the conduct of this study. Appendix A lists the public meeting agendas and meeting participants. The committee most importantly thanks NIOSH for having asked these questions in the first place, for working on updating the respirator test standards, and for having a steadfast dedication to scientific research in support of the health of the public.

John C. Bailar III, M.D., Ph.D.
Committee Chairman

Contents

Summary

Millions of Americans use respirators in their places of work to protect themselves from exposures to such respiratory hazards as toxic vapors and gases, harmful particulate matter, and airborne pathogens. Some respirators filter the ambient air, while others employ a separate air supply; but in either case the respirator will protect its user only if it fits properly. It must mold to the user's face in such a way that no air from the outside can leak in, even when the user is moving or speaking.

It is the responsibility of the National Institute for Occupational Safety and Health (NIOSH) to certify that respirators from manufacturers meet certain minimum performance levels. NIOSH performs this task with the help of fit-test panels, each of them a group of about 25 people who have been chosen because, collectively, their facial dimensions are assumed to be representative of the respirator-wearing workforce as a whole. A respirator will be certified only if it performs effectively on the members of the panel—or at least on an appropriate subset of them. If, for example, a line of respirators in various sizes is being certified, it is not necessary that any one size fits all 25 panel members, but each of the test subjects should be able to be fitted suitably with at least one of the respirators.

If such a fit-test face panel is to function effectively, the faces of its members must accurately represent the faces of the entire diverse U.S. respirator-wearing workforce. This, in turn, demands having good anthropometric data—particularly data on facial dimensions—from a representative sample of the respirator-wearing workforce. Once such data have been collected and analyzed, an appropriate fit-test panel can be designed from them.

In short, certification fit testing of respirators depends upon two main factors: a well-conducted anthropometric survey of a representative sample of the respirator-wearing workforce, and a fit-test panel based on these anthropometric data that accurately represents the facial shapes and sizes of the millions of workers who use—or who should be using—respirators in their jobs.

For many years NIOSH has been using the fit-test panels developed in 1972 by researchers at Los Alamos National Laboratory (LANL) based upon anthropometric data available from a U.S. Air Force study. The population sample used by the LANL researchers was a group of men and women serving in the U.S. Air Force. It is unlikely that this sample was ever representative of the broader U.S. workforce—Air Force personnel are generally young and in good health, for instance, and the U.S. Air Force has height and weight requirements as well—but in the intervening years the U.S. workforce has become much more diverse, with more women workers and more minorities. Furthermore, the growing obesity problem in the United States means that workers are, on average, much heavier than they were two or three decades ago. In addition, the ethnic composition of the U.S. workforce had changed over the 30 years. So fit-test panels based on physical characteristics of Air Force personnel from the early 1970s are unlikely to accurately represent the broad U.S. workforce today.

Because of this situation, in 2001 NIOSH contracted with Anthrotech, Inc., to collect new anthropometric data that would be representative of today's respirator-wearing workforce and to use those data to design new fit-test panels. After Anthrotech finished that task, NIOSH contracted with the Institute of Medicine (IOM) to establish an *ad hoc* committee to review the NIOSH-sponsored Anthrotech study. This report contains the findings, conclusions, and recommendations of that IOM committee (Box S-1).

THREE OVERARCHING THEMES

The various elements of the NIOSH-sponsored Anthrotech study—anthropometric measurements, statistical sampling techniques, fit testing, and so on—are complicated, and this review must necessarily wade into them in some detail; but the basic message of this report can be summarized with the following three broad statements:

1. the results of the NIOSH-sponsored Anthrotech study represent a clear improvement over the anthropometric data and corresponding LANL fit-test face panels that have been used since the 1970s;
2. nonetheless, the NIOSH-sponsored Anthrotech study has a number of weaknesses that limit its effectiveness and reliability; and, therefore,
3. there are certain steps that should be taken to address the weaknesses, in order to move toward more effective testing and certification of respirators in the future.

These three statements can also be seen as the report's overarching themes, themes that are touched upon again and again throughout the course of the review.

ANTHROPOMETRIC MEASUREMENTS

The field of anthropometry is a well-established one, with measuring techniques that have been honed over decades of practice. In their survey, the Anthrotech researchers used traditional tools such as calipers and measuring tapes to take 18 facial and head dimensions from the 4,026 subjects in their survey. They also recorded height and weight for comparison to other similar datasets, and neck circumference was added partway through data collection when it was learned that this measurement plays a role in some national and international respirator standards.

Taking such anthropometric measurements requires a researcher to first identify and mark a series of landmarks on the subject's face. Both the placement of these landmarks and the measurement of the distance between pairs of landmarks are potential sources of error.

Measurement Error

Ideally, in a large field study on anthropometric measurement, a pilot study is conducted to check how accurately landmarks are placed and distances measured by the technicians who will perform the study and to determine how closely the measurements taken by different technicians agree. This makes it possible to assess how much error can be expected in the study and to determine the sources of error, thereby offering a means for improvement.

The Anthrotech researchers did make special efforts to reduce human errors in landmark placement and dimension measurements, having the field technicians practice on each other until an allowable level of accuracy was achieved. However, data that could be used to independently assess the precision of measurements—that is, how closely measurements made by different technicians agreed and how closely measurements agreed when made by the same technician on different occasions—were not reported. There was also no apparent record of an attempt to measure the relationship between individual differences in facial shape and the level of measurement error.

For these reasons, the committee concluded that the NIOSH-sponsored Anthrotech report did not adequately address the potential effects of measurement error on the validity and quality of its anthropometric measurements and makes the following recommendation:

> **Recommendation 2-1:** ***Analyze Measurement Error.***
>
> **In future studies NIOSH should perform additional analyses of the impact of measurement error, including the effects of intraobserver and interobserver variations in measurement.**

Use of Three-Dimensional Scan Data

In addition to the traditional anthropometric measurements, the Anthrotech researchers also performed three-dimensional (3D) scans on approximately a quarter of the subjects in an effort to develop a set of standard head forms. Although the datasets from these 3D scans were archived, the data were not used in the development of the proposed fit-test panels. NIOSH informed the committee that this was because there were discrepancies between the 3D data and the traditional measures.

This decision not to use the 3D data concerned the committee because 3D data have a number of advantages over the traditional, manually collected data, such as providing a more accurate and complete summary of the facial geometry, and providing information about the localized variation around a landmark. The use of 3D scans in anthropometry is still a developing area, and it is necessary to test any newly acquired scans (or scanning devices) against already validated means of collecting data. Though no uniform, evidence-based, best-practice standards exist against which measures collected from 3D image data can be compared, an appropriate test must be defined for every study until such standards are developed.

In light of the potential advantages, the committee recommends the following:

> **Recommendation 2-2: *Consider Utilizing Three-Dimensional Scan Data.***
>
> **NIOSH should consider collecting and utilizing data from 3D scans, alone, or in combination with traditional manually collected data, to ensure the most robust set of data are used to develop future anthropometric face panels.**

DATA SAMPLING

To create a population sample that reflected the race, ethnicity, age, and gender diversity of the respirator-wearing workforce in the United States, NIOSH developed a plan that called for approximately 4,000 subjects divided, evenly into men and women, three age categories (18-29, 30-44, and 45-65), and four racial/ethnic categories (white, African-American, Hispanic, and Other). Unfortunately, the NIOSH-sponsored Anthrotech study did not appropriately subdivide the sample population based on race and ethnicity. The Other category was overly diverse, including Asian, American Indian, and Alaskan Native subjects, while not including other groups that might be designated as "Other." Given the diversity of the respirator wearing workforce, it is important that the Other group be included in analyses of the entire target population. However, its small sample size and limited diversity may make it difficult, if not impossible, to perform useful analysis of the Other category as a distinct subgroup.

For logistical reasons, the Anthrotech researchers decided to limit their sample population to workers from eight states: California, Illinois, Kentucky, New York, Ohio, Pennsylvania, Texas, and Virginia. Within each state, the researchers selected work sites that were deemed representative and contacted the work sites to see if they were willing to participate in the survey. There are no details in the report on the criteria Anthrotech used to select the various establishments, the response rate from these establishments, or how participating sites may have differed from nonparticipating sites. The committee found that the 41 work sites listed in the final report were more often larger establishments, but it is not clear whether this was a choice made by the Anthrotech investigators or was due to larger companies being more willing to participate.

Once a work site was identified, Anthrotech investigators worked with a single individual who provided access to test subjects and assisted with both scheduling and recruitment. Unfortunately, the criteria for selection of the test subjects are ill defined in the report, so it is difficult to ascertain if the selection process was random or if issues that arose during the selection of subjects biased the sample.

The final sample consisted of 3,998 subjects, which was very close to the original target number. The final distribution, however, did not follow the original plan of having equal numbers of subjects per category, but instead ended up being closer to the actual demographic makeup of the U.S. workforce. Nor was the distribution even across geographic region, as originally planned. Instead, the final distribution was more heavily weighted toward Texas, Ohio, and Illinois. It is not clear what difference either of these factors may have made to the sample, but since race and ethnicity are not evenly distributed across the United States, the limited geographic distribution may have unintentionally introduced a racial and ethnic bias into the sample.

Defining the Target Population

Although a clear definition of the target population is critical to survey design, the Anthrotech report does not provide such a definition. In addition, although the survey intends to reflect “respirator users,” it was unclear if that included anyone who may ever need to use a respirator, or simply those who use or should be using respirators.

Finally, another problem is that the selection of the subjects in this survey did not seem to be random, while a well-designed survey will have random sampling. Unfortunately, the committee could not determine exactly how the subjects were selected, and this left many questions unanswered. Did the sample include overrepresentation of workers whom the management knew had adapted well to the respirators they wore? Conversely, did workers volunteer for the study because they recognized they had problems? Either situation would have seriously biased the population sample.

Because of these and other shortcomings in the creation of the sample, the committee recommends the following:

> **Recommendation 3-1: *Define Target Populations More Precisely.***
>
> **Future anthropometric face panel studies undertaken by, or on behalf of, NIOSH should have a statistically rigorous and valid sampling plan and implementation strategy that precisely define the target population and also ensure that the samples of selected subjects included in the studies are representative of the predefined sample population (e.g., the current workforce that wears respirators, workers who should be using respirators, the general United States workforce).**

DATA ANALYSIS AND FIT-TEST FACE PANELS

When the 4,000 subjects in the population sample were divided into groups according to sex, age, and race/ethnicity, the sizes of the groups in the sample were not in the same proportions as those groups are in the general U.S. workforce. Therefore, the first step in Anthrotech's data analysis was to weight each sample cell to adjust for that disparity. This is a workable strategy, but it raises the issue of which population to use as a reference when calculating the weights. Ideally that population would be the target population of the survey—those in the U.S. workforce who should use respirators, for example—but the Anthrotech researchers were apparently unable to find data on this population, so they defaulted to the entire U.S. workforce. The committee was unable to tell if this was an appropriate tactic, but it is at least conceivable that there is a difference in anthropometric measurements between the entire U.S. workforce and the subset of workers who should routinely wear or who should wear respirators in an emergency.

Benchmarking the Target Population

Perhaps the most important consideration in this weighting, however, is to make sure that it is done in such a way as to capture the true demographic makeup of the U.S. respirator-using workforce. That workforce has become more and more diverse over the past several decades, resulting in an increased range of facial dimensions, and that trend can only be expected to continue in the next few decades. Thus the committee makes the following recommendation:

> **Recommendation 4-1:** ***Ensure Appropriate Representation of Demographics Groups.***
>
> **NIOSH should benchmark its sample population against the current and future United States workforce that should be wearing respirators to ensure adequate representation of demographic groups on the panel (e.g., age, gender, race, and ethnicity).**

To develop those fit-test panels from their survey data, the Anthrotech researchers used methods similar to those employed by the original LANL face panel designers. In particular, they chose to rely on the same facial dimensions as in the LANL face panels. Anthrotech's rationale for this choice was not clear to the committee, as there is no evidence that these parameters lead to the most effective fit-test panels.

Expanding Face Panels

There were two clear differences between the fit-test face panels offered in the NIOSH-sponsored Anthrotech report and those created in the 1972 LANL study. First, the proposed face panels were not confined to a strictly rectangular arrangement of cells as had been the case earlier. The Anthrotech investigators found that, in offsetting some of the cells, they were able to achieve a greater coverage of the target population. And, second, there was a clear shift of the cells to the upper-right quadrant, where the larger faces reside. This was the result of a major difference in facial dimensions between the earlier LANL sample and the current one—of the individuals surveyed in the current sample, 15.3 percent would not have been covered by the LANL face panel, most of them because of having larger faces.

Thus the shift in the face panel was necessary to provide coverage for the larger faces in the current survey; but the committee noted that the shift came at the expense of smaller-faced individuals, including many in minority populations, even though small faces still make up a considerable proportion of the workforce. Thus the committee recommends the following:

> **Recommendation 4-2:** ***Include Large and Small Faces in Panel.***
>
> **NIOSH should develop an expanded anthropometric face panel that includes the larger-sized faces described in the NIOSH-sponsored Anthrotech study, while retaining the small-sized subjects from the LANL face panel. This may require adjusting the total number of subjects in the face panel.**

Facial Dimensions and Fit

The proposed face panel based on Anthrotech survey is more representative of the current U.S. workforce than the LANL face panel. A recent study found that the LANL face panels, expected to accommodate more than 95 percent of the civilian population, only accommodate 84 percent of civilian population. However, this in itself does not mean that the updated panel will result in better fitting respirators. Because of an absence of fit-test data comparing the two face panels, the committee was unable to determine the extent to which the new panel is an improvement. Thus the committee recommends the following:

> **Recommendation 4-3:** ***Perform Studies to Compare the Proposed Face Panel to the LANL Face Panel.***
>
> **NIOSH should perform a study in which it compares the range of quantitative fit provided for specified respirators on subjects representing the LANL face panel and subjects representing the proposed NIOSH-sponsored Anthrotech bivariate face panel (adjusted in accordance with recommendation 4-2).**

And, indeed, the ultimate test of the usefulness of the new fit-test face panels will be determined not by how representative they are of the facial dimensions of the respirator-wearing workforce, but rather by how good a job they do in identifying respirators that will fit a substantial portion of that workforce. Unfortunately, at the present time there is no good understanding of how various facial dimensions affect the fit of a respirator. Thus, although the fit-test panels proposed in the NIOSH-sponsored Anthrotech study cover well over 95 percent of the workforce in terms of including workers with a certain range of facial dimensions, this does not translate clearly into statements about respirator fit.

In particular, the present state of knowledge does not permit one to conclude with any degree of confidence that respirators that fit members of the proposed fit-test panels will also fit 95 percent of the population of workers who should be using respirators. Thus the committee recommends the following:

> **Recommendation 4-4:** ***Analyze an Appropriate Proportion of the Respirator-Using Population That Can Be Fitted to Respirators.***
>
> **NIOSH should perform a statistical analysis of the proportion of workers who should be using respirators to determine the proportion of that population that is included in the proposed NIOSH face panels. Based on that analysis, NIOSH should either adjust the proposed face panel to meet a 95 percent confidence level and some appropriate margin of error, or state the confidence metric as it stands. This recommendation assumes that NIOSH will take into account Recommendation 4-1 in the design of its future face panel(s).**

More generally, since there is not currently a good understanding of the relationship between various facial dimensions and fit, it would have made sense for the Anthrotech researchers to have performed fit testing as part of their survey. The failure to include fit testing with anthropometric facial measurements limited the ultimate utility of the data collected in the NIOSH-sponsored Anthrotech study. Further, half-face respirators in particular have not had proper analyses performed on the relationship between facial dimensions and fit. For that reason 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 face masks in the workplace, us-**

ing 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.

Alternative Face Panel Approaches

In addition to creating new fit-test panels using the same methods as the earlier LANL panels (but with a new population survey), the Anthrotech investigators also created fit-test panels based on a principal component analysis (PCA) of the facial measurements obtained from their survey. The investigators identified a group of 10 facial measurements as being best correlated with fit and then did a PCA on those 10 variables to come up with 2 new variables that were linear combinations of those 10. The 2 new variables can be described as the overall size of the face (from small to large) and the general shape of the face (from a small face with a short, wide nose to a long face with a long, narrow nose). Working with those two new variables, the Anthrotech investigators proposed a fit-test panel that would be based on a new system of five facial groups defined by a combination of size and shape instead of the traditional face length and face width. The committee, however, was unable to determine whether the PCA-based fit-test panel would be an improvement over the proposed panel that Anthrotech constructed using the same approach as the LANL panel but with new data.

The committee did suggest another nontraditional approach to panel design that NIOSH might consider. Traditionally, the cells in a fit-test panel have had members in proportion to how the broader target population is distributed across the panel. That is, if 20 percent of the respirator-using workforce had facial dimensions that put them in a particular cell, then 20 percent of the panel members come from that cell as well. In the committee's suggested approach, NIOSH might investigate creating fit-test panels that are populated in proportion to variance, thus making it more likely that workers in those facial regions with greater variability have as much protection as those workers in the regions with less variability. If, for example, the 20 percent of the population in one cell all have facial dimensions similar to one another, they can be represented effectively by fewer panel members, while cells with more highly variable populations need—and with this approach will have—larger numbers of panel members to be representative.

FUTURE DIRECTIONS

Finally, the committee has a number of suggestions for future directions that NIOSH should take to best ensure the safety of respirator-using workers.

The committee concluded that the proposed NIOSH-sponsored Anthrotech face panel represents an improvement over the LANL face panel, and its application is likely to improve the availability of respirators that fit a broader segment of the workforce. However, the Committee also found that this study could have been greatly improved. In addition, the NIOSH face panels require periodic updates.

Recommendation 5-1: ***Update the Panel More Often, Using a Scientifically Valid Design.***

NIOSH should plan to update the face panel more often to reflect the rapidly changing demographic structure of the U.S. workforce. To do so, it should (1) establish a valid sample of the target population for its respirator certification, (2) assure that the sample that is selected to establish a valid panel is representative of the target population, (3) apply 3D measures to describe the essential fit characteristics of the panel, and (4) rely on quantitative fit testing to determine the extent to which a respirator covers the fit characteristics of the face panel.

The current use of isoamyl acetate for fit testing is a qualitative and subjective process that does not provide NIOSH certification personnel with a specific value to analyze leakage around the facepiece. Therefore the committee makes the following recommendation:

Recommendation 5-2: ***Replace Isoamyl Acetate with Quantitative Measures.***

NIOSH should use quantitative measures for respirator fit-test certification. The current use of qualitative measures as a fit-test agent for certification—for example, isoamyl acetate—should be discontinued.

The committee is concerned that filtering facepiece respirators are not currently certified against a fit-test panel. This failure may result in families of respirators that do not adequately fit some of the population of workers who should be using respirators.

Recommendation 5-3: ***Utilize the Revised Anthropometric Face Panel for Filtering Facepiece Respirators.***

NIOSH should include filtering facepiece respirators in the revised anthropometric face panel used for certification of half-facepiece respirators. Plans for any additional data gathering should be developed in consultation with experts in statistical sampling and measurement.

The committee noted that certification requirements for single-size facepieces (“one size fits all”) are different from those for facepieces that are available in multiple sizes (e.g., small, medium, large), which can make it difficult for manufacturers of multiple-sized facepieces to obtain certification for each individually sized facepiece. Thus the committee recommends

Recommendation 5-4: ***Modify Certification Requirements.***

NIOSH should modify its certification requirements to encourage manufacturers to develop specific sizes designed to fit underrepresented anthropometric categories. Certification requirements should be

modified to allow families of respirators (e.g., small, medium, and large) to be certified against a fit-test panel and not specify what portion of the panel each individual size respirator must fit, provided that the family adequately covers the entire panel.

Finally, the committee noted that the current respirator size designations of small, medium, and large are not adequately informative for wearers and fit testers. In particular, fit testers and respirator-wearing workers have difficulty determining which size and brand of facepiece is most likely to fit any given worker. This is largely due to inadequate details on the potential sizing of the facepieces on their packaging. To address this issue, the committee recommends

Recommendation 5-5: ***Develop Improved Descriptions of Face Mask Sizes.***

NIOSH should encourage manufacturers to develop improved methods of describing facial sizes and shapes in product literature. For example, NIOSH and manufacturing companies should further explore the use of face panel images, and respirator containers should include corresponding pictures of small, medium, and large sizes, and long/narrow and small/wide face pictures.

BOX S-1

Summary of Conclusions and Recommendations

Anthropometric Measurements

Conclusion 2-1: The NIOSH-sponsored Anthrotech report did not adequately address the potential impact of measurement error on the validity and quality of the anthropometric face dimension data.

Recommendation 2-1: Analyze Measurement Error. In future studies NIOSH should perform additional analyses of the impact of measurement error, including the effects of intraobserver and interobserver variations in measurement.

Conclusion 2-2: Three-dimensional scan data may offer advantages over traditional, manually collected anthropometric data; however, there is no evidence base of best practice against which 3D scans may be compared.

Recommendation 2-2: Consider Utilizing Three-Dimensional Scan Data. NIOSH should consider collecting and utilizing data from 3D scans, alone or in combination with traditional manually collected data, to ensure the most robust set of data are used to develop future anthropometric face panels.

The NIOSH-Sponsored Anthrotech Study's Sampling Strategy

Conclusion 3-1: The proposal and NIOSH-sponsored Anthrotech Report did not adequately define or represent an appropriate target population.

Recommendation 3-1: Define Target Populations More Precisely. Future anthropometric face panel studies undertaken by, or on behalf of, NIOSH should have a statistically rigorous and valid sampling plan and implementation strategy that precisely define the target population, and also ensure that the samples of selected subjects included in the studies are representative of the predefined sample population (e.g., the current workforce that wears respirators, workers who should be using respirators, the general United States workforce).

Data Analysis and Fit-Test Panels

Conclusion 4-1: The demographic makeup of the United States workforce has been, and will continue to become, more diverse, resulting in an increased range of facial dimensions.

Recommendation 4-1: Ensure Appropriate Representation of Demographics Groups. NIOSH should benchmark its sample population against the current and future U.S. workforce that should be wearing respirators to ensure adequate representation of demographic groups on the panel (e.g., age, gender, race, and ethnicity).

Conclusion 4-2: The proposed NIOSH-sponsored Anthrotech face panel selects larger-dimension faces at the expense of the smaller faces currently included in the LANL face panel, even though some of these small faces still make up a considerable proportion of the workforce.

Recommendation 4-2: Include Large and Small Faces in Panel. NIOSH should develop an expanded anthropometric face panel that includes the larger faces described in the NIOSH-sponsored Anthrotech study, while retaining the smaller subjects from the LANL face panel. This may require adjusting the total number of subjects in the face panel.

Conclusion 4-3: The proposed NIOSH-sponsored Anthrotech face panel is likely to be more representative of the current U.S. workforce than the LANL panel, but information is not available to determine the extent to which the new panel provides a better fit for that workforce.

Recommendation 4-3: Perform Studies to Compare the Proposed Face Panel to the LANL Face Panel. NIOSH should perform a study in which it compares the range of quantitative fit provided for specified respirators on subjects representing the LANL face panel, and subjects representing the proposed NIOSH-sponsored Anthrotech bivariate face panel (adjusted in accordance with Recommendation 4-2).

Conclusion 4-4: The present state of knowledge does not permit the committee to conclude with any degree of confidence that respirators that fit the proposed NIOSH-sponsored Anthrotech study face panel are likely to fit 95 percent of the population of workers who should be using respirators. Further, the committee was unable to determine a level of confidence or margin of error for the proposed face panel. However, the proposed panel, based on newer data, appears to be more representative of the population than the 30-year-old data used in the LANL face panel.

Recommendation 4-4: Analyze an Appropriate Proportion of the Respirator-Using Population That Can Be Fitted to Respirators. NIOSH should perform a statistical analysis of the proportion of workers who should be using respirators to determine the proportion of that population that is included in the proposed NIOSH face panels. Based on that analysis, NIOSH should either adjust the proposed face panel to meet a 95 percent confidence level and some appropriate margin of error, or state the confidence metric as it stands. This recommendation assumes that NIOSH will take into account Recommendation 4-1 in the design of its future face panel(s).

Conclusion 4-5: The ultimate utility of the data collected in the NIOSH-sponsored Anthrotech study is limited because the study did not include the collection of fit-testing data along with facial measurements.

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 face masks in the workplace, using quantitative measures. These research findings should be utilized in the design of future anthropometric face panel studies.

Conclusion 4-6: Proper analyses of facial dimensions have not been performed for half-face respirators; lip length and menton-sellion length may not be the most appropriate dimensions to use when developing anthropometric face panels.

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-face respirators, including at least one nasal dimension.

Conclusion 4-7: The use of multiple features in the development of face panels is likely to be inherently better than the use of just facial height and width, but it is not yet well understood which features are directly relevant to fit and how they can best be combined.

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.

Future Directions: Additional Analyses and Research to Practice

Conclusion 5-1: The proposed NIOSH-sponsored Anthrotech face panel represents an improvement over the LANL face panel, and its application is likely to improve the availability of respirators that fit a broader segment of the workforce. However, the committee also found that this study could have been greatly improved. In addition, the NIOSH face panels require periodic updates.

Recommendation 5-1: Update the Panel More Often, Using a Scientifically Valid Design.NIOSH should plan to update the face panel more often to reflect the rapidly changing demographic structure of the U.S. workforce. To do so, it should (1) establish a valid sample of the target population for its respirator certification, (2) assure that the sample that is selected to establish a valid panel is representative of the target population, (3) apply three-dimensional measures to describe the essential fit characteristics of the panel, and (4) rely on quantitative fit testing to determine the extent to which a respirator covers the fit characteristics of the face panel.

Conclusion 5-2: Qualitative fit testing is a subjective process and does not provide NIOSH certification personnel with a specific value to analyze leakage around the facepiece.

Recommendation 5-2: Replace Isoamyl Acetate with Quantitative Measures. NIOSH should use quantitative measures for respirator fit-test certification. The current use of qualitative measures as a fit-test agent for certification, for example isoamyl acetate, should be discontinued.

Conclusion 5-3: The failure to use anthropometric face panels for certification of filtering facepiece respirators may result in families of respirators that do not adequately fit some of the population of workers who should be using respirators.

Recommendation 5-3: Utilize the Revised Anthropometric Face Panel for Filtering FacePiece Respirators. NIOSH should include filtering facepiece respirators in the revised anthropometric face panel used for certification of half-face respirators. Plans for any additional data gathering should be developed in consultation with experts in statistical sampling and measurement.

Conclusion 5-4: Manufacturers of multiple-sized facepieces often have difficulty obtaining certification for each individually sized facepiece.

Recommendation 5-4: Modify Certification Requirements. NIOSH should modify its certification requirements to encourage manufacturers to develop specific sizes designed to fit underrepresented anthropometric categories. Certification requirements should be modified to allow families of respirators (e.g., small, medium, and large) to be certified against a fit-test panel and not specify what portion of the panel each individual size respirator must fit, provided that the family adequately covers the entire panel.

Conclusion 5-5: The current size designations of small, medium, and large for respirators in product literature are not adequately informative for wearers and fit testers.

Recommendation 5-5: Develop Improved Descriptions of Face Mask Sizes. NIOSH should encourage manufacturers to develop improved methods of describing facial sizes and shapes in product literature. For example, NIOSH and manufacturing companies should further explore the use of face panel images, and respirator containers should include corresponding pictures of small, medium, and large sizes, and long/narrow and small/wide face pictures.

1

Introduction

Millions of Americans use respirators in their daily work to protect themselves from potential exposures to toxic vapors and gasses; harmful particulate matter; airborne bacteria, fungi, and viruses; or other respiratory hazards. To provide an appropriate level of protection, it is essential for respirator facepieces to mold to the user's face in such a way that no air from the outside may leak in, even when the user is moving or speaking. The respirator-wearing workforce of the United States is quite diverse, thus manufacturers are required to provide respirators that will fit the faces of a diverse range of face size and shape.

It is the responsibility of the National Institute for Occupational Safety and Health (NIOSH) to certify that respirators from manufacturers meet certain minimum performance levels. Respirator "fit-test" panels derived from human facial size and shape data are used in NIOSH certification. The dimensions of the face panel depend on whether it is to be used to certify a full- or half-face respirator. Each face panel consists of about 25 persons who are chosen because their facial dimensions represent various categories of size and shape. NIOSH considers a mask (or set of masks) that passes a qualitative fit test to adequately fit the panel and be suitable for the marketplace (Chapters 4 and 5).

The data for, and design of, the face panels have not been updated since the establishment of the 1972 Los Alamos National Laboratory (LANL) anthropometric face panel. In 2001 NIOSH contracted with Anthrotech, Inc., to perform a study, "A Head-and-Face Anthropometric Survey of U.S. Respirator Users," that would gather facial size data for use in the development of new fit-test face panels (Appendix C). These proposed face panels in turn are to be used in testing of respirators to ensure that respirators certified by NIOSH fit as many respirator-wearing workers in today's workforce as possible (Anthrotech, 2004).

This report is a review of that 2001 NIOSH-sponsored Anthrotech study.

HISTORICAL BACKGROUND

Because it is not feasible to test the fit of a respirator on every worker who might use it prior to release, the historical practice has been to test each respirator's fit against a representative collection of subjects who have faces of various sizes and shapes. In 1934, for instance, the U.S. Bureau of Mines issued its first test schedule for dust respirators (Schedule 21). Later, revised regulations required three men of differing facial features (lean, average, and full) to wear respirators in an atmosphere of coal dust (Bureau of Mines, August 20, 1934, and March 23, 1965). In the 1960s, tests for self-contained breathing apparatus and certain other types of respirators used 15 to 20 men with widely varying facial shapes and sizes to test the suitability of fit (Bureau of Mines, March 23, 1965). Other fit tests analyzed the subjects' nasal secretions, and those that were free of coal dust were considered to have an appropriate fit (Drinker and Hatch, 1954). In 1972 new regulations (Code of Federal Regulations [CFR], 30 CFR 11) required facepieces to be designed and constructed in a range of sizes in order to fit persons with various facial shapes and sizes. Fitting requirements varied slightly from one type of device to another. For certain devices (such as gas masks and pesticide respirators), the manufacturer had the option to specify which facial sizes each mask was designed to fit, and the mask was then tested on faces in those size ranges (Code of Federal Regulations, 1972).

NIOSH and the Occupational Safety and Health Administration (OSHA) share responsibility for overseeing respiratory protection in the workplace and have established regulations for this purpose. Specifically, NIOSH has issued regulations which define respirator testing and certification in 42 CFR 84 (National Institute for Occupational Safety and Health, June 2, 1995). OSHA has issued regulations which define conditions under which employers are required to maintain respiratory protection programs in general industry (29 CFR 1910.134); shipyards (29 CFR 1915.154); marine terminals (29 CFR 1917.92); and construction (29 CFR 1926.103) (Occupational Safety and Health Administration, 1998). This report focuses on the establishment of the scientific base required for certification standards of respirators, not their use in the workplace. However, the committee does recognize that effective certification is not enough to guarantee that respirators do their job properly. Even the best respirators may not be protective if they are not used in the context of a respiratory protection program as described in the OSHA regulations.

CERTIFICATION OF FACE MASK RESPIRATORS

To ensure proper fit of respirators, manufacturers must demonstrate that the respirators meet NIOSH's certification requirements (42 CFR 84.135), which read:

> Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either by providing:
>
> 1. more than one facepiece size; or
> 2. one facepiece size that will fit varying facial shapes and sizes (NIOSH, 1995).

This regulation does not specify how the face masks are to be designed, selected, and fitted to the various facial shapes and sizes, but historically NIOSH has certified respirators by testing them on panels of human subjects (Code of Federal Regulations, 2004). Because of the cost and time required by testing masks on human subjects, anthropometric face panels typically contain no more than about two dozen people. Therefore, each panel member must represent a large subset of the total population of respirator users and the entire anthropometric face panel must represent an overwhelming majority (e.g., 95 percent) of the same population (Campbell et al., 2001). This in turn means that the reliability of the certification process depends heavily on how well the anthropometric face panel represents the target population.

LOS ALAMOS NATIONAL LABORATORY PANEL

The test panels in use today are based on military anthropometric data collected from 1967–1968 (Hack et al., 1974; Hack and McConville, 1978). Researchers at LANL utilized facial and other measurement data available from a large number of young men and women in the U.S. Air Force to design respirator face panels (Hack et al., 1974). The original panel consisted of 16 men and was later expanded to include 9 women for a total of 25 persons. For more than 30 years, new respirators have been tested and certified by NIOSH against groups of 25 people, 16 male and 9 female, chosen to have facial shapes and sizes representative of that 25-person LANL panel (Campbell et al., 2001).

Military personnel, however, tend to have physical characteristics that differ from those of the general civilian workforce. Specifically, they tend to be younger, they must adhere to strict height and weight requirements, and they generally have a lower percentage of body fat. Thus it is reasonable to ask whether personal protective equipment designed and sized according to data from U.S. Air Force personnel would provide appropriate protection to the full range of civilian workers.

Respirators sized for the general working population must take into account the differences among workers in age, health status, and ethnicity—which the LANL anthropometric face panels do not do. Furthermore, the demographics of the U.S. workforce have changed significantly since 1972. The result is that there has been a growing concern among those who regulate respirators that the LANL face panels do not adequately represent the modern U.S. workforce.

Several studies add weight to this concern. In 1975, Leigh studied 1,467 Dow Chemical employees in the Atomic Energy Commission's Rocky Flats Plant in Colorado and found that 10.3 percent of half-face respirator users and 12.6 percent of full-face respirator users had measurements that fell outside the LANL face panel specifications (Leigh, 1975). A U.S. Bureau of Mines survey of 48 male mine-rescue workers also indicated a need for a more extensive survey of the industrial population (Stein, 1978). And in 2001, when NIOSH compared the face length and width measurements of the 2,391 civilian subjects in the Civilian American and European Surface Anthropometry Resource (CAESAR) survey with the same measurements from the subjects of the 1972 Air Force study, it found that approximately 16 percent of today's workforce have facial measurements that are outside the range of measurements in the Air Force's LANL face panel dataset (Zhuang, 2001).

Researchers have also found that face length and lip length—which were used to define the LANL half-face fit-test panel—are not as predictive of fit as other facial dimensions, such as interpupillary distance, nose breadth, and nose protrusion (Zhuang, 2001). This raises the question of how well the LANL half-mask face panel may determine whether a particular respirator design will fit most of the workers who will need to use it.

THE 2001 NIOSH-SPONSORED ANTHROTECH STUDY

As previously mentioned, in 2001 NIOSH contracted with Anthrotech, Inc., to perform a comprehensive anthropometric study of respirator users in the U.S. workforce and to propose new fit-test face panels based on their findings. To accomplish these aims, Anthrotech recruited 4,026 subjects from 41 different sites in eight states. The subjects were employed in various industries and organizations that required either the regular or the occasional use of respirators. Each subject was measured for 21 dimensions, such as Menton-Sellion length, bizygomatic breadth, and lip length, using traditional anthropometric tools (see Chapter 2). Three-dimensional (3D) surface scans were also acquired on approximately a quarter of these individuals, allowing investigators to collect linear measurements that were used in the development of the LANL face panel, while also recording the various curves and contours of the subjects' faces (see Chapter 2) (Anthrotech, 2004).

Based on the data collected Anthrotech proposed two new panels for half- and full-face respirator fit testing. These panels were directly comparable with the panels based on the earlier LANL data, as each was based on the same pair of manually collected linear measurements used in the corresponding LANL face panel (e.g., Menton-Sellion length and lip length for the half-face panel). In other words, though new data were used, the data were analyzed using many of the same methods employed for the earlier panels. NIOSH also performed a principal component analysis (PCA) to identify the combination of facial dimensions that best accounted for the variation among faces in the data set and designed a panel based on those facial dimensions as well. NIOSH suggested that perhaps this new PCA-based face panel might be superior to the traditional two-dimensional panels for the purpose of testing respirators.

The final report provided by Anthrotech describes the sampling and measurement procedures and discusses the fundamentals of the analysis of the data collected. It also includes its proposed anthropometric face panels, summary tables of anthropometric statistics, and a brief examination of the 3D data collection and interpretation.

The results of this survey and the analysis that followed were detailed in the 2004 Anthrotech report to NIOSH, "A Head-and-Face Anthropometric Survey of U.S. Respirator Users" (Anthrotech, 2004) (Appendix C) and supporting documents, (Zhuang et al., 2004; Zhuang and Bradtmiller, 2005; Zhuang et al., 2005).

THE INSTITUTE OF MEDICINE REVIEW OF THE NIOSH-SPONSORED ANTHROTECH STUDY

In 2005, NIOSH contracted with the Institute of Medicine (IOM) to establish an *ad hoc* committee to review the NIOSH-sponsored Anthrotech study (Box 1-1). The committee's charge was to study the NIOSH-sponsored Anthrotech study along with its supporting information and reports, and to examine and report on the adequacy and relevance of the study protocol, the analyses conducted, the resulting anthropometric dataset, and the appropriateness of the respirator fit-test panels derived from the new dataset. In particular, the committee was requested to assess how well the revised panel of facial characteristics represents the diverse U.S. workforce; whether the sample population, data collection methods, and data analyses were appropriate; whether the selected anthropometric features and parameters were adequately considered in the new respirator face panels; and whether the conclusions were well supported by the study results.

The committee was also asked to make recommendations concerning additional analyses that NIOSH may wish to undertake and additional information NIOSH might derive from current and future research. Finally, the committee discussed a model for translating the suggested respirator criteria derived from research into practice, with consideration given to the potential economic and social impact these changes would have on both manufacturers and the workforce.

BOX 1-1

STATEMENT OF TASK

The committee will review the NIOSH-sponsored Anthrotech report, "Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users." The Committee will examine the adequacy and validity of the NIOSH study, the data collected, and the recommended revisions to the set (panel) of facial characteristics (anthropometric features) that are to be used in testing the fit of respirators.

- This review will examine both the content and the form of the study, the appropriateness of its sample and its sample methodology, and the adequacy of the resultant data.
- Issues to address include whether the revised panel of facial characteristics is representative of the diverse U.S. workforce and the adequacy of the anthropometric features and parameters considered in the revised panel.
- It will make recommendations concerning additional analyses that NIOSH might undertake to obtain further information regarding the revisions to the respirator panel.
- The committee will also examine how the data obtained from the study was analyzed, conclusions reached from the data, and recommend additional information that NIOSH might derive from current and possible future efforts.

Finally, the committee will suggest methods for translating the suggested respirator criteria derived from research into practice.

Study Process

In assessing the NIOSH "Head-and-Face Anthropometric Survey," the IOM committee received presentations from NIOSH's National Personal Protective Technology Laboratory as well as from experts from the military and industry. It reviewed an extensive body of journal articles as well as manuscripts and other supporting materials provided by NIOSH. A full discussion of the committee's process can be found in Appendix A.

The product of the committee's work is this report. Chapter 2 describes and analyzes the anthropometric measurements performed by Anthrotech for its NIOSH-sponsored study. Chapter 3 looks at the survey methods used by Anthrotech in the study. Chapter 4 examines how Anthrotech analyzed its data to derive fit-test panels and suggests some ways that analysis could be improved. And Chapter 5 discusses future directions, pointing toward further analyses of the data and offers suggestions for moving from research to practice. Although the revised panel is likely to have some impact on respirator manufacturers and manufacturing practices, discussion of this impact was outside the committee's statement of task and will not be included in this report.

REFERENCES

Anthrotech. 2004. *A head-and-face anthropometric survey of U.S. respirator users: Final report.* Prepared by B. Bradtmiller and M. Friess for NIOSH/NPPTL.

Bureau of Mines. August 20, 1934. *Procedure for testing filter-type dust, fume, and mist respirators for permissibility: Schedule 21b.* Washington, DC: Bureau of Mines.

———. March 23, 1965. *Filter-type dust, fume, and mist respirators, requirements investigation, testing, and certification: Schedule 21b.* Washington, DC: Bureau of Mines.

Campbell, D. L., C. C. Coffey, and S. W. Lenhart. 2001. Respiratory protection as a function of respirator fitting characteristics and fit-test accuracy. *American Industrial Hygiene Association Journal* 62:36-44.

Code of Federal Regulations. 1972. Respiratory protective devices: 30 CFR 11.

———. 1995. Respiratory protective devices: 42 CFR § 84.

———. 1998. Respiratory protective devices: 29 CFR § 1910, 1915, 1917, 1918, 1926.

———. 2004. Respiratory protective devices: 42 C.F.R. § 84.135.

Drinker, P., and T. Hatch. 1954. Dust respirators and air masks. In *Industrial dust: Hygienic significance, measurement, and control*. 2nd ed, edited by P. Drinker, and T. Hatch. New York: McGraw-Hill. Pp. 333-346.

Hack, A. L., and J. T. McConville. 1978. Respirator protection factors: Part I — development of an anthropometric test panel. *Am Ind Hyg Assoc J* 39(12):970-975.

Hack, A. L., E. C. Hyatt, B. J. Held, T. D. Moore, C. P. Richards, and J. T. McConville. 1974. *Selection of respirator test panels representative of U.S. adult facial sizes.* Los Alamos, NM: Los Alamos Scientific Laboratory.

Leigh, J. 1975. *Dow chemical corporation: Quantitative respirator man-testing and anthropometric survey. Dow chemical corporation report to U.S. energy research and development administration.* Golden, CO.

Stein, R. L. 1978. Selected head and facial dimensions of mine rescue team personnel. *American Industrial Hygiene Association Journal* 39(7):576-578.

Zhuang, Z. 2001. *Anthropometric survey of respirator users: Study protocol.* National Institute for Occupational Safety and Health.

Zhuang, Z., and B. Bradtmiller. 2005. Head-and-face anthropometric survey of U.S. respirator users. *J Occup Environ Hyg* 2(11):567-576.

Zhuang, Z., J. Guan, H. Hsiao, and B. Bradtmiller. 2004. Evaluating the representativeness of the LANL respirator fit test panels for the current U.S. civilian workers. *Journal of the International Society for Respiratory Protection* 21:83-93.

Zhuang, Z., Coffey, C.C., and R.B. Ann. 2005. The effect of subject characteristics and respirator features on respirator fit. *J Occup Environ Hyg* 2(12):641-649.

2

Anthropometric Measurements

Anthropometry, the measurement of human dimensions, is a well-established field with techniques that have been honed over decades of work. The U.S. military, in particular, has performed a number of comprehensive anthropometric studies to provide information for use in the design of military clothing and equipment (Gordon et al., 1989). In recent years, traditional measurement techniques, performed manually with such instruments as calipers and measuring tapes, have been supplemented, and even in some cases replaced, by three-dimensional (3D) scans and digitizers.

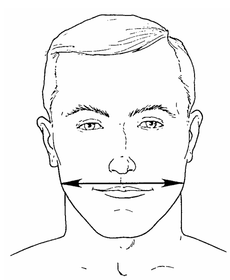
THE ANTHROTECH MEASUREMENTS

To establish a comprehensive dataset, Anthrotech investigators used traditional manual measurement techniques to survey 4,026 subjects for 18 facial and head dimensions, as well as height and weight (Box 2-1). Neck circumference was added partway through data collection when it was learned that these metrics are used in the development of some national and international respirator standards (e.g., neck dams for escape hoods) (Anthrotech, 2004).

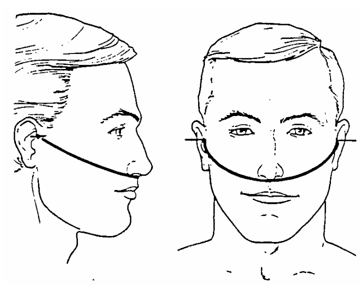
Before the field study, Anthrotech prepared a measurer's handbook, which included illustrated instructions for measuring each dimension, as well as a table of values representing allowable measurement error for technicians. Study instruments included an anthropometer, a spreading caliper, a sliding caliper, and a steel measuring tape.

BOX 2-1

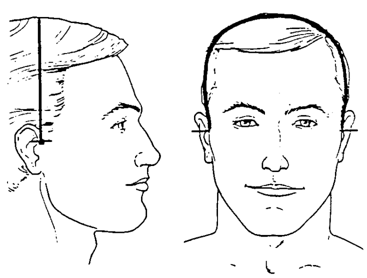
FACIAL DIMENSIONS MEASURED IN THE NIOSH-SPONSORED ANTHROTECH STUDY



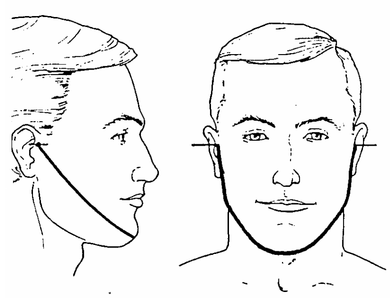
Bigonial breadth: The straight line distance between right and left gonion landmarks (see Box 2-2) on the corners of the jaw



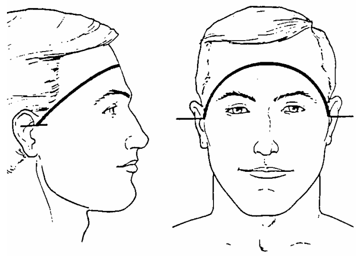
Bitragion subnasale arc: The surface distance between the left and right tragion landmarks across the subnasale landmark (see Box 2-2) at the bottom of the nose



Bitragion coronal arc: The surface distance between the right and left tragion landmarks (see Box 2-2) across the head in the coronal plane



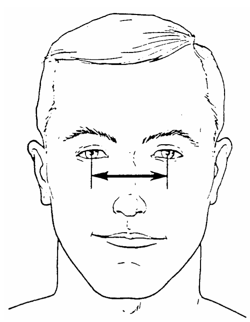
Bitragion chin arc: The surface distance between the left and right tragion landmarks across the anterior point of the chin



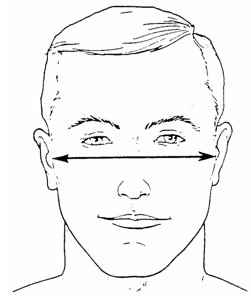
Bitragion frontal arc: The surface distance between the left and right tragion landmarks above the ridges of the eyebrows

Head length: The maximum length of the head at the midsagittal plane

Head circumference: The maximum circumference of the head just above the ridges of the eyebrows

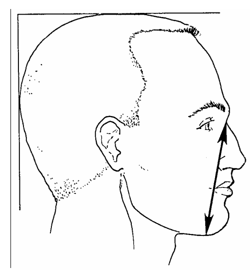


Interpupillary breadth: The horizontal distance between the center of the left and the center of the right pupil

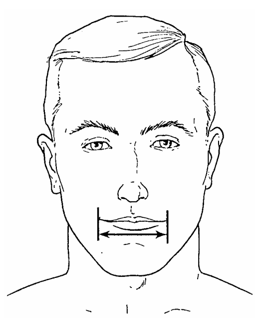


Bizygomatic breadth: The maximum horizontal breadth of the face between the zygomatic arches

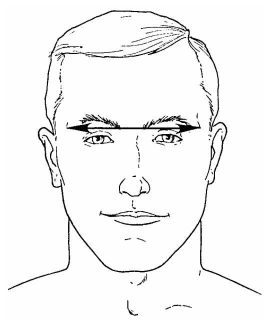
Head breadth: The maximum horizontal breadth of the head above the level of the ears



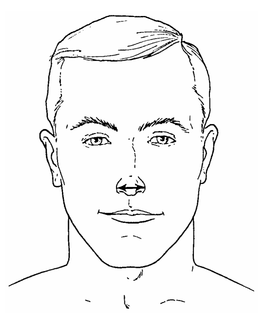
Menton-sellion length: The distance in the midsagittal plane between the menton landmark (see Box 2-2) at the bottom of the chin and the sellion landmark (see Box 2-2) at the deepest point of the nasal root depression



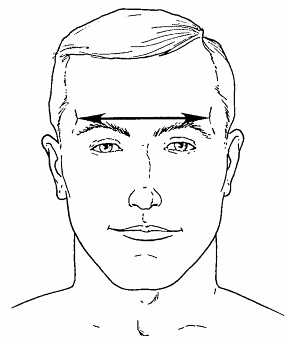
Lip length: The straight-line distance between the left and right chelion landmarks (see Box 2-2) at the corners of the closed mouth



Maximum frontal breadth: The straight-line distance between the left and right zygofrontale landmarks at the upper margin of each bony eye socket



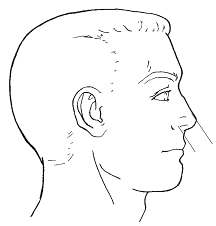
Nose breadth: The straight-line distance between the right and left alare landmarks (see Box 2-2) on the sides of the nostrils



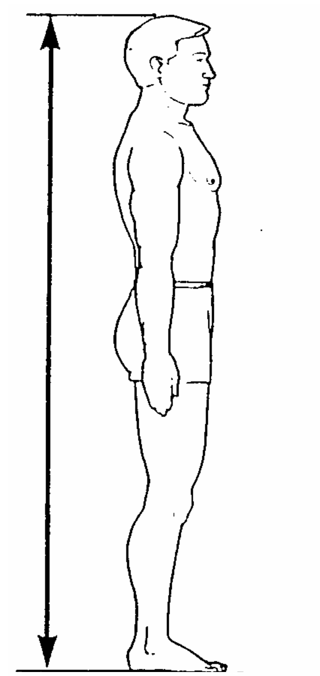
Minimum frontal breadth: The straight-line distance between the right and left frontotemporale landmarks (see Box 2-2) on the temporal crest on each side of the forehead

Nasal root breadth: The horizontal breadth of the nose at the level of the deepest depression of the root (sellion landmark) and at a depth equal to one-half the distance from the bridge of the nose to the eyes

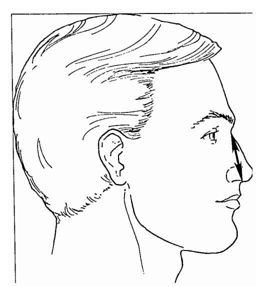
Neck circumference: The distance around the exterior surface of the neck



Nose protrusion: The straight-line distance between the pronasale landmark at the tip of the nose and the subnasale landmark under the nose.



Stature: The vertical distance between the standing surface and the top of the head



Subnasale sellion length: The straight-line distance between the subnasale landmark under the nose and the sellion landmark at the deepest point of the nasal root

Weight: The subject's weight (in kg)

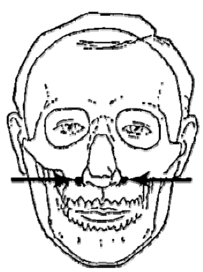
SOURCE: Anthrotech, 2004.

LANDMARKS

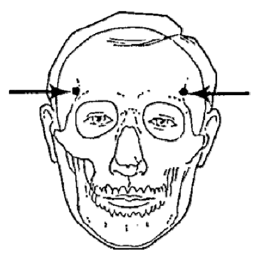
To acquire the anthropometric measurements described above, the investigator must first identify and mark a series of landmarks on the subject's face (Box 2-2). In many cases this is a relatively straightforward procedure, but there can be complications. For example, many of the landmarks are located by palpating the skin to identify the underlying bone structure. This works well for the traditional measurements done by hand with calipers and measuring tape. However, it can be difficult when using 3D scans (described below) as some bony landmarks are not as readily apparent without palpation.

BOX 2-2

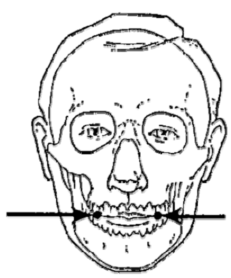
LANDMARKS USED TO MAKE FACIAL MEASUREMENTS



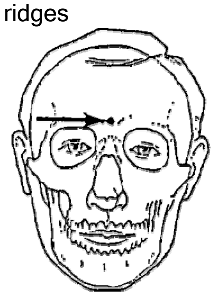
Alare: The lateral point on the flare of the nose



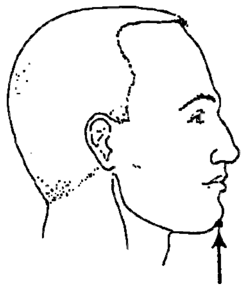
Frontotemporale: The point of deepest indentation of the temporal crest of the frontal bone above the brow ridges



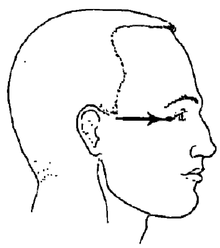
Cheilion: The lateral point of the juncture of the fleshy tissue of the lips with the facial skin at the corner of the mouth



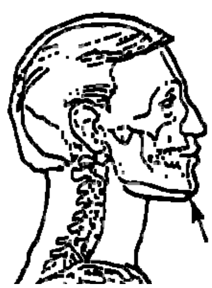
Glabella: The anterior point on the frontal bone midway between the bony brow ridges



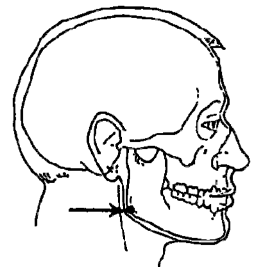
Chin: The protruding point on the bottom edge of the chin, along the jaw line



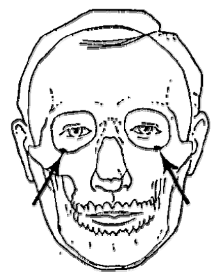
Ectocanthus: The outside corner of the eye formed by the meeting of the upper and lower eyelids



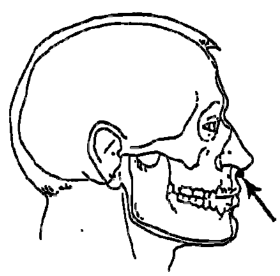
Menton: The inferior point of the mandible in the midsagittal plane



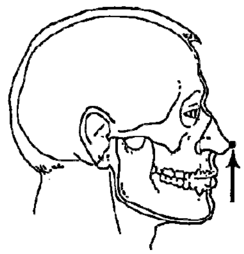
Gonion: The lateral point on the posterior angle of the mandible



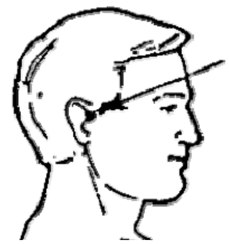
Infraorbitale: The lowest point on the anterior border of the bony eye socket



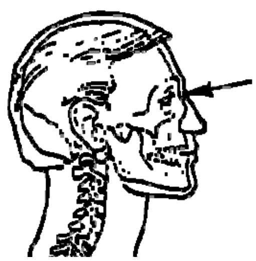
Subnasale: The point of the intersection of the philtrum (groove of the upper lip) with the inferior surface of the nose, in the midsagittal plane



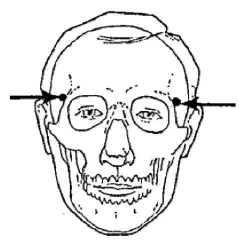
Pronasale: The point of the anterior projection of the tip of the nose



Tragion: The superior point on the juncture of the cartilaginous flap of the ear with the head



Sellion: The point of the deepest depression of the nasal bones at the top of the nose



Zygofrontale: The lateral point of the frontal bone on its zygomatic process

SOURCE: Anthrotech, 2004.

ERROR ESTIMATION

The accuracy and quality of the anthropometric data collected by Anthrotech is important in that it affects the validity of the respirator fit-test face panels derived from these data, which ultimately impact respirator face panels and certification. In general, data validity could be described by accuracy—a measure of how close the measurements are to an evidence-based best practice standard or gold standard if there is one—and precision (the reliability, repeatability, reproducibility, and consistency of measurements of the same person). Measurement errors include errors in both accuracy and precision; measurements from the same person can be both inaccurate, imprecise, both, or neither. Measurement errors may arise from: (1) human error, which in this case could include inaccurate and imprecise identification and placement of landmarks and dimension measurements from field technicians, in addition to other human errors such as data entry errors; (2) equipment error (less a problem in the NIOSH-sponsored Anthrotech study as the calipers and measuring tapes are standard equipment that are calibrated and have little chance of change); (3) systematic bias; and (4) random error. Human measurement error in this type of study often is a major source of error.

Ideally, in a large field study on anthropometric measurement, a pilot study is conducted to: (1) determine the accuracy of the placement of landmarks; (2) determine the accuracy of measuring distances between marked landmarks (these would both be done to evaluate intraobserver error); and (3) determine the contribution of multiple observers to measurement error (interobserver error). This allows the assessment of how much error can be expected in the study and determine the sources of error, thereby offering a means for improvement. For example, if interobserver error is greater than intraobserver error, technicians can identify ways to improve the accuracy of their measures, which should decrease both inter- and intraobserver error.

The NIOSH-sponsored Anthrotech study made special efforts to reduce human error, but did not adequately account for potential error in measurements. Their quality control measures included providing a handbook with detailed measurement instructions and having the field technicians practice on each other until an allowable level of accuracy was achieved in identifying and marking certain landmarks and dimension measurements. The accuracy was controlled to be between 1 and 3 mm, depending on the dimension measured (Zhuang and Bradtmiller, 2005; Anthrotech, 2004), which was based on standard practice in the anthropometric field (Gordon et al., 1989). However, the committee did not find data in the 2004 report and all the materials it reviewed that could be used to assess the precision of measurements from the technicians (intraobserver and interobserver variations in measurements) (Anthrotech, 2004). In addition, the committee did not find any record in the protocol, report, or other materials it reviewed of an attempt to evaluate the potential relation between biological variation (individual differences in facial shape) and measured error. A useful measure in this regard can be found in the panel report of the 1988 Army survey of anthropometric measures (Gordon et al., 1989). More examples of designs for estimating measurement error are available from such articles as Aldridge et al. (2005), Corner and Richtsmeier (1992), Kohn and J. (1992), Richtsmeier et al. (1995), Valeri et al. (1998), Weinberg and Kolar (2005), and Weinberg et al. (2005).

Conclusion

The NIOSH-sponsored Anthrotech report did not adequately address the potential impact of measurement error on the validity and quality of the anthropometric face dimension data.

Recommendation 2-1: ***Analyze Measurement Error.***

In future studies NIOSH should perform additional analyses of the impact of measurement error, including the effects of intraobserver and interobserver variations in measurement.

THREE-DIMENSIONAL MEASUREMENTS

To develop a set of standard head forms, NIOSH requested that Anthrotech perform 3D scans on approximately a quarter of the subjects (1,045 individuals).[1] However, NIOSH did not regard the 3D scans as a potential source of data for face panel revision. Given the perceived limitation of 3D scans and the investigators' concern over the time and expense required to relocate the scanner to each site, the investigators chose to scan only a portion of the subjects (Anthrotech, 2004). The datasets from these 3D scans were archived. NIOSH informed the committee that the decision not to use the 3D scan data was due to discrepancies between the 3D scan data and the traditional measures (Table 2-1). Although the causes of the differences are unknown, many of these are well outside the 1 to 3mm acceptable margin of error. NIOSH did not explain to the committee how it was decided that the traditional data were more accurate or more reliable than the 3D data. The 2004 report does reference that absence of standardized data analysis methods (Anthrotech, 2004); however, this in itself does not explain why the traditional data

[1]These surface head scans were performed using a Model 3030/RGB laser scanner (Cyberware, Inc, Monterey, CA). The software products used for image manipulation included *INTEGRATE*, a UNIX-based 3D data visualization, analysis, and manipulation tool developed by the U.S. Air Force specifically for 3D anthropometry, and *MORPHEUS,* a public domain program that computes a generalized procrustes analysis (GPA) and provides various outputs for further statistical analysis.

TABLE 2-1 Differences Between Traditional and 3D Measurements

Dimension (mm)	Min	Max	Mean	Std Dev
Bigonial breadth, absolute	0.07	45.00	12.46	6.67
Bizygomatic breadth, absolute	0.45	50.39	12.16	5.98
Interpupillary breadth, absolute	0.00	21.70	3.29	2.43
Lip length, absolute	0.00	14.60	3.49	2.85
Maximum frontal breadth, absolute	0.01	32.56	7.04	4.29
Menton-sellion length, absolute	0.00	16.32	4.28	3.04
Minimum frontal breadth, absolute	0.02	32.71	5.88	4.13
Nasal root breadth, absolute	0.00	11.05	2.53	2.07
Nose breadth, absolute	0.02	12.22	2.43	1.66
Nose protrusion, absolute	0.00	14.87	2.01	1.73
Subnasale-sellion length, absolute	0.00	11.94	2.82	2.15

NOTE: Reported numbers represent the absolute value of difference in mean differences between extracted and directly measured dimensions.
SOURCE: Anthrotech, 2004.

may be more reliable than the 3D data. The study published by Anthrotech indicates that, upon review of the 3D measurements, there were no landmarking errors, thus suggesting that any discrepancies may have resulted from errors in manual measurements (Anthrotech, 2004).

The decision to focus solely on the traditional data and to ignore the 3D scan data is of concern because the 3D scan data have several advantages over traditional manually collected data, including the following:

- 3D scan data generally have better resolution than caliper data and provide a more accurate and complete summary of the facial geometry.
- 3D scan data can provide information on the localized variation around a landmark, which, if applied correctly, can be useful for designing masks.
- Databases from 3D scans may be reanalyzed if additional measurements are required.
- 3D scan data often rely on non-bony landmarks (Valeri et al., 1998), which eliminates the need for palpating the bony landmarks during traditional manual measurements.
- Collecting measures from an image is a relatively simple process with the advantage of checking measurements frequently.
- Surface data may be used in mathematical modeling and simulation analysis (finite element analysis and animation).

- If the leaks in respirator fit testing can be identified at certain parts of the respirator seal, 3D contour data can be reanalyzed to further correlate local features around the leak with the fit factor of the mask.

Data from the 3D scanned images can be used to derive all of the traditional anthropometric measures, such as linear distances and angles, but they can also be used to derive a variety of new measures, such as surface contours or arcs along surfaces, and one or more of these new measures might offer ways to improve fit that are not possible with the traditional data. Of course, working with such novel measures may require the development of new analytical tools of greater complexity, but given the advantages of the 3D data, it seems to be a direction worth pursuing.

Validation of Three-Dimensional Scan Data

As described above there are many potential advantages of 3D scan data over traditionally collected anthropometric data. However, before 3D surface scans can be used, further data validation must be conducted. These efforts will require establishing an evidence-based best practice standard against which measures collected from the 3D image data can be compared. NIOSH should validate the 3D scans against an external gold standard already proven to be accurate. One potential method would be to use point digitizers to acquire the same landmarks or linear measures as collected from the 3D scan on a mannequin head where the measurements are already known. This would allow repeat measures for validation and verification of the 3D scan data collected from scans. Mannequin tests should be followed by tests of live individuals, so that the effects of movement and possibly day-to-day variation (e.g., changes in hydration, or possibly from injury) may be evaluated.

A study of the precision of data collected from 3D scan images will require comparisons of relevant data sets at several levels, including (1) a comparison of multiple datasets collected from single images; (2) a comparison of datasets collected from multiple images of the same subject; and (3) a comparison of various datasets collected from several images of several specimens or subjects.

Conclusion

Three-dimensional scan data may offer advantages over traditional, manually-collected anthropometric data; however, there is no evidence base of best practice against which 3D scans may be compared.

Recommendation 2-2: ***Consider Utilizing Three-Dimensional Scan Data.***

NIOSH should consider collecting and utilizing data from 3D scans, either alone, or in combination with traditional manually collected data, to ensure the most robust set of data are used to develop future anthropometric face panels.

REFERENCES

Aldridge, K., S. A. Boyadjiev, G. T. Capone, V. B. DeLeon, and J. T. Richtsmeier. 2005. Precision and error of three-dimensional phenotypic measures acquired from 3dMD photogrammetric images. *Am J Med Genet A* 138(3):247-253.

Anthrotech. 2004. *A head-and-face anthropometric survey of U.S. respirator users: Final report.* Prepared by B. Bradtmiller and M. Friess for NIOSH/NPPTL.

Corner, B. D., and J. T. Richtsmeier. 1992. Cranial growth in the squirrel monkey (saimiri sciureus): A quantitative analysis using three-dimensional coordinate data. *Am J Phys Anthropol* 87(1):67-81.

Gordon, C. C., T. Churchill, C. E. Clauser, B. Bradtmiller, J. T. McConville, I. Tebbetts, and R. A. Walker. 1989. *1988 anthropometric survey of U.S. Army personnel: Methods and summary statistics.* United States Army Natick research, development, and engineering center.

Kohn, L., and Cheverud, J. 1992. *Calibration, validation, and evaluation of scanning systems: Anthropometric imaging system repeatability, electronic imaging of the human body*. Paper presented at Proceedings of a working group: CSERIAC, Dayton, OH. Pp. 114-123.

Richtsmeier, J. T., C. H. Paik, P. C. Elfert, T. M. Cole, 3rd, and H. R. Dahlman. 1995. Precision, repeatability, and validation of the localization of cranial landmarks using computed tomography scans. *Cleft Palate Craniofac J* 32(3):217-227.

Valeri, C. J., T. M. Cole, 3rd, S. Lele, and J. T. Richtsmeier. 1998. Capturing data from three-dimensional surfaces using fuzzy landmarks. *Am J Phys Anthropol* 107(1):113-124.

Weinberg, S. M., and J. C. Kolar. 2005. Three-dimensional surface imaging: Limitations and considerations from the anthropometric perspective. *J Craniofac Surg* 16(5):847-851.

Weinberg, S. M., N. M. Scott, K. Neiswanger, and M. L. Marazita. 2005. Intraobserver error associated with measurements of the hand. *Am J Hum Biol* 17(3):368-371.

Zhuang, Z., and B. Bradtmiller. 2005. Head-and-face anthropometric survey of U.S. respirator users. *J Occup Environ Hyg* 2(11):567-576.

3

The NIOSH-Sponsored Anthrotech Study's Sampling Strategy

The validity of the National Institute for Occupational Safety and Health (NIOSH)-sponsored Anthrotech report depends largely on the sample population that it assembled; therefore, the committee examined the details of that sampling in this chapter.

THE ANTHROTECH SAMPLING PLAN

The goal of the NIOSH-sponsored Anthrotech study was to survey a group of individuals reflecting the racial, ethnic, age, and gender diversity of the respirator wearing workforce in the United States. The sampling plan used in the study (Appendix C) called for approximately 4,000 subjects that would be divided evenly into men and women, three age categories (18-29, 30-44, and 45-65), and four racial/ethnic categories (White, African American, Hispanic, and "Other") (Table 3-1) (Zhuang, 2001). It was unclear to the committee why the NIOSH protocol directed Anthrotech to sample by "age, race, and gender," and not use ethnic and racial categories from the United States Census, which uses White, African American, Hispanic, Asian/Pacific, and American Indian (U.S. Census Bureau, 2000; Anthrotech, 2004). The committee recognizes that issues of race and ethnicity are complex, and the terms are often inconsistently applied. However, to remain consistent with the designations used in the NIOSH-sponsored Anthrotech report the committee uses the terms as they are used in the original Anthrotech report.

TABLE 3-1 Proposed Demographic Sample Distribution

	Male Age Group				Female Age Group			
Race	18-29	30-44	45-65	Total	18-29	30-44	45-65	Total
White	166	166	166	498	166	166	166	498
African American	166	166	166	498	166	166	166	498
Hispanic	166	166	166	498	166	166	166	498
Other	166	166	166	498	166	166	166	498
Total	664	664	664	1,992	664	664	664	1,992

SOURCE: Anthrotech, 2004.

NIOSH requested that Anthrotech obtain measurements from 166 subjects in each age, gender, and racial/ethnic category. The proposed number of 166 subjects per category was based on a standard developed by the International Organization for Standardization (ISO). Standard 15535 recommends $n = (1.96 \times CV/a)^2 \times 1.534$, where n is the sample size per cell, CV is the coefficient of variation for a specific measurement (standard deviation divided by mean times 100), and a is the level of precision desired. The investigators chose to define CV based on the menton-sellion length (CV=6.5/121.9=5.3%), as it was one of the more biologically variable measurements. Thus, if the CV is met for this measurement, it would likely also be met for the other measurements (Zhuang, 2001). The 95 percent confidence limits (reflected in the term 1.96), the choice of a 1 percent level of precision (1 percent of the mean), and the value 1.534 (a constant computed using a Bonferroni type of argument to adjust for the multiple comparison) were based on procedures outlined in the ISO 15535—General Requirements for Establishing an Anthropometic Database. However, the committee is unsure about the accuracy of the calculation for this task, since there was no discussion in the NIOSH-sponsored Anthrotech report and only limited discussion in the protocol, if the 95 percent confidence limits were appropriate for this specific task (Zhuang, 2001; Anthrotech, 2004).

To ensure that the sample adequately captured the variation of measurements within each of the racial groups, Anthrotech oversampled the African American, Hispanic, and “Other” groups—that is, the sample included a larger percentage of these minorities than is found in the general population. During the analysis, each subcategory was then weighted to accurately represent its proportion within the total population. The advantages of this approach are that it provides the needed level of precision for each group separately, and it provides the flexibility to reweight the data in the future as population demographics change.

Unfortunately, the NIOSH-sponsored Anthrotech study did not appropriately subdivide the sample population based on race and ethnicity. The "Other" category was overly diverse, including Asian, American Indian, and Alaskan Native subjects, while not including other groups that might be designated "Other." Further, the groups included in "Other" have vastly different facial characteristics, so it is possible that most or all of those groups may have been undersampled. Given the diversity of the respirator-wearing workforce, it is important that the "Other" group be included in analyses of the entire target population. However, its small sample size and great diversity may make it difficult, if not impossible, to perform useful analysis of the "Other" category as a distinct subgroup.

SAMPLING PROTOCOL

Anthrotech's sampling protocol involved three steps to obtain a characteristic sample population: (1) identify a subset number of representative geographical locations, (2) choose representative worksites, and (3) identify individuals willing to have their facial dimensions measured.

Because of the need to have investigators present at the worksites, as well as the difficulty and expense of moving raters from one site to another, the NIOSH-sponsored Anthrotech study limited the sample geographically to eight states: California, Illinois, Kentucky, New York, Ohio, Pennsylvania, Texas, and Virginia (Anthrotech, 2004).

Within each state, Anthrotech investigators selected worksites that were deemed representative. The NIOSH-sponsored Anthrotech report indicates that each potential study site was telephoned to ascertain the willingness to participate in the study. "More often than not," the report says, "the organization or company invited chose not to participate." When an organization did agree to participate, Anthrotech provided the company with a packet of information explaining the study protocol and purposes.

The report provides no further details on either the criteria Anthrotech used to select the various establishments, response rate from these establishments, or any comparison of participating versus nonparticipating sites. This committee found that the 41 worksites listed in the final report were more often larger establishments. It is not clear whether this was due to a decision by Anthrotech to approach larger companies or whether larger employers were more likely to agree to participate. Anthrotech did note some difficulty identifying companies that had the time and energy to participate (Anthrotech, 2004). The committee is unsure, and there is no discussion in the report, on how this selection bias may have skewed the final datasets.

Once a work site was identified, Anthrotech investigators worked with a single individual who provided access to test subjects. This point of contact assisted with both scheduling and recruitment. Unfortunately, the criteria for selection of the test subjects are ill defined in the report, so it is difficult to ascertain if the selection process was random, or how potential issues that arose during the selection of the subjects may have biased the sample.

Anthrotech may have introduced an additional source of bias by providing monetary incentives to participate at some worksites. This is difficult to determine as the number and size of incentives is not reported. However, monetary incentives are well-known to create biases in survey data, partly because these monetary incentives appeal more to some kinds of potential participants than others and partly by increasing bias in responses. The first of these is not likely to be great here, and the second should not apply to facial measurements.

SAMPLE DISTRIBUTION

In some instances Anthrotech was not able to meet the sampling quotas, while in others the quotas were surpassed (e.g., the final male-female ratio was closer to 60:40 rather than the desired 50:50). Due to the weighting of the subpopulations, the NIOSH-sponsored Anthrotech report regards the final sample as accurate, although the report does not define exactly what is meant by “accurate.”

Researchers initially measured 4,026 subjects. The final sample was 3,998, after eliminating 27 subjects who were younger than 18 or older than 66, and an additional subject that failed to provide an age (Table 3-2). This final total was very close to the original target number of 24 × 166 = 3,984. The final distribution was also closer to the actual demographic makeup of the U.S. workforce than were the planned equal numbers per category. This has certain advantages, as the imbalance among

TABLE 3-2 Number of Individuals Measured in Each Demographic Category

	Male Age Group				Female Age Group			
Race	18-29	30-44	45-65	Total	18-29	30-44	45-65	Total
White	271	611	485	1,367	151	194	174	519
African American	101	255	278	634	51	213	325	589
Hispanic	155	182	75	412	53	36	37	126
Other	24	47	59	130	52	65	103	220
Total	551	1,095	897	2,543	307	508	639	1,454

NOTE: The total count in this table is 3,997 because one subject did not provide age.
SOURCE: Anthrotech, 2004.

categories adds to the variance of comparison among groups. Both objectives may be important, but the committee notes that little has yet been published comparing groups.

Geographic Distribution

As with demographic variation, Anthrotech intended to have an even distribution across geographic regions. However, the final distribution was more heavily weighted (~60 percent) toward Texas, Ohio, and Illinois (the midsection of the United States) (Table 3-3). While the NIOSH-sponsored Anthrotech study found no evidence that geographic regions affected face size and shape, the 2000 U.S. Census shows that most residents from Illinois and Ohio come from white European ancestors, whereas states in the southeast and southwest have more residents with ancestry other than Caucasian (U.S. Census Bureau, 2006). Additionally, many immigrants tend to concentrate in distinct areas of the United States (e.g., Asian immigrants in California, and Hmong and Somali immigrants in Minnesota) (Camarota and McArdle, 2003; Ronningen, 2004). Thus the limited geographic distribution may have unintentionally introduced a racial and ethnic bias.

TABLE 3-3 Geographic Distribution

State	n	%
California	229	5.69
Illinois	1,564	39.12
Kentucky	93	2.31
New York	120	2.98
Ohio	751	18.78
Pennsylvania	29	0.72
Texas	857	21.44
Virginia	355	8.82
Total	3,998	100.00

SOURCE: Anthrotech, 2004.

Occupational Distribution

The test sample was achieved by surveying workers from a variety of different occupations, including construction, firefighting, health care, law enforcement, manufacturing, and others (Table 3-4) (Anthrotech, 2004). However, the study protocol did not explain why these industries were chosen as the representative sample population. Further, an analysis of the results indicates that in some of the categories, such as law enforcement and health care, the representation of men and women is out of the range of what might be expected. Consequently, the committee questions if the tallies were recorded correctly or if there was an unintended selection bias.

These data presented in the NIOSH-sponsored Anthrotech report (Table 3-4) differ from those published that are reproduced below in Table 3-5 (Zhuang and Bradtmiller, 2005). NIOSH explained that the discrepancy resulted from a data sorting error in the Excel spreadsheet. The data presented in Table 3-5 is consistent with collected data from the survey (Personal communication, Z. Zhuang, National Personal Protective Technology Laboratory, October 27, 2006).

LIMITATIONS OF THE SAMPLE POPULATION

Overall the committee found limited analysis in the NIOSH-sponsored Anthrotech study comparing the categorized subgroups, so it is not known whether age, race, and gender affect specific measurements, composite measure, or ultimately the overall utility of anthro-

TABLE 3-4 Occupational Distribution

	Men		Women		Total	
Occupation	n	%	n	%	n	%
Construction	594	23.35	47	3.23	641	16.03
Firefighting	429	16.86	60	4.13	489	12.23
Health care	776	30.50	75	5.16	851	21.29
Law enforcement	381	14.98	1,100	75.65	1,481	37.04
Manufacturing	121	4.76	7	0.48	128	3.20
Others	243	9.55	165	11.35	408	10.21
Total	2,544	100.00	1,454	100.00	3,998	100.00

SOURCE: Anthrotech, 2004.

TABLE 3-5 Occupational Distribution

	Men		Women		Total	
Occupation	n	%	n	%	n	%
Construction	594	23.4	47	3.2	641	16.0
Firefighting	774	30.4	74	5.1	848	21.2
Health care	381	15.0	1,100	75.7	1,481	37.1
Law enforcement	121	4.8	7	0.5	128	3.2
Manufacturing	429	16.9	60	4.1	489	12.2
Others	244	9.6	166	11.4	410	10.3
Total	2,543	100.0	1,454	100.0	3,997	100.0

SOURCE: Zhuang and Bradtmiller, 2005.

pometric face panels. Further, Anthrotech was unable to find a reference reflecting the ethnic and geographic distribution of respirator users, so the data set were weighted against the U.S. workforce as a whole. Anthrotech's plan calls for reweighting of this sample, should data characterizing the population of respirator users become available in the future.

If survey data are to serve as a sound foundation for conclusions, both the sample and the analysis of the sample must meet certain criteria. These include

- precise definition of the target population (the population to be covered by inferences from the data);
- precise operational definition of the sampling frame (the persons to be sampled, including any clustering variables such as employer);
- some form of random sampling from the frame;
- understanding the nature (and if possible the general size and direction) of biases likely to impair inferences from the data to the target population;

- specific uses of the data, with careful consideration of the need for statistical power, particularly in light of the expected biases in the data;
- to the extent feasible, study of the data to learn about important influences on the findings; and
- understanding the nature, sources, and size of variations in measurement.

The committee found no evidence that these matters received adequate consideration in the design and analysis of the NIOSH-sponsored Anthrotech survey.

Defining the Target Population

A clear definition of the target population is critical to survey design, which was not done in the NIOSH-sponsored Anthrotech study. The survey intends to reflect "respirator users," but that term is ambiguous: Does "respirator user" mean workers who typically use respirators? What about part-time workers, occasional users, workers who only wear respirators in emergency situations, and other workers who should be wearing respirators? These questions may impact the target sample population, because the demographics (and facial measurements) of workers in these additional categories may differ from those of regular, full-time users.

Identification of Subjects

Anthrotech identified establishments that were willing to participate as measuring sites a number of ways, including searching public databases, the Internet, and telephone directories. However, the report did not provide sufficient information about how workers who use respirators were recruited for participation in this study (Anthrotech, 2004). Were they self-selected, selected by management, or randomly selected? Does the sample include overrepresentation of workers whom the management knew had adapted well to the respirators they wore? If so, the hard-to-fit may be seriously underrepresented.

Other Potential Biases

An understanding of potential biases is critically important in the interpretation of survey data. For example, responders are likely to differ from non-responders, so non-response rates are important. However, the committee recognizes that it would be difficult to even define non-response with a sample such as that in the Anthrotech study.

Additionally, random sampling at each stage of a multilevel scheme is important. Equal probabilities are not needed, but each person in the sampling frame must have a known, nonzero probability of being selected, and correct calculation of variances requires that pairwise probabilities also be known (e.g., the probabilities of each possible pair of workers within and between establishments will differ if sampling is clustered by establishment). It is not clear from the survey protocol or report if NIOSH and Anthrotech considered using a random sampling approach (Zhuang, 2001; Anthrotech, 2004).

Conclusion

The proposal and NIOSH-sponsored Anthrotech Report did not adequately define or represent an appropriate target population.

Recommendation 3-1: ***Define Target Populations More Precisely.***

Future anthropometric face panel studies undertaken by, or on behalf of, NIOSH should have a statistically rigorous and valid sampling plan and implementation strategy that precisely define the target population and also ensure that the samples of selected subjects included in the studies are representative of the predefined sample population (e.g., the current workforce that wears respirators, workers who should be using respirators, the general United States workforce).

REFERENCES

Anthrotech. 2004. *A head-and-face anthropometric survey of U.S. respirator users: Final report.* Prepared by B. Bradtmiller and M. Friess for NIOSH/NPPTL.

Camarota, S., and N. McArdle. 2003. *Where immigrants live: An examination of state residency of the foreign born by country of origin in 1990 and 2000.* Washington, DC: Center for Immigration Studies.

Ronningen, B. J. 2004. *Estimates of selected immigrant populations: 2004.* St. Paul, MN: Minnesota State Demographic Center.

U.S. Census Bureau. 2006. *Ancestry: 2000.* http://www.census.gov/prod/2004pubs/c2kbr-35.pdf (accessed December 15, 2006).

Zhuang, Z. 2001. *Anthropometric survey of respirator users: Study protocol.* Pittsburgh, PA: National Institute for Occupational Safety and Health.

Zhuang, Z., and B. Bradtmiller. 2005. Head-and-face anthropometric survey of U.S. respirator users. *J Occup Environ Hyg* 2(11):567-576.

4

Data Analysis and Fit-Test Panels

To establish an effective face panel, the National Institute for Occupational Safety and Health (NIOSH)-sponsored Anthrotech study performed a number of different analyses on the data it collected. This chapter reviews how the study analyzed the dataset and critiques those analyses.

WEIGHTING OF DATA

As a result of variability in sample collection, the number of subjects surveyed by Anthrotech in each demographic category was not in the correct proportions to accurately represent the demographic distribution of the U.S. workforce. Therefore, the first step in Anthrotech's data analysis was to weight each sample cell (Table 4-1). Although it was necessary to weight each sample cell, it is unclear if choosing to weight the data against the entire U.S. workforce, versus the population of current and potential respirator-wearing workers, may have an impact on the final distributions.

Using these weights as multipliers against the data in each cell, the Anthrotech investigators then derived basic summary statistics for each of the dimensions measured and provided summary tables of those analyses. Based on these statistics, Anthrotech developed revised face panels utilizing the methods that had been developed for the earlier Los Alamos

TABLE 4-1 Sample Weights

	Male Age Group			Female Age Group		
Race	18-29	30-44	45-66	18-29	30-44	45-66
White	1.516531	1.070699	1.473671	1.502991	1.881647	2.407866
African American	0.835324	0.424599	0.312164	1.000204	0.324416	0.181680
Hispanic	0.808564	0.691170	0.933218	1.124507	1.823606	1.150489
Other	2.332153	1.338566	0.741441	0.597626	0.566132	0.265141

SOURCE: Anthrotech, 2004.

National Laboratory (LANL) face panels (Hack et al., 1974; Hack and McConville, 1978). The proposed face panels are meant to represent the current U.S. workforce, and not the subset of young men and women who belonged to the U.S. Air Force in the early 1970s. However, without additional data comparing the outcome of the LANL face panel and the proposed face panel, including quantitative fit tests, it is not possible for the committee to determine if the updated target population was an improvement and appropriate given the demographics of the current workforce too broad.

Data Stratification

Data stratification is a useful sampling technology that uses information about the reference population to conduct sampling in a more efficient manner. The reference population is broken up into strata based on auxiliary variables (e.g., age, gender, ethnicity, and race), and a random sample of a certain size is obtained from each of the strata. The sample number can be determined based on issues of variability and cost—a problem of optimal design (Neyman, 1934). Typically, and assuming that information about variability within strata is available, the larger the stratum variance, the larger the sample size from that stratum. Stratified sampling works best when strata have small (internal) variability while variability across strata is large by comparison.

In the survey conducted by Anthrotech, the distribution of subjects based on demographics was not known until after the subjects were sampled, thus the sampling plan used a poststratification method. That is, subjects were assigned to the various strata only after they had been sampled and measured. This implies, for example, that the number of subjects per stratum is not known until after all the subjects are sampled. The initial goal of sampling exactly 166 subjects in each of the 24 strata using 3984 subjects, although difficult to accomplish, could have been attained by seeking out specific groups (Zhuang, 2001). Nevertheless, poststratification provides a way to utilize the information that was collected. To adjust for undersampling or oversampling in some of the strata, as compared to the target population, stratum-specific weights are used and the 24 cells become “adjustment cells.” In the NIOSH-sponsored Anthrotech study, the weights are computed as the relative frequency of a given stratum in the census (N_i/N: where N_i is size of ith stratum and N is total count over all strata) divided by a relative frequency of the same stratum (n_i/n: where n_i is the sample count in ith stratum and n is the sum of counts over all strata) in the study (Anthrotech, 2004). Under the assumption of random sampling within strata, the weighted estimators of population means, for example, are unbiased. As the N_i and N counts for the target population are unavailable, the investigators instead used counts obtained from the 2000 U.S. Census for the U.S. population in each stratum, not for the U.S. workforce. Because “The primary purpose of the study is to build an anthropometric database that can be representative of the nation’s workers who wear, or have the potential to wear, respirators,” it is unclear if it is appropriate to calculate weights using data from the U.S. Census. For the purposes of this analysis and critique, and absent any better dataset, the committee has chosen to proceed under the assumption that the default target population was the U.S. workforce. However, due to the absence of a more appropriate dataset, it would likely have been in the study’s best interest to establish a dataset that was directly proportional to the workforce population that should be wearing face masks.

Giving each of the members of stratum i the weights w_i computed as above, allows the weighted average to be expressed as so that the weighted average can then be written as an unweighted average, where *j* is the jth person in the ith stratum. This stratified weighted average produces unbiased estimators of population parameters.

$$\frac{1}{n}\sum_{i=1}^{k}\sum_{j=1}^{n_i} w_i \times y_{ij} = \frac{1}{n}\sum_{i=1}^{k}\sum_{j=1}^{n_i} y_{ij}^{*}$$

Nevertheless, as a result of the way the researchers implemented the sampling plan, the committee can not guarantee that the various population estimators are unbiased. Specifically:

1. The sample needs to be a random sample (though not necessarily with equal probabilities in each stratum). The survey did not use random sampling. Rather, it was a convenience sample with subjects that were then assigned to each stratum. This approach has two important consequences.
    a. Under poststratification (as opposed to stratification) the estimators are no longer unbiased unless $n_i/n = N_i/N$ for each strata
    b. Even if $n_i/n = N_i/N$ for all strata (i), it is unclear whether this “reference” population is similar to the “target” population. Therefore the assumption of there being no bias in the resulting estimators of population parameters can not be guaranteed.
2. When calculating weights, the researchers show that the weights were calculated *within* gender (Zhuang and Bradtmiller, 2005). For example, when calculating the weight for white men aged 18-29, the researchers provided n_i/n = 271/2,543 and N_i/N = 14,281,917/88,336,773. The ratio of these two fractions then gives the weight = 1.517127. (These fractions, and hence the weights, are computed from the following sample and reference population information, should n_i/n not be equal to 271/3,997 and N_i/N = 14,281,917/178,189,001 the total sum used instead of gender sum used). This obviously has a significant effect on the size of the weights and the remaining analyses. There does not seem to be any reason given for deciding to do this. If instead they had decided to calculate weights within age groups, for example, the weights would have been different. This is illustrated in the tables that follow (Tables 4-2 through 4-7).

TABLE 4-2 Sample Size by Race

	Male Age Group				Female Age Group			
Race	18-29	30-44	45-65	Total	18-29	30-44	45-65	Total
White	271	611	485	1,367	151	194	174	519
African American	101	255	278	634	51	213	325	589
Hispanic	155	182	75	412	53	36	37	126
Other	24	47	59	130	52	65	103	220
Total	551	1,095	897	2,543	307	508	639	1,454

NOTE: Final sample reflects congruence with original sample target, which eliminated those under 18 and over 65 years of age; however, later measurements include those aged 66. Category labeled "Other" includes Asian, Pacific Island, Native American, and mixed race.
SOURCE: Anthrotech, 2004.

TABLE 4-3 The Population

	Male Age Group				Female Age Group			
Race	17-29	30-44	45-66	Total	17-29	30-44	45-66	Total
White	14,281,917	22,696,728	24,837,527	61,816,171	14,015,193	22,658,895	25,873,039	62547127
African American	2,931,853	3,762,579	3,015,740	9,710,172	3,150,101	4,267,251	3,646,329	11063681
Hispanic	4,355,241	4,371,414	2,432,261	11,158,916	3,680,475	4,054,145	2,628,754	10363374
Other	1,945,066	2,816,269	1,520,179	5,651,514	1,919,105	2,272,463	1,686,478	5878046
Total	23,514,077	33,016,989	31,805,707	88,336,773	22,764,875	33,252,753	33,834,600	89852228

NOTE: Population totals based on U.S. Census 2000 data.
SOURCE: Personal communication, Z. Zhuang, National Personal Protective Technology Laboratory (NPPTL), July 13, 2006.

TABLE 4-4 The Sample Fraction Based on Gender-Specific Total

	Male Age Group				Female Age Group			
Race	17-29	30-44	45-66	Total	17-29	30-44	45-66	Total
White	0.106567	0.240267	0.190720	0.537554	0.103851	0.133425	0.119670	0.356946
African American	0.039717	0.100275	0.109350	0.249312	0.035076	0.146492	0.223521	0.405089
Hispanic	0.060952	0.071569	0.029493	0.162013	0.036451	0.024759	0.025447	0.086657
Other	0.009438	0.018482	0.023201	0.051121	0.035763	0.044704	0.070839	0.151307
Total	0.216673	0.430594	0.352733	1.000000	0.211142	0.349381	0.439477	1.000000

NOTE: Data contained in this table is a ratio of Table 4-2 sample sizes for each category to total sample aggregate.
SOURCE: Personal communication, Z. Zhuang, NPPTL, July 13, 2006.

TABLE 4-5 Population Fraction Based on Gender-Specific Totals

	Male Age Group				Female Age Group			
Race	17-29	30-44	45-66	Total	17-29	30-44	45-66	Total
White	0.161676	0.256934	0.281169	0.699778	0.155980	0.252180	0.287951	0.696111
African American	0.033189	0.042594	0.034139	0.109922	0.035059	0.047492	0.040581	0.123132
Hispanic	0.049303	0.049486	0.027534	0.126322	0.040961	0.045120	0.029256	0.115338
Other	0.022019	0.024749	0.017209	0.063977	0.021358	0.025291	0.018769	0.065419
Total	0.266187	0.373763	0.360051	1.000000	0.253359	0.370083	0.376558	1.00000

NOTE: Data contained in this table is a ratio of Table 4-3 population for each category to total population aggregate.
SOURCE: Personal communication, Z. Zhuang, NPPTL, July 13, 2006.

TABLE 4-6 Weighting Factors Based on Gender-Specific Totals

	Male Age Group				Female Age Group			
Race	17-29	30-44	45-66	Total	17-29	30-44	45-66	Total
White	1.517127	1.069367	1.474251	1.301782	1.501958	1.890047	2.406211	1.950184
African American	0.835652	0.424766	0.312287	0.440902	0.999516	0.324193	0.181555	0.303962
Hispanic	0.808882	0.691441	0.933585	0.779704	1.123734	1.822352	1.149698	1.330964
Other	2.333071	1.339092	0.741733	1.251487	0.597215	0.565743	0.264959	0.432360
Total	1.228517	0.868017	1.020745	1.000000	1.199948	1.059252	0.856832	1.000000

NOTE: Weighting factors determined as the fraction of race to age group in the U.S. population divided by the fraction of the same group in the sample.
SOURCE: Zhuang et al., 2004.

TABLE 4-7 *Corrected* Weighting Factors Based on Population Totals

	Male Age Group				Female Age Group			
Race	17-29	30-44	45-66	Total	17-29	30-44	45-66	Total
White	1.1822	0.8332	1.1492	1.0143	2.082	2.6227	3.338	2.7033
African American	0.6522	0.3307	0.2428	0.3436	1.3828	0.4484	0.2522	0.4213
Hispanic	0.6289	0.5385	0.7234	0.6075	1.5564	2.533	1.5914	1.8449
Other	1.8167	1.0424	0.5764	0.9752	0.8308	0.7853	0.3682	0.5993
Total	0.9573	0.6764	0.7954	0.7792	1.6633	1.4683	1.1877	1.3862

SOURCE: (Personal communication, Z. Zhuang, NPPTL, July 13, 2006).

As Tables 4-6 and 4-7 demonstrate, there are significant differences in the weights, depending whether the data are corrected or not. For example, the male weights in Table 4-7 are roughly 3/4 of the weights used in the Anthrotech report; the exact fraction is 0.7792 (1.1822/1.517127) for white men in the 18-29 age group. The weights for women also changed by a factor of 1.3862. Thus, using the "corrected" weights (Table 4-7) could have a great impact on all subsequent analyses, and therefore raises a concern about the analyses presented in the NIOSH-sponsored Anthrotech study. In particular, since one of the main arguments for updating the LANL face panel relies on the high proportion of the population no longer covered by the LANL face panel when fitting the weighted Anthrotech data into it, it remains to be seen whether this conclusion holds when using the revised set of weights.

The set of weights used for the data summaries and statistical analyses were computed within gender, and no discussion supporting this choice was presented. Instead, the set of weights given in Table 4-7 should have been used. Although it is conceivable that similar conclusions will be reached, the committee strongly believes that NIOSH should rework all the data summaries and statistical analyses using the set of weights provided in Table 4-7.

Conclusion

The demographic makeup of the United States workforce has, and will continue to become, more diverse, resulting in an increased range of facial dimensions.

Recommendation 4-1: ***Ensure Appropriate Representation of Demographics Groups.***

NIOSH should benchmark its sample population against the current and future United States workforce that should be wearing respirators, to ensure adequate representation of demographic groups on the panel (e.g., age, gender, race, and ethnicity).

ESTABLISHING THE FACE PANEL

To develop the proposed respirator fit-test panels, NIOSH contracted with Anthrotech "to assess and refine the LANL fit-test panels," relying on the same facial dimensions and utilizing methods similar to those used by the original LANL face panel designers (Zhuang, 2001). The rationale for choosing to assess and refine the LANL face panels, using the same parameters, and not consider using strategies that have been developed since the 1970s to develop the updated face panels was not clear to the committee. The NIOSH-sponsored Anthrotech report notes, however, that, unlike the LANL face panel, the proposed face panel was not confined to a strictly rectangular arrangement of cells (Anthrotech, 2004). They found that, in offsetting some of the cells, they were able to achieve a greater coverage of the target population. However, there was no discussion of whether the number of boxes is appropriate, or whether there may be problems of fit for persons near the edges of the boxes.

The updated full- and half-face panels proposed by the NIOSH-sponsored Anthrotech study were based on the menton-sellion length and bizygomatic breadth facial dimensions. The full-face panel accommodates 96.2 percent of the study population—that is, 96.2 percent of the nearly 4,000 workers recruited for the study have faces with a bizygomatic breadth and menton-sellion length that fall into one of the boxes of this panel (Figure 4-1). The revised half-face panel, which relies on menton-sellion length and lip length, accommodates 97.2 percent of the study population (Figure 4-2). As was done in the development of the LANL face panel, the NIOSH-sponsored Anthrotech study populated the individual cells so that the cells that represent larger percentages of the study population—the middle cells—were assigned more subjects than the cells representing smaller percentages of the study population. Further, the individual cells were populated so that men and women were distributed nearly equally (13 men and 12 women), and no cell was allowed to be populated with only one member.

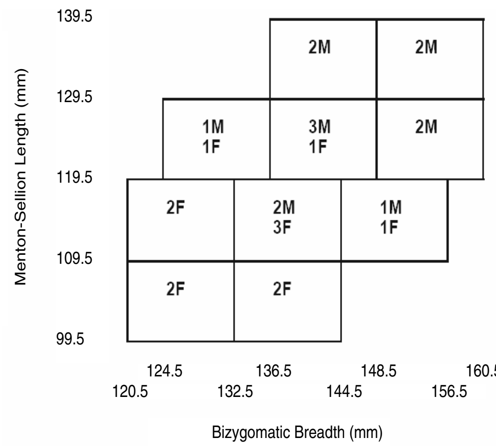


FIGURE 4-1 Revised full-face panel.
SOURCE: Anthrotech, 2004.

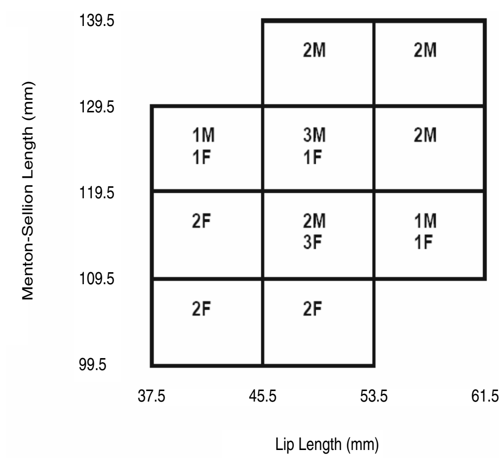


FIGURE 4-2 Revised half-face panel.
SOURCE: Anthrotech, 2004.

Sample Size

Concerns over the sample sizes within individual cells are related to the variability of facial characteristics within each cell: the greater the variability, the less information a sample of given size can provide about those faces. Thus there are competing objectives. It is better to have a good fit for a large number of workers than for a smaller number, which argues for more panel members in the most-populated cells. However, the greater variability in the smaller cells required larger samples of faces to give the worker the same degree of respiratory protection as workers in the more homogeneous cells. Equal number in cells seems a reasonable compromise between these competing objectives.

In testing the fit of masks for certification, NIOSH assigns test subjects to cells based on their facial dimensions as measured at the time of the fit test. NIOSH staff members told the committee that they rely on a small pool of volunteers who are geographically proximate to their laboratory in Pittsburgh, Pennsylvania, when performing certification tests. Although time efficient and cost-effective, this procedure introduces biases—as the small panel of volunteers is not representative of the target population—and should be discontinued. Instead, subjects must be selected according to a sound statistical sampling design.

Differences in the Proposed Face Panel and the LANL Face Panel

Anthrotech's analysis of the data demonstrated significant differences between the new sample and the 1972 U.S. Air Force data that was used to develop the LANL face panel (Hack et al., 1974). An overlay of the proposed NIOSH-sponsored Anthrotech study panel and the LANL face panel shows a clear shift to the upper-right quadrant, representing larger faces (Figure 4-3). This trend is also observed in an analysis of the facial dimensions (Table 4-8). Further, Figure 4-4 shows the revised data for the face widths and face lengths from the NIOSH-sponsored Anthrotech study's 4,000 subjects plotted against the bivariate panel that LANL constructed from the 1972 survey. Of those surveyed, 15.3 percent would not be included in the LANL face panel, mostly those individuals with larger faces. However, the shift of the face panel toward individuals with larger faces comes at the expense of smaller-faced individuals, including many minority populations.

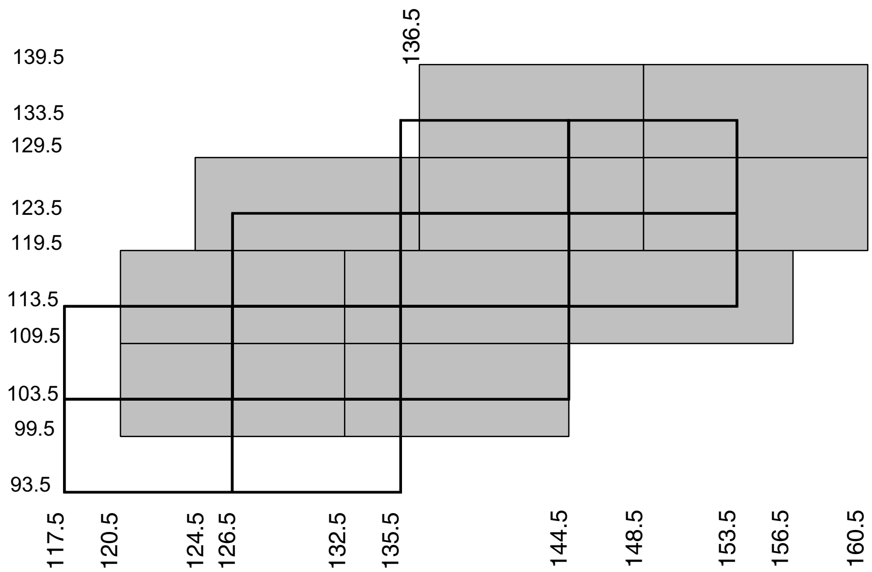


FIGURE 4-3 Revised Anthrotech panel superimposed over LANL panel for full face pieces.
SOURCE: Anthrotech, 2004.

TABLE 4-8 Differences in Key Measurements Between LANL and NIOSH Surveys

		Men		Women	
Facial Dimension	Survey	Mean (mm)	Std Dev	Mean (mm)	Std Dev
Menton-Sellion Length	LANL	120.3	6.1	106.3	6.1
	NIOSH	122.7	7.1	113.4	6.1
	Difference	2.4		7.1	
Bizygomatic Breadth	LANL	142.3	5.2	129.0	5.8
	NIOSH	143.5	6.9	135.0	6.5
	Difference	1.2		6.0	
Lip Length	LANL	52.3	3.8	43.8	4.2
	NIOSH	51.1	4.2	48.0	4.0
	Difference	1.2		4.2	

SOURCE: Zhuang, November 3, 2005.

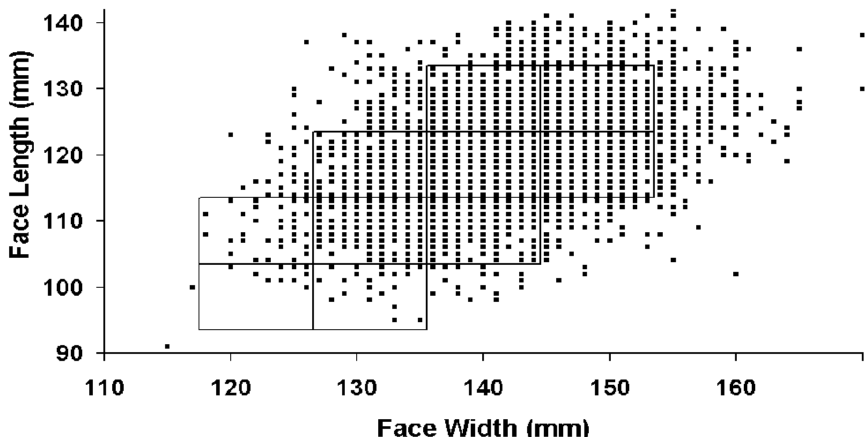


FIGURE 4-4 Distribution of facial sizes against LANL panel boxes. Face length is menton-sellion length and face width is bizygomatic breadth.
SOURCE: Adapted from (Anthrotech, 2004).

Conclusion

The proposed NIOSH-sponsored Anthrotech face panel selects larger dimension faces at the expense of the smaller faces currently included in the LANL face panel, even though some of these small faces still make up a considerable proportion of the workforce.

Recommendation 4-2: ***Include Large and Small Faces in Panel.***

NIOSH should develop an expanded anthropometric face panel that includes the larger-sized faces described in the NIOSH-sponsored Anthrotech study, while retaining the small-sized subjects from the LANL face panel. This may require adjusting the total number of subjects in the face panel.

VALIDITY OF THE PROPOSED FACE PANELS

To evaluate the validity of the new face panel, NIOSH compared the proposed face panel to the data collected in the 2002 Civilian American and European Surface Anthropometry Resource (CAESAR) study[1] (CAESAR, 2002). This comparison revealed that the proposed panel accommodated 98 percent of the population included in the CAESAR. However, there was no discussion of how well persons near the edges of the cells may be fitted, nor could there be, since no fit data were collected.

Manufacturers in the United States have also conducted analyses of the anthropometric face panels (Colten, July 10, 2006; Frund, July 10, 2006). Notably, the Minnesota Mining and Manufacturing Company (3M) found that while the LANL face panel accommodates most of the U.S. respirator population, it is less inclusive of foreign populations. This is particularly true in the case of citizens from Asian countries and highlights a potential problem with the proposed face panels.

However, for U.S. workers, at least, the CAESAR data and the comparisons to the LANL face panel imply that the proposed face panels accommodate a larger percentage of the workforce than do the LANL face panels. In this limited sense, at least, it would seem that the proposed face panels are an improvement over the LANL face panels.

Conclusion

The proposed NIOSH-sponsored Anthrotech face panel is likely to be more representative of the current United States workforce than the LANL panel, but information is not available to determine the extent to which the new panel provides a better fit for that workforce.

Recommendation 4-3: ***Perform Studies to Compare the Proposed Face Panel to the LANL Face Panel.***

NIOSH should perform a study in which it compares the range of quantitative fit provided for specified respirators on subjects representing the LANL face

[1]The CEASAR study collected information from 4,000 ethnically, racially, and gender diverse volunteers in 10 geographic regions in the United States.

panel and subjects representing the proposed NIOSH-sponsored Anthrotech bivariate face panel (adjusted in accordance with Recommendation 4-2).

THE IMPACT OF FACE DIMENSION ON FIT

Understanding and well-representing various anthropometric features of the U.S. workforce are essential to developing appropriate anthropometric face panels, which in turn will ensure that NIOSH-certified respirators are capable of fitting a large percentage of workforce that should be wearing a respirator. In other words, the ultimate test of a face panel is not only that it represents the facial measurements of the workforce, but that it ensures that only those respirators that are likely to fit the greatest number of people are approved.

The committee heard anecdotal evidence from a respirator fit-test expert that he and his staff are capable of fitting nearly all wearers to either a half- or full-face respirator, provided that one or more brand and size of NIOSH-certified respirators are available (McKay, July 10, 2006). He also noted that there were no commonalities between those persons he was unable to fit with a respirator.

The committee is uncertain if the bivariate face panels that the NIOSH-sponsored Anthrotech study provide are an acceptable means of determining if tested respirators can be relied on to fit the group of workers for which the sizes are designed. One potential problem with the proposed face panels is that, although Anthrotech chose face length and face width as the foundation for the face panels, there is no consensus within the literature as to which anthropometric features have the greatest impact on respirator fit.

Literature Review of Facial Measurements and Fit

In the following section the committee reviews the currently available literature that explores the relationship between facial measurements and fit. A review of this literature helps provide an understanding of how facial measurements, such as face length and width, are correlated to fit.

In 1982, Liau and colleagues compared the facial features of 190 white male subjects with quantitative fit-test results for half-face respirators (10 sizes from four manufacturers) and found significant correlations between fit and face width and mouth width (Liau et al., 1982). In 1990, Oestenstad and colleagues evaluated the distribution of leak sites on three sizes of a single manufacturer's half-face respirator for 73 subjects. Seventy-nine percent had face piece leaks that included the nose, 33 percent had leaks only at the nose, and 51 percent had leaks that included the chin. The researchers found that chin and combined nose and chin leaks were significantly correlated with much lower fits (higher aerosol penetration) than any other type of leak. Of the measurements obtained by the researchers, three nasal dimensions (menton-subnasale, binocular breadth, and nasal root breadth) were found to be significantly correlated with fit for all subjects (Oestenstad, Dillion, and Perkins, 1990).

In 1992, Oestenstad and Perkins found significant correlations between four facial dimensions (menton-subnasale, binocular breadth, nasal root breadth, and nose width) and fit in 68 subjects wearing one of three sizes of a single manufacturer's half-face respirator. They were best able to predict fit when taking the race and the gender of the subjects into account. The dimensions of binocular breadth and nasal root breadth, as well as those of face length and lower face length, were significantly correlated with fit in most of the regression models (Oestenstad and Perkins, 1992). However, in 1990, Gross and Horstman found no association between any of 10 facial measurements and the fit of respirators (Gross and Horstman, 1990).

In 1998 Brazile et al. evaluated fit and facial dimensions in White, African American, and Mexican American subjects. They found that only nose protrusion was significantly correlated with respirator fit (Brazile et al., 1998). This differed slightly with the findings of a 2003 study performed by Han and Choi, which analyzed the relationship between fit and facial dimensions in 150 Korean subjects (112 men and 38 women) using three medium-sized elastomeric half-face respirators (Han and Choi, 2003). As with the Oestenstad and Perkins study, the researchers found the greatest correlation in models that took the gender of the subject into account (Oestenstad and Perkins, 1992). In five of their models, the bitragion-menton arc was significantly correlated with fit. However, no dimension was correlated with fit for all gender/brand subgroups. For the mask that had the highest degree of fit (i.e., fit the most subjects), bizygomatic breadth and nose protrusion were found to be good predictors of fit.

Also in 2003, Kim et al. performed a study of mask fit and facial dimensions and found significant differences in a range of facial measurements between Koreans and White ethnic groups, especially for face width, lip width, nose width, and nasal root breadth (Kim et al., 2003). The authors note that "Koreans generally have a significantly wider face width and nose breadth and relatively narrow lip width than those of Whites and Australians. Nasal root breadth was also significantly narrower in Koreans." The researchers found no correlation between fit and any facial dimensions for men in quarter-face respirators. On the other hand, fit in women was significantly correlated with bitragion-subnasale arc.

In 2005 Zhuang et al. reviewed the literature and concluded that "face length,[2] face width,[3] and lip length have not been shown to be consistently correlated with fit factor, while other dimensions such as nasal root breadth have been shown to correlate with fit factor" (Zhuang, 2005). The researchers drew from a pool of 33 subjects (18 women, 15 men) to fill 25 member panels and perform fit tests on 18 models of N95 filtering face-piece respirators (ranging from one to three sizes per model) using a Portacount Plus quantitative fit test. Each subject donned the same respirator six times and performed six 1-minute exercises. Respirator size was selected using subjects' face and lip length measurements, based on a procedure established by another study (Coffey et al., 2002).

Zhuang and colleagues found that cup-style respirators (as opposed to those that fold flat) with three sizes achieved the highest geometric mean fit factor for all subjects (240), which was significantly different from other cup-style respirators, and all folding style respirators (Zhuang, 2005). There were no differences between men and women for 16 of the 18 respirator models tested. Bigonial breadth, face width (bizygomatic breadth), and nose protrusion were significantly correlated with fit in the most model/size subsets (5 or 6 of 21 subsets). The researchers also found that men who failed the fit test had larger face dimensions than those who passed.

Thus, although the NIOSH-sponsored Anthrotech study chose face length and face width as the foundation for the bivariate face panel, the data presented above demonstrates there is no consensus within the literature as to which features actually have the greatest effect on respirator fit. Indeed, that case is even more compelling for half-face respirators; most published studies—including Zhuang's 2005 studies sponsored by NIOSH (Zhuang and Bradtmiller, 2005)—find at least one nasal dimension to be more highly correlated with fit than are face width and face

[2]Menton-sellion length.
[3]Bizygomatic breadth.

length. Thus, while face length and width may well be appropriate for the bivariate full-face panel, there are likely better dimensions upon which to base a half-face panel.

The committee concludes that the NIOSH protocol should have instructed Anthrotech to include an analysis of how various facial measures affect fit. The results of that analysis should have been used to inform decisions about which measurements to use when designing face panels. NIOSH personnel did indicate to the committee that they have conducted total inward leakage[4] (Box 4-1) testing on the fit panels, and are planning to conduct an analysis of that data. Unfortunately, the study design did not call for fit-testing subjects, and this omission limited how much can be learned from their data about the effect of facial features on respirator fit.

BOX 4-1

Total Inward Leakage vs. Quantitative Fit Test

The committee notes that the term *total inward leakage* is unique to NIOSH, as the rest of the scientific community uses the term *quantitative fit test*. The term may have been adapted to describe filtering facepiece studies wherein the filter element cannot be altered, and therefore, leakage measurements include both the filter element and the facepiece. However, this is still a quantitative fit test if the challenge aerosol is chosen properly to match the filtering element. Rather than establishing a new term that may cause confusion among the professional and research communities, NIOSH may wish to use the conventional *quantitative fit test* terminology. Furthermore, here NIOSH is interested in how well facepieces fit users with its anthropometric panel and not how filters perform, which is the subject of existing and different certification requirements.

Conclusion

The present state of knowledge does not permit the committee to conclude with any degree of confidence that respirators that fit the proposed NIOSH-sponsored Anthrotech study face panel are likely to fit 95 percent

[4]The total inward leakage of a respirator is determined by measuring the concentration of a challenge aerosol outside the respirator as well as the concentration within the breathing zone (inside the respirator). Respirator fit testing normally considers face seal leakage. Total inward leakage defines a protective level achieved by a respirator when the contributions of all leakage paths (including filters) are considered.

of the population of workers who should be using respirators. Further, the committee was unable to determine a level of confidence or margin of error for the proposed face panel. However the proposed panel, based on newer data, appears to be more representative of the population than the 30-year-old data used in the LANL face panel.

Recommendation 4-4: ***Analyze an Appropriate Proportion of the Respirator-Using Population That Should Be Fitted to Respirators.***

NIOSH should perform a statistical analysis of the proportion of workers who should be using respirators to determine the proportion of that population that is included in the proposed NIOSH face panels. Based on that analysis NIOSH should either adjust the proposed face panel to meet a 95 percent confidence level and some appropriate margin of error, or state the confidence metric as it stands. This recommendation assumes that NIOSH will take into account Recommendation 4-1 in the design of its future face panel(s).

Conclusion

The ultimate utility of the data collected in the NIOSH-sponsored Anthrotech study is limited because the study did not include the collection of fit-testing data along with facial measurements.

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 face masks in the workplace, using quantitative measures. These research

findings should be utilized in the design of future anthropometric face panel studies.

Conclusion

Proper analyses of facial dimensions have not been performed for half-facepiece respirators; lip length and menton-sellion length may not be the most appropriate dimensions to use when developing anthropometric face panels.

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.

Principal Component Analysis

Although the face panels that the NIOSH-sponsored Anthrotech study developed were, in the end, simply updates of the original LANL face panels that used new and more comprehensive survey data, NIOSH did develop a separate face panel derived from a principal component analysis (PCA) of the anthropometric data collected in Anthrotech's survey (Box 4-2). For this panel the NIOSH researchers used PCA to derive two new variables, each of them linear combinations of several different anthropometric measures, and then based the panel on those new variables.

BOX 4-2

Principal Components Analysis

To represent the form of the face appropriately, generally a number of different anthropometric measurements are needed. However, it is difficult to visualize and to use all of these different measurements simultaneously, and, further, the measurements tend to be correlated. To make visualization possible, it is important to find the best lower-dimensional summary of the multi-dimensional data, preferably a summary with no more than two or three dimensions of data. Assuming that the histogram of these measurements is bell-shaped (symmetric with a single mode), it is possible to find optimal lower-dimensional summaries of the data by using the statistical technique of PCA.

To understand how PCA works, suppose there are 10 different measurements taken from a number of individuals. A simple one-dimensional summary of the measurements for each individual could be a weighted sum of the measurements, some of the measurements being weighted more than the others depending on their importance. Choosing the weights in this weighted sum would depend on what the summary statistics are supposed to represent. In a one-dimensional PCA, the weights are chosen so that the weighted sum captures the largest proportion of total variance in the data. If this proportion is not sufficiently large, the one-dimensional representation is deemed inadequate. In that case, a second weighted sum of the measurements is performed in such a fashion that, in conjunction with the first weighted sum, it accounts for the largest proportion of the total variance. This process continues until the proportion of total variance explained by the weighted sums is considered adequate.

To perform the principal component analysis of the survey data, Zhuang evaluated the various anthropometric measurements using such methods as expert opinion and regression analysis in order to zero in on the variables that were best correlated with fit (Zhuang, November 3, 2005). After the screening, the analysis was performed on 10 variables:

1. Minimum frontal breadth
2. Face width (bizygomatic breadth)
3. Bigonial breadth
4. Menton-sellion length
5. Interpupilary distance
6. Head breadth
7. Nose protrusion
8. Nose breadth
9. Nasal root breadth
10. Subnasale-sellion length

The PCA resulted in two principal components that can be described (approximately) as the overall size of the face (from small to large) and the general shape of the face (from a small face with a short, wide nose to a long face with a long, narrow nose). Figure 4-5 shows the overall facial size trends of the individuals in the survey plotted against these two principal components. Working from the distribution of faces as plotted on these two dimensions, NIOSH researchers proposed a new system of five facial groups defined by a combination of size and shape. These facial form groups can be thought of as

1. an average group,
2. faces that are smaller than average,
3. faces that are larger than average,
4. faces that are shorter and wider than average, and
5. faces that are longer (from forehead to chin) and narrower than average (Figure 4-5).

It is unclear to the committee whether these PCA-derived features correlate well with fit. In performing this analysis, the underlying and generally unspoken assumption is that how well it fits the various members of a group will depend in large part on how well the respirator fits a

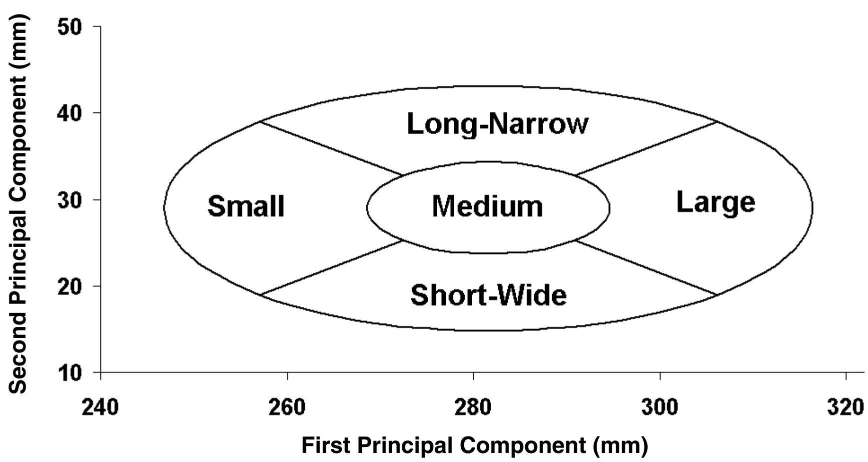


FIGURE 4-5 Facial size trends as compared to principal components.
SOURCE: Zhuang, November 3, 2005.

face that represents the average form of the members of that group. In PCA analysis it is possible that dimensions and shapes that determine fit are represented in the first two components only weakly, or not at all.

As described above, there is a great deal of potentially conflicting literature on this topic. The average "face" identified in the NIOSH-sponsored Anthrotech study is a composite and does not exist in reality. An important variable that determines fit may very well be the amount and nature of variation around the average. For example, the variation around a particular group mean (i.e., the average face on the panel) is more important to fit than the average form itself. It is also possible that fit depends critically on some measure that contributes little to overall facial shape. The NIOSH-sponsored Anthrotech study paid little attention to these matters, yet different mean forms will undoubtedly have different variances, different fits, and local aspects of these will very likely vary in magnitude (as pertains to fit around a specific part of the face).

The committee reviewed the data and found that male and female faces have similar shapes depending on what variables are used to describe them. The committee also found that age seems to have a very small correlation with every other variable, and yet, may have sufficient power to predict fit to justify its inclusion on the panel. The committee found no statistical analysis that provides guidance in this regard, as NIOSH data on fit are not available to the committee (or may not exist within NIOSH). One of the manufacturers (3M) stated that they have collected this type of information but that it may be proprietary (Colten, July 10, 2006).

Are the PCA Face Panels an Improvement over the Proposed Bivariate Face Panels?

One issue that remains unanswered with respect to PCA is whether performing such an analysis will provide a better face panel than the proposed or the LANL face panels. Although the new proposed face panel is not without its own limitations, as discussed above, it may well be better than the PCA face panel.

PCA may provide a more informative classification of faces. The researchers made an effort to include in their analysis only those variables that correlated with aspects of fit. However, in the absence of fit data, it is not possible to determine how well they succeeded. The 10 facial dimensions chosen for the PCA were age- and race-adjusted, suggesting that these factors should not affect the final classifications obtained from the PCA (Zhuang, November 3, 2005). However, the committee has identified several potential problematic issues related to PCA:

- The analysis does not explain the basis or methods for stating that the PCA is age- and race-adjusted (Zhuang, November 3, 2005).
- The regression analyses carried out were based on simulated workplace protection factors rather than on real-world conditions.
- Anthrotech selected its variables based on published studies that reported correlations between certain facial features and fit, but unless the populations used in those studies were similar to the population of interest to NIOSH, choices to include or exclude variables for the PCA based on these studies may be inappropriate.
- If the variable selection step were not suspect, then the five-class categorization scheme based on PCA might well be a better way to classify subjects into various respirator sizes than a similar five-category classification based on a bivariate panel. As it is, however, there is no way to be sure that a PCA-based scheme would be superior. It would be simple to work from the data underlying the bivariate panels (e.g., bizygomatic breadth and the menton-sellion length) to construct a five-group classification system that is similar to the one Anthrotech derived from the PCA. As shown in Figure 4-3, the set of data points is roughly elliptical in extent. That ellipse can then be divided into five regions in the same way that the data were in Figure 4-4. The resulting regions could then be called “long-narrow,” “small,” and so on. Given the various concerns described above about the PCA, it is not at all obvious that the five-class size system defined this way from the data on face width and length would be superior to the system defined by the two variables derived from the PCA. Again, a fundamental issue is that fit was not examined, and the relationship between fit and the general shape of the head and face is not known.

ALTERNATIVE NONLINEAR FACE PANEL DESIGN

As an alternative to the linear relationships used to develop both the PCA and the NIOSH-sponsored Anthrotech study face panels, the committee developed an alternative strategy that is based on a nonlinear relationship between facial measurement and fit. This is described in the section that follows.

The two proposed face length- and width-based face panels developed from the NIOSH-sponsored Anthrotech study and the related PCA-derived face panels described above are based on similar assumptions. Working from the total sample population, a small number of cells are defined that together include most of the target population (there are 10 cells for each of the length- and width-based face panels and 5 for the PCA panel). Then for each of those cells a certain number of subjects are chosen—the number of subjects in each cell is approximately proportional to the percentage of the study population that is covered by the cell. Thus the middle cells in the bivariate panels, which contain a larger percentage of the study population than do the outer cells, have four or five panel members as compared with only two panel members in each of the outer cells. The underlying idea claims to be that because the middle cells cover a larger percentage of the study population, they should be represented by more subjects on the panel. However, the committee does not agree with this assumption. If the cells on the margin cover a wider range of subjects, they may well need more subjects, not fewer.

Proposed Distribution of Face Panel Subjects

A more efficient way to distribute face panel members would be to distribute them among the cells according to the variance of the study population contained in each individual cell. For example, cells with greater variance would require more test subjects be tested to provide a reasonable guarantee that a given respirator will fit most people whose facial dimensions fall within that cell. Conversely, the smaller the variance within a subset, the better that subset will be represented by a small number of individuals. In this scheme, if every subject in a cell had exactly the same dimensions, it would be enough to test any one of them.

This more efficient panel design can be accomplished with the following four steps:

1. Divide the population into equiprobable, or equally-sized, subsets that are mutually exclusive and exhaustive. The individual probabilities of these subsets should be small (not more than 0.10), and the shape could be elliptical (for a bivariate normal distribution). Each subset defines a cell in the panel.
2. Compute the generalized variance (trace or determinant of the covariance matrix) for each of these subsets.
3. Assign the number of individuals to a subset, or cell, in proportion to the generalized variance of that subset.
4. Randomly select individuals within each subset to be the members of that cell.

Two examples of this approach are illustrated in Figure 4-6, which are notional illustrations of how the total sample distribution of facial measurements may be divided into cells representing equiprobable, or equally-sized, subsets of the total distribution. The contours in the background are the nonparametric density contours that were computed from the Anthrotech data. Because the shapes of the cells are based on the distribution of the sample, these contour lines may assist in defining the size and shape of each cell, which is not necessarily rectangular and not a representation of the exact split of the observed distribution. It should be noted that the proportion of the population in each cell is the same, and hence the cells that are in the middle have smaller area, whereas the cells on the outer boundaries have a larger area and larger number of panel members. The number of individuals needed to represent each cell is approximately related to the variance within the cell.

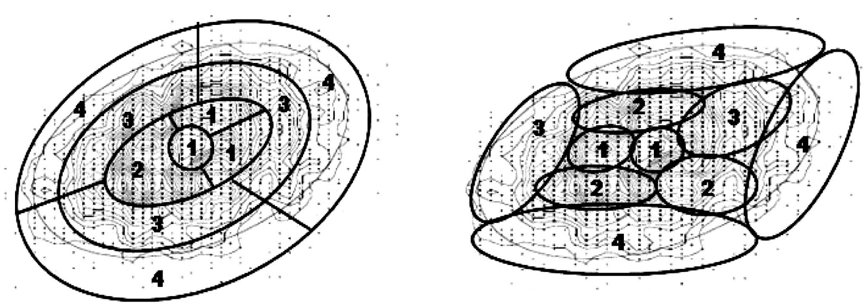


FIGURE 4-6 Two alternatives strategies for the committee's proposed total sample distribution of facial measurements.

Conclusion

The use of multiple features in the development of face panels is likely to be inherently better than the use of just facial height and width, but it is not yet well understood which features are directly relevant to fit and how they can best be combined.

Recommendation 4-7: ***Utilize Multiple Features in the Development of Face Panels.***

NIOSH should examine the potential effects of a non-linear relationship between respirator fit and facial dimensions.

REFERENCES

Anthrotech. 2004. *A head-and-face anthropometric survey of U.S. respirator users: Final report* Prepared by B. Bradtmiller and M. Friess for NIOSH/NPPTL.

Brazile, W. J., R. M. Buchan, D. R. Sandfort, W. Melvin, J. A. Johnson, and M. Charney. 1998. Respirator fit and facial dimensions of two minority groups. *Applied Occupational and Environmental Hygiene* 13(4):233-237.

Civilian American and European Surface Anthropometry Resource. 2002. *Final report from CAESAR.* Falls Church, VA: General Dynamics International.

Coffey, C. C., R. B. Lawrence, Z. Zhuang, D. L. Campbell, P. A. Jensen, and W. R. Myers. 2002. Comparison of five methods for fit-testing n95 filtering-facepiece respirators. *Appl Occup Environ Hyg* 17(10):723-730.

Colten, C. E. July 10, 2006. Presentation to Committee for the Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users: Respirators: Design and anthropometry—3M OH&ESD. Pittsburgh, PA: National Personal Protective Technology Laboratory.

Frund, Z. N. July 10, 2006. Presentation to Committee for the Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users: Manufacturer's perspective on anthropometric measurements study & designing masks to meet new panel. Pittsburgh, PA: National Personal Protective Technology Laboratory.

Gross, S. F., and S. W. Horstman. 1990. Half-mask respirator selection for a mixed worker group. *Applied Occupational and Environmental Hygiene* 5:229-235.

Hack, A. L., and J. T. McConville. 1978. Respirator protection factors: Part I—development of an anthropometric test panel. *Am Ind Hyg Assoc J* 39(12):970-975.

Hack, A. L., E. C. Hyatt, B. J. Held, T. D. Moore, C. P. Richards, and J. T. McConville. 1974. *Selection of respirator test panels representative of U.S. adult facial sizes.* Los Alamos, NM: Los Alamos Scientific Laboratory.

Han, D. H., and K. L. Choi. 2003. Facial dimensions and predictors of fit for half-mask respirators in Koreans. *AIHA J (Fairfax, Va)* 64(6):815-822.

Kim, H., D. H. Han, Y. M. Roh, K. Kim, and Y. G. Park. 2003. Facial anthropometric dimensions of Koreans and their associations with fit of quarter-mask respirators. *Ind Health* 41(1):8-18.

Liau, Y. H., A. Bhattacharya, H. E. Ayer, and C. Miller. 1982. Determination of critical anthropometric parameters for design of respirators. Paper read at American Industrial Hygiene Association, Cincinnati, OH.

McKay, R. T. July 10, 2006. Presentation to Committee for the Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users: Respirator fitting issues. Pittsburgh, PA: National Personal Protective Technology Laboratory.

Neyman, J. 1934. On the two different aspects of the representative method: The method of stratified sampling and the method of purposive selection. *Journal of the Royal Society* 97(4):558-625.

Oestenstad, R. K., and L. L. Perkins. 1992. An assessment of critical anthropometric dimensions for predicting the fit of a half-mask respirator. *Am Ind Hyg Assoc J* 53(10):639-644.

Oestenstad, R. K., H. K. Dillion, and L. L. Perkins. 1990. Distribution of face-seal leak sites on a half-mask respirator and their association with facial dimensions. *Am Ind Hyg Assoc J* 51(5):285-290.

Zhuang, Z. 2001. *Anthropometric survey of respirator users: Study protocol.* Pittsburgh, PA: National Institute for Occupational Safety and Health.

———. November 3, 2005. Presentation to Committee for the Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users: Respirator fit test panels representing the current U.S. civilian workforce. Washington, DC: National Academy of Sciences Keck Center.

Zhuang, Z., and B. Bradtmiller. 2005. Head-and-face anthropometric survey of U.S. respirator users. *J Occup Environ Hyg* 2(11):567-576.

Zhuang, Z., J. Guan, H. Hsiao, and B. Bradtmiller. 2004. Evaluating the representativeness of the LANL respirator fit test panels for the current U.S. civilian workers. *Journal of the International Society for Respiratory Protection* 21:83-93.

Zhuang, Z., Coffey, C.C., and R.B. Ann. 2005. The effect of subject characteristics and respirator features on respirator fit. *J Occup Environ Hyg* 2(12):641-649.

5

Future Directions: Additional Analyses and Research to Practice

The National Institute for Occupational Safety and Health (NIOSH) requested that the committee make recommendations for areas that require additional research and analysis for moving from research to practice. This chapter discusses those recommendations and the rationales behind them.

FACE PANELS REQUIRE PERIODIC UPDATES

As described in detail in the previous chapters, there are several potential weaknesses in the NIOSH-sponsored Anthrotech study. However, the proposed face panel represents a clear improvement over the existing LANL face panel, which only accommodates 84 percent of the civilian population (Zhuang, 2001). The application of the proposed face panels will improve the availability of respirators that fit a broader segment of the workforce.

New technologies, particularly in the area of digitized imaging, may allow NIOSH to create a continuously updated virtual face panel, which could be used to create digital or actual patterns. This can be done by considering the proposed face panel—with appropriate revisions as recommended throughout this report—as the baseline.

The demographics of the workforce, especially racial and ethnic, are shifting at a rapid pace. For example, one-third of those employed in the construction trade are Hispanic, which is a 50 percent increase from 5 years ago (U.S. Census Bureau, 2000; U.S. Department of Labor, 2006). This rate of change is expected to continue and most likely intensify as increasing free trade leads to easier movement of workers from one country to another.

The committee recognizes the significant investment NIOSH has made in developing the proposed Anthrotech face panel and NIOSH's limited resources. It is the committee's opinion that, while there is room for improvement in future NIOSH studies, it would be a disservice to the community of respirator users if the "good" features of the revised panel are abandoned in pursuit of longer-term "better." The LANL face panel was established in 1972, 34 years ago (Hack et al., 1974). The changing demographics of the respirator workforce requires that NIOSH face panels be more frequently updated. The development of these future panels would be greatly improved if NIOSH assured that the samples included in the panels were representative of workers who should be using respirators, and if NIOSH incorporated and validated three-dimensional measures, and measured quantitative fit.

Conclusion

The proposed NIOSH-sponsored Anthrotech face panel represents an improvement over the LANL face panel, and its application is likely to improve the availability of respirators that fit a broader segment of the workforce. However, the Committee also found that this study could have been greatly improved. In addition, the NIOSH face panels require periodic updates.

Recommendation 5-1: *Update the Panel More Often, Using a Scientifically Valid Design.*

NIOSH should plan to update the face panel more often to reflect the rapidly changing demographic structure of the U.S. workforce. To do so, it should (1) establish a valid sample of the target population for its respirator certification, (2) assure that the sample that is selected to establish a valid panel is representative of the target population, (3) apply three-dimensional measures to describe the essential fit characteristics of the panel, and (4) rely on

quantitative fit testing to determine the extent to which a respirator covers the fit characteristics of the face panel.

FACE PANEL VALIDATION

As discussed in Chapter 4, there are several concerns regarding the validity of the panel proposed by the NIOSH-sponsored Anthrotech study as currently designed. In addition to the analyses described in the preceding chapters, the committee recommends that NIOSH use its existing fit and facial dimensions data, and new quantitative fit tests, to evaluate the current LANL face panel, the proposed bivariate face panel, and the principal component analysis-derived face panel. Specifically, NIOSH should examine the following questions:

- Using the same brand of respirators, do the proposed face panels have an improved pass rate compared to the LANL face panels?
- Is there a specific subpopulation of respirator wearers selected by either of the proposed face panels who fail to obtain a satisfactory fit and who would have not been included in the proposed face panel?
- Do the proposed face panels exclude individuals who fail to obtain an adequate fit and who would have been included by the LANL face panel?

If there are no substantial differences in identifying wearers who fail to obtain a satisfactory fit among the different face panels, the identification of a new anthropometric face panel is more of an intellectual exercise than a practical improvement. Conversely, if one or both of the new panels do identify such test subjects, respirator manufacturers will have to develop new or redesign facepieces to meet certification requirements.

QUALITATIVE FIT TESTING

NIOSH currently uses a qualitative fit test as a part of its certification process. This involves the use of isoamyl acetate (IAA), also known as banana oil. Test subjects are asked to wear different respirators, while

IAA is introduced to the outside air. If a test subject indicates that they can sense the presence of IAA, the respirator fails the fit test. There are many potential difficulties that arise by using a qualitative test design, including the following:

1. *Individual variability in IAA sensitivity thresholds.* Because of individual variations in sensitivity, it is not possible to correlate a failed fit test with how much of the test substance leaked into the facepiece. The committee heard from NIOSH personnel that some respirator fit failures may be a result of above-average sensitivity of some subjects to the odor of IAA rather than from a poorly fitting respirator.
2. *Uncertainty of individuals as to whether they detect IAA.* NIOSH personnel informed the committee that during some fit-test exercises, test subjects are uncertain as to whether they briefly detected the odor of IAA. This raises doubts among the committee about these test results.
3. *Inability to determine quantitative numbers for respirator fit.* The IAA test is designed to produce a single pass/fail criterion. It does not assess how much better (or worse) the respirator may fit the subject than the pass criteria.

Conclusion

Qualitative fit testing is a subjective process and does not provide NIOSH certification personnel with a specific value to analyze leakage around the facepiece.

Recommendation 5-2: *Replace Isoamyl Acetate with Quantitative Measures.*

NIOSH should use quantitative measures for respirator fit-test certification. The current use of qualitative measures as a fit-test agent for certification, for example isoamyl acetate, should be discontinued.

CERTIFICATION OF FACE MASKS

Although certifying respirators against an anthropometric face panel does not eliminate the need for individual fit testing, it increases the likelihood that certified respirator facepieces will fit the workers they are designed to protect. As discussed in Chapter 4, the committee heard anecdotal evidence from a fit-test expert that in the case of half- or full-face respirators—which are certified against fit-test panels—it is possible to fit most respirator wearers if proper training is provided and different respirator brands and sizes are available (McKay, July 10, 2006). For example, in a recent study performed in the auto body repair and refinishing industry, it was shown that for half-face cartridge respirators, 92 percent of workers (both new and previously fit-tested workers) can be fitted with a respirator after two tries. Those without previous testing experience had a 72 percent pass rate (Liu et al., 2006). However, the same is not true for filtering facepiece respirators, which are not currently certified against a fit-test panel. Anecdotal evidence from experts who met with the committee and NIOSH suggests that there are brands that fit only a small proportion of faces in the workforce (McKay, July 10, 2006).

Conclusion

The failure to use anthropometric face panels for certification of filtering facepiece respirators may result in families of respirators that do not adequately fit some of the population of workers who should be using respirators.

Recommendation 5-3: ***Utilize the Revised Anthropometric Face Panel for Filtering Facepiece Respirators.***

NIOSH should include filtering facepiece respirators in the revised anthropometric face panel used for certification of half-facepiece respirators. Plans for any additional data gathering should be developed in consultation with experts in statistical sampling and measurement.

Challenges for Manufacturers

As described in the previous chapter, the LANL face panel has specific certification requirements for single-size facepieces (e.g., one size fits all) that are different from those facepieces that are available in multiple sizes (e.g., small, medium, large). NIOSH representatives told the committee that, because of these different certification requirements, it can be more difficult for manufacturers that produce multiple-size facepieces to meet the certification requirements than for those manufacturers that produce single-sized facepieces. NIOSH certification rules permit masks that are designed as "one size fits all" to fail on up to two panel members; whereas, masks that are available in multiple sizes will need to fit all panel members within specific panel categories, including the segments that border the next sizes. NIOSH should examine their certification requirements to ensure that they do not introduce an undue burden on manufacturers that make multiple-sized facepieces. The committee is concerned that certification requirements appear to make it more difficult for a set of multiple-sized respirators to pass than a single-sized respirator.

Given the indicated difficulty in certification that some manufacturers of multiple-sized facepieces have, and the ultimate goal of ensuring that everyone who needs a respirator is protected, the committee recommends that NIOSH certify a family of respirators (e.g., small, medium, and large) against a fit-test panel and not specify what portion of the panel the respirators must fit, provided that the family adequately covers the entire panel. This will eliminate current inequities among those manufacturers submitting a single size versus those submitting multiple sizes.

Future NIOSH certification regulations may wish to also take into account the importance of market forces in the development of respirator facial sizes, and the agency should do nothing to discourage those manufacturers who may wish to target a specific underrepresented range of wearers or facial shapes and sizes.

Conclusion

> *Manufacturers of multiple-sized facepieces often have difficulty obtaining certification for each individually sized facepiece.*
>
> **Recommendation 5-4:** ***Modify Certification Requirements.***
>
> **NIOSH should modify its certification requirements to encourage manufacturers to develop specific sizes designed to fit underrepresented anthropometric categories. Certification requirements should be modified to allow families of respirators (e.g., small, medium, and large) to be certified against a fit-test panel and not specify what portion of the panel each individual size respirator must fit, provided that the family adequately covers the entire panel.**

Clarifying Face Mask Packaging Requirements

The committee heard from experts and NIOSH staff that it is current industry practice to limit designation of fit attributes of half-face respirators to size—that is, small, medium, and large (McKay, July 10, 2006). This is largely due to inadequate details on the potential sizing of the facepieces on their packaging. As a result, fit testers and respirator-wearing workforces have difficulty determining which size and brand of facepiece is most appropriate for specific segments of the population. Respirator users would be helped by having more information on leakage characteristics of each respirator, in addition to the size information. This could be obtained by both manufacturers and certifiers producing data on fit characteristics and providing additional fit attributes, such as type of face (round, long, etc.) that would capture more facial features.

Conclusion

The current size designations of small, medium, and large for respirators in product literature are not adequately informative for wearers and fit testers.

Recommendation 5-5: ***Develop Improved Descriptions of Face Mask Sizes.***

NIOSH should encourage manufacturers to develop improved methods of describing facial sizes and shapes in product literature. For example, NIOSH and manufacturing companies should further explore the use of face panel images, and respirator containers should include corresponding pictures of small, medium, and large sizes, and long/narrow and small/wide face pictures.

PROVIDE ACCESS TO PRIMARY DATA

The committee believes that a number of stakeholders may benefit from access to NIOSH's revised face panel and the primary data that were used to develop the face panels. Special care is recommended to ensure that only good quality and reliable data is made accessible to stakeholders. In addition, guidelines to approve requests for use of the data need to be established to ensure good use of the data. They include the following:

- *Regulators*. NIOSH for its certification program and OSHA in future revisions of respiratory protection standards
- *Respirator manufacturers*. By introducing the design of newer face piece models that will better fit the needs of their customers
- *Respirator program administrators*. By improving the selection and fit of respirators, and by fitting more of their employees
- *Respirator users (workers)*. By having a selection of facepieces that better fit the variety and sizes of their faces (especially those in the outlying areas of design)

- *Researchers in the field of respiratory protection*. By using data from the panel to validate fit-testing methods and protection factors for different types of respirators
- *The international community of respirator manufacturers, regulators, and researchers*. By identifying basic approaches to the collection and analyses of anthropometric data necessary for identifying the sizes and shapes of respirators to fit the ethnic diversity of workers. It may also be possible to establish one or more universally accepted face panels for this purpose.

IMPROVING THE PRACTICE OF RESPIRATORY PROTECTION

NIOSH can enhance the practice of respiratory protection in two broad areas: through periodic recertification of respirators against a regularly updated panel (see Recommendation 5-1) and through improvements in the practice of using respirators in the workplace. It is difficult for the committee to define the exact frequency of the periodic recertification as it would be based on many changing variables, such as changes in the workforce demographics.

The committee notes that, although certification of respirators is important and necessary, certification alone does not ensure that workers are properly protected. Limited research studies have confirmed that the selection of a respirator based solely on its size, without the benefit of individual fit testing, will produce a poorly-fitting respirator 30 to 40 percent of the time (Coffey et al., 1999). The effectiveness of the protection offered depends on the appropriate fit to a worker's face, which in turn is affected by the user's facial size and contours, the training in selecting the right respirator, and wearing it properly. Therefore, in addition to certification, it is critical that individual fit testing be conducted by employers, as currently required by OSHA. This step will ensure, not only that users are provided with respirators that fit them appropriately, but it also ensures that they have the competence necessary to don and use the devices properly. As such, in circumstances where fit testing can not be realistically conducted, it may behoove the employer to, instead, offer hoods, or other loose-fitting respirators that offer protection without needing to be fitted to each wearer.

Although the characteristics of the workforce are dynamic, NIOSH's certification of respirators is static: once certified, a respirator is certified forever. NIOSH may wish to examine the possibility of updating certification regulations to keep up with changes in the workforce. That is, NIOSH might wish to periodically retest certified respirators by comparing them to a fit-test panel that is updated regularly.

The Occupational Safety and Health Administration (OSHA) has issued regulations that require employers to maintain respiratory protection programs in general industry, shipyards and marine terminals, and construction. The implementation of a respiratory protection program requires significant technical expertise. However, most employers are very small and do not have the necessary resources readily available. In addition, there is a growing trend for workers to be self-employed as independent contractors. For instance, in the construction industry, the self-employed portion of total employment now approaches one-third, up from about 7 percent 30 years ago (U.S. Department of Labor, 2006). Thus, in the real world, many workers who should be covered by respiratory protection programs work under conditions of minimal safety supervision and often with no respiratory protection.

Simplification of respirator use is therefore critical if the goal is to increase use of appropriate respiratory protection. Additional interdisciplinary research is needed to develop respirators that do not require fit testing, are more user friendly, and require minimal maintenance. To this end, using virtual face panels to model future respirators could enhance product development. Included in these interdisciplinary teams should be researchers who focus on the impact of human factors, biomechanics, biomaterials, respiratory protection, and others. It could also make possible the progressive development of low-cost disposable respirators that provide significantly greater protection against a much broader range of hazards.

Increased Confidence in the Protection Factors

The proper use of the face panel, along with quantitative fit testing, can define protection factors used by employers. NIOSH can determine minimally acceptable protection factors for each style of respirator (e.g., half-face negative pressure, full-face negative pressure), and use those standards as part of the certification process. If most half-face respirators can provide a fit factor of 500 (the current minimum acceptable level is 100), this could become the new standard (Code of Federal Regulations, 1998). However, these efforts are dependent on NIOSH beginning to use quantitative fit testing in their certification process.

DEVELOPING FACE PANELS APPLICABLE TO THE WORLD'S WORKFORCE

Representatives from large respirator manufacturers described to the committee that their companies conduct fit testing using the current LANL face panel. But because they also sell respirators outside the United States, these companies must also examine facial sizes from other countries (e.g., the Asian and Pacific rim nations) to determine what modifications in their facepieces will improve the fit to workers from other countries and to produce respirators that may target a specific range of facial sizes or unique facial shapes.

Although the proposed NIOSH-sponsored Anthrotech face panel was designed to represent only the U.S. workforce, NIOSH personnel indicated an interest in using it as the foundation for the development of international standards. Maintaining an up-to-date head and face panel can be both financially and scientifically challenging. It is also an area where international scientific collaboration could be beneficial. Because the U.S. population is among the world's most diverse, with representation from most racial groups and ethnicities, it makes sense to start with a face panel that is representative of the U.S. population and build on that to accommodate ethnicities that are less well-represented in the United States than they are elsewhere. The following actions would support such development:

- Validate a digitized scanning protocol that investigators can use to develop head and facial images.
- Develop a detailed ethnic, geographic, and demographic classification system to be applied to head and facial images derived from digitized scanning.
- Establish a database to store an ever-expanding number of images.
- Enlist and approve or register investigators from around the world to perform digital scanning of images with certification to assure that scanning is done according to protocol.
- Develop an electronic system for submission of images from investigators who have been approved.

- Make the database available to approved investigators so that they can create virtual head-and-face panels suitable to their research interests or needs.

REFERENCES

Code of Federal Regulations. 1998. Respiratory protective devices: 29 C.F.R. § 1910, 1915, 1917, 1918, 1926.

Coffey, C. C., D. L. Campbell, and Z. Zhuang. 1999. Simulated workplace performance of n95 respirators. *Am Ind Hyg Assoc J* 60(5):618-624.

Hack, A. L., E. C. Hyatt, B. J. Held, T. D. Moore, C. P. Richards, and J. T. McConville. 1974. *Selection of respirator test panels representative of U.S. adult facial sizes.* Los Alamos, NM: Los Alamos Scientific Laboratory.

Liu, Y., M. H. Stowe, D. Bello, S. R. Woskie, J. Sparer, R. Gore, F. Youngs, M. R. Cullen, and C. A. Redlich. 2006. Respiratory protection from isocyanate exposure in the autobody repair and refinishing industry. *J Occup Environ Hyg* 3(5):234-249.

McKay, R. T. July 10, 2006. Presentation to Committee for the Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users: Respirator fitting issues. Pittsburgh, PA: National Personal Protective Technology Laboratory.

U.S. Census Bureau. 2006. *Occupations: 2000*. http://www.census.gov/prod/2003pubs/c2kbr-25.pdf (accessed December 15, 2006).

U.S. Department of Labor. 2006. *Career guide to industries: Construction*. http://www.bls.gov/oco/cg/cgs003.htm (accessed December 15, 2006).

———. 2006. *Employed persons by detailed occupation, sex, race, and Hispanic or Latino ethnicity*. http://www.bls.gov/cps/cpsaat11.pdf (accessed December 15, 2006).

Zhuang, Z. 2001. *Anthropometric survey of respirator users: Study protocol.* National Institute for Occupational Safety and Health.

A

Data Sources and Methods

The Committee on the Assessment of the National Institute for Occupational Safety and Health's (NIOSH's) Head-and-Face Anthropometric Survey of U.S. Respirator Users conducted four in-person meetings, heard from subject matter experts, and reviewed a wide body of technical literature prior to making its final findings, conclusions, and recommendations.

In accordance with National Academies' procedures, a list of the committee members was posted for public comment for 20 days prior to the first committee meeting, and members of the public were given the opportunity to provide comment on the committee's work throughout the course of the study.

The committee was provided a copy of NIOSH's 2004 report *A Head-and-Face Anthropometric Survey of U.S. Respirator Users* in addition to copies of other relevant articles: *Analysis of 3D Data for the Improvement of Respirator Seals—Final Report* (2004)*, Study Protocol—Anthropometric Survey of Respirator Users* (2001)*, Supporting Statement—Anthropometric Survey of Respiratory Users* (2002)*,Program to Establish Quantitative Respirator Fit Testing at NIOSH TCB* (1977), *Respirator Studies for the National Institute of Occupational Safety and Health* (1976), *Selection of Respirator Test Panels Representative of U.S. Adult Facial Sizes* (1976), *Final Report—Anthropometry for Respirator Sizing* (1972), *Appendix A—References and Background Bibliography on Anthropometry (1944-1970) and Respiratory Protective Devices (1919-1962)* (1970), and *Appendix B—General Qualifications, Experience and Facilities—Personnel Resumes* (1970) provided by the sponsor. Additionally, the committee reviewed a wide body of other technical literature written by industrial hygienists, dentists, plastic surgeons, anthropologists, and other experts concerned with and experienced in measuring the head and facial features of persons.

MEETINGS

The committee's first meeting was held on November 3-4, 2005. During the course of that meeting, the committee became acquainted with each other and with their charge. They also heard from the sponsor regarding their view on the study.

A second meeting of the committee was held on December 8-9, 2005. The committee used this meeting to gain a deeper understanding of the sponsor's perspectives on the study of the potential impact the revised panel will have on outside parties.

Following that second meeting, the work of that committee was put on hold, so that several members of that committee and the Academies staff could answer an urgent request from the Department of Health and Human Services regarding the potential reusability of respirators (see the IOM report *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu,* 2006). During this interim period, the committee continued to communicate via e-mail and discuss questions central to their statement of task.

The committee's work resumed on July 10-11, 2006, with a meeting in Pittsburgh, Pennsylvania. During this meeting the committee heard from respirator manufacturers and the sponsor. Additionally, the committee was given the opportunity to tour the National Personal Protective Technology Laboratories (NPPTL).

The committee's final meeting was held in Irvine, California, on August 23-24, 2006. This served as a writing meeting for the committee wherein they came to consensus on their conclusions and recommendations and the structure of the report.

Agendas for the open meetings are provided in Boxes A-1 through A-3.

BOX A-1

Agenda: Committee Meeting

Thursday, November 3, 2005
Washington, D.C.
Room 201

OPEN SESSION

12:00 p.m.	Lunch
1:00	Welcome and Introductions *John Bailar* Committee Chair Professor Emeritus, University of Chicago
1:15	Background and Charge to the Committee *Maryann D'Alessandro* National Institute for Occupational Safety and Health, (NIOSH) National Personal Protective Technology Laboratory, (NPPTL)
1:30	NPPTL Overview *Les Boord* NIOSH, NPPTL *William Newcomb* ISO Update
2:00	History of the Respirator Panel *Roland Berry Ann* NIOSH, NPPTL
2:30	Break
2:45	Current Research of the Respirator Panel *Ziqing Zhuang* NIOSH, NTTPL
3:45	Open Questions to the NPPTL Presenters
4:15	Similar Efforts in the DoD *Alex Pappas* Edgewood Chemical Biological Center
4:45	Discussion
5:30	Adjourn Meeting

BOX A-2

Agenda: Committee Meeting

Thursday, December 8, 2005
Washington, D.C.
Keck Center, Room 206

OPEN SESSION

10:00 a.m.	Welcome and Introductions *John Bailar* Committee Chair Professor Emeritus, University of Chicago
10:15	Use of the Anthropometric Panel - Total Inward Leakage vs. Fit Test vs. User Seal Check - Demonstration of Respirator Fit-Test Techniques - Standard-Setting Organizations *William Newcomb* National Institute for Occupational Safety and Health, (NIOSH) National Personal Protective Technology Laboratory, (NPPTL)
11:15	Review of 3D Imaging Techniques Used in the NIOSH Data Collection *Ziqing Zhuang* NIOSH, NPPTL
12:00 p.m.	Lunch (Provided in Room 206)
1:00	Review of Potential Impact of the Revised Panel on Workforce Users *Jim Platner* Center to Protect Workers' Rights
1:45	Discussion of the Committee's Statement of Task *Maryann D'Alessandro* NPPTL
2:30	Open Questions for All Speakers
3:00	Adjourn Open Session

BOX A-3

Agenda: Committee Meeting Number 3

Monday, July 10, 2006
Pittsburgh, PA
National Personal Protective Technology Laboratory
Pittsburgh, PA 15236
Bldg. 140 (Conference Room)

OPEN SESSION

7:00 a.m.	**Meet in Lobby for Shuttle Transportation to NPPTL** Crowne Plaza Hotel–Pittsburgh Int'l Airport 1160 Thorn Run Road Coraopolis, PA 15108
8:15	**Continental Breakfast**
8:45	**Call to Order and Introductions**
	Review the Statement of Task *Maryann D'Alessandro* *National Personal Protective Technology Laboratory (NPPTL)*
9:00	**Anthropometrics Research to Practice** LANL Panel Representation *Roland Berry Ann, NPPTL* Current Certification Testing *Heinz Ahlers, NPPTL* Total Inward Leakage *Bill Hoffman, NPPTL*
10:15	**Time for Questions**
10:30	**Break**
	Manufacturer's Anthropometric Data
10:45	*Jeffrey Birkner, Moldex*
11:05	*Julie Tremblay, Aearo*
11:25	*Bob Weber, 3M*
11:45	**Time for Questions**
12:15	**Lunch**

1:15	**Fit-Test Issues** *Roy McKay* University of Cincinnati
1:45	**Time for Questions**
2:00	**Break**
2:15	**Tour of NPPTL**
2:30	**Respirator Certification Lab Tours–Heinz Ahlers** Tour of Certification Lab–Bldg. 37
3:30	**Technology Research Branch Lab Tours–Ron Shaffer** Tour of Anthropometrics and Chemistry Lab–Bldg. 13 Tour of Physiology Lab–Bldg. 29
5:30	**Adjourn Meeting**

B

Acronyms

3D	Three-dimensional
3M	Minnesota Mining and Manufacturing Company
CAESAR	Civilian American and European Surface Anthropometry Resource
CV	Coefficient of variation
GPA	Generalized procrustes analysis
ISO	International Standards Organization
LANL	Los Alamos National Laboratory
NIOSH	National Institute for Occupational Safety and Health
NPPTL	National Personal Protective Technology Laboratory
OSHA	Occupational Safety and Health Administration
PCA	Principal component analysis
QlFT	Qualitative fit test
QnFT	Quantitative fit test
TiL	Total inward leakage

C

2001 NIOSH Protocol and 2004 NIOSH-Sponsored Anthrotech Report: A Head-and-Face Anthropometric Survey of United States Respirator Users

In 2001 NIOSH contracted Anthrotech, Inc., to perform a comprehensive anthropometric study of respirator users in the United States workforce and to propose new fit-test face panels based on their findings. To accomplish these aims, Anthrotech recruited 4,026 subjects from 41 different sites in eight states. The subjects were employed in various industries and organizations that required either the regular or the occasional use of respirators. Each subject was measured for 21 dimensions, such as menton-sellion length, bizygomatic breadth, and lip length using traditional anthropometric tools. Based on the data collected, Anthrotech proposed two new panels for half- and full-face respirator fit testing. The results of this survey and the analysis that followed were detailed in the 2004 Anthrotech report to NIOSH "A Head-and-Face Anthropometric Survey of U.S. Respirator Users."

A complete version on the 2001 NIOSH protocol and the 2004 Anthrotech report to NIOSH may be found by viewing Appendix C at the following website: *http://www.nap.edu/catalog/11815.html*.

D

Committee and Staff Biographies

COMMITTEE

John C. Bailar III is Professor Emeritus of the University of Chicago and has been an Institute of Medicine (IOM) member since 1993. He holds both an M.D. and a Ph.D. His primary areas of expertise are epidemiology and biostatistics. More specifically he has interests that include risk assessment, especially of chemical hazards and air pollutants; biostatistics and epidemiology, especially as related to cancer; misconduct in science; combining research results; and Persian Gulf syndrome. Dr. Bailar has chaired six National Research Council (NRC) studies and has been a member of many more. He is also currently a member of the National Academies Report Review Committee.

Lisa M. Brosseau is an Associate Professor in the School of Public Health at the University of Minnesota. She received her Sc.D. in Environmental Health Sciences, Industrial Hygiene, from Harvard University. Her research interests include performance of respiratory protection devices, aerosol measurement, filtration, and health and safety interventions in small businesses.

Howard J. Cohen is a Professor and Chair of the Occupational Safety and Health program at the University of New Haven. He formerly was the Manager of Industrial Hygiene at the Olin Corporation and Editor in Chief of the *American Industrial Hygiene Association Journal*. He is a graduate of Boston University where he received a B.A. degree in Biology. Dr. Cohen received his Masters of Public Health and Doctorate of Philosophy degrees in Industrial Health from the University of Michigan.

He is certified in the comprehensive practice of industrial hygiene (CIH) by the American Board of Industrial Hygiene. Dr. Cohen is the past chair of the ANSI Z88.2 committee on respiratory protection and a current member of the editorial board of the *Journal of Occupational and Environmental Hygiene*. He is the past chair of the American Industrial Hygiene Association's respiratory protection committee, a past president of the Connecticut River Valley Chapter of the American Industrial Hygiene Association, and a past officer and treasurer of the American Board of Industrial Hygiene.

Alan Hack is retired from the Los Alamos National Laboratory (LANL). He is certified in Comprehensive Practice of Industrial Hygiene (CIH) and is a Certified Safety Professional (CSP). He has a Masters in Industrial Safety that he received in 1967 from New York University. He has extensive experience with facial measurements and respirator fit testing. Mr. Hack is currently working as a consultant. He is a member of two committees: the ANSI Committee on Respiratory Protection and the American Industrial Hygiene Association Committee on Respiratory Protection.

Subhash R. Lele is a Professor in the Department of Mathematical and Statistical Sciences at the University of Alberta. He has a Ph.D. in Statistics from Pennsylvania State University. Dr. Lele has expertise in statistical analysis of forms and shapes with applications in medicine, spatial data analysis and its applications in public health, ecology, and environmental sciences.

Youcheng Liu is an Assistant Professor of Medicine at Yale University. He received his M.D. in 1983 from Nanjing Medical University, an M.P.H. in Environmental Health Sciences in 1987 from Peking University School of Public Health, an M.S. in Environmental Health in 1994 and a Sc.D. in Industrial Hygiene in 1997, both from the Harvard School of Public Health. Dr. Liu's expertise is in exposure assessment and modeling, indoor air sciences, industrial hygiene, and occupational epidemiology, with considerable expertise in respirator fit testing and respirator workplace performance evaluation.

Knut Ringen is a private consultant in disease management, environment, safety and health risk management, workers' compensation, and group health insurance. Dr. Ringen specializes in the development of research and service programs with an emphasis on workers and other special populations, and has been instrumental in developing many health programs that have achieved national significance. Among many honors, he is elected to the European Academy of Sciences and the Collegium Ramazzini. He received his Doctor of Public Health degree from Johns Hopkins University for his research on the development of health policy, a Master's degree in hospital administration from the Medical College of Virginia, and a Master's of Public Health degree from Johns Hopkins University.

Joan T. Richtsmeier is a Professor of Anthropology at Pennsylvania State University. Dr. Richtsmeier received her Bachelor's degree from St. Mary's College in 1977, her Master's degree from the University of Nebraska-Lincoln in 1979 and her Ph.D. in Anthropology from Northwestern University in 1986. She conducted postdoctoral research at Northwestern University Medical School before joining the faculty of the Department of Cell Biology and Anatomy at the Johns Hopkins University School of Medicine as Assistant Professor in 1987. She became Full Professor of Cell Biology and Anatomy in 1999. Dr. Richtsmeier moved her laboratory to the Department of Anthropology at Pennsylvania State University in 2000. Dr. Richtsmeier's interests include craniofacial growth and evolution, quantitative morphology, the relationship between ontogenetic mechanisms and phylogenetic change, and the molecular basis of craniofacial development. Her current research focuses on phenotype-genotype correlations in craniosynostosis and craniofacial dysmorphology in Down syndrome.

Javier Rojo is a Professor of Statistics at Rice University. He holds a Ph.D. in Statistics from the University of California, Berkeley. His research interests include nonparametric statistics, survival analysis reliability, decision theory, and partial orders of probability distributions. Dr. Rojo was Program Director for Probability and Statistics at the National Science Foundation and is an elected Fellow of the Royal Statistical Society, the American Statistical Association, and the Institute of Mathematical Statistics. Dr. Rojo was a member of the Committee on Fellows of the American Statistical Society and chaired the committee in

2004. He is a member of several advisory boards and Director of the Summer Institute of Statistics—an REU NSF/NSA-supported center at Rice University.

Albert A. Sciarretta is President of CNS Technologies, Inc. His company conducts assessments of advanced military technologies, as well as designs and executes operational demonstrations and experiments. He has a background in human factors engineering and recently designed a test scenario for assessing human performance in a combat environment. His expertise includes adapting commercial off-the-shelf (COTS) technology for military use. He is a retired Army officer with two Master's degrees: one in Operations Research and the other in Mechanical Engineering; both were obtained at Stanford University in 1984. Mr. Sciarretta has worked on many NRC study committees in the past.

STAFF

Emily Ann Meyer is a program officer at the IOM. She earned a law degree at Hamline University, where she also served as a research fellow. Prior to coming to IOM, she worked in the Division of Engineering and Physical Sciences' National Materials Advisory Board. More recently, she was the study director for the IOM committee that produced the report *Cord Blood: Establishing a National Stem Cell Bank Program.* She is currently directing the study on Evaluating the National Institute of Occupational Safety and Health Head-and-Face Survey of U.S. Respirator Users.

Andrew Pope is director of the board on Health Sciences Policy in the Institute of Medicine. With a Ph.D. in physiology and biochemistry, his primary interests are in science policy, biomedical ethics, and the environmental and occupational influences on human health. During his tenure at the National Academies, and since 1989 at the Institute of Medicine, Dr. Pope has directed numerous studies on topics that range from injury control, disability prevention, and biologic markers to the protection of human subjects of research, National Institutes of Health priority-setting processes, organ procurement and transplantation policy, and the role of science and technology in countering terrorism. Dr. Pope is the recipient of the National Academy of Sciences President's Special Achievement Award and the Institute of Medicine's Cecil Award.

Bruce M. Altevogt is a senior program officer in the Board on Health Sciences Policy at the Institute of Medicine. He received his doctorate from Harvard University's Program in Neuroscience. While at Harvard, Dr. Altevogt studied how the glial cells in the central and peripheral nervous system form a network of cells through intracellular communication, which is critical for maintaining myelin. Following his Ph.D., Dr. Altevogt was a policy fellow with the Christine Mirzayan Science & Technology Policy Graduate Fellowship Program at the National Academies. He has over 10 years of research experience. In addition to Dr. Altevogt's work at Harvard, he also performed neuroscience research at National Institutes of Health and University of Virginia. He received his B.A. from the University of Virginia in Charlottesville where he majored in biology and minored in South Asian studies. Since joining the Board on Health Sciences Policy, he was a program officer on the IOM studies *Spinal Cord Injury: Progress, Promise, and Priorities* and *Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem*, he is serving as the director of the Neuroscience and Nervous System Disorders Forum and a co-study director on the National Academy of Sciences Human Embryonic Stem Cells Research Advisory Committee.

Sarah L. Hanson is a research associate in the Board on Health Sciences Policy at the Institute of Medicine. Ms. Hanson previously worked for the Committee on Sleep Medicine and Research. She is currently the research associate for the Forum on Neuroscience and Nervous System Disorders. Prior to joining the Institute of Medicine, she served as research and program assistant at the National Research Center for Women & Families. Ms. Hanson has a B.A. from the University of Kansas with a double major in political science and international studies. She is currently taking pre-med courses at the University of Maryland and hopes to attend medical school in the future.

Amy Haas is the administrative assistant for the Board on Health Sciences Policy. She previously served as a senior project assistant for the Clinical Research Roundtable. Prior to joining IOM, she worked as a project manager for a medical education and publishing firm in Washington, DC. She graduated from Whitman College in Walla Walla, Washington with a B.A. in biology.

Lora K. Taylor is a senior project assistant for the Board on Health Sciences Policy working on the Sleep Medicine and Research project. She has 14 years of experience working in the academy and prior to joining the Institute of Medicine, she served as the administrative associate for the Report Review Committee and the Division on Life Sciences' Ocean Studies Board. Ms. Taylor has a B.A. from Georgetown University with a double major in psychology and fine arts.

Vilija Teel is senior project assistant for this study, providing administrative support for the project. Ms. Teel plans and coordinates logistical arrangements for committee meetings, including coordinating travel and lodging for committee members, overseeing the attendee registration process during open sessions, and providing support throughout the committee meeting. She also provides support for the project's financial management, including processing payment requests and ensuring timely reimbursement of travel and incidental expenses. Ms. Teel earned a B.A. in English/Linguistics from Vilnius University and has taken additional course work in finance and management areas. She is proficient in all of the major office-environment software programs. In addition to English, she has a good grasp of many other languages.