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ACTION PLAN

NPPTL Facial Anthropometrics Research Roadmap

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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,
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."

NPPTL is responding to the IOM report by developing an action plan for addressing the issues and recommendations described in the report. The action plan will provide a long-term strategy for facial anthropometrics and respirator fit research at NPPTL. The action plan will also describe how to implement research to practice. This draft action plan was developed by:

- analyzing the IOM recommendations to determine if existing data is available to make decisions on whether the recommendations could and/or should be implemented or not;
- reviewing on-going and proposed NPPTL research projects; and
- reviewing on-going research in NIOSH, academia, government, and industry related to anthropometrics and respirator fit.

The next two sections describe: (1) the NPPTL assessment of the IOM recommendations, i.e., detailed point by point response to each IOM recommendation; and (2) NPPTL facial anthropometrics research roadmap, i.e., prioritized 10-year plan for a sequence of research projects to address information gaps.

Timeline to finalize the action plan is described as follows:

- Detailed draft action plan posted to NPPTL website (July/August 2007)
- Open docket to solicit comments for 90 days (September – November 2007)
- Revise action plan based on comments received (January 2008)

The final action plan will be used to prioritize and select future NPPTL research projects including funding, staffing, and upgrading laboratory capabilities.

II. Assessment of the IOM Recommendations

The detailed conclusions and recommendations by the IOM committee and point by point response to each recommendation by NPPTL are described as follows.

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

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intraobserver and interobserver variations in measurement.

Action Item 2-1: NPPTL will characterize the measurement error in future studies. A new study has been initiated to investigate how face size and respirator fit change over time. Measurement error will be analyzed in that study and a comparison will be made between traditional measurement data and 3-D scan data. Recently, NPPTL obtained the capability to extract scan data which will enable improved analysis of 3-D data. Future research is planned to develop standardized methods for 3-D head-scanning & automated facial anthropometrics. That research will be needed in order to reduce intra- and inter-observer variations seen with automated systems.

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 3-D scans may be compared.

Recommendation 2-2: Consider Utilizing 3-D Scan Data. NIOSH should consider collecting and utilizing data from 3-D 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.

Action Item 2-2: NPPTL will conduct a study to analyze the 3-D data collected from the field survey. The objective is to identify features of facial and/or respirator variation that influence respirator effectiveness using modern methods of biological shape analysis (morphometrics). The identified features will be compared to those obtained from traditional measurement tools. Future research is also planned to develop standardized methods for 3-D head-scanning & automated facial anthropometrics.

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).

Action Item 3-1: There is little demographic information on respirator users and the new NPPTL panels incorporate the best available information. This concern was discussed in the NAS report titled "Measuring Respirator Use in the Workplace". If new surveillance data such as the number of male and female users, their race and age become available, NPPTL can reweigh the current sample to determine if revisions need to be made. Future panels (if needed) will utilize the best available

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information to develop appropriate sampling plans.

Data Analysis and Fit-Test Panels

Conclusion 4-1: 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 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).

Action Item 4-1: The current facial anthropometric survey consists of four ethnic groups: White, African American, Hispanic, and Others. We plan to conduct additional analyses to demonstrate differences in facial dimensions among gender, race, and age groups. This data will be incorporated into improved headforms and sizing systems. If future data show that facial dimensions for any group are not representative of that group anymore, NPPTL will benchmark respirator users for that group. Future panels (if needed) will utilize the best available demographic information to develop appropriate sampling plans.

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.

Action Item 4-2: The two new NPPTL panels already cover more than 95% of the current U.S. workforce. Subsequent analysis has validated the representativeness of the survey design. For example, the NPPTL bivariate panel also covers about 95% of the subjects from a survey titled "Civilian American and European Surface Anthropometry Resources" conducted by U.S. Air Force in 2002. The NPPTL bivariate panel also covers more than 95% of a sample of 114 subjects measured by 3M Company in St. Paul, MN and another sample of 86 subjects recruited by NPPTL in Pittsburgh, PA for respirator certification testing. Some international data has been collected to demonstrate the applicability of the fit test panels. An analysis of the Chinese population was conducted. That study found that >95% of the Chinese respirator users surveyed fall with the boundaries of the NPPTL bivariate and PCA panels. As part of our continuing efforts to analyze the 2003 anthropometric survey data and planned analysis of future data collections that incorporate respirator fit test data, we will explore alternative panel designs, including expanding the panel to cover 99% of the workforce, including larger numbers of subjects, or nonlinear designs (pages 77-78 of the NAS report).

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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.

Action Item 4-5: NPPTL has initiated a study to investigate correlation between respirator fit and facial dimensions and 3-D parameters. Data collection has been completed. More analyses will be conducted to investigate how respirator fit correlates to facial dimensions, 3-D parameters, and shape parameters. If possible, simple and efficient derived measurements relevant to respirator fitting/efficacy will be identified. Another study will be initiated to analyze the 3-D data collected from the field survey (Appendix B). The objective is to identify features of facial and/or respirator variation that influence respirator effectiveness using modern methods of biological shape analysis (morphometrics). The identified features will be compared to those obtained from traditional measurement tools. These results are expected to be applicable to respirator performance in workplace. We agree that nasal features are important to respirator fit and will be considered in continuing studies to assess alternative panel designs.

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.

Action Item 4-6: More analyses will be conducted to investigate how respirator fit correlates to facial dimensions, 3-D parameters, and shape parameters. If possible, simple and efficient derived measurements relevant to respirator fitting/efficacy will be identified. A study will be initiated to analyze the 3-D data collected from the field survey. The objective is to identify features of facial and/or respirator variation that influence respirator effectiveness using modern methods of biological shape analysis (morphometrics). The identified features will be compared to those obtained from traditional measurement tools.

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.

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Action Item 4-7: NPPTL will consider multiple features in the development of future fit-test panels using the results from various studies described above to address the committee's recommendations.

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 3-D 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.

Action Item 5-1: NPPTL will determine if the NPPTL panel needs to be revised and updated in 2013. The 2010 U.S. census data will be used to reweigh the current sample and see if a revision is necessary. If other facial measurements (e.g. in the nasal region), shape statistics, and/or 3-D parameters are found to be more relevant to respirator fit, they may be used to develop new fit-test panels. If an alternative design (e.g., nonlinear, larger number of subjects, wider boundaries to incorporate a larger % of the workforce, etc.) is found to be a significant improvement over the current NPPTL panels, this information may be used in the design of future panels. If necessary, new anthropometric data will be collected.

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 face piece.

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, such as isoamyl acetate, should be discontinued.

Action Item 5-2: NPPTL will replace Isoamyl Acetate with quantitative measures for respirator fit-test certification.

Conclusion 5-3: The failure to use anthropometric face panels for certification of filtering face-piece 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 Face-

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Piece Respirators. NIOSH should include filtering face-piece 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.

Action Item 5-3: NPPTL will utilize the NPPTL panel for certifying filtering-facepiece respirators. This will be done when the TIL program is implemented for all half masks. Dr. Doug Landsittel is providing statistical support to develop performance requirements and subject selection criteria. As was done with all previous NPPTL surveys and data collections, external scientific peer-review will be performed prior to initiation. Additional statistical input will be sought as part of the NIOSH peer-review process to ensure that the statistical sampling, measurement, and analysis use the best available practices.

Conclusion 5-4: Manufactures of multiple-sized face pieces often have difficulty obtaining certification for each individually sized face piece.

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.

Action Item 5-4: When the TIL program is implemented, NPPTL will establish certification requirements to encourage manufacturers to develop specific sizes designed to fit underrepresented anthropometric categories. Certification requirements will allow families of respirators (e.g., small, medium, and large) to be certified against the NPPTL 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.

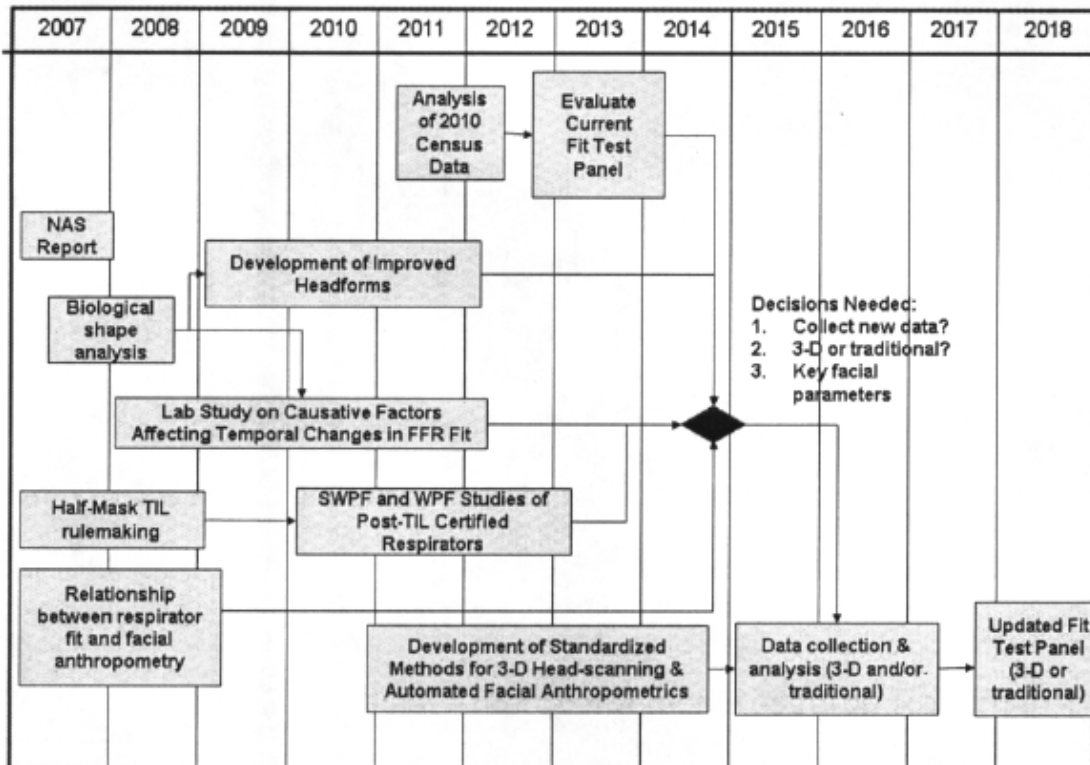
Action Item 5-5: NPPTL will encourage manufacturers to develop improved methods of describing facial sizes and shapes in product literature. For example, NPPTL and manufacturing companies will further explore the use of face panel images, and respirator containers should include corresponding pictures of small, medium, and large sizes, and long/narrow and small/wide face pictures. NPPTL also plans to conduct additional research to develop improved headforms and sizing

systems for respirators.

III. NPPTL Facial Anthropometrics Research Roadmap

The draft action plan, i.e., NPPTL facial anthropometrics research roadmap is illustrated graphically in Figure 1. The action plan is described in text as follows.

Figure 1. NPPTL Facial Anthropometrics Research Roadmap



On-Going Research Projects

Two NPPTL on-going projects can be used to implement some of the action items. These projects are titled “Development of computer-aided face-fit evaluation methods” and “Frequency of fit testing”. They are subsequently referred to as Project A and Project B in this action plan. Within the scope of these two projects, there are several smaller studies. These smaller studies are shown in Figure 1 and are discussed in more detail below.

To implement Action Items 4-5, 4-6, and 4-7, more analyses will be conducted to investigate how respirator fit correlates to facial dimensions, 3-D parameters, and shape parameters. This activity is an on-going study under the project plan for Project A. This

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study is titled "An Investigation of the Relationship between Respirator Half-Facepiece Fit and Facial Anthropometry Using Three-Dimensional Laser Scanning Technology". Data collection for this study has been completed. After the analyses and if possible, simple and efficient derived measurements relevant to respirator fitting/efficacy will be identified and incorporated into future panels. This activity is anticipated to be completed by the end of 2008.

To implement Action Items 2-2, 4-5, 4-6, and 4-7, another study (within the scope of Project A) was initiated to analyze the 3-D data collected from the field survey (denoted as "Biological shape analyses" in Figure 1). The objective is to identify features of facial and/or respirator variation that influence respirator effectiveness using modern methods of biological shape analysis (morphometrics). The identified features will be compared to those obtained from traditional measurement tools. A detailed study plan is described in Appendix B. This activity is also anticipated to be completed by 2008.

To implement Action Items 3-1, 4-1, and 5-5, more analyses will be conducted to determine differences in facial dimensions among race and age groups. Data from the NIOSH survey in 2003 will be used for this activity. This information will be incorporated into representative headforms for respirator testing and improved sizing systems. This activity is also anticipated to be completed by 2008.

Since face seal leakage is the single most important detriment to adequate respirator performance, it is widely accepted that every respirator wearer must be fit tested (typically once a year) to verify that the respirator model and size have been properly selected. In 2007, NPPTL initiated a study to assess the causative factors affecting temporal changes in filtering-facepiece respirator fit. The study is being conducted under project plan for Project B. The goals of this study are to (a) assess the rate at which respirator fit changes as a function of time for a representative sample of subjects wearing filtering-facepiece respirators and (b) investigate the factors that affect such change. The specific aims of this study are to (1) determine – for time intervals of 6, 12, 18, 24, 30, and 36 months – the number of instances where a subject's respirator penetration increases more than 25%, (2) determine – for the same time periods – the number of instances where a subject's fit becomes unacceptable, (3) determine the corresponding percentages of test subjects whose respirator penetration increases more than 25% and whose fit becomes unacceptable during the these time intervals, (4) assess the extent to which changes in fit are associated with recognizable changes in the subject characteristics, and (5) investigate the correlation between respirator fit and subject characteristics at every six month interval. An external scientific peer review of this protocol (Appendix A) with seven scientific reviewers was initiated in April 2007 and completed in June 2007. NPPTL researchers are analyzing the reviews to determine how best to modify the protocol to address the scientific review comments. Data collection will begin upon approval of the revised protocol by NPPTL leadership. This research addresses the recommendation provided by the National Academies in the report published in 2007 which states: "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." This

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study will investigate how face size and respirator fit change over time. This data will provide a critical dataset to analyze alternative panel designs. Thus, Action Items 2-1, 4-2, 4-3, 4-5, 4-6, and 4-7 can be implemented through this study. This study is anticipated to be completed in 2012.

New Research Projects

Currently, analyses are being conducted to determine differences in facial dimensions among race and age groups using the data from the NIOSH survey in 2003. This information will be incorporated into representative headforms for respirator testing and improved sizing systems. Beginning in 2009, a new project will be initiated to evaluate the new headforms and determine their utilities in designing and testing respirators.

After the NPPTL total inward leakage program for half masks is implemented, a project will be initiated to determine how well future certified respirators using new total inward leakage requirements and the NIOSH panel fit the user population. Simulated workplace protection factor (SWPF) or workplace protection factor (WPF) studies will be conducted. This activity will be done to implement Action Item 4-4. This project will be initiated in 2010 as shown in Figure 1.

To implement Action Items 2-1 and 2-2, NPPTL will initiate studies on the development of standardized methods for 3-D head scanning and automated facial anthropometrics. The goal of this research will be to develop a standardized procedure that could be incorporated into existing ISO standards for anthropometrics databases or as separate standard practice with a consensus standards organization. This project will potentially be initiated in 2011.

After the above studies are completed, NPPTL will decide if a revised fit-test panel is needed in 2013. The 2010 U.S. census data will be used to reweigh the current sample and see if a revision is necessary. If shape statistics and/or 3-D parameters are found to be more relevant to respirator fit, they will be used to develop new fit-test panels. If necessary, new anthropometric data will be collected. A new project to collect new anthropometric data will be initiated in 2014. Updated fit test panels will be developed at the end of 2017. These activities are conducted to implement Action Items 2-1, 3-1, 4-1, 4-2, 4-7, and 5-1.

Research to Practice

To implement Action Items 5-2, 5-3, and 5-4, NPPTL will incorporate the newly developed NPPTL bivariate panel into the total inward leakage (TIL) program as part of the rulemaking process since the committee concluded that the results of the NIOSH-sponsored Anthrotech study represent a clear improvement over the anthropometric data and corresponding LANL fit-test panels. The new panel based on principal component analysis (PCA) will be used to screen subjects. All test subjects need to fall within the boundaries of the PCA panel. They will then be classified by the NPPTL bivariate panel.

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The establishment of TIL performance requirements represents NPPTL's objective to improve the reliability and performance requirement for respirators. A public meeting was held June 26, 2007 to introduce the recommended TIL performance requirements for half-facepiece respirators to stakeholders and solicit input. In addition, the concept was posted on the NPPTL website and a Federal Register notice issued to announce the availability of the concept for public review and comment. The rule-making process is anticipated to be completed in 2009.

Results from NPPTL anthropometrics research have, to date, impacted several respirator standards developed by NPPTL scientists. Head circumference and neck circumference data have been used in the new NIOSH CBRN standard for escape respirators/hoods. The anthropometrics research results have also been incorporated into the proposed NIOSH certification standards for Closed-Circuit Escape Respirators. Section §84.306 Wearability test requirements states that NIOSH will conduct the wearability test on a total of three of the units submitted for approval. Three human subjects (two (2) males and one (1) female), one subject per unit, will conduct the test. The three subjects will range in height and weight as follows: one subject of height ≥ 174 cm and weight ≥ 90 kg; one subject of either $163 \text{ cm} \leq \text{height} < 174 \text{ cm}$, regardless of weight, or $72 \text{ kg} \leq \text{weight} < 90 \text{ kg}$, regardless of height; and one subject of height < 163 cm and weight < 72 kg. These selection criteria for selecting human test subjects came directly from the results of NPPTL anthropometrics research.

Results from NPPTL anthropometrics research have been incorporated into a technical specification standard for ISO TC94 Personal Protective Equipment, SC15 Respiratory Protective Devices, WG1 General, PG5 Human Factors. That standard is titled "ISO 16976-2 Respiratory Protective Devices — Human Factors — Part 2: Anthropometrics". It is currently being reviewed by each delegate. This standard is anticipated to be completed in 2008. NPPTL will further apply this standard into various parts of ISO TC94 SC15, WG2 Filtering Devices and WG3 Supplied Air Devices standards.

ISO TC94 SC6 Eye and Face Protection committee is also waiting for the results of NPPTL research results to be incorporated into the ISO eye and face protection standards. An NPPTL researcher was selected as one of the leaders to lead this standard development effort. Research results are anticipated to be incorporated into various parts of ISO TC94 SC6 standards in the next five years.

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