
Toward Better Fitting Respirators: Summary from a Workshop and Research Roadmap

Lisa M Brosseau

University of Minnesota, School of Public Health, Division of Environmental Health Sciences, 807 MMC, 420 Delaware St SE, Minneapolis MN 55455
E-mail: brosseau@umn.edu

ABSTRACT

Respirator fit and the value of fit testing are the least understood and most controversial aspects of respirator performance. Research has shown that testing fit is necessary for proper respirator performance; however, it is not yet possible to predict the contribution of facial features and respirator design characteristics.

This project was supported by the National Institute for Occupational Safety and Health. Research goals were to 1) evaluate barriers and incentives for recent innovations in respirator design and fit test methods and 2) develop recommendations for future actions that might lead to improvements in respirator fit. Four successful innovations (the ambient aerosol quantitative fit test method, strap cradle or head harness, double-flanged facepiece and flat fold design for filtering facepiece respirators) and two less successful innovations (adhesive face seal and user seal checks) were selected. Information was gathered via literature reviews, patent searches and interviews.

Results showed that technology push and market pull played an important role in the success of these six innovations; regulations generally had a neutral, or, in a few cases, limiting effect on their adoption. Researchers and research publications were sometimes important contributors to success. Health and safety professionals also played an important role in the adoption of new products or methods.

There continues to be high potential for innovation in design and fit test methods for better-fitting respirators. Success will depend on a combination of specialized knowledge about materials and technology, preliminary and supporting research, significant financial support, regulatory assistance and flexibility, and ultimately, health and safety professional and user acceptance.

Future research should focus on further clarifying how respirator fit is influenced by respirator design and facial characteristics. More investigation is also needed on user seal check methods and their role in establishing initial and long term fit. It is recommended that key stakeholders such as respirator users and program managers, inventors, researchers and manufacturers continue to be involved in setting and evaluating research directions and findings. A formal program is also recommended to assist inventors and small businesses with research, development and commercialization of innovations.

Keywords: respirator fit, innovation, research needs

INTRODUCTION

Fit and the value of fit testing remain the least understood and most controversial aspects of respirator performance. It has been demonstrated that fit testing is necessary to assure that respirators are properly worn and provide at least the preliminary level of expected protection (Duling et al. 2007; Lawrence et al. 2006; Coffey et al. 2006; Campbell et al. 2005; Coffey et al. 2004; Coffey et al. 2002; Campbell, Coffey, and Lenhart 2001). However, it is still not possible to identify or predict with any certainty which combination of facial features and respirator design characteristics will assure both initial and long-term fit.

In response to its update of 42 CFR Part 84 in the early 1990s, NIOSH received many comments about testing respirator fit for certification of particulate respirators. Some suggested eliminating fit testing as part of respirator certification while others recommended that manufacturers be required to submit test data. Some thought that NIOSH should continue to certify fit, but noted that qualitative tests (e.g. using isoamyl acetate and filters modified with a carbon-impregnated layer) were not meaningful and should be replaced by a quantitative method (Department of Health and Human Services 1995).

As noted in the preamble to the Final Rule, "problems associated with testing the facepiece-fit in a certification program have been recognized for years. Efforts have been made to seek more meaningful test results; nevertheless, the validity of the test results remains questionable." Current approaches to certifying respirator fit do not assure that the respirator will fit in the workplace. Thus, every respirator user should receive a fit test, although these will not necessarily assure long-term protection (Department of Health and Human Services 1995).

This paper describes the results of a nine-month project conducted in response to a NIOSH request for quotations seeking recommendations for research, procedures and policies leading to improvements in the fit of half-mask air purifying respirators. This request by NIOSH for research that may eventually lead to a "no fit test" respirator was prompted by on-going and increasing user requests for more comfortable, easier to use, easier to fit personal protective devices.

There has been some concern that the rate or nature of innovation in respirator design has not been adequately responsive to these needs. This investigation focused on the nature and process of product innovation and development in respiratory protective equipment, with the goal of understanding how future NIOSH research and regulatory activities could encourage on-going development of more comfortable respirators that are easier to use and fit without compromising long-term protection.

Two research tasks were undertaken: 1) evaluate barriers and incentives for recent innovations in respirator design and fit test methods and 2) develop and offer a workshop to explore new ideas and research directions for better fitting respirators. Project outcomes included recommendations for future NIOSH actions that could be used as input to the agency's research agenda.

It should be noted that this project did not seek to eliminate the need for fit testing, but rather to explore developments in respirator design and test methods that may lead in this direction. Respirators that fit well each time they are worn and need no fit testing could offer significant advantages to employers and employees, including lower costs (in both time and money) for fit testing and greater assurance of protection. Such respirators might also ensure better fit for un-trained or naïve wearers. On the other hand, annual fit testing offers an opportunity to conduct training about proper donning, maintenance and other factors that can play an important role in on-going respirator performance and protection.

BACKGROUND

Innovation, as defined by the Product Development and Management Association (www.pdma.org), is the “act of creating a new product or process” where “the act includes invention as well as the work required to bring an idea or concept into final form.” New products can result from “market pull” (recognition of market needs) or “technology push” (advances in technology) (Ashford, Heaton, and Priest 1979).

Product innovation can be either stimulated or discouraged by government actions (e.g. regulations or incentives). For example, when high levels of product safety and efficacy must be demonstrated prior to marketing (as is true for respirators), manufacturers face additional testing costs in addition to the price of research and development. In combination, these may prevent smaller companies from entering the market. Regulations can also lower profitability by increasing development costs (requiring more expensive materials or methods), introducing delays to marketing (via permits or certification), redirecting personnel (who must participate in regulatory-related meetings and activities) and decreasing the period of patent protection (Ashford, Heaton, and Priest 1979; Rothwell 1992).

On the other hand, regulations can also reduce risk and limit unpredictable product liability suits, encourage innovation in new technologies or markets and encourage companies to conduct joint research and development efforts (Ashford, Heaton, and Priest 1979). Companies that respond positively to government regulation can become more innovative in the long run, due to improved problem-solving skills and higher levels of creativity (Rothwell 1992). A review of the effect of environment, health and safety regulations on the chemical industry found that regulations of products tended to lead to product innovation, particularly when regulations were both stringent and technology-forcing in nature (Ashford, Ayers, and Stone 1985).

The *direct* impact of regulations on the success of a particular product innovation, however, is generally very small. Rather, the effects of regulation are more likely to be indirect ones: diverting resources from commercial innovation to compliance research and development; delaying launch of new products; or increasing uncertainty when regulatory changes appear likely but have not yet occurred (Rothwell 1992).

The development and testing of a new respirator design can require considerable resources prior to commercialization and marketing. While certification procedures ensure that respirators meet high performance standards, their requirements may hinder or slow innovation. There may be other barriers to innovation, as well, such as litigation, competition from off-shore sources or inadequate regulatory enforcement of respirator selection and use.

Safety equipment manufacturers must spend considerable resources on user education to ensure that companies purchase equipment that meets appropriate standards and is not just low cost (Mintner 2005). Safety equipment manufacturers also expend considerable resources toward the development of product standards, but are frustrated to find that many non-U.S. companies do not understand or follow U.S. requirements for product certification. OSHA used to be a major driver for product development and innovation, but has become much less so with few or no new standards.

Other factors unrelated to regulation have also had considerable effect on safety equipment manufacturers. Loss of manufacturing jobs due to automation and globalization has lowered the demand for safety equipment in the United States. OSHA enforcement of personal protection standards has been lacking, even in high risk, high growth industries such as construction and small manufacturing businesses. On the other hand, there has been growth in demand for safety equipment in global markets (Mintner 2005).

METHODS

An Advisory Board was formed, consisting of representatives from a broad range of stakeholders, including respirator and fit test equipment manufacturers, research laboratories, fit test companies and users (employers and employees).

Members of the Advisory Board and the American Industrial Hygiene Association Respiratory Protection Committee as well as to NIOSH employees and other professionals identified by Advisory Board members were sent a survey requesting information about recent innovations in materials, design, technology, certification, regulations and fit testing that contributed to significant improvements in respirator performance (in particular, fit). Respondents were also asked to identify innovations that had not been successful or widely adopted.

Approximately 60 people received the survey; 16 completed surveys were returned. Respondents listed numerous successful and unsuccessful innovations in facepiece design, fit testing and regulations (Tables I and II). Four successful innovations (the ambient aerosol quantitative fit test method, strap cradle or head harness, double-flanged facepiece and flat fold design for filtering facepiece respirators) and two less successful innovations (adhesive face seal and user seal checks) were selected for further investigation. Literature reviews, patent searches and interviews were conducted for each innovation. Interviews sought information on incentives for development, costs of development and marketing, effect on respirator use and regulation, effect of regulations, reasons for success (or not) and effect on respirator fit. For each innovation, we identified the incentives for development; the costs of and effects of regulations on research, development and commercialization; its effect on respirator use and regulation; the reasons for success or failure; and the long-term effect on respirator fit.

A one-day workshop, held November 2008, included eleven speakers representing a broad range of stakeholders and thirteen poster presentations. Workshop attendees were invited to participate in one of three afternoon break-out sessions focused on 1) new materials and designs, 2) new fit test methods and 3) knowledge gaps about fit.

RESULTS

Workshop proceedings and the project final report can be found at <http://cpheo.sph.umn.edu/cpheo/mcohs/courses/nofit/home.html>. A brief summary of the key findings is included here.

Innovations

Ambient Aerosol Quantitative Fit Test Method (TSI PortaCount®)

This innovation was prompted by the need for an automated, easy-to-use fit test method that did not require generating an aerosol, was portable, gave accurate and reliable quantitative results and allowed measurement of higher fit factors than were possible with qualitative tests. Military users sought a method that could be easily employed in field settings by personnel with minimal training. The Army spent approximately \$1 million to develop and test the original prototypes; additional funds were spent by TSI for commercialization and by the Army for developing final specifications. Both continued to spend money on testing and design improvements. The TSI Portacount® revolutionized quantitative fit testing, making it an acceptable and eventually expected aspect of respirator programs. Prior to rulemaking, OSHA agreed that anyone using the Portacount® would receive a *de minimis* violation (no fine and no required corrective action). Eventually OSHA listed the ambient aerosol-CNC method in its 1998 regulatory update as an accepted fit testing approach. This innovation was successful because it was

cost effective, simple to use, portable, produced quick and accurate results and used ambient aerosols. Its effects on respirator fit included greater discrimination between different respirators (models and sizes) and improvements in fit testing for respirators with fit factors greater than 100.

Table I. Innovations Identified by Survey Respondents as Successful (Number of Respondents; n=16)

Facepiece Materials Silicone and other similar flexible polymer facepiece materials (9)	Filter Design Electrostatic filter media, decreased pressure drop (7)
Elastomeric Respirator Facepiece Designs Head harness or cradle for straps (6) Double or triple flanges or flaps for sealing peripheries (2) Ratchets for harness assemblies (2) Foam materials in facial sealing area (1) Using "yoke" to attach headband to facepiece (1) Improvements in attachment of cartridges to facepiece (1) Using center section of hard plastic to reduce weight and cost and make connections easier (1) "Rhombus" shaped cartridges offset out of field of view (1) Easy and quick bayonet mounts for cartridges (1) Single strap design across cross-section of facepiece (1) Adjustable straps with numbers at adjustment points (1) Latch on half-mask respirator (1) Drop down feature (respirator hangs around neck when not in use) (1) Ergonomic design of face seal (1)	Other Respirator Design Aspects Better speech transmission (3) Multiple size facepieces (2) Self-monitoring devices (1) Fit check button on valve or filter (1) Use of anthropometric data to design facepieces (1) Increase in respirator makes and models (1) Elimination of quarter mask (1)
	Regulatory Changes Filter certification changes (2) End of service life programs (1) Modification of the NIOSH facial dimension panel (1) OSHA revised standard (1)
Fit Testing Quantitative fit testing (3) PortaCount® (4) Reliable qualitative fit tests for particulate filters (4) LANL panels (1) Quantitative fit test adapters (1) Negative pressure fit test method (1)	Filtering Facepiece Design Flat fold filtering facepiece respirators (2) Filtering facepiece respirators (3) Molded "around the nose" area instead of metal strip (2) Supporting filter media to prevent collapse during moisture buildup (1) Exhalation valves for filtering facepiece respirators (1) Closed-cell foam on nose area (1)
Other Centralized respirator medical evaluation, training, fit testing for unions (1)	Cartridge Designs Increase in cartridges for specific gases (1) Multi-contaminant cartridges (1)

Table II. Innovations Identified by Survey Respondents as Unsuccessful (Number of Respondents; n=16)

Elastomeric Respirator Facepiece Designs Adjustable pneumatic sealing periphery (3) Replaceable face seals (2) Adhesive on sealing surface (1) Breath responsive respirators (1) Personal face-forming face seal (1) Ultra-soft face seal or gel seal (1) Multiple head harness adjustment points (1) Face seal inserts (1)
Cartridge Designs End of service life indicator for organic vapor cartridges (1) End of service life indicators (1)
Other Respirator Design Aspects Scanning faces to design respirators (2) Measuring devices with each box of masks (1) One size fits all (1)
Other Hotel/fire emergency escape respirators (1)

Strap Cradle or Head Harness

This innovation resulted from manufacturer competition to meet user expectations for more comfortable and better fitting respirators. Users found that a head harness held the facepiece in place while allowing the mask to move (but not unseal) with facial movements. Respirators with head harnesses also fit more consistently when repeatedly donned. The R&D and commercialization costs for this innovation were probably minimal, while its impact was significant. A head strap cradle or similar design was eventually adopted by most manufacturers. While a design that allows more attachment points and more consistent placement of the head suggests a better-fitting respirator, no published data were found to support or refute this hypothesis. This innovation had no direct effect on regulations and vice versa.

Double-Flanged Facepiece

For full facepiece respirators, fit may have been the most important reason for this innovation, although comfort may have played a role. Presumably, similar reasons apply to the use of flanges on half-facepiece respirators. No information was found on the costs of research, development or commercialization of this innovation. There appeared to be no direct effect of this innovation on respirator regulations or vice versa. No published research was found on the effect of flanged designs on fit; anecdotal accounts indicate that it fit better and was more comfortable. Flanged facepieces were adopted by some manufacturers for full and half facepiece elastomeric respirators and continue to be offered on some designs. This design may contribute to both fit and comfort.

Flat-Fold Design for Filtering Facepiece Respirators

The flat-fold design was considered more convenient to wear, particularly in settings where respirators were frequently donned and doffed. Its similarity to surgical mask design was an incentive in the healthcare industry. Anecdotally, this design is thought to fit a broader range of face sizes. One

interviewee indicated a cost of approximately \$1 million to develop a new flat fold respirator, although this included other design innovations. Initially this design was not highly accepted because users did not like the “look”; however, market forces and a research publication eventually led to greater acceptance (Lee, 2004). This design innovation did not have any direct effect on respirator regulations, or vice versa.

Adhesive Face Seal

This innovation is the most recent development in respirator design. The primary incentive for this development was user pressure for better fitting respirators that did not require fit testing. However, no data are available to indicate that these respirators obviate the need for fit testing. One manufacturer indicated the costs for research, development, testing and commercialization to be more than \$2 million. A second designer found that current certification regulations were a significant impediment to commercialization. To date, NIOSH has certified a single adhesive face seal respirator. It is too early to assess the long term success of this innovation as a respirator design.

User Seal Checks

It was recognized as early as the 1960s that respirator fit is the most important aspect of protection and that performing a check every time the respirator is donned may help identify poor seals. The user seal check was not really an innovation, but rather a common-sense method for checking fit that gradually gained more acceptance with its incorporation into consensus and regulatory standards. ANSI standards, NIOSH guidance documents and OSHA standards apparently built upon each other in moving this method from a recommended to a required practice. A 1995 research study solidified the user seal check as a required practice and contributed to its adoption into the 1998 OSHA respiratory protection standard (Myers, Jaraiedi, and Hendricks 1995). The user seal check does not appear to have had a significant impact on respirator fit; anecdotally, the seal check can be difficult to use with filtering facepiece respirators.

Workshop Breakout Sessions

New Materials and Designs for Better Fit

Participants identified several environmental factors important to half-mask respirator design, including temperature variations and contamination. A wide range of material properties were thought to be important to good design, including mechanical, chemical and physical properties, comfort, ability to withstand degradation, thermal conductivity, transparency, compatibility with other parts of the respirator, cost and speech transmission.

Participants noted that protection and comfort are both important. Numerous characteristics of good design were identified, including low weight, able to fit many facial profiles, does not impair field of vision, uniform pressure on the face, good strap design, can be easily donned multiple times, has a limited number of parts, does not interfere with communication, is portable and easy to store. The most important point about design, however, was that each work environment is different and requires a tailored design approach.

Opinions were mixed about designing a respirator that could fit all sizes. The best design was one that allowed for user adjustments. Some participants noted that regulatory requirements were more stringent for single size respirators, which may prevent improvements in design.

This group identified a number of areas where research could lead to better fitting respirators, including new materials, technologies and sensors. Participants wanted more information on

decontaminating respirators, whether cross-contamination occurs during repeat donning, the efficacy of biocidal coatings and whether infection rates in emergency departments are improved by the use of respirators. It was emphasized that collaboration between NIOSH, manufacturers and users would also lead to better designs.

New Fit Test Methods

The most important ideas emerging from this breakout session were 1) the need for a user seal check that really works and 2) that the goal should be for continuous fit checking rather than no fit test.

Knowledge Gaps about Fit

Participants in this session identified the following wearer characteristics as the biggest contributors to fit:

- Symmetry
- Chin characteristics
- Sweat
- Nose dimension
- Head dimensions (straps and harnesses)

The group noted the very wide variability in the demographics of the United States workforce, leading to wide variety in facial features. Nasal dimensions were thought to be one of the more important features for fitting half-mask respirators. Participants called for more data for all groups (race/ethnicity, gender and age). In addition, they noted that aging, elasticity of the face and weight changes may all contribute to respirator fit. More research is needed to identify the reasons some people cannot pass a fit test and how respirators interface with other personal protective equipment.

DISCUSSION

The results of this project suggest that in the past 30 to 40 years there have been numerous important improvements in the design of negative pressure half facepiece respirators and in tests used to evaluate fit. In most cases, technology push or market pull (or both) played an important role in making these improvements a success; regulations generally had a neutral or, in a few cases, limiting effect on their adoption.

The TSI PortaCount® is a good example of an innovation where technology push (condensation nuclei counters) and market pull (Air Force and Army needs) combined to yield an instrument that has, in many ways, revolutionized our approach to and expectations for fit tests. It is important to note, however, that this innovation would probably not have occurred without the funds and field testing provided by the Army research center. A larger, bulkier, less user friendly and more expensive instrument might have resulted, which would have had a much smaller impact.

Filtering facepiece respirators have also had a significant impact on our expectations for respirators. This design -- in its many variations -- was also the result of a combination of technology push (melt blown electrostatic filters and better molding methods) and market pull (asbestos abatement workers, among others). Conversely, the flat fold design was not an immediate commercial success until new market forces (healthcare workers' expectations for respirators that look more like surgical masks) and a research study combined to make this a more successful type of filtering facepiece respirator.

Researchers and research publications can play an important role in the adoption of an innovation. For example, publications prior to development of the PortaCount® supported this innovation

and published research following its development supported its efficacy in comparison to current fit test methods. The publication by Myers et al. appears to have lent enough support to the user seal check for its inclusion in the revised 1998 OSHA respiratory protection standard (Myers, Jaraiedi, and Hendricks 1995). Current skepticism about this innovation, however, indicates that one publication may not ensure full agreement from the professional community.

Health and safety professionals also play an important role in determining the success of an innovation in respirator design or fit testing. This group relies on published research, user input and their own personal experience before fully adopting an innovation.

While regulatory agencies with a mission of approving products must, by definition, place greater emphasis on product performance than on manufacturer profits, they must also take care not to stifle new ideas or prevent competition. Given the lengthy process for developing or amending regulations, agencies must be careful to develop performance-based standards that leave enough room for innovation while also ensuring product performance. It is difficult to ensure the on-going utility of any standard, however, as new approaches, technology or product uses will eventually occur that were never envisioned when the standards were first developed.

There are some things an agency can do to maintain regulatory flexibility and encourage innovation while not straying from its mission of certifying product performance. First, by employing non-prescriptive performance-based standard, an agency allows for flexibility when new ideas, methods and uses are presented for approval. Second, good communication with and input from all stakeholders and on-going identification of new stakeholders can ensure recognition of new needs and suggest new areas needing research or oversight. Third, a healthy mix of internal and external research – with regular interactions– can lead to new ideas and perspectives.

Our results also suggest that there continues to be high potential for innovation in designs and fit test methods for better-fitting respirators, despite many areas where knowledge remains lacking. Respirator design innovations continue in universities, government agencies and companies. This study suggests, however, that, as with all innovations, success depends on a combination of specialized knowledge (of materials and technology), preliminary and supporting research, significant financial support, regulatory assistance and flexibility, and ultimately, health and safety professional and user acceptance.

With respect to the innovations explored, there are still a number of areas where further research would be useful in the quest for a “no fit test” respirator. This is true for innovations related to respirator design – the flat fold style for filtering facepiece respirators and the double flanged edge and strap cradle for elastomeric respirators – as well as for fit test methods – in particular, the user seal check.

Our exploration of the adhesive respirator reveals some interesting barriers to innovation, namely the issues of licensing an addition to a respirator that may cause a change that invalidates certification and manufacturers’ concerns about marketing an improvement that jeopardizes current products. And the very successful PortaCount® illustrates the key role a large stakeholder can play in the research, development and commercialization of an innovation.

There are a number of important areas in design and fit testing that could benefit from further research, including better designs for a broader range of environmental conditions, a better understanding of the role of comfort, considering the trade-off between multiple sizes and a one-size-fits-all approach, and exploring approaches that provide continuous fit checks. Research is also needed on the influence of facial characteristics, facial responses and demographic differences.

At this point in time, it is not known whether the future holds a true “no fit test” respirator. Insisting that fit testing must always be required, however, could be an unnecessary barrier to innovations in half-

mask negative pressure respirator designs. The best research takes place in an environment where all prior assumptions are open to question, even if current policies and practices prevent the adoption of new approaches. Even the most open-ended and performance-based policies and procedures are generally reflective of current knowledge and technology. Thus, regulatory agencies must create an environment where new ideas are encouraged and regulations are responsive to innovations.

In addition, research that may lead in new directions should be encouraged, even if there is a high risk that it will fail to yield anything useful. Basic research that seeks to explain the underlying fundamentals of respirator fit is as important as applied research that seeks to test specific methods or designs.

It should be noted that this project may have some limitations. The number of respondents to the innovation survey was small (16) and it was not possible to identify the total number of people receiving the survey. Some important innovations may have been missed, although advisory board review did not indicate this was the case. It is possible that interviewees may have been reluctant to share information that might limit marketplace success. It is not likely, however, that this had a significant effect on this project, given the general nature of the information being sought.

CONCLUSIONS AND RECOMMENDATIONS

The results of this project suggest that there remain a number of unanswered questions about respirator fit. Recommendations for improvements are offered in the areas of research and stakeholder input.

Recommendations for Research

Research in the areas of respirator design, anthropometrics and user seal checks, in particular, may lead to improvements in the fit of half facepiece negative pressure respirators. Recommendations 1.1 through 1.5 are focused on those specific areas where research is needed for improvements in fit. These five recommendations are listed in order from highest to lowest priority, which was determined by considering both the potential impact on respirator fit and the current availability of appropriate technologies, materials or methods.

Recommendation 1.1: Conduct research to clarify the role of respirator design (technologies, materials and systems) in respirator fit. In particular, investigations involving the following respirator features could lead to more comfortable, better fitting and more protective respirators:

- Strap designs (e.g. attachment points, head cradle)
- Methods for cooling the facepiece to limit slip due to sweat (e.g. thermoelectric coolers, small fans, thermal compression devices)
- Methods for increasing protection by inducing positive pressure inside the facepiece (e.g. small fans)
- Improvements that lower breathing resistance for filtering facepiece respirators (increasing filter area, adding an exhalation valve, understanding differences between folded and cup styles)
- Technologies and materials for improving facepiece seals (e.g. encapsulated gels, shape memory polymers, wet and dry adhesives)

This recommendation is of highest priority because significant improvements in respirator fit are likely to result and technologies or materials are currently available for such improvements.

Recommendation 1.2: Conduct research to clarify the influence of facepiece design, multiple facepiece sizes and aging on the interaction between facial measurements and respirator fit. Such investigations may lead to a better understanding about which anthropometric features are most closely associated with

well-fitting respirators. Some percent of this research should be devoted to “high risk” research, i.e. research that may not lead to immediate practical applications but rather seeks to illuminate fundamental properties or principles or explore unique or untested technologies or methods.

This recommendation is of high priority because results will lead to improved knowledge about facial features important to respirator fit, which will lead to improvements in respirator design. The technology or materials needed to illuminate the role of facial features are probably available.

Recommendation 1.3: Conduct research on the role of user seal checks in establishing respirator fit, particularly for filtering facepiece respirators.

Research in this area is of high priority because it is feasible, would improve user understanding about fit and may lead to improvements in respirator design. The technology or materials needed to illuminate the role of user seal checks are probably available.

Recommendation 1.4: Conduct research on new methods for checking facepiece seals. In particular, efforts should be made to identify methods that continuously track and report facepiece fit.

Research in this area is of moderate priority. Although the results could have considerable impact on respirator design, technologies and materials are exploratory at this time.

Recommendation 1.5: Conduct research to elucidate the effect on respirator fit of a) other types of personal protective equipment (PPE) and b) environmental conditions such as temperature, relative humidity and dust.

Research in these areas is of low to moderate priority because it could lead to improvements in respirators (and other PPE) but would be largely exploratory in nature at this time.

Recommendations for Implementing Research Findings

The following recommendations are offered specifically to the NIOSH Personal Protective Technology Laboratory to ensure implementation and incorporation of research findings into its programs and activities.

Recommendation 2.1: Quantitative assessments of respirator fit using a human test panel should be included in the certification requirements of all half-mask negative pressure air purifying respirators. This recommendation should be accomplished through rulemaking to allow involvement of all stakeholders.

Recommendation 2.2: Consultative panel(s) representing key stakeholders - including respirator users and program managers, inventors, researchers, and manufacturers - should be used to ensure a forum for identifying issues, exchanging ideas, discussing research findings and defining future research directions.

Recommendation 2.3: Collaborations among government agencies should be continued to combine resources for supporting internal and external research that is responsive to common needs.

Recommendation 2.4: A formal assistance program should be developed to provide financial and other types of support to inventors and small businesses seeking to bring new ideas to market. It is envisioned that such assistance would extend beyond that offered by the Small Business Innovative Research program and would include advice about commercialization and certification.

Recommendation 2.5: A method should be established for conducting regular reviews of certification regulations in light of new technologies for respirator design and performance. This should include opportunities for respirator manufacturers to identify areas where current regulations may prevent new innovations from being pursued or adopted.

Recommendation 2.6: More opportunities should be available, in addition to stakeholder meetings, for interactions between internal NIOSH researchers and external investigators. Such interactions would ensure that research conducted by each of these groups is informed by up-to-date information and has practical application.

Acknowledgements

Thanks are extended to Nicole Koktavy for her assistance with interviews, literature reviews and report preparation; interviewees for their time and input; and Advisory Board members for their contributions throughout the project. This project was supported by the National Institute for Occupational Safety and Health (NIOSH) (RFQ 2008-Q-10205). The findings and conclusions are those of the author and do not necessarily represent the views of NIOSH.

REFERENCES

- Ashford, N. A., C. Ayers, and R. F. Stone. 1985. Using regulation to change the market for innovation. *Harvard Environmental Law Review* 9, (2): 419-66.
- Ashford, N. A., G. R. Heaton, and W. C. Priest. 1979. Environmental, health, and safety regulation and technological innovation. In *Technological innovation For a Dynamic Economy.*, eds. C. T. Hill, J. M. Utterback, 161-221Pergamon Press.
- Campbell, D. L., C. C. Coffey, P. A. Jensen, and Z. Zhuang. 2005. Reducing respirator fit test errors: A multi-donning approach. *Journal of Occupational and Environmental Hygiene* 2, (8) (Aug): 391-9.
- Campbell, D. L., C. C. Coffey, and S. W. Lenhart. 2001. Respiratory protection as a function of respirator fitting characteristics and fit-test accuracy. *AIHAJ : A Journal for the Science of Occupational and Environmental Health and Safety* 62, (1) (Jan-Feb): 36-44.
- Coffey, C. C., R. B. Lawrence, D. L. Campbell, Z. Zhuang, C. A. Calvert, and P. A. Jensen. 2004. Fitting characteristics of eighteen N95 filtering-facepiece respirators. *Journal of Occupational and Environmental Hygiene* 1, (4) (Apr): 262-71.
- 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. *Applied Occupational and Environmental Hygiene* 17, (10) (Oct): 723-30.
- Coffey, C. C., R. B. Lawrence, Z. Zhuang, M. G. Duling, and D. L. Campbell. 2006. Errors associated with three methods of assessing respirator fit. *Journal of Occupational and Environmental Hygiene* 3, (1) (Jan): 44-52.
- Department of Health and Human Services. 1995. *Respiratory protective devices; final rules and notice.* Vol. 42 CFR Part 84.
- Duling, M. G., R. B. Lawrence, J. E. Slaven, and C. C. Coffey. 2007. Simulated workplace protection factors for half-facepiece respiratory protective devices. *Journal of Occupational and Environmental Hygiene* 4, (6) (Jun): 420-31.
- Lee, K., A. Slavcev, and M. Nicas. 2004. Respiratory protection against mycobacterium tuberculosis: Quantitative fit test outcomes for five type N95 filtering-facepiece respirators. *Journal of Occupational and Environmental Hygiene* 1, (1) (January): 22-8.
- Lawrence, R. B., M. G. Duling, C. A. Calvert, and C. C. Coffey. 2006. Comparison of performance of three different types of respiratory protection devices. *Journal of Occupational and Environmental Hygiene* 3, (9) (Sep): 465-74.

-
- Mintner, S. G. 2005. Safety equipment manufacturers focus on product performance. *Occupational Hazards*.
- Myers, W. R., M. Jaraiedi, and L. Hendricks. 1995. Effectiveness of fit check methods on half mask respirators. *Journal of Applied Occupational and Environmental Hygiene* 10, (11): 934-42.
- Rothwell, R. 1992. Industrial innovation and government environmental regulation: Some lessons from the past. *Technovation* 12, (7): 447-58.