Innovations in Respirator Design and Fit Testing

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Institute of Medicine reports recommended long-term research activities to develop respirators with improved fitting characteristics or respirators that don’t need fit testing.

Input to the NIOSH research agenda from a variety of resources:
- Workshop
- Literature review
- Final report

Prioritize the NIOSH research agenda and suggest possible future changes to respirator certification testing procedures and policies.

Half facepiece negative pressure respirators.
Research Goals

- Advisory Board representing range of stakeholders
- Plan and hold one-day workshop
- Identify successful and less successful innovations
  - Interview experts for each innovation
  - Review written materials (patents, research reports and publications, etc.)
  - Prepare final report
Advisory Board

- Nicole Vars McCullough, 3M Company
- Alan Hack, Los Alamos National Laboratory (retired)
- Jeff Weed, Weed Respiratory Protection Solutions
- Peter Nelson, Silent Power, Inc. and Breathe Safely
- Janice Bradley, International Safety Equipment Association
- Howard Cohen, University of New Haven
- Jeff Birkner, Moldex Metric Inc.
- Bill Borwegen, Service Employees International Union
- Curt Hering, Toronto EMS
- Mark Catlin, Service Employees International Union
Workshop

- November 6, 2008 – Pittsburgh PA
- 120 participants
- 11 speakers; 13 posters
- 3 breakout sessions
  - New materials and designs for better fit
  - Fit test methods that would ensure long term fit
  - What do we need to know about fit that would lead to better materials, designs or fit tests?
- Presentations and summaries of breakout sessions available on-line at:
  - http://cpheo.sph.umn.edu/cpheo/mcohs/
Innovation

- “Market Pull” – recognition of market needs
- “Technology Push” – advances in technology

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<tr>
<th>Positive Effects of Regulations</th>
<th>Negative Effects of Regulations</th>
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<tr>
<td>Encourage collaboration on research and development</td>
<td>Decrease period of patent protection</td>
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<td>Encourage innovation in new technologies or markets</td>
<td>Redirect personnel (participate in regulatory-related activities)</td>
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<td>Reduce risk</td>
<td>Delays to marketing (testing and approval)</td>
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<td>Limit unpredictable product liability</td>
<td>Additional costs and expertise (may prevent smaller companies from entering the market)</td>
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Innovations

- Surveyed respirator professionals (Advisory Board, AIHA committee, NIOSH researchers)
  - 16 completed surveys
- Selected 4 successful innovations
  - Double flanged facepiece (elastomeric respirators)
  - Flat fold design (filtering facepiece respirators)
  - Ambient aerosol fit test method
  - Head-strap cradle
- Selected 2 less successful innovations
  - Adhesive respirators
  - User seal checks
Interviews

- 23 interviews
- Interview questions addressed:
  - Incentives for the innovation
  - Costs of research, development and commercialization
  - Effect on respirator use and regulations
  - Effect of regulations on innovation
  - Primary reasons for success (or lack of success)
  - Effect on respirator fit
Findings

- Technology push and market pull were important to many of the innovation we examined.
- Additional drivers also important:
  - Significant levels of funding for research and development
  - New stakeholders and new uses
  - Researchers and research publications
  - Health and safety professionals
Regulatory Agency Goals

- Emphasis on high levels of product performance to ensure worker protection
- Performance-based approaches to allow for new ideas and designs
- Responsive to changes in technology, materials, designs and uses
Does Innovation Continue?

- Yes – in companies, universities, government agencies
- Success depends on combination of:
  - Specialized knowledge
  - Preliminary and supporting research
  - Significant financial support
  - Regulatory assistance and flexibility
  - Health and safety & user acceptance
Research Recommendations

- Additional research would assist designers, manufacturers, professionals, regulators and users:
  - Effectiveness of user seal checks
  - Effectiveness of different filtering facepiece designs
  - Improvements in face seals through use of new technologies and materials
  - Strap designs
  - Trade-off between protection and comfort
  - Methods for constantly checking fit (during wear)
Recommendations for Other Activities

- Advisory panels representing key stakeholders
- Formal collaborations with government agencies
- Formal assistance to inventors and small businesses
- Advisory committee to conduct regular review of regulations in light of new research
- More interactions between internal and external researchers
Acknowledgements

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Opinions are my own and do not necessarily reflect those of NIOSH