Progress Toward a "B95" Respirator for Healthcare Personnel

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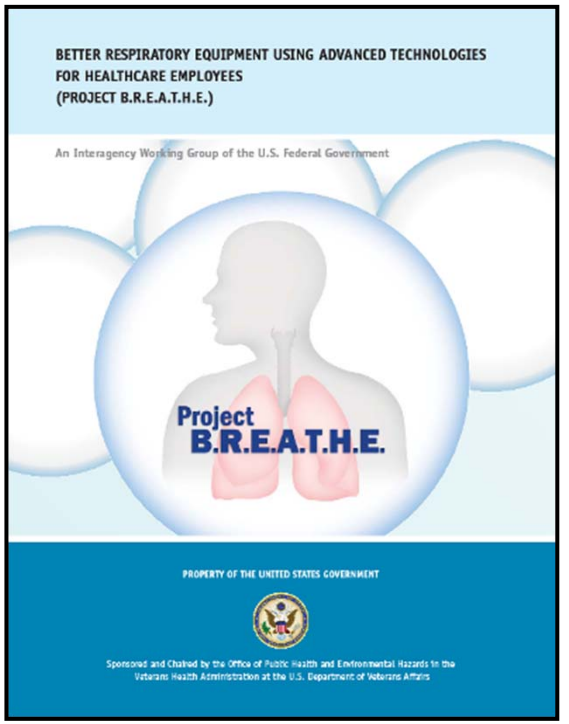
Project BREATHE - Better Respiratory Equipment using Advanced Technologies for Healthcare Employees

- **Partnership:** Veterans Health Administration (VHA)
- **Objective:** To improve respirator compliance among healthcare personnel (HCP) by promoting the development of better respirators

Project BREATHE Working Group

- **Identified 28 "Idealized" characteristics**
- **Respirators should:**
  - Perform their intended functions safely and effectively (9 requirements identified including fit & reusability/fomite concerns)
  - Support, not interfere with, occupational activities (5 requirements… speech, hearing, etc.)
  - Be comfortable and tolerable for the duration of wear (10 requirements… breathing resistance, facial pressure, etc.)
  - Comply with current standards and guidelines (4 requirements… OSHA, NIOSH, FDA)



http://www.publichealth.va.gov/docs/cohic/project-breathe-report-2009.pdf

Project BREATHE Working Group

- **Healthcare is a unique environment with challenges different from that of industrial workplaces**
- **Need a new type of respirator ("B95") designed specifically for healthcare**
- **See Gosch et al, "B95: A new respirator for healthcare personnel" American Journal of Infection Control for additional details**
  - DOI: 10.1016/j.ajic.2013.03.293

Path Forward

Develop clinically-validated "B95" test methods	"B95" prototype development	Development of a "B95" standard
• Comfort • Fit • Occupational interference	• Collaborations with Georgia Tech, 3M, and Scott Safety	• Draft "B95" requirements, criteria, and test methods developed • Focus on comfort & fit

Development of a "B95" Standard

- **Two approaches**
  - "Short-term": collaborate with a consensus standards development organization (SDO) to develop a voluntary consensus standard
  - "Long-term": develop the scientific basis to support possible future changes to any outdated, unnecessary, or burdensome OSHA, NIOSH, or FDA regulations

Consensus Standards Approach

- **42 CFR Part 84 sets the minimum respirator performance requirements for all workplaces; nothing specific for healthcare**
- **Voluntary consensus standards can fill this gap**
  - SDO sets additional requirements for specific applications, but requires NIOSH certification as the baseline
  - Similar concept used for firefighter SCBA

Selection Process

Starting point

- 28 Project BREATHE characteristics for the "ideal" healthcare respirator

Example selection criteria

- Not in the existing NIOSH & FDA Surgical N95 respirator standards?
- Still an end-user priority?
- Suitable test methods readily available?
- Preferences: peer-reviewed science & human subject-based

Results

- 7 "B95" requirements that will be assessed using 10 "B95" test methods
- 3M 1870 FFR used to set pass/fail level

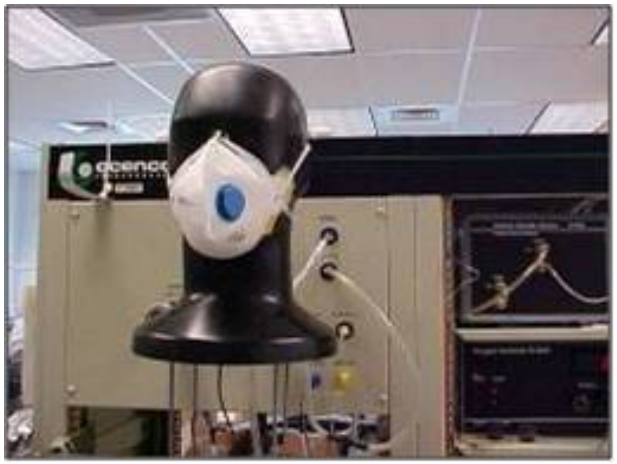
Safety & Effectiveness

Requirement	Test Method	Pass/Fail Criterion
Respirator fit	35 person NIOSH bivariate fit test panel	≥ 75% (26/35) of subjects pass a quantitative fit test
Reuse / Gauging Fit	Measure fit from 10 repeated donnings on a headform	GM fit factors ≥ 100

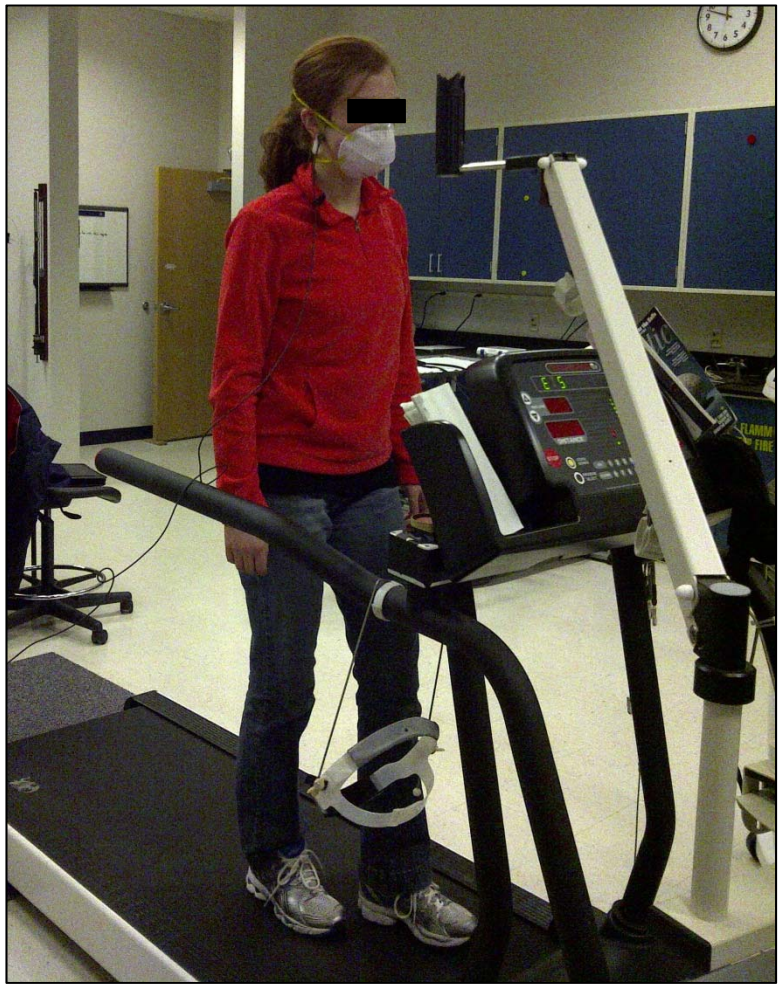
Comfort – Machine Tests

Requirement	Test Method	Pass/Fail Criterion
Breathing resistance	Filter airflow resistance (TSI 8130)	≤ 10 mm H_2O
Air Exchange	Average inhaled CO_2	≤ 3.0%
	Average inhaled O_2	≥ 16.5%

Note: measuring inhaled CO_2 and O_2 using the NIOSH automated breathing & metabolic simulator (0.5 l/min oxygen consumption)



Comfort – Human Subject



- **"Roberge" protocol - 20 subjects walking on treadmill for 1 hr at 3.5 mph (low-moderate work rate)**

Comfort – Human Subject

Requirement	Test parameter	Pass/Fail Criterion
Air exchange	Transcutaneous CO_2	≤ 4 mm Hg increase over baseline
	O_2 saturation	≤ 1% decrease over baseline
Facial heat	Air temp inside FFR	≤ 2.5°C increase over baseline
	Skin (cheek) temp inside FFR	≤ 2.5°C increase over baseline
Moisture management	Moisture retention	≤ 4% of respirator weight (g) / hr

Next Steps

- **In collaboration with stakeholders, continue improvement of "B95" requirements, test methods, and criteria (2013-2014)**
- **Use draft "B95" test methods to assess the Project BREATHE prototypes (Summer/Fall 2013)**
  - **Opportunity to validate NPPTL's lab-based test methods against VHA's clinical setting simulator data**
- **Contact SDOs (ASTM, ISO, NFPA, ISEA, ASSE, etc.) to determine interest in developing "B95" standard that enhances NIOSH N95 requirements (~2014)**

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