

# Current Issues and Advances in PPE: A Research Update

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# Presentation Overview

## Role of NIOSH

Respiratory Protection Activities  
Protective Ensemble Activities

# Every Day in the USA

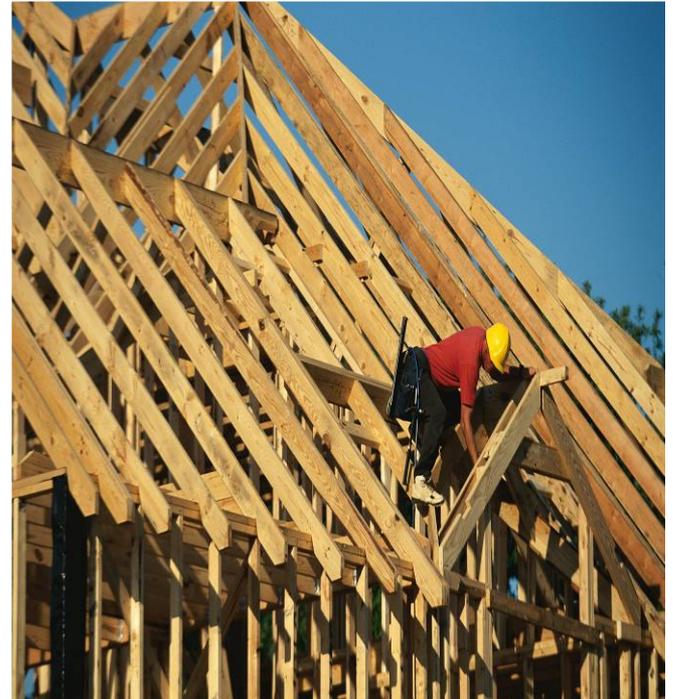


- 9,000 workers are treated in an emergency department for work-related injury or illness; 200 are hospitalized
- 5986 workers sustain lost-time injuries or illnesses
- 664 workers develop work-related diseases
- 134 workers die from work-related diseases
- 16 workers die from injuries at work

**Employer's workers' compensation costs totaled  
\$87.1 billion in 2004.**

# OSH Act of 1970

- **PL 91-596 (1970) created OSHA and NIOSH**
- **To assure safe and healthful working conditions for working men and women**



# Occupational Safety and Health

## Regulation/Enforcement

Department of Labor  
(DOL)

Mine Safety  
and Health  
Administration  
(MSHA)

Occupational  
Safety and Health  
Administration  
(OSHA)

## Research and Prevention Recommendations

Department of  
Health and Human Services  
(HHS)

Centers for Disease  
Control and Prevention  
(CDC)

National Institute for  
Occupational Safety  
and Health (NIOSH)

# National Institute for Occupational Safety and Health

- **The sole federal government organization charged with conducting occupational safety and health research**

# NIOSH Divisions & Laboratories



- Office of the Director, NIOSH
- Office of Extramural Programs
- Pittsburgh Research Laboratory (PRL)
- National Personal Protective Technology Laboratory (NPPTL)

- Division of Respiratory Disease Studies (DRDS)
- Division of Safety Research (DSR)
- Health Effects Laboratory Division (HELD)
- Education and Information Division (EID)
- Division of Applied Research and Technology (DART)
- Division of Surveillance Hazard Evaluation and Field Studies (DSHEFS)
- Office of Compensation Analysis and Support (OCAS)
- Research to Practice (r2p)
- Spokane Research Laboratory

# NIOSH PPT Vision & Mission

The **VISION** is to be the leading provider of quality, relevant, and timely PPT research, training, and evaluation.

The **MISSION** of the PPT program is to prevent work-related injury, illness and death by advancing the state of knowledge and application of personal protective technologies (PPT).



PPT in this context is defined as the technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment worn by individuals to reduce the effects of their exposure to a hazard.

# NIOSH PPT Program

## *Relevance and Impact*

### Mine Escape Issues

- Mine Emergency Respirator Investigations
- New Technology Workshops
- Escape Respirator Research
- Escape Respirator Standards Development
- MSHA Collaboration

### CBRN Issues

- Respirator Standards Development
- CBRN PPT Research
- Respirator Certification
- NFPA/IAFF Collaboration
- TSWG IAA
- OSHA Collaboration

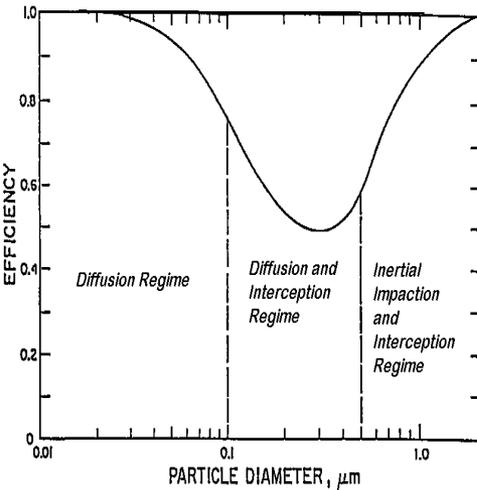


### Nanotechnology Issues

- Filtration Research
- Protective Clothing Research
- Respirator Research
- Respirator Certification
- Workplace Guidance

### Pandemic Issues

- N95 Respirator Research
- Standards (Total Inward Leakage)
- Certification
- FDA Collaboration
- National Academies Activities
- Pandemic Planning



# Respirator Protection Activities

# Technology Evaluation



- **Respirator certification**

- Application processing
- Respirator testing and QA Plan evaluation



- **Post certification**

- Product and site audits
- Respirator equipment evaluations



# Post Approval Programs

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- **Manufacturer Site Auditing**
- **Certified Product Auditing**
- **Certified Product Investigation Program**
- **Firefighter SCBA evaluation lab**
  - Coordination with the Division of Safety Research
- **Long Term Field Evaluation**

# PPT & Standards

- **Federally Mandated and Consensus Standards**
- **Federally Mandated and Administered**
  - OSHA 29 Code of Federal Regulations (CFR) 1910.132-138
  - NIOSH 42 CFR, Part 84
  - Developed by federal agencies following rulemaking process
- **Consensus Standards**
  - Developed by Standards Setting Organizations (SDOs)
  - Standards Setting Committees with balanced representation:
    - Users
    - Labor
    - Government
    - Academia
    - Subject Matter Experts

# Develop Standards for Personal Respiratory Equipment

- **Develop conceptual requirements**
  - Technical concept
  - Website posting
  - Public & Stakeholder meetings
  - Docket
- **Finalize criteria and standard test procedures for certification**
- **Finalize the preamble and comply with all federal requirements**
- **Submit to the Federal Register “Notice of Proposed Rulemaking”**
- **Hold additional public meetings as information exchange meetings**
- **Rulemaking records, submitted comments, scientific reports, test data and related information will be publicly accessible through the NIOSH website**
- **Publish a final rule in the Federal Register**
  - Contains all regulatory text
  - Includes responses to public meetings and docket comments
  - Explains changes from the proposed rule to the final rule and the rationale

# Develop Standards for Personal Respiratory Equipment

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## Notices for Proposed Rulemaking (NPRM) in Agency Review

- Quality Assurance Module
- Closed Circuit Escape Respirator

## Concepts Completing Development in 2008

- Total Inward Leakage for FFR and half masks
- Powered Air-Purifying Respirators

## Concepts in Development

- Closed Circuit SCBA
- Supplied Air Respirators

*PPT Approach is to develop two NPRM each year*

# CBRN Respirator Standards Development

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## **Outputs:**

**Multiple CBRN Respirator Approvals and Multiple Manufacturers for each type of CBRN respirator**

## **Outcomes:**

- **DHS Adoption of NIOSH CBRN respirator standards**
- **IAB Adoption of NIOSH CBRN respirator standards**
- **NFPA adoption of NIOSH CBRN respirator standards**
- **BSI adoption of NIOSH CBRN Test Criteria**
- **Increase in the national inventory of CBRN respirators**

# CBRN Respirator Standards Development

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## **Standards Completed:**

- **SCBA – January 2002**
- **SCBA upgrades – March 2003**
- **Gas masks (APR) –March 2003**
- **Escape sets – October 2003**
- **PAPR – October 2006**

**Future CBRN Respirator Standards (SAR, CC-SCBA, Combination Units) will be incorporated as performance requirements through rulemaking updates to 42 CFR Part 84**

# New CCER / SCSR Certification Standard

- Description
- Applicability to new and previously approved CCERs
- Required components, attributes, and instructions
- General testing conditions and performance concepts
- **Capacity tests**
- **Performance tests**
- **Wearability tests**
- **Environmental treatments**
- Additional testing
- **Post-certification testing**
- **Voluntary Registration**



# Long-Term Field Evaluation (LTFE)

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- **Product auditing program to determine how well SCSRs endure the underground coal mining environment**
- **Results from multiple phases of testing indicate that SCSRs experience some performance degradation**
- **Suspected problems and nonconformities are reported for investigation under the CPIP**
- **Redesign LTFE Implemented 2Q FY 2008**

# Workshops on Self-Contained Self-Rescue Breathing Systems

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- **Collaboration with National Technology Transfer Center (NTTC)**
- **Series of workshops**
  - Two workshops during 2005 (June & December)
  - One workshop July 2006
  - Two Workshops February & March 2008
- **Innovative and creative technology for closed circuit escape respirators (CCER)**
  - Listen, learn, share and apply

# Closed Circuit Escape Respirator (CCER) Technology

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**Application of innovative and creative technology to:**

- **Provide respiratory protection with increased capacity (duration)**
- **Reduce physiological burden of escape respirators**
- **Improve ruggedness and durability of escape respirators**
- **Improve the capability to provide realistic training**

**Notes from previous workshops located at:**

**<http://www.nttc.edu/clients/niosh/workshopnotes.asp>**

# Respiratory Protection Research

- **Influenza Pandemic**

- FFR shortage
- Performance (laboratory)

- **Respirator Fit Research**

- Facial anthropometrics
- Frequency of fit testing
- Novel respirator designs

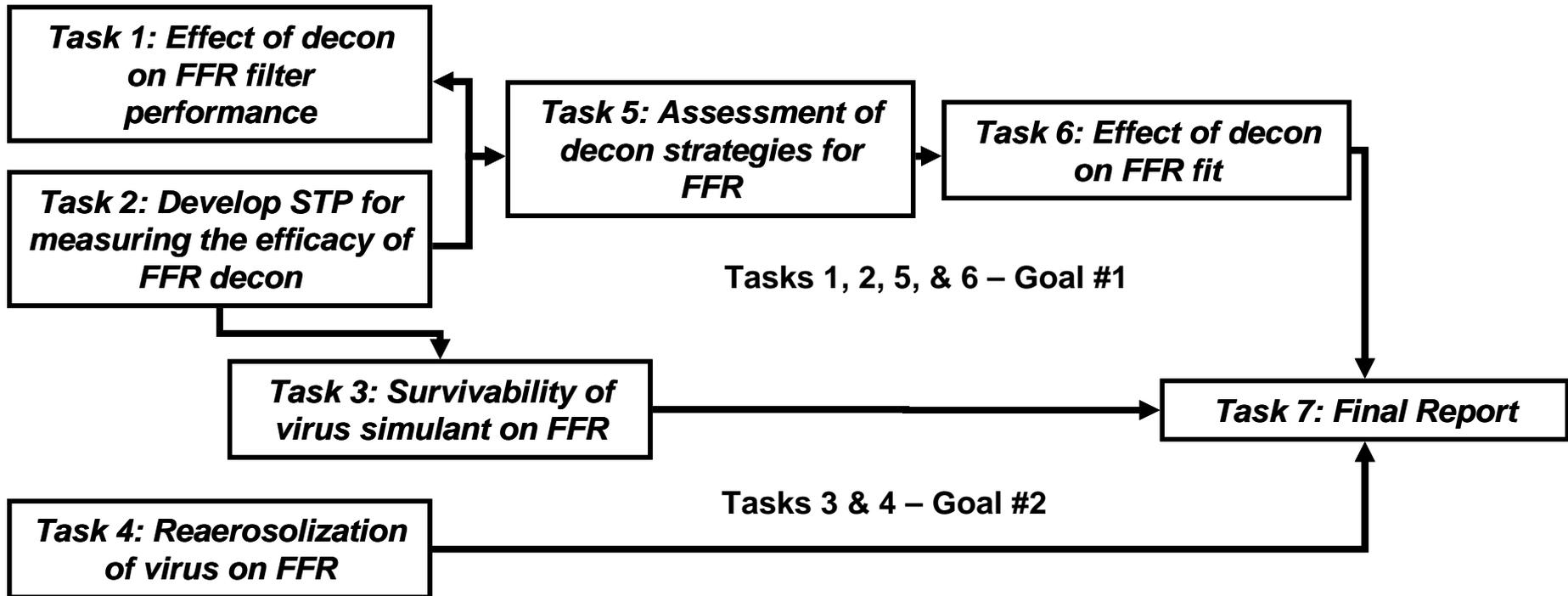
- **Aerosol/Filtration Studies**

- Nanoparticles



# Reusability of Filtering Facepiece Respirators

**Goals – conduct laboratory studies to (1) understand the efficacy of decontamination and to assess the impact of decontamination on FFR performance and (2) increase the information available on the risks associated with handling a respirator exposed to viruses**



# Metabolic Evaluation of N95 Respirator Use with a Surgical Mask

- **IOM recommends extending lifetime of FFR by avoiding contamination using a medical mask**
- **Physiological burden with respirator use**
  - Increased CO<sub>2</sub> levels speculated to cause increased frequency of headaches among health care workers
- **Does wearing a surgical mask as a protective covering over an N95 FFR increase the inhaled CO<sub>2</sub> concentration and breathing resistance?**



Roberge R [2008] Effect of surgical masks worn concurrently over N95 filtering facepiece respirators: extended service life versus increased user burden. *Journal of Public Health Management* 14(2) E19-E26.

Vojtko MR, Roberge MR, Vojtko RJ, Roberge RJ, Landsittel DP: Effect on breathing resistance of a surgical mask worn over an N95 filtering facepiece respirator. *Journal of the International Society for Respiratory Protection* (in press).

# Metabolic Evaluation of N95 Respirator Use with a Surgical Mask

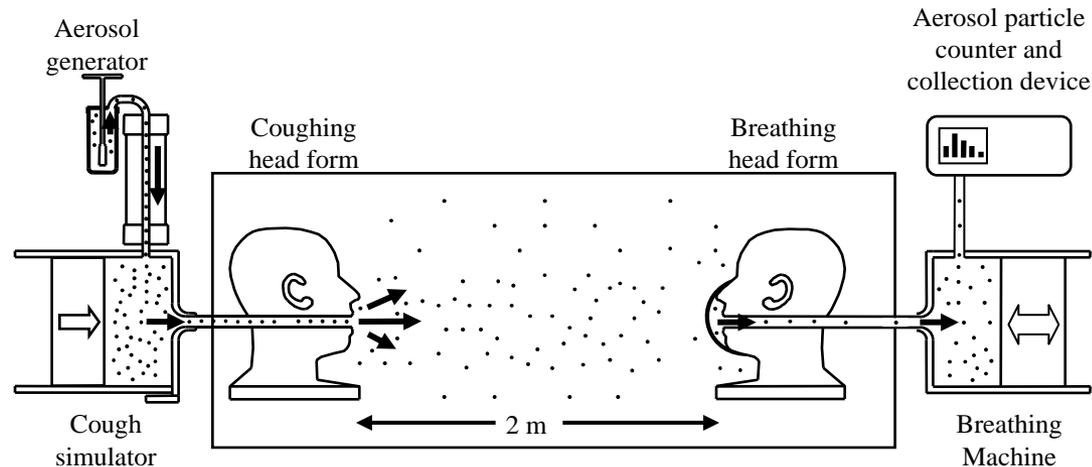
- **Approach – measure breathing resistance and  $O_2/CO_2$  concentration inside the N95 FFR with and without the surgical mask**
  - Phase I: breathing machine and automated breathing and metabolic simulator
  - Phase II: subjects exercising on treadmill
- **Established collaboration with VA – field study on “Tolerability Assessment of Respirators in Healthcare Workers”**
- **Status – Phase I peer-review completed and data collection 25% complete. Phase II protocol under review by NIOSH Human Subjects Review Board.**
- **Goal –Complete Phase I data collection by Summer 2008. Phase II protocol data collection initiated in 2008.**



# Respirator and Surgical Mask Efficacy From Cough Aerosols

- **Goal** – develop an experimental system that simulates a coughing patient and a normally breathing healthcare worker
- **Approach** – examine the effects of distance on exposure, and test the efficacy of surgical masks and N95 FFRs at protecting healthcare workers from cough-generated aerosols

## System Concept



# PAPR/N95 FFR Combination

- **Questions**

- How much protection is provided by a loose-fitting PAPR if the motor or battery fails?
- Any extra protection provided by wearing a fit tested N95 FFR concurrently with a loose-fitting PAPR?

- **Approach – Measured protection factors using ambient aerosol method while mounted on a mannequin and using breathing simulator**

- **Preliminary findings**

- A protection factor of  $<10$  is achieved if the motor/battery fails on a loose-fitting PAPR
- 2-3 orders of magnitude greater protection if a sealed N95 FFR is used concurrently with a non-functioning PAPR



*Roberge R [2008]. Evaluation of the rationale for the concurrent use of n95 filtering facepiece respirators with loose-fitting powered air-purifying respirators during aerosol-generating medical procedures. American Journal of Infection Control 36:2, 134-140.*

*Roberge MR, Vojtko MR, Roberge RJ, Vojtko RJ, Landsittel [2008]. Wearing an N95 respirator concurrently with a powered air-purifying respirator: Effect on protection factors. Submitted to Respiratory Care.*

# N95/P100 TIL Testing

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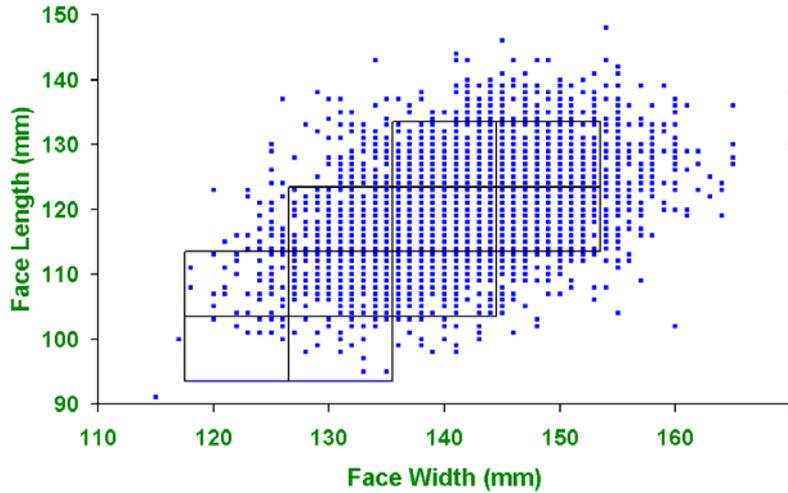
- **Background – significant interest in assessing the differences in protection provided by an N95 versus P100**
- **Current concept**
  - N95 and P100 FFRs, elastomeric half-masks, and full facepiece respirators
  - Aerosols: corn oil and NaCl
  - Use new NPPTL fit test facility
- **Status**
  - Protocol in development

# Project BREATHE

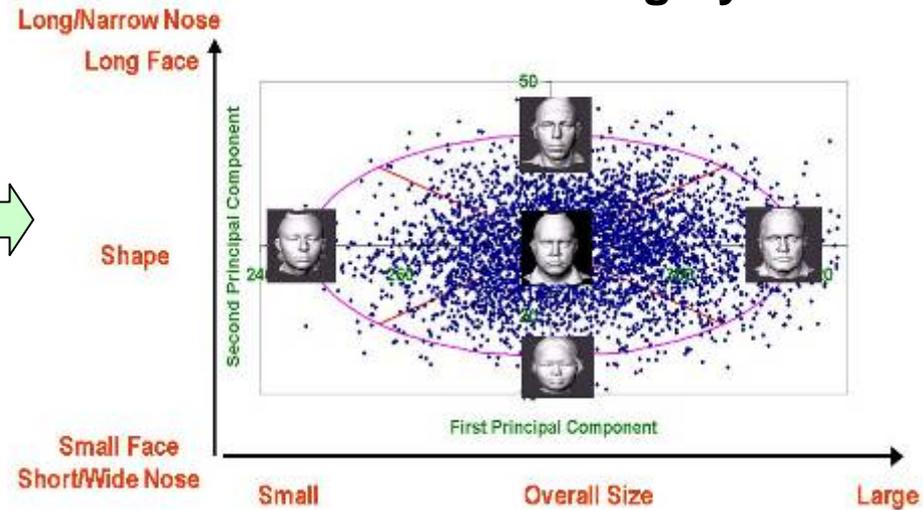
- **BREATHE - Better Respirator Equipment using Advanced Technology for Healthcare Employees**
- **Background**
  - Respirators on the market today were originally designed for the general needs of industrial workers and do not take into account the unique needs of the healthcare worker
  - VHA - largest integrated healthcare system in the US and uses > 1 million respirators/year
- **Concept**
  - Multi-agency working group - VHA (Champion), NIOSH, other government agencies (DoD, CDC, FDA, etc.) to develop appropriate design criteria
  - Solicit manufacturers to develop a respirator designed specifically for use by healthcare workers
  - Prototype testing done at NIOSH (laboratory) and VHA (field)
- **Current status**
  - Still in very early planning stages; MOU between VHA and NIOSH in process
  - VHA beginning to solicit members of the multi-agency working group

# Facial Anthropometrics Research

## 2003 Facial Anthropometrics Survey



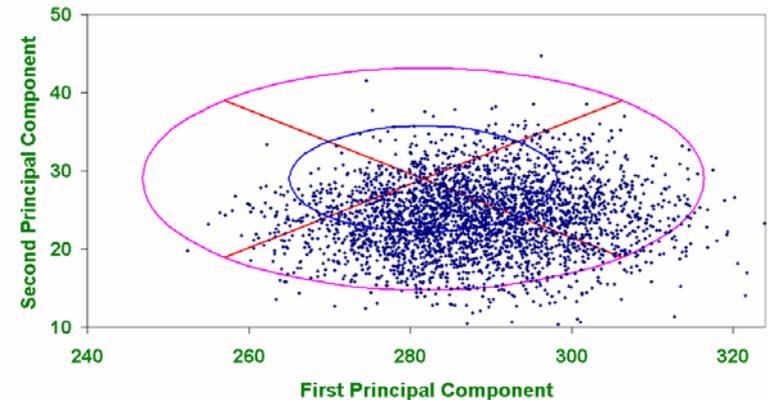
## Fit Test Panels & Sizing Systems



## Representative Headforms



## Appropriateness of NIOSH anthropometrics data for ISO



# Respirator Fit Research

- Goal – investigate the relationships between half-facepiece respirator fit data and facial anthropometry
- Approach – obtained respirator fit (4 models) and anthropometric data for 30 human test subjects
- Current status – data collection complete, data analysis being finalized
- Key finding to date – correlation found between respirator size and fit test panel cells



| NIOSH face size category | Respirator size with highest passing rate | Fit Test Passing Rate  |                        |                        |
|--------------------------|---|------------------------|------------------------|------------------------|
|                          |   | Respirator Size        |                        |                        |
|                          |   | Small                  | Medium                 | Large                  |
| Small (NIOSH Cells 1-3)  | Small                                     | $\frac{22}{27} = 81\%$ | $\frac{18}{27} = 67\%$ | $\frac{7}{27} = 26\%$  |
| Medium (NIOSH Cells 4-7) | Medium                                    | $\frac{32}{48} = 67\%$ | $\frac{40}{48} = 83\%$ | $\frac{32}{48} = 67\%$ |
| Large (NIOSH Cells 8-10) | Large                                     | $\frac{12}{43} = 28\%$ | $\frac{33}{44} = 75\%$ | $\frac{36}{42} = 86\%$ |

# Frequency of Fit Testing

- **Background**

- OSHA regulations (29CFR 1910.134) require respirator users to pass a fit test before using a respirator. Fit testing and training should be conducted annually
- Factors causing changes in respirator fit are not well quantified

- **Approach – Multi-year laboratory study to investigate how changes in weight and facial shape/size affect changes in fit over time**
- **Status – protocol being revised based upon external scientific review**
- **Goal – initiate data collection in 2008**



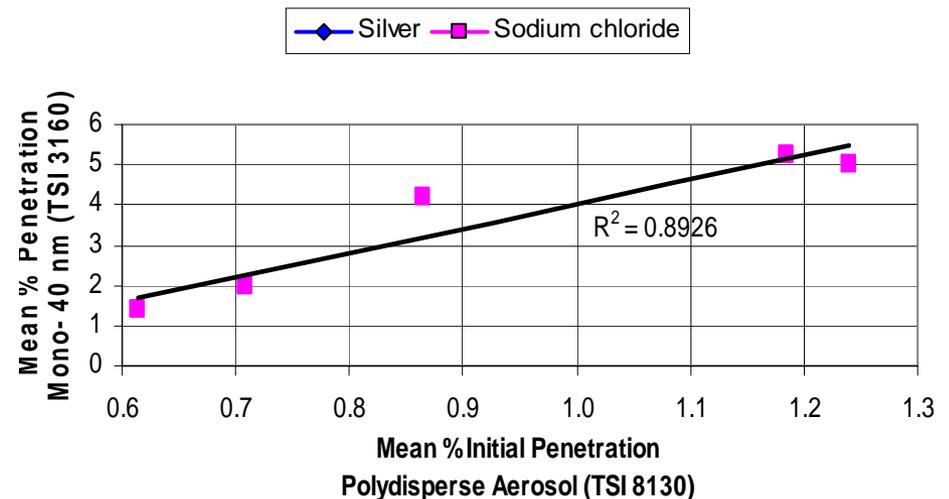
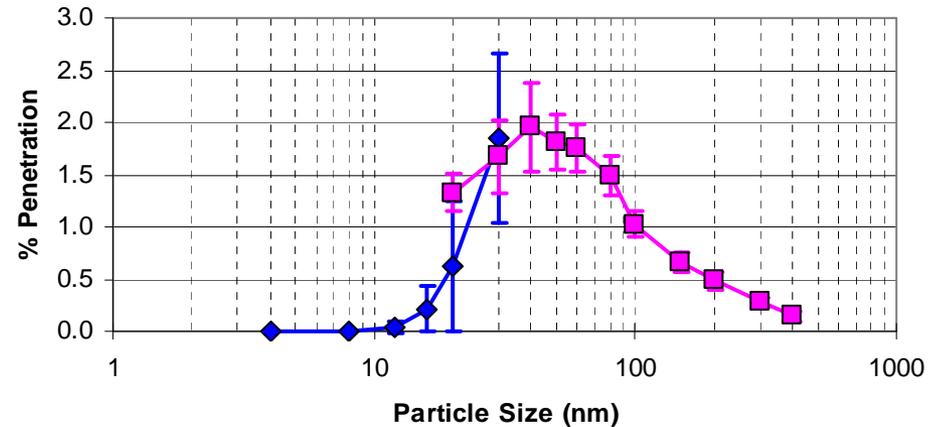
# "No-Fit-Test" Filtering-Facepiece Respirator Workshop and Research Roadmap

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- **Goal** – assess current state of technology available to enhance the fitting performance of negative pressure half-mask APRs and future interdisciplinary research needs and challenges in developing and certifying APRs with improved fitting characteristics
- **Background** – improving the fitting performance of respirators mentioned as a priority research need in 3 recent IOM reports
- **Approach**
  - literature analysis to identify technologies (e.g., shape memory polymers, visual indicators) with potential to improve fitting performance
  - workshop to identify promising technologies, discuss barriers to commercialization, and to identify research gaps
  - final report which can be used to prioritize research and guide future changes to respirator certification
- **Status**
  - Contract should be awarded in March
  - One day workshop tentatively scheduled for Fall 2008

# Filtration of Nanoparticles

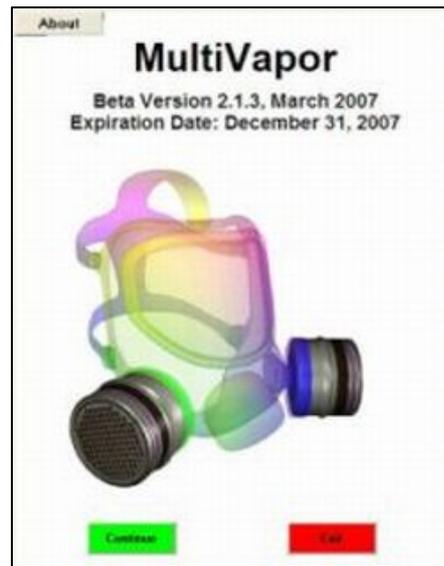
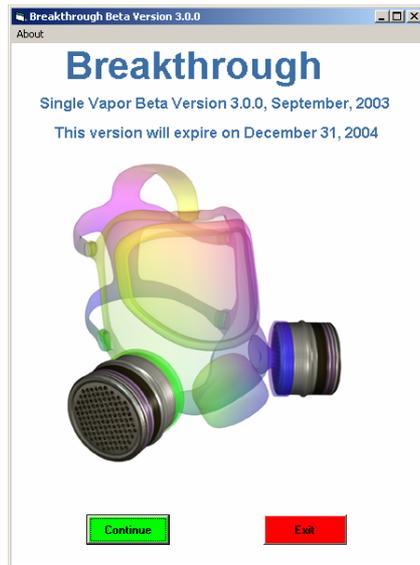
- **Goal** – understand the effectiveness of FFRs for protection against nanoparticles
- **Background** – concerns have been raised that nanoparticles (< 100 nm) may not be captured by respirator filter media as expected by theory
- **Approach** – Measure filtration performance of N95, P100 FFRs, dust masks, and European certified FFPs using three test systems (monodisperse 4 – 30 nm, monodisperse 20 – 400 nm, and polydisperse)
- **Key finding to date** -- NIOSH certified respirators should provide expected protection levels (consistent with their APF) when used in the context of a complete respiratory program



Rengasamy S, Verbofsky R, King WP and Shaffer R [2007]. Nanoparticle penetration through NIOSH-approved N95 filtering facepiece respirators. *Journal of International Society for Respiratory Protection*, 24:49-59.

# ESLI & Electronics Research

- Develop/Integrate Chemical Sensors for Real-Time Determination of Respirator Cartridge Service Life
- Respirator Cartridge End-of-Service Life Modeling



# Protective Ensemble Activities

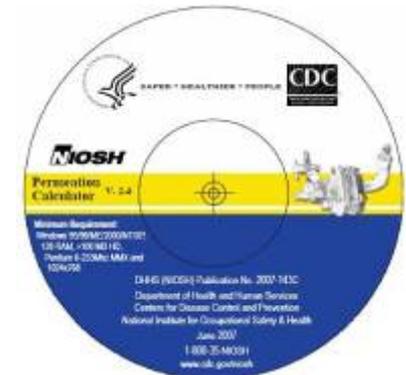
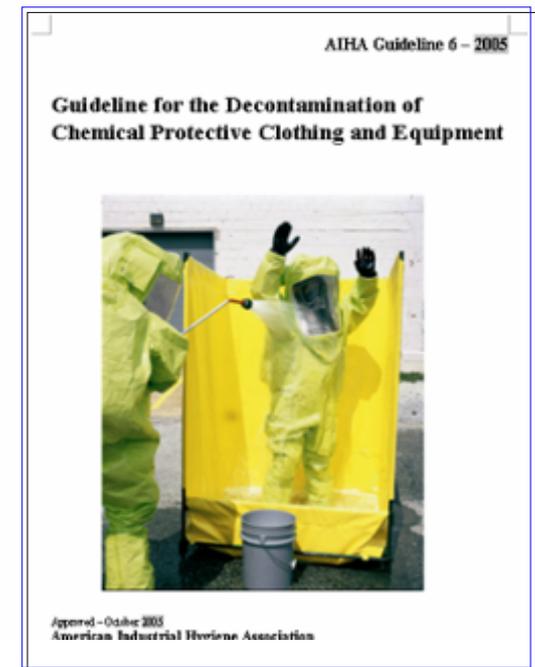
# Improve Chemical/Barrier Protective Clothing Testing and Use Practices to Reduce Worker Exposure to Chemical Dermal Hazards

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- **It has been estimated that more than 13 million workers in the US are potentially exposed to chemicals that can be absorbed by the skin**
- **Protective clothing acts as a barrier to prevent the hazard from reaching the skin**
- **Research is needed to improve the way testing is done and protective clothing used to increase protection and/or reduce burden**
- **Four current research projects**

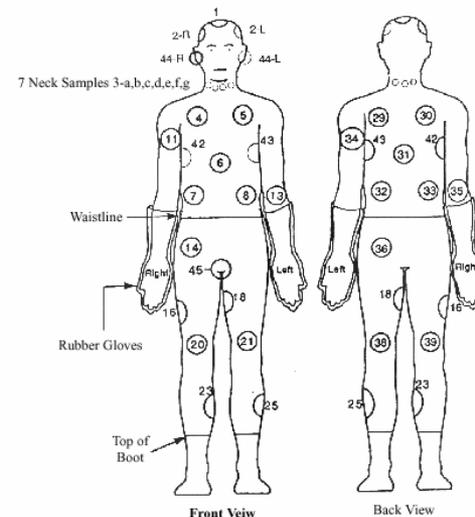
# Chemical Protective Clothing Decontamination Efficacy

- **Goal** – develop suitable methods for CPC decontamination
- **Background** – non-disposable CPC is expensive and repeated use without effective decontamination may result in secondary exposure
- **Approaches** – heat extraction, detergent, and self-decontamination
- **Key finding** – some CPC materials can be re-used multiple times after decontamination, but chemical resistance and material degradation should both be carefully investigated



# PPE Ensemble Test Methods

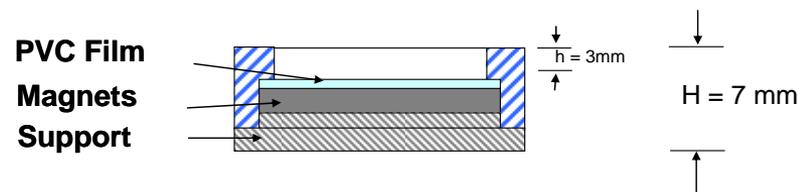
- Goal – develop magnetic passive aerosol sampler (MPAS) prototypes that can be used for measuring particle penetration through protective clothing
- Background – current testing based on active filtration principles, which may overestimate the particle penetration due to additional driving force
- Current status – MPAS prototypes are promising for man in simulant testing (aerosol-MIST)



Top View



Magnets underneath the PVC film



# *Nanoparticle Penetration through Protective Clothing*

- **Goals** – investigate air flow driven penetration of nanoparticles through non-woven materials used in protective clothing
- **Background** – speculated that penetration of nanoparticles through clothing is likely to be even greater than for larger particles
- **Literature survey** – some fabric swatches behave like filter media and particle penetration is driven by pressure differences and is a function of the air permeability of the fabric
- **Current status** – FY09 new start funded by the NIOSH nanotechnology program

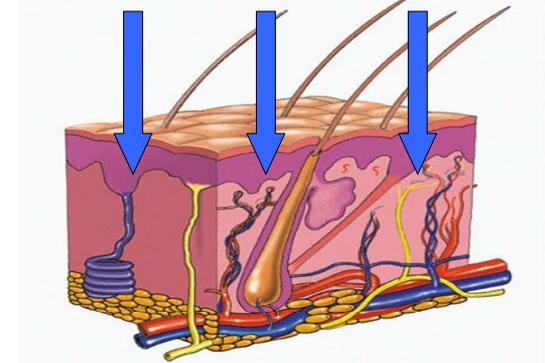
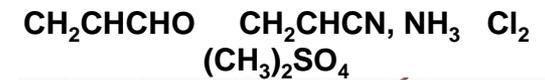


Photo obtained from Health hazard evaluation report: HETA-2005-0291-3025, Methner-MM; Birch-ME; Evans-D; Hoover-MD



# Risk Based Permeation Criteria

- Part of a larger project funded by TSWG and managed by IPP, Inc.
- NPPTL primary objective – develop cumulative permeation procedures for the evaluation of protective clothing material barrier performance against toxic industrial chemicals (TICs)
- Background – current selection criteria do not account for specific toxicity and skin effects of TICs, which results in ensembles that are over designed and create undue wearer stress
- Current status – new project for FY08



Skin Permeation Model



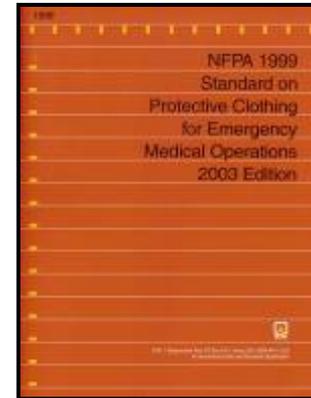
# Improve Emergency Responder Protective Clothing to Reduce Exposure to Thermal, Biological, and Chemical Dermal Hazards

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- **Estimated 1.5 million first responders (Fire, EMS, Law) rely on PPE as their last line of defense**
- **Protective clothing acts as a barrier to prevent the CBRN and thermal hazards from harming the skin**
- **PPT available for the responder community often lack appropriate test methods and standards based on quality science**
- **Three current research projects**

# Improved Criteria for Emergency Medical Protective Clothing

- **Goal** – establish performance criteria for protective clothing and equipment used by emergency medical personnel
- **Background** – mixed industry response to 2003 edition of NFPA 1999 because of conflicting or inappropriate criteria
- **Approach** – obtained end-user input and conducted testing on currently available equipment to determine criteria for revised standard
- **Key finding** – criteria in 2008 edition of NFPA 1999 better match end user expectations and use practices



# *Improved Lab Preconditioning Methods to Address PPE Durability*

- **Goal - develop appropriate preconditioning methods to better simulate actual wear conditions consistent with expected exposures and service life**
- **Background – current criteria for barrier material performance are intended to demonstrate protection over the expected service life, but the lack of scientific studies may result in inappropriate tradeoffs that do not balance protection and the stress-related impact of clothing on wearers**
- **Current status – contract awarded to IPP and peer-review will be initiated in March**





# Stored Thermal Energy in Fire Fighter Protective Garments

- **Current project activities are part of a multi-organizational project funded by a DHS Fire Grant through the NFPA Research Foundation**
- **NPPTL role - manage variability studies between test laboratories using the previously developed stored thermal energy test apparatus (funded by NPPTL)**
- **Background – significant numbers of fire fighter burn injuries occur when energy stored within the layers of the protective equipment are suddenly transferred to the skin through compression of the layers and current standards do not adequately evaluate the risk caused by stored energy**
- **Current status – data collection has been initiated**

NIST



# Investigate Physiological and Ergonomic Impact of Protective Ensembles on Individual Wearers in Affecting Worker Exposure to Dermal Hazards

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- **PPE designed to offer dermal protection often presents physiological/ergonomic burdens (e.g., restricted movement, heat stress, etc.) to the user**
- **Research is needed to better understand the relationships between new technologies for PPE and burden and then to investigate mitigation strategies**
- **Four current research projects**



# Next Generation Structural Fire Fighting PPE – Project HEROES™



- Part of a larger project funded by TSWG and managed by IAFF
- NPPTL primary role – physiological and ergonomic testing of Project HEROES prototype ensemble
- Approach – compared Project HEROES prototype (PE) to standard ensemble (SE)
- Key findings –PE does not adversely affect the wearer’s overall functional mobility, but did increase thermal stress compared to the SE



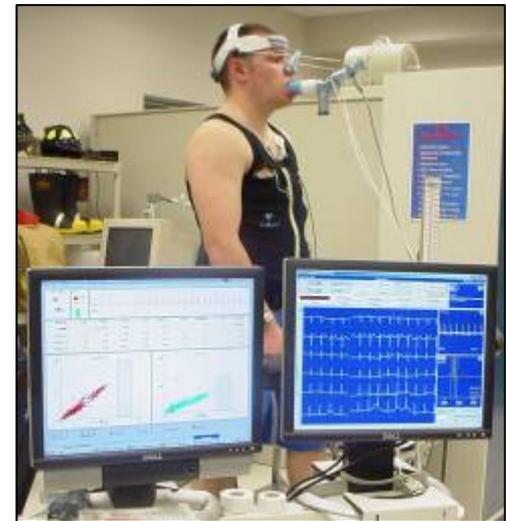
# Physiological Models and Countermeasures

- **Goals – develop protocols to assess the physiological burden of PPE ensembles and investigate physiological countermeasures**
- **Background – overexertion and heat stress are among the most common causes of firefighter injuries and deaths**
- **Approach – transition Project HEROES protocol to ASTM std, initiated research on sensor vests, and cooling systems**
- **Current status – ASTM std published in 2007; research in progress on sensor vests and cooling systems**



# Correlation of Physiological Data with Total Heat Loss (THL) Test

- **Goal** – investigate physiological basis for setting THL values in future PPE performance standards
- **Background** – THL performance criteria are used in several NFPA standards to estimate heat stress levels caused by turnout gear composites
- **Planned approach** – subjects wearing PPE ensembles with different THL values will be exercised at various work rates to correlate THL values with physiological variables (core/skin body temperature, heart rate, etc.)
- **Current status** – protocol will be developed in FY08 and submitted for external peer-review



# *Biomechanical and Physiological Study of Firefighter Boots*

- **Goal – determine the effect of boot weight and design on firefighters’ biomechanical and physiological responses**
- **Approach – 50 firefighters will be recruited and tested while performing several simulated firefighting tasks in the laboratory. The study will evaluate the effects of boot weight and material (rubber versus leather) on male and female firefighters’ oxygen consumption, joint loading, dynamic balance, and gait characteristics**
- **Current status – data collection nearly completed; interim findings presented to NFPA in 2007**

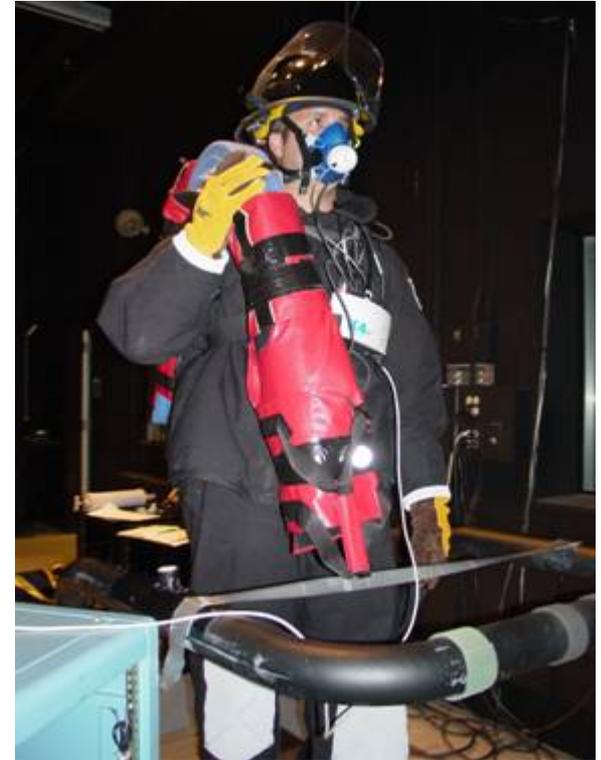


Photo taken from Turner and Chiou presentation at the meeting of the NFPA Technical Committee on Structural and Proximity Fire Fighting Protective Clothing and Equipment, Portland, ME, July 9 – 10, 2007

# Quality Partnerships Enhance Worker Safety & Health



Visit Us at: <http://www.cdc.gov/niosh/npptl/default.html>

***Disclaimer: The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.***

Thank you