NPPTL Mission . . .

To prevent work-related illness and injury by ensuring the development, certification, deployment, and use of personal protective equipment and fully integrated, intelligent ensembles.

This will be accomplished through the advancement and application of personal protective technology standards.

NIOSH/NPPTL Personal Protective Technology Programs

Public Meeting October 12 & 13, 2006

Pittsburgh, PA

Les Boord, Director NPPTL

NIOSH/NPPTL Personal Protective Technology Programs

AGENDA

Thursday, October 12, 2006

- **Research Topics - Poster Session**
- **Standards Development - Presentations**

Friday, October 13, 2006

- **PPT Cross Sector**
- **Research Projects – Presentations**

NIOSH/NPPTL Personal Protective Technology Programs

<u>Meeting Objective</u>

To provide program information to our stakeholders and customers.

NIOSH/NPPTL Personal Protective Technology Programs

- **Recap of 1st Two Days**
- **NIOSH Personal Protective Technology Program**

federal register

Thursday
June 8, 1995

Part II

Department of Health and Human Services
Public Health Service
42 CFR Part 84

Department of Labor
Mine Safety and Health Administration
30 CFR Parts 11, 49, 56, 57, 66, 70, 72, and 75

Department of Labor
Mine Safety and Health Administration

Department of Health and Human Services
Centers for Disease Control and Prevention

Respiratory Protective Devices; Final Rules and Notice

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 Research Program Portfolio

Industry Sectors

- Agriculture, forestry, and fishing
- Construction
- Healthcare and social assistance
- Mining
- Manufacturing
- Services
- Transportation, warehousing, and utilities
- Wholesale and retail trade

Cross Sector Programs

- Authoritative Recommendations Development
- Cancer, reproductive, cardiovascular, neurologic & renal diseases
- Communications and information dissemination
- Emergency preparedness/response
- Global collaborations
- Health hazard evaluation (HHE)
- Hearing loss prevention
- Immune, dermal and infectious diseases
- Musculoskeletal disorders
- Personal protective technology
- Radiation dose reconstruction
- Respiratory diseases
- Training grants
- Traumatic injury
- Work organization and stress-related disorders

Emphasis Areas

- Economics
- Exposure assessment
- Engineering controls
- Work life initiative
- Occupational health disparities
- Small business assistance and outreach
- Surveillance

PPT Cross Sector Membership

- Cross Sector Manager - **Les Boord, NPPTL**
- Program Coordinators
  - **Maryann D'Alessandro, NPPTL**
  - **Jeff Welsh, PRL**
- Program Assistant Coordinator
  - **Angie Shepherd, NPPTL**

- Roland Berry Ann, NPPTL
- George Bockosh, NPPTL
- John Kovac, NPPTL
- Bill Haskell, NPPTL
- Charles Oke, NPPTL
- Ed Fries, NPPTL
- Nina Turner, DSR
- Chris Coffey, DRDS
- Lynda Ewers, DSHEFS
- Chuck Kardous, DART
- John Sammarco, PRL
- Ken Williams, NPPTL
- Ron Shaffer, NPPTL
- Jon Szalajda, NPPTL
- Heinz Ahlers, NPPTL
- Bill Hoffman, NPPTL
- Bill Newcomb, NPPTL

PPT Cross Sector
PPT Program Plan – Action Timeline

- **1Q 2006 (Oct 2005 – Dec 2005)**
  - PPT Cross Sector leadership meet bi-weekly
  - Develop draft mission, vision, definition and logic model and discuss strategy for PPT Cross Sector
- **2Q 2006 (Jan 2006 – Mar 2006)**
  - PPT Cross Sector Team established
    - NPPTL Program Managers, Epidemiologist, Standards Coordinator
    - NPPTL Branch Chiefs
    - NIOSH Division volunteers and solicited participants
  - Begin monthly cross sector meeting
  - Develop draft logic model (Value creation system)

PPT Cross Sector
Mission, Vision, Definition

- **Mission Statement –**

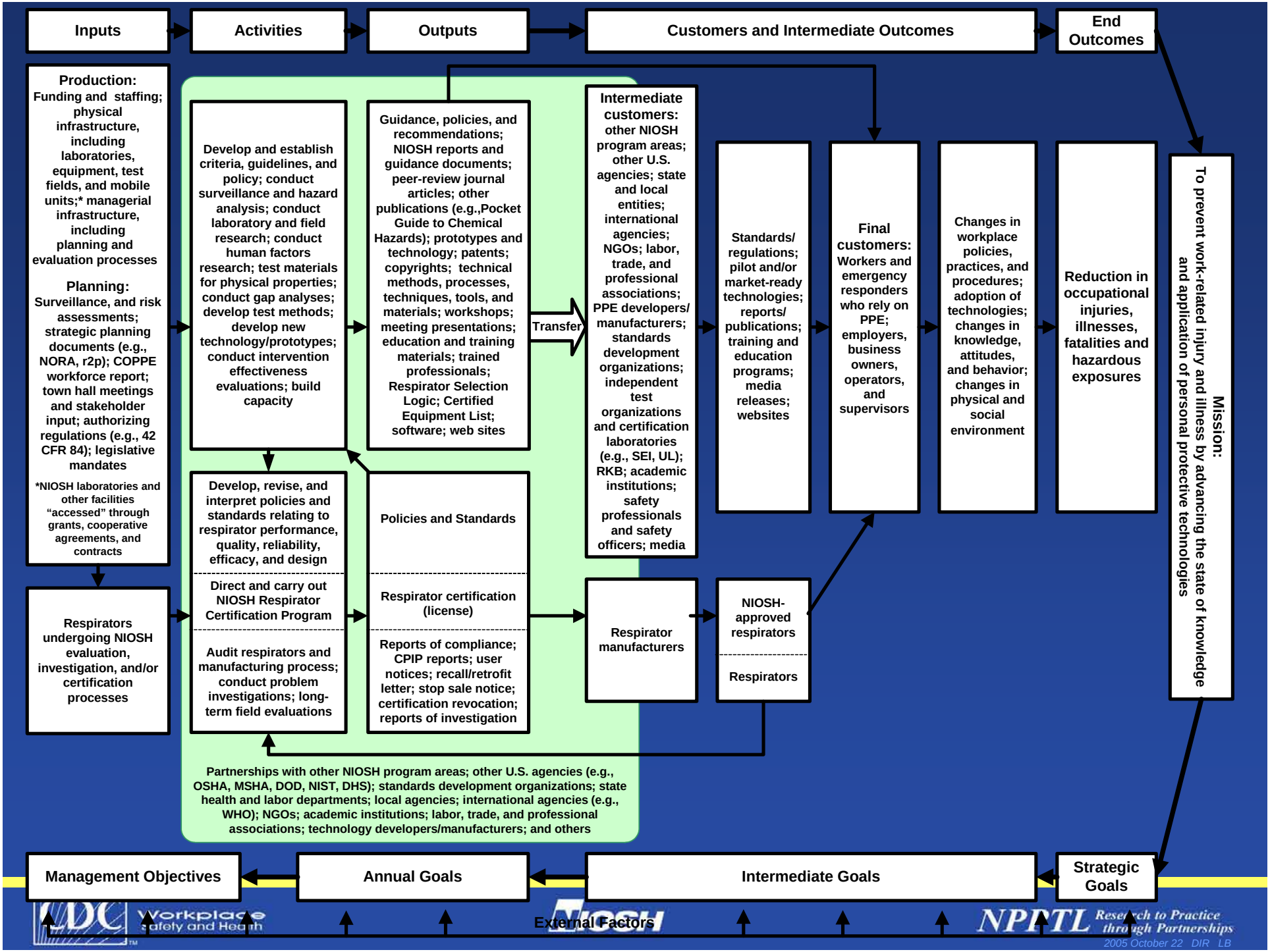
To prevent work-related injury and illness by advancing the state of knowledge and application of personal protective technologies.

- **Vision Statement –**

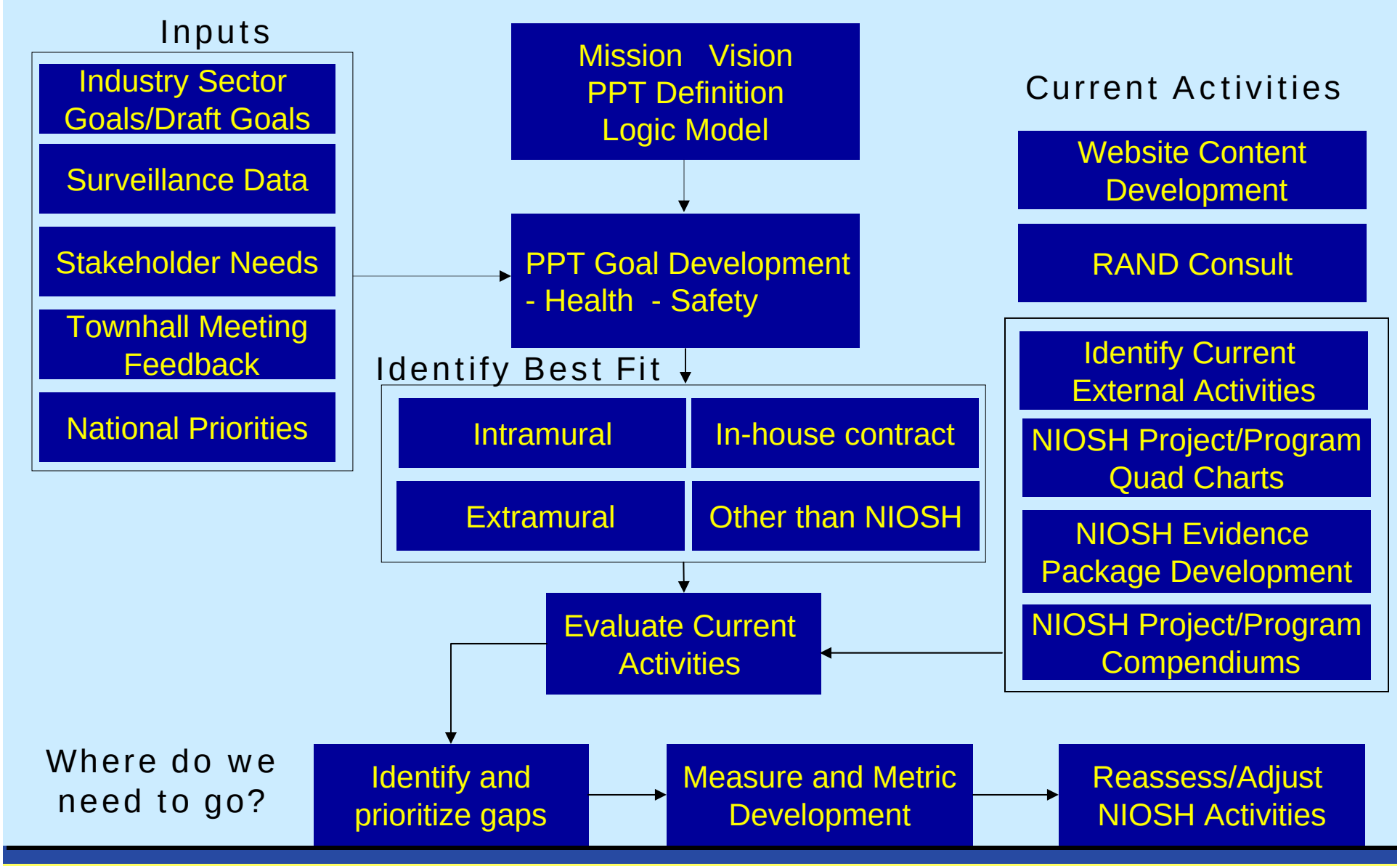
Be the leading provider of quality, relevant and timely PPT research, training and evaluation.

- **PPT Definition –**

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.


Inputs
Activities
Outputs
Customers and Intermediate Outcomes
End Outcomes
Production: Funding and staffing; physical infrastructure, including laboratories, equipment, test fields, and mobile units;* managerial infrastructure, including planning and evaluation processes
Planning: Surveillance, and risk assessments; strategic planning documents (e.g., NORA, r2p); COPPE workforce report; town hall meetings and stakeholder input; authorizing regulations (e.g., 42 CFR 84); legislative mandates
*NIOSH laboratories and other facilities "accessed" through grants, cooperative agreements, and contracts
Respirators undergoing NIOSH evaluation, investigation, and/or certification processes
Develop and establish criteria, guidelines, and policy; conduct surveillance and hazard analysis; conduct laboratory and field research; conduct human factors research; test materials for physical properties; conduct gap analyses; develop test methods; develop new technology/prototypes; conduct intervention effectiveness evaluations; build capacity
Develop, revise, and interpret policies and standards relating to respirator performance, quality, reliability, efficacy, and design
Direct and carry out NIOSH Respirator Certification Program
Audit respirators and manufacturing process; conduct problem investigations; long-term field evaluations
Guidance, policies, and recommendations; NIOSH reports and guidance documents; peer-review journal articles; other publications (e.g.,Pocket Guide to Chemical Hazards); prototypes and technology; patents; copyrights; technical methods, processes, techniques, tools, and materials; workshops; meeting presentations; education and training materials; trained professionals; Respirator Selection Logic; Certified Equipment List; software; web sites
Policies and Standards
Respirator certification (license)
Reports of compliance; CPIP reports; user notices; recall/retrofit letter; stop sale notice; certification revocation; reports of investigation
Transfer
Intermediate customers: other NIOSH program areas; other U.S. agencies; state and local entities; international agencies; NGOs; labor, trade, and professional associations; PPE developers/ manufacturers; standards development organizations; independent test organizations and certification laboratories (e.g., SEI, UL); RKB; academic institutions; safety professionals and safety officers; media
Respirator manufacturers
Standards/ regulations; pilot and/or market-ready technologies; reports/ publications; training and education programs; media releases; websites
NIOSH-approved respirators
Respirators
Final customers: Workers and emergency responders who rely on PPE; employers, business owners, operators, and supervisors
Changes in workplace policies, practices, and procedures; adoption of technologies; changes in knowledge, attitudes, and behavior; changes in physical and social environment
Reduction in occupational injuries, illnesses, fatalities and hazardous exposures
Mission: To prevent work-related injury and illness by advancing the state of knowledge and application of personal protective technologies
Partnerships with other NIOSH program areas; other U.S. agencies (e.g., OSHA, MSHA, DOD, NIST, DHS); standards development organizations; state health and labor departments; local agencies; international agencies (e.g., WHO); NGOs; academic institutions; labor, trade, and professional associations; technology developers/manufacturers; and others
Management Objectives
Annual Goals
Intermediate Goals
Strategic Goals
External Factors
Workplace Safety and Health
NIOSH
NPPTL Research to Practice through Partnerships
2005 October 22 DIR LB

PPT Cross Sector Strategy



PPT Cross Sector
PPT Program Plan – Action Timeline

- 1Q 2006
  - Finalize Mission, Vision, Definition, Logic Model with Team
  - Begin monthly meetings in Feb 2006
  - Develop Quad Charts for all PPT Projects
  - Begin evidence package development and web site development
- 2Q 2006
  - Identify Sector and General Goal Development Leads
    - Review sector strategic goals and/or initial sector strategy
    - Review injury, illness and fatality data and Draft Sector Descriptions to identify priority PPT needs aligning to surveillance data as well as stakeholder and user needs.
- 3Q 2006
  - Consult with RAND on Evidence Package development
  - Develop PPT Draft Goals, expected performance measures, outputs, and outcomes

PPT Draft Goal 2

- 2.0 Develop informational materials to provide guidance to identify appropriate PPE for all life cycle stages.
  - **2.1 Develop working agreements with appropriate stakeholders to collaborate on developing selection and use guidance documents**
  - **2.2 Collaborate with appropriate stakeholders on PPE guidance and training**
    - **2.2.1 Collaborate with stakeholders and appropriate standards-setting bodies on the guidance documents needed for respiratory protection**
    - **2.2.2 Collaborate with stakeholders and appropriate standards-setting bodies on the guidance documents needed for protective clothing and ensembles**
    - **2.2.3 Collaborate with stakeholders and appropriate standards-setting bodies on the guidance documents needed for hearing protection PPE**
    - **2.2.4 Collaborate with stakeholders and appropriate standards-setting bodies on the guidance documents needed for head protection PPE**
    - **2.2.5 Collaborate with stakeholders and appropriate standards-setting bodies on the guidance documents needed for eye and face PPE**
  - **2.3 Collaborate with stakeholders and appropriate standards-setting bodies on the guidance documents needed for PPE decontamination**

PPT Draft Goal 1

- 1.0 Identify and develop performance requirements and evaluation criteria for PPT to achieve harmonized standards to improve the quality and performance of PPE through all lifecycle stages.
  - **1.1 Develop working agreements with appropriate standards development organizations for collaboration.**
  - **1.2 Participate on appropriate standards-setting bodies to improve the quality and performance of personal protective equipment (PPE)**
    - **1.2.1 Participate on appropriate standards-setting bodies for respiratory protection equipment**
    - **1.2.2 Participate on appropriate standards-setting bodies for protective clothing and ensembles**
    - **1.2.3 Participate on appropriate standards-setting bodies for hearing protection PPE**
    - **1.2.4 Participate on appropriate standards-setting bodies for head protection PPE**
    - **1.2.5 Participate on appropriate standards-setting bodies to address issues related to eye and face PPE**
  - **1.3 Provide input on the performance requirements and test methods needed to provide appropriate PPE**

PPT Draft Goal 3

- 3.0 Conduct research to address personal protective technology (PPT) knowledge gaps and improve existing technologies.
  - **3.1 Identify performance requirements needed to prevent inhalation exposures**
  - **3.2 Identify performance requirements needed to prevent dermal exposures**
  - **3.3 Identify performance requirements needed to prevent hearing exposures**
  - **3.4 Identify performance requirements needed to prevent traumatic injuries to the head**
  - **3.5 Identify performance requirements to prevent traumatic injuries to the eye and face**

PPT Program Plan – Action Timeline

- 4Q 2006 – 1Q 2007 ((Oct 2006 – Dec 2006)
  - Evidence package development
    - Develop history of program, compendiums
    - Quad charts for each program serve as foundation of web site and presentation
  - Links from quad charts to provide additional information
    - Consult with RAND on strategy and evidence package development
    - Finalize Goals and Performance Measures
  - Incorporate partner and stakeholder lists and letters
- 2Q 2007 (Jan 3007 – Mar 2007)
  - Continue to refine and finalize evidence package
- 3Q 2007 (May 2007)
  - Evidence package to National Academies

NIOSH Personal Protective Technology Programs

We want your feedback!

Les Boord

NIOSH / NPPTL

E-mail: zfx2@cdc.gov

Phone: 412-386-6111

Thank you!!!

National Personal Protective Technology Laboratory

GENERAL REMARKS ON THE NPPTL RESEARCH PROGRAM

Ron Shaffer
Chief, Research Branch

NPPTL Public Meeting

October 13, 2006

CDC Workplace Safety and Health | NIOSH | NPPTL Research to Practice through Partnerships

Research Focus Areas

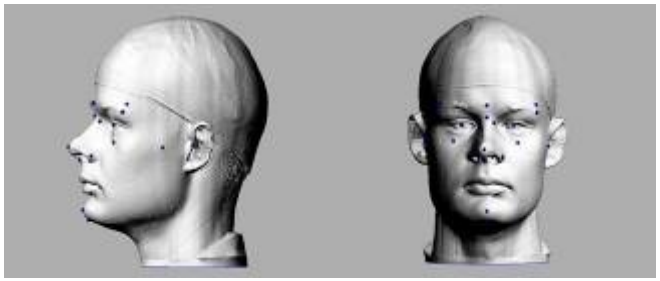
- **Respiratory Protection**
- **Sensors & Electronics – Integration with PPT**
- **Protective Clothing & Ensembles**
- **Human Performance**

Respiratory Protection Research

- **Aerosol/Filtration Studies**
  - Nanoparticles
  - Bioaerosols

- **Respirator Fit Test Research**
  - Facial anthropometrics

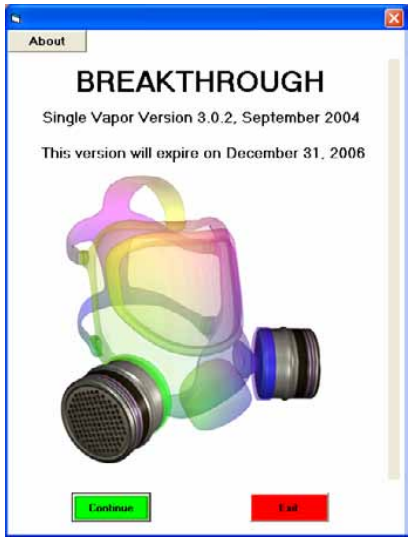
- **Influenza Pandemic**
  - Reusability of filtering facepiece respirators (FY07 new start)



Sensors & Electronics Research

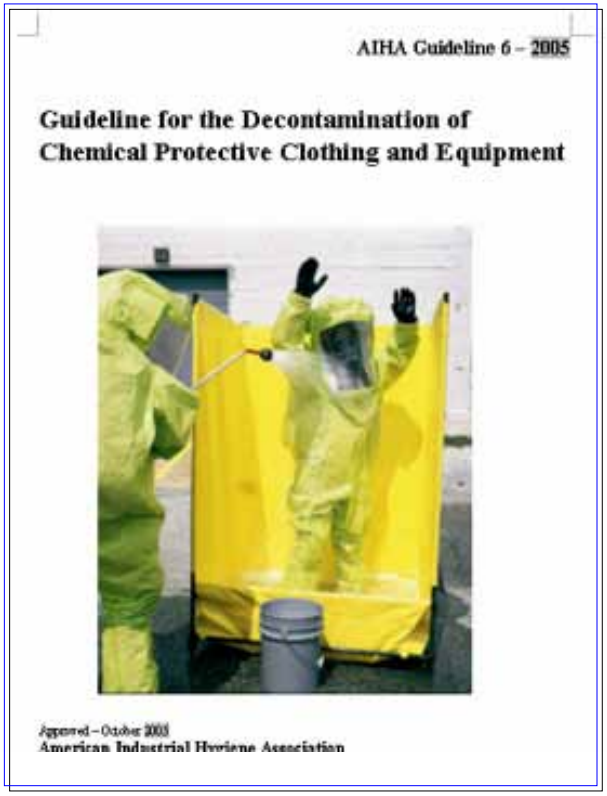
- **Develop/Integrate Chemical Sensors for Real-Time Determination of Respirator Cartridge Service Life**

- **Respirator Cartridge End-of-Service Life Modeling**



Protective Clothing & Ensembles Research

- **Decontamination Efficacy of Chemical Protective Clothing (CPC)**
- **Improved Criteria for Emergency Medical Protective Clothing and Equipment**
- **Development of Bench and MIST Protocols for Particulate Penetration Measurements of Protective Clothing and Ensembles**
- **Validation of PPE Preconditioning Methods (FY07 New Start)**


AIHA Guideline 6 – 2005

Guideline for the Decontamination of Chemical Protective Clothing and Equipment

Approved – October 2003
American Industrial Hygiene Association

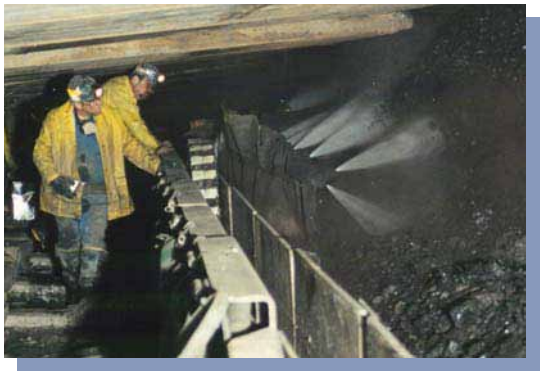
Human Performance Research

- **Project HEROES – Physiological/Ergonomic Evaluation of Firefighter PPE Prototype with Advanced Chem/Bio Protection**
- **Physiological Models and Countermeasures**
  - Test methods to assess the physiological "burden" of PPE ensembles
  - Embedded cooling garments to reduce the heat stress of firefighters
  - Evaluate portable physiological monitoring equipment (e.g., sensor vest)
- **Metabolic Evaluation of N95 Respirators with Protective Coverings (FY07 new start)**

Summary

- **Standards focus – ASTM, NFPA, ISO**
- **Diverse mix of PPT research projects from the 4 research focus areas**
- **R2P through partnerships**

Quality Partnerships Enhance Worker Safety & Health



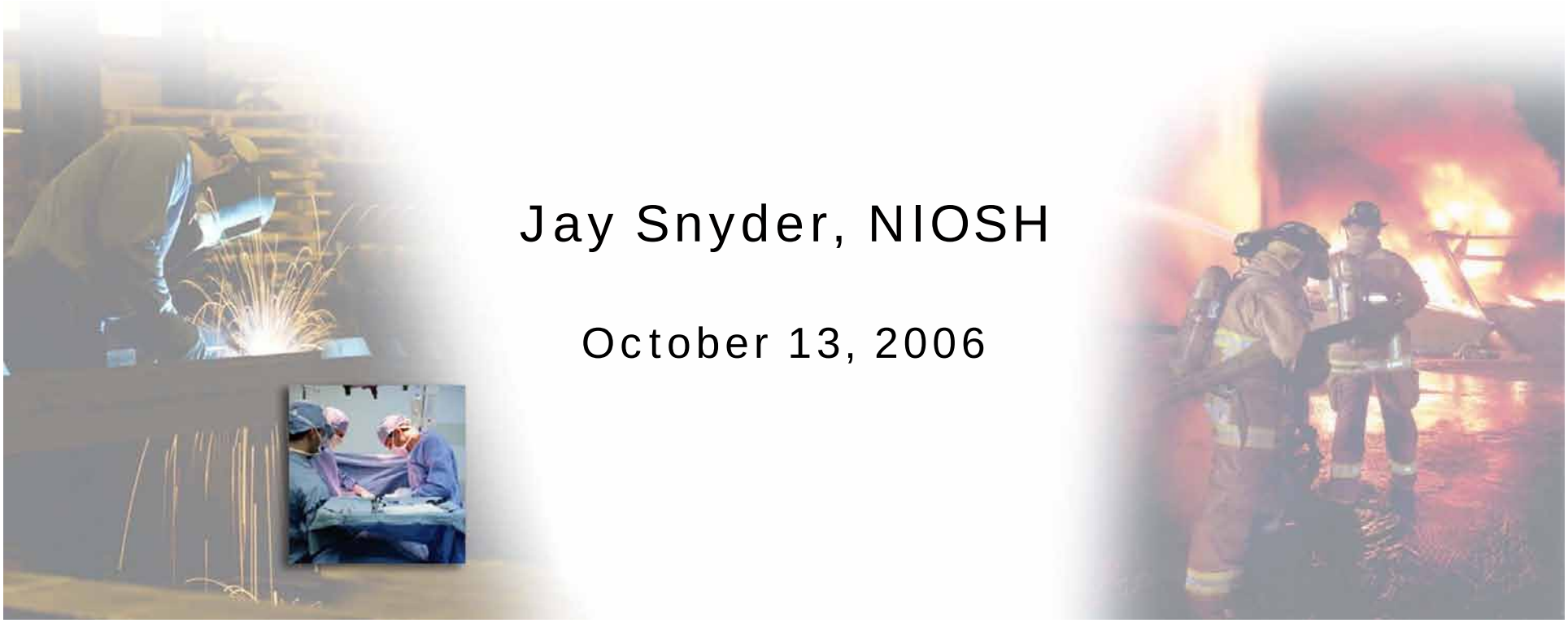
Visit Us at: http//www.cdc.gov/niosh/npptl/default.html

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

National Personal Protective Technology Laboratory

End-of Service Life Sensor Program



Jay Snyder, NIOSH

October 13, 2006

Presentation Overview

- **NIOSH/NPPTL End of Service Life Program**
- **NIOSH Cartridge Simulator**
- **CMU Sensor Development**

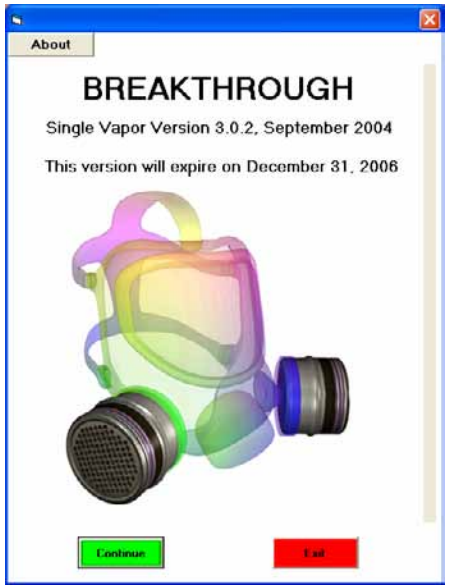
Respirator Cartridge Change Schedules

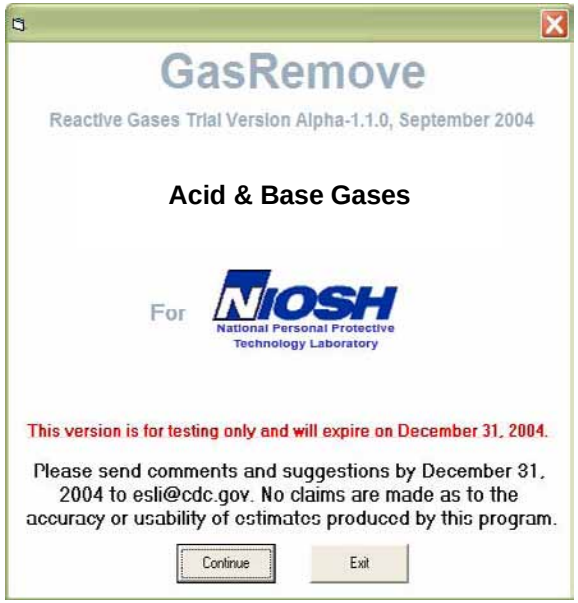
- **OSHA Standard 1910.134(d)(3)(iii)(B)(2)**
- **Employers are required to use end-of-service indicator when available**
- **As an alternative- must develop cartridge / canister change schedules based on**
  - Manufacturer recommendations
  - Breakthrough test data
  - Mathematical models

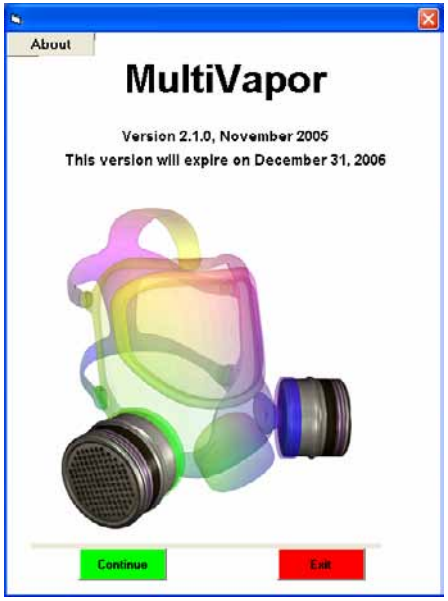
- **Reliance on odor thresholds are not permitted as the primary basis for determining the service life**
- **Service life data affected by temperature, humidity, air flow through the filter, work rate, and presence of other chemicals**

Summary of Models

- **Single vapor with relative humidity effects**
- **Reactive gas**
- **Multi-vapor with relative humidity effects**







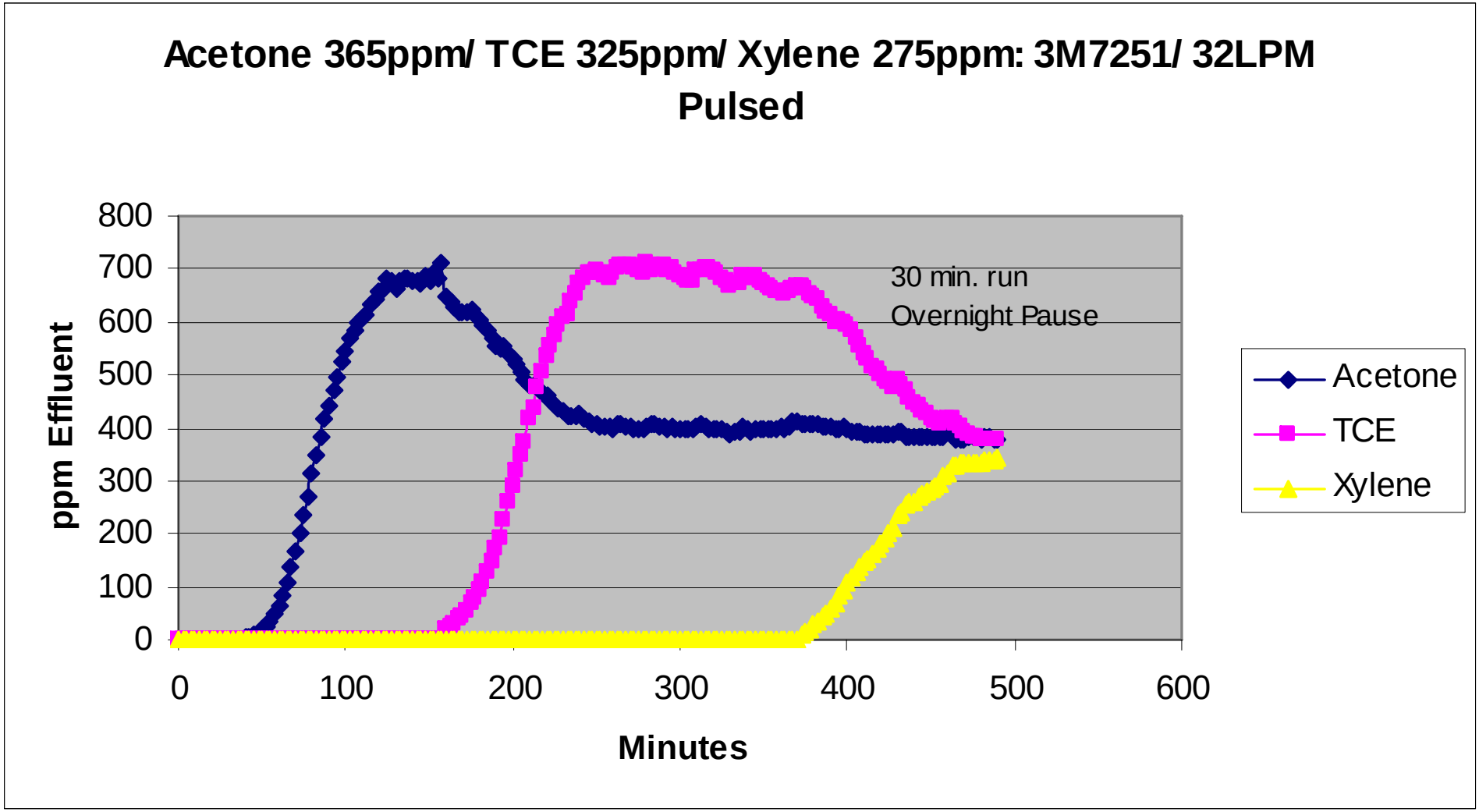
NIOSH Certification Criteria

4.3.1. Data demonstrating that the ESLI is a reliable indicator of sorbent depletion *less than or equal to 90% of service life*. The data shall include the results of a flow-temperature study at low and high temperatures, humidities, and contaminant concentrations which are reasonably representative of actual workplace conditions where it is anticipated that a given respirator will be used. A minimum of two contaminant levels must be utilized for each study, including the limit level (permissible exposure limit, threshold limit value, etc.) and the limit level times the assigned protection factor for the respirator type.

End-of-Service Life

Almost

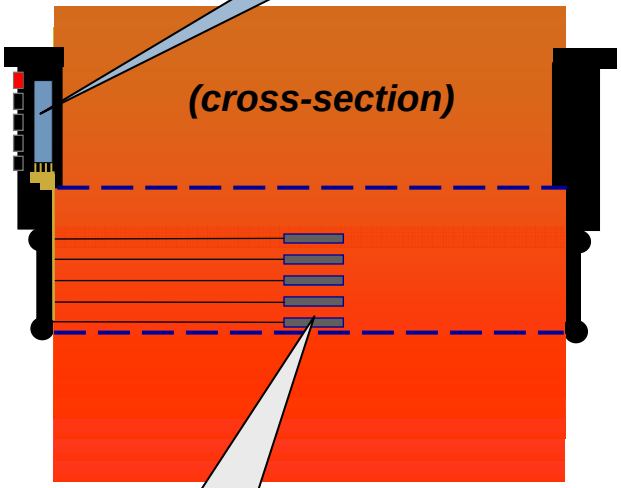
Multiple Solvent Assault with a Break



ESLI Sensor Concept

Saturation indicators

Controller



Embedded MEMS sensors

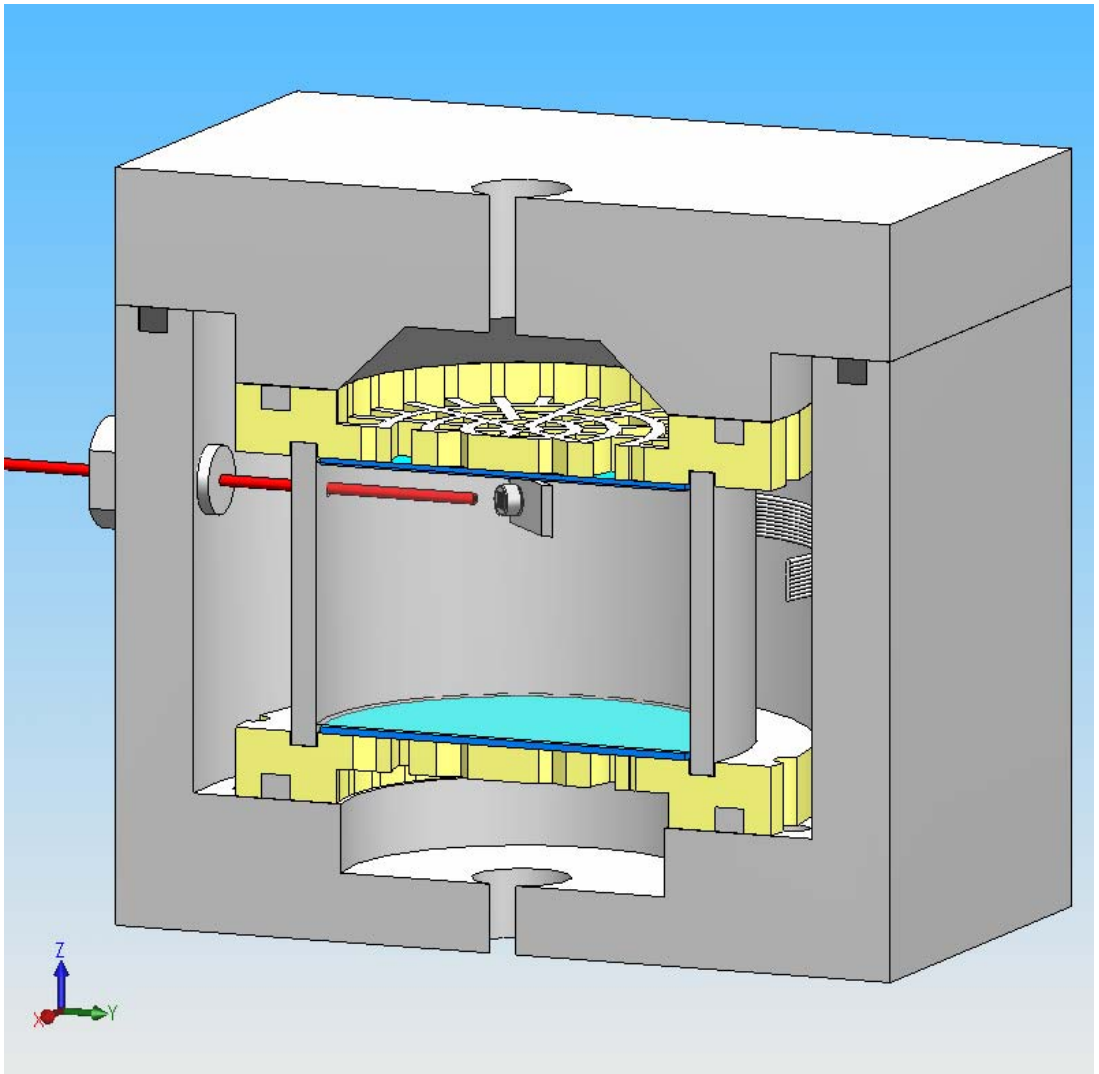
External Peer Review

- Conducted 05/13/2005
- Seven external reviewers

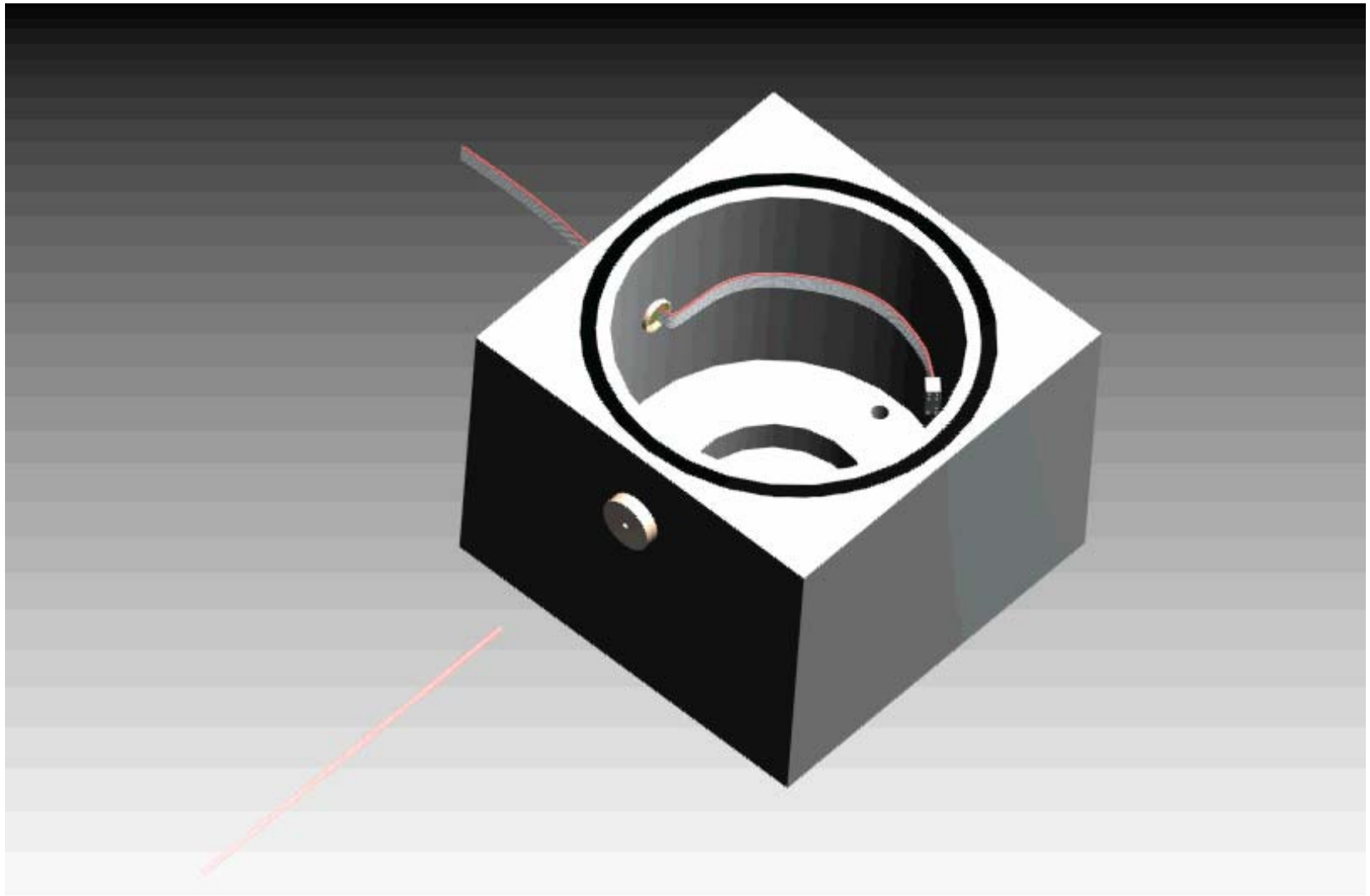
Recommendations

- Continue CMU sensor development
- Expand experimental program to determine effects of sensor placement, temperature, and humidity

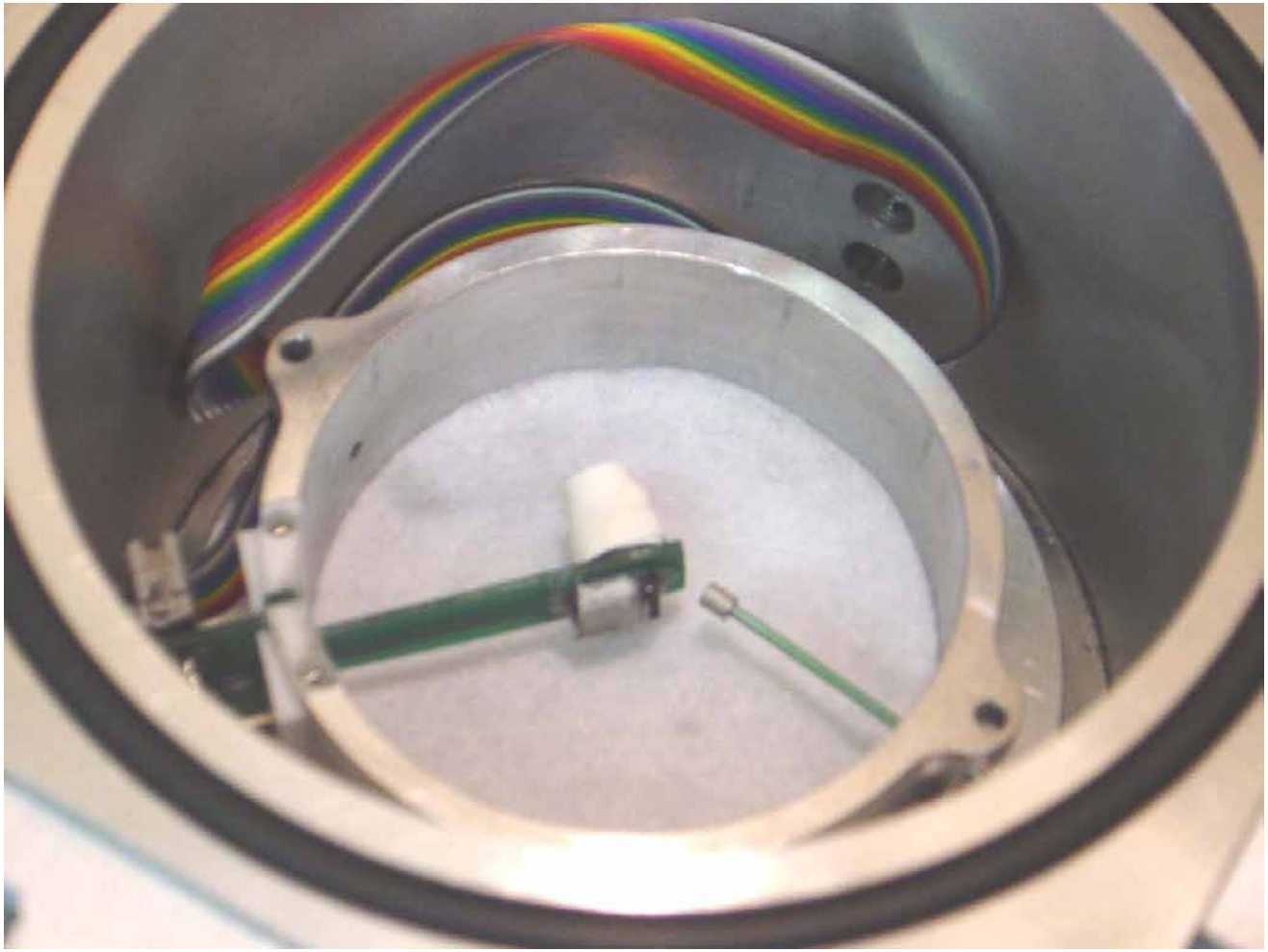
Cross Section of Cartridge Simulator



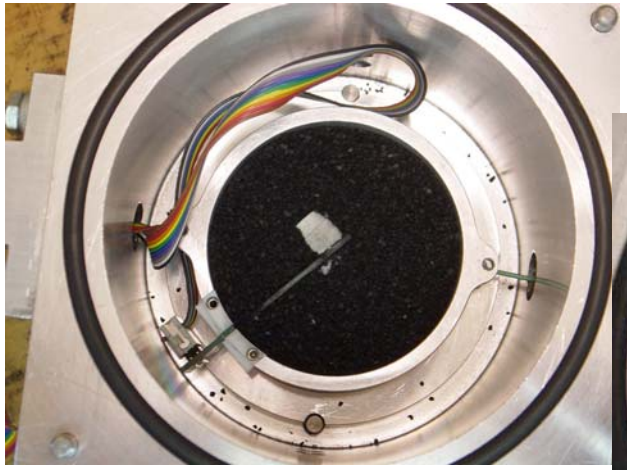
Cartridge Simulator

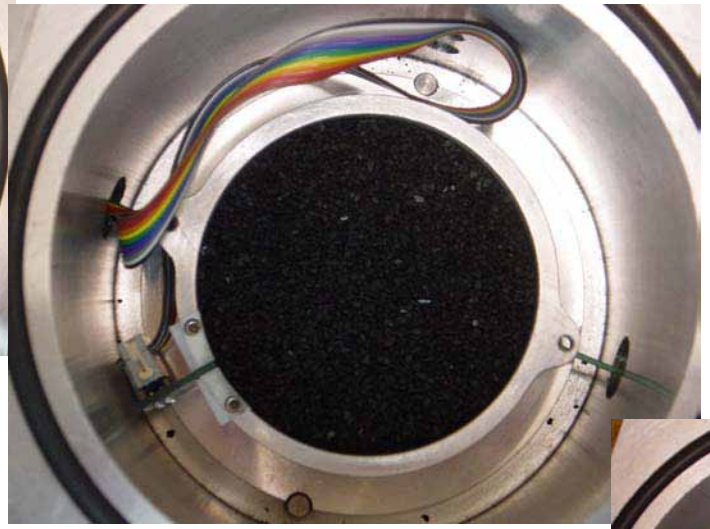


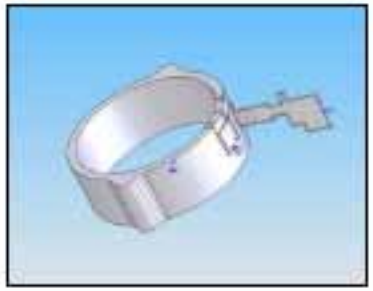
Simulator with Sensor



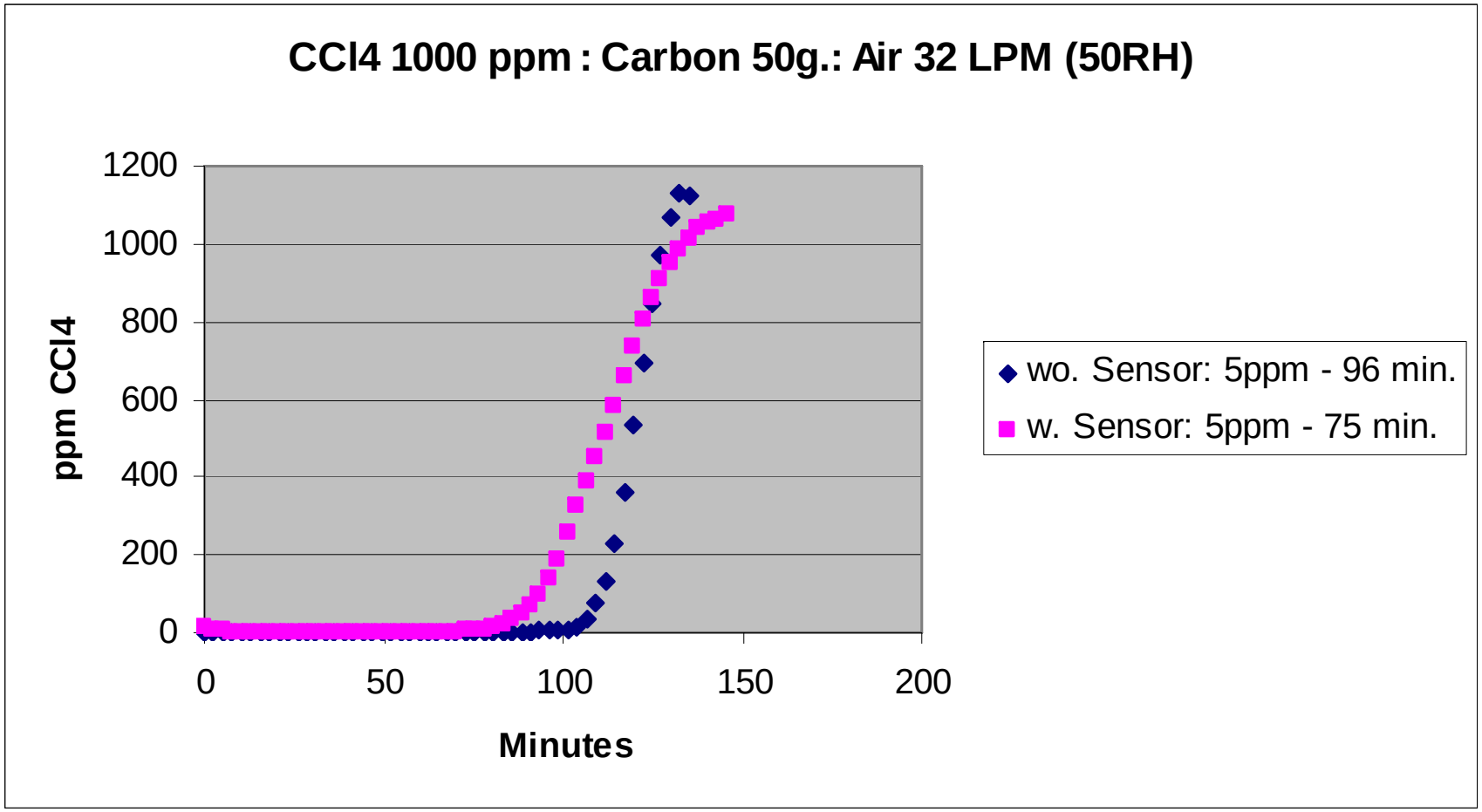
Loading the Cartridge Simulator



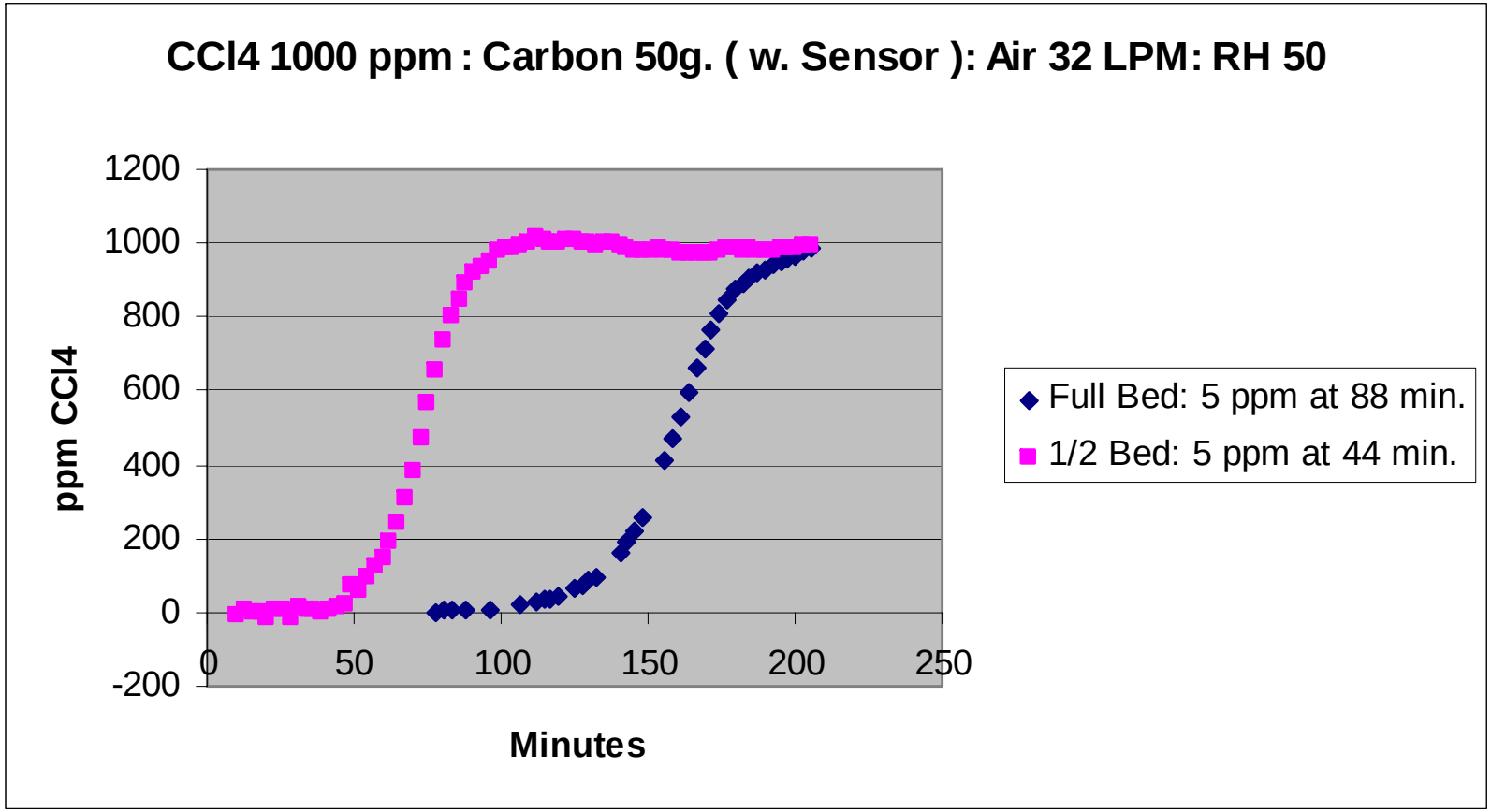




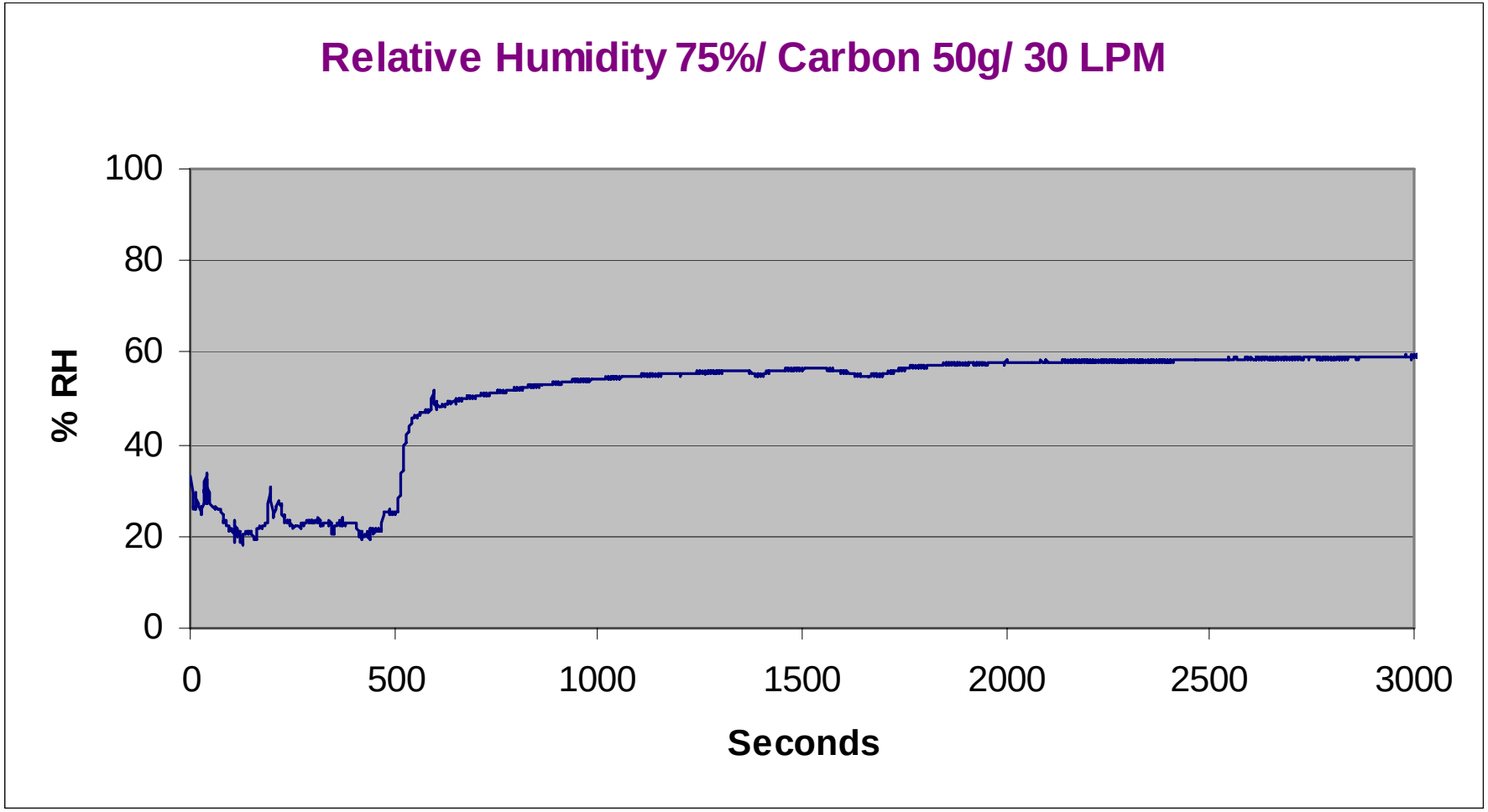
Simulator Breakthrough Data



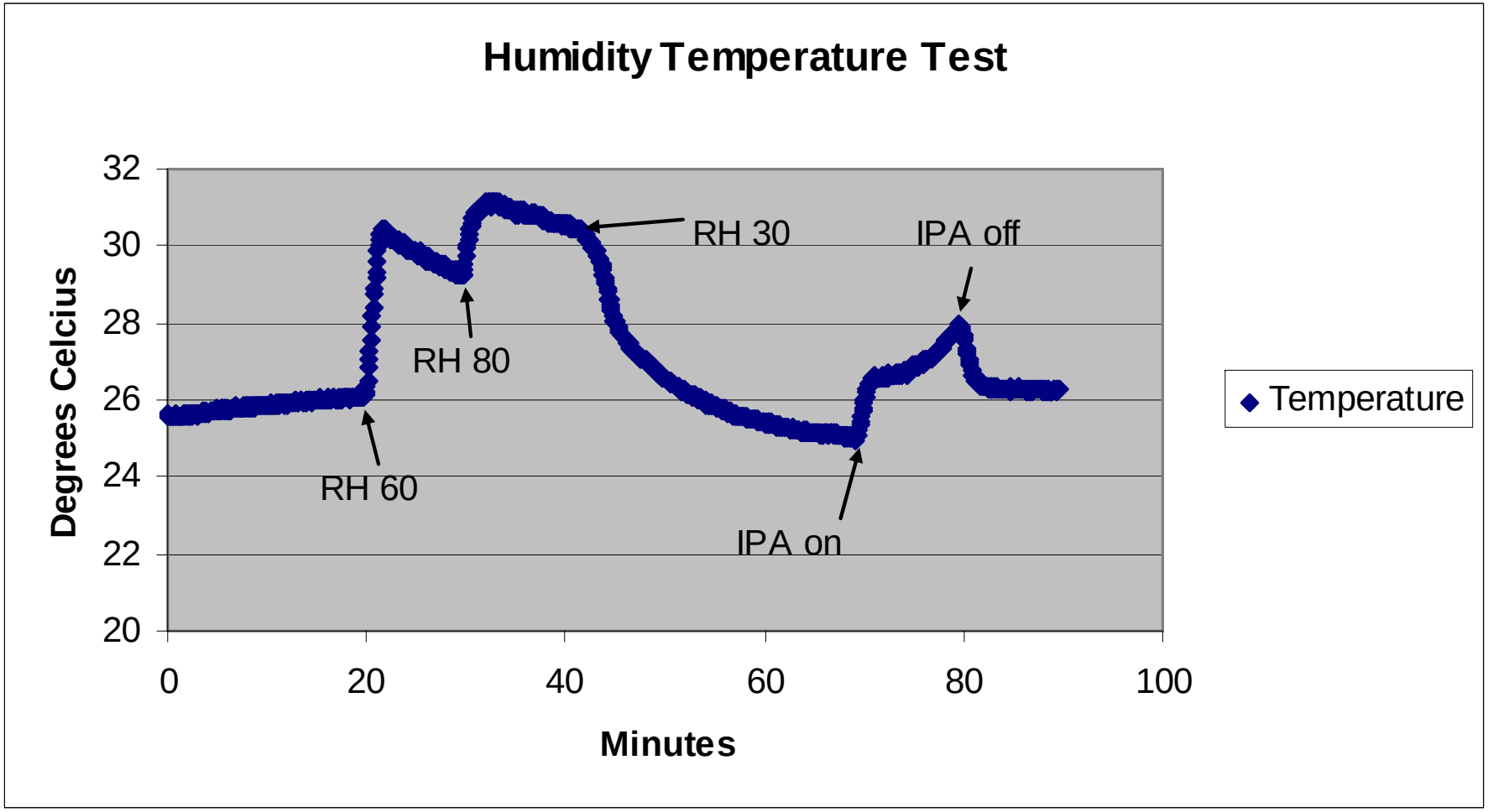
Simulator Data with GC Probe



Packed Simulator Response to RH



Temperature Data from Carbon Bed



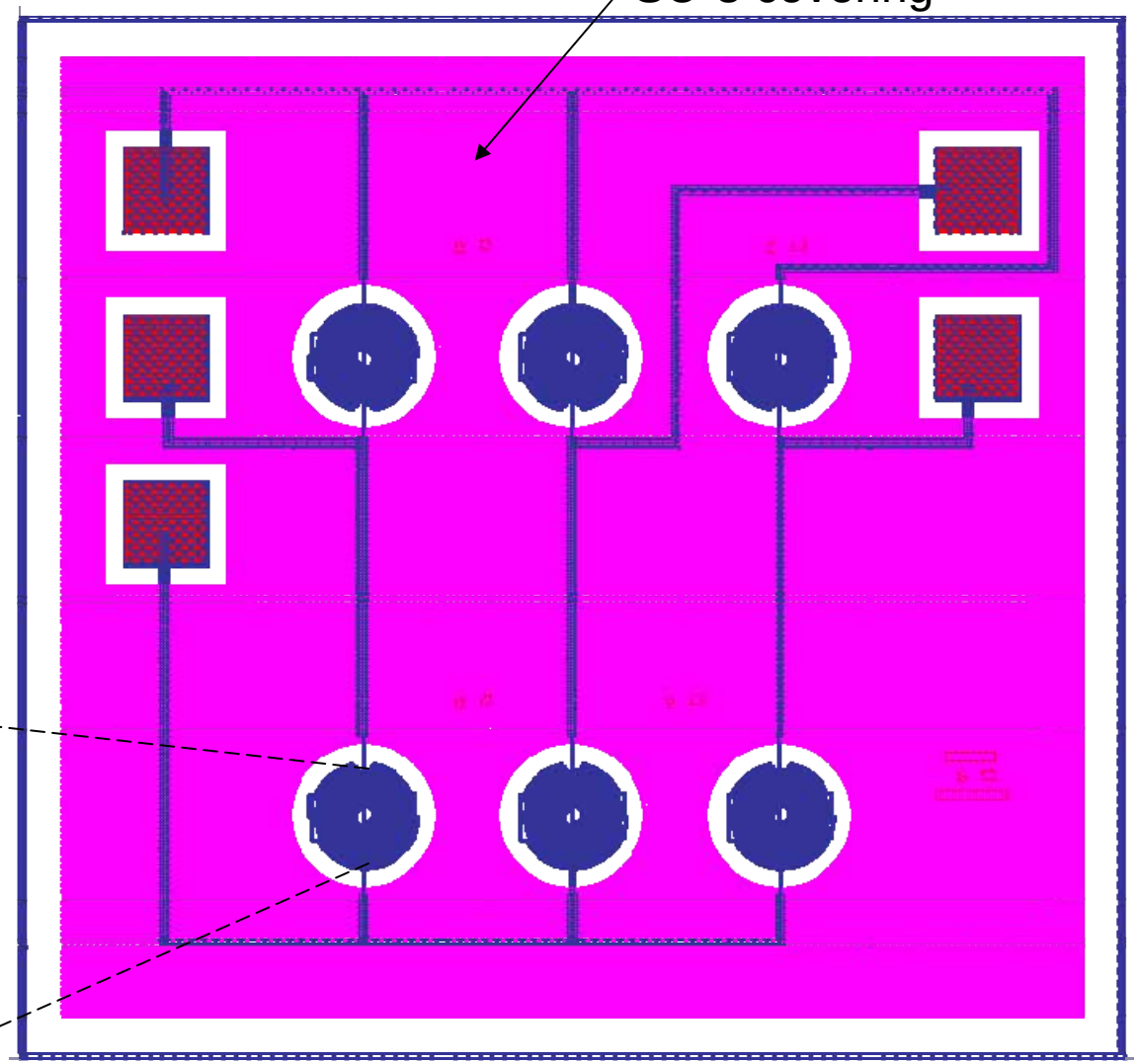
4th Gen NIOSH Sensor Layout

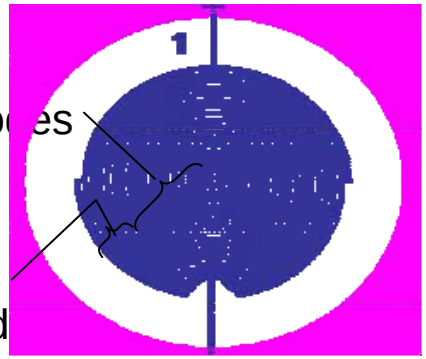
Bridge circuit configuration with one reference, one exposed sensor

Chips fit three separate bridges to accommodate different polymers

SU8 epoxy creates cavity for encapsulating reference sensor

Spiral electrode design modified to ensure polymer from ink jetted splat covers active electrodes



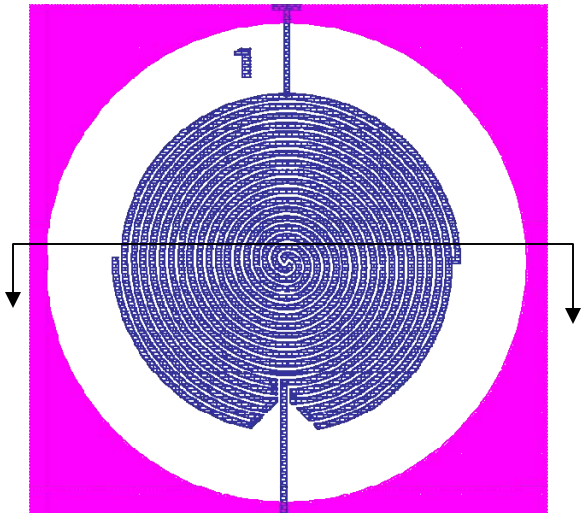


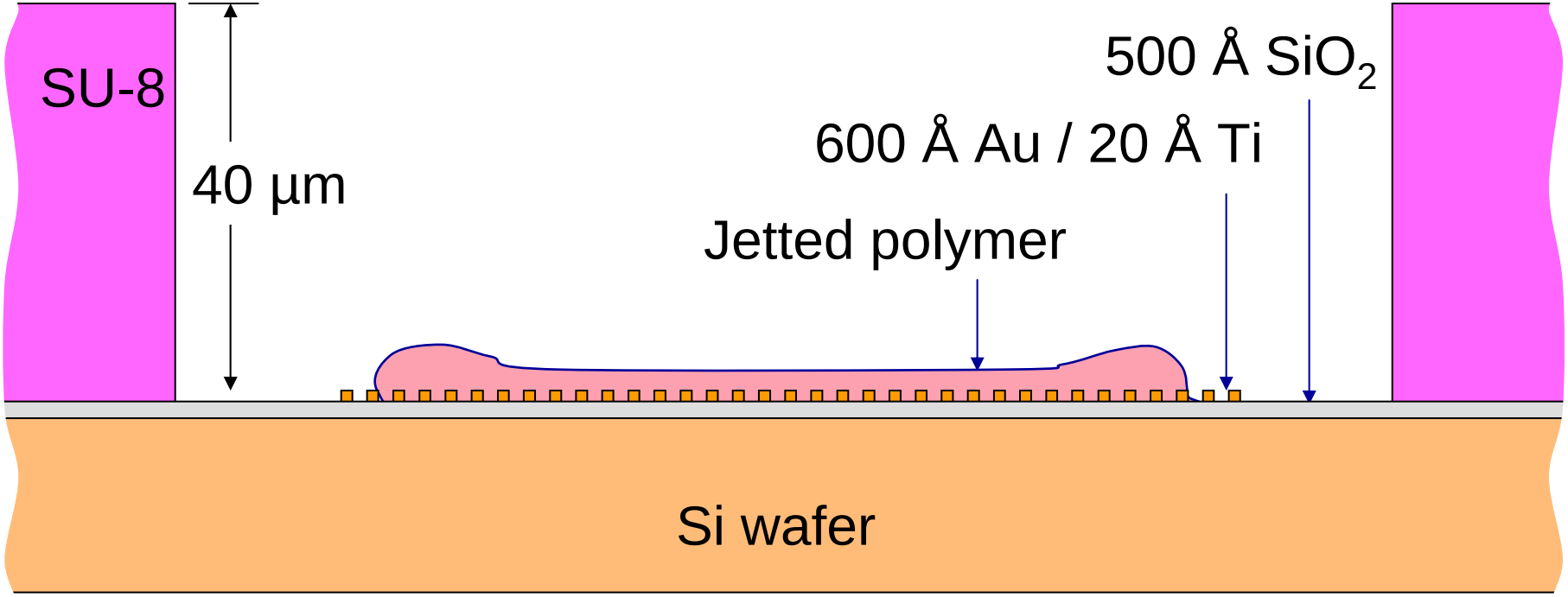
Active electrodes

Extra spread patterns

Spiral ChemFET Cross Section

- **Jetted polythiophene channel**
- **Gold source and drain electrodes**
  - 4 µm lines, 3 µm spaces (channel length)
- **Si wafer acts as gate electrode for field-effect action**



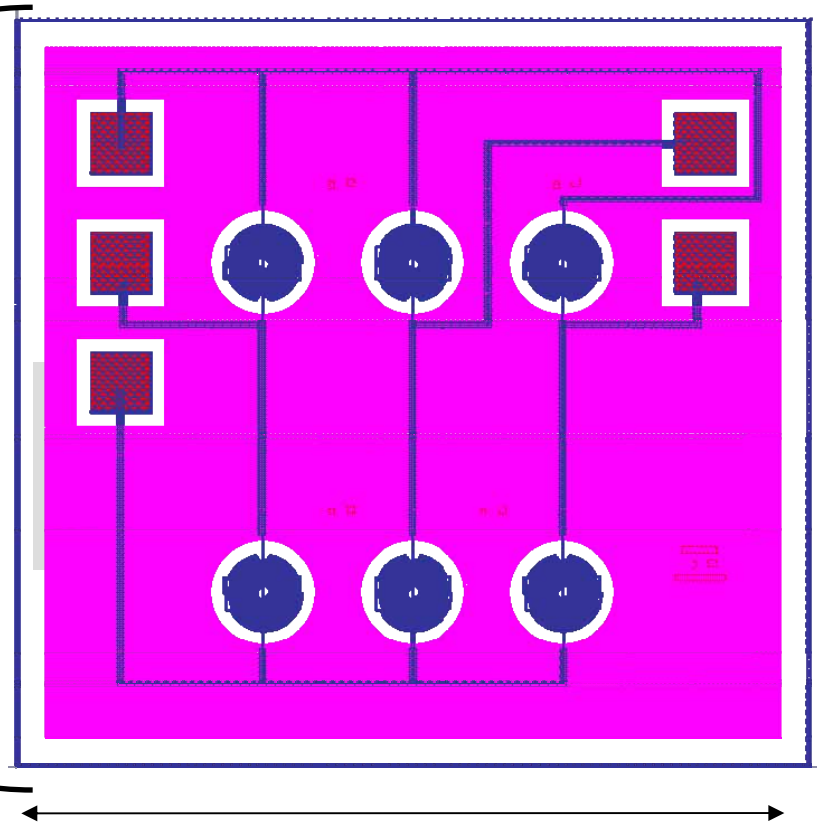


4rd Gen NIOSH Sensor

TO-5 Package with Sensor Array

0.25 inches

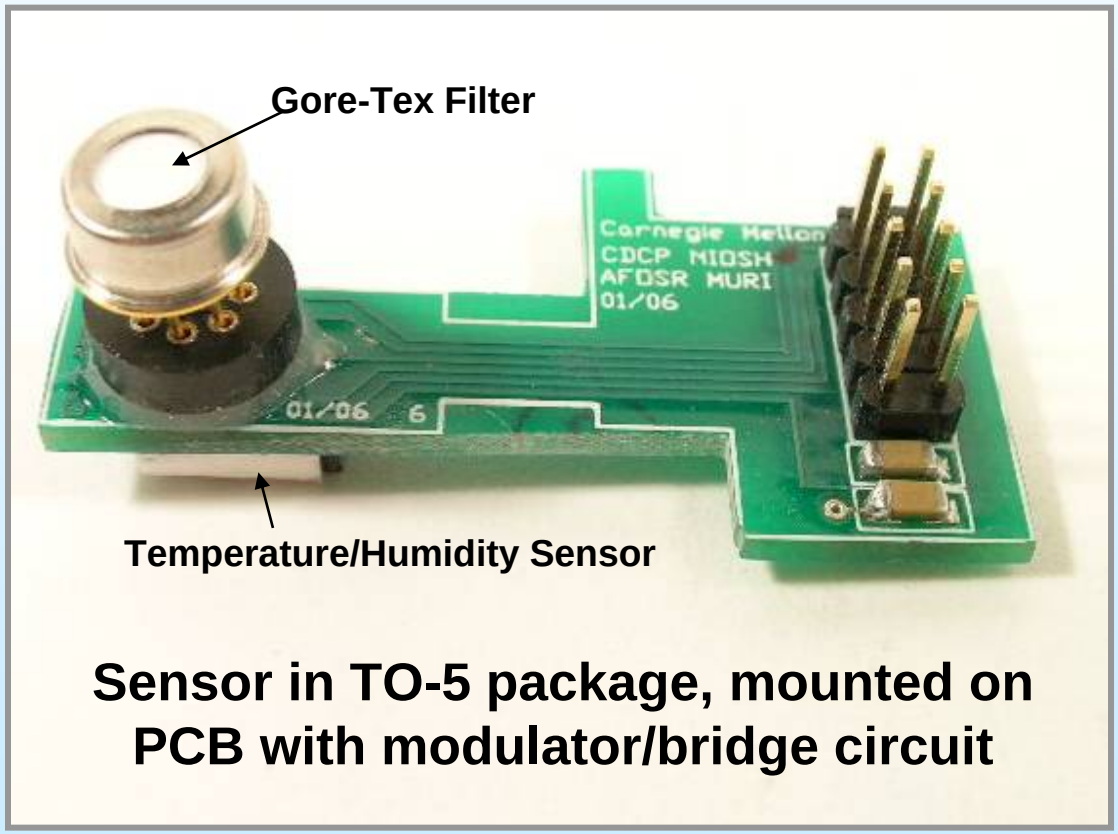
6-Sensor Array Design



2.65 mm

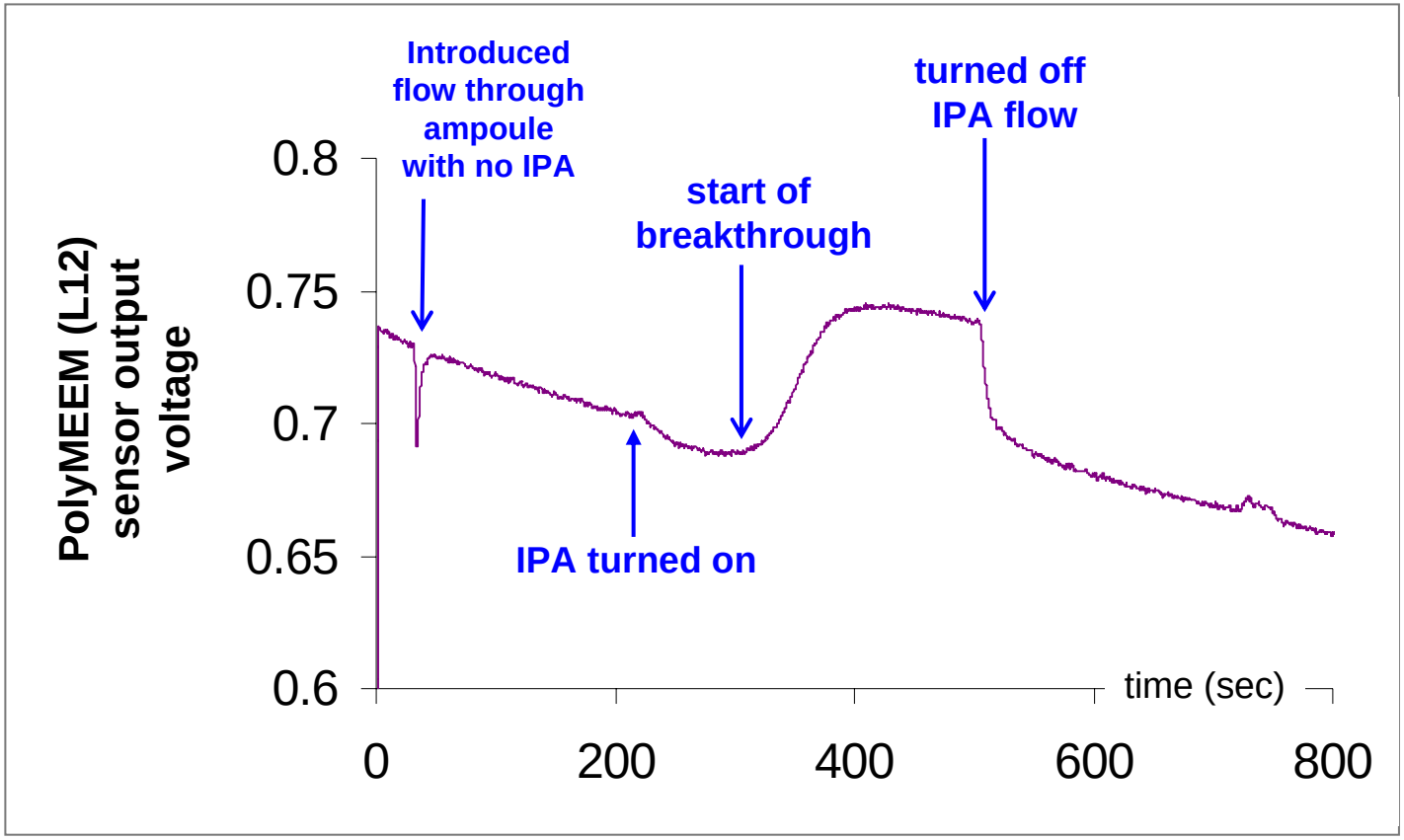
Complete TO-5 Package

Sensor Package and Electronics

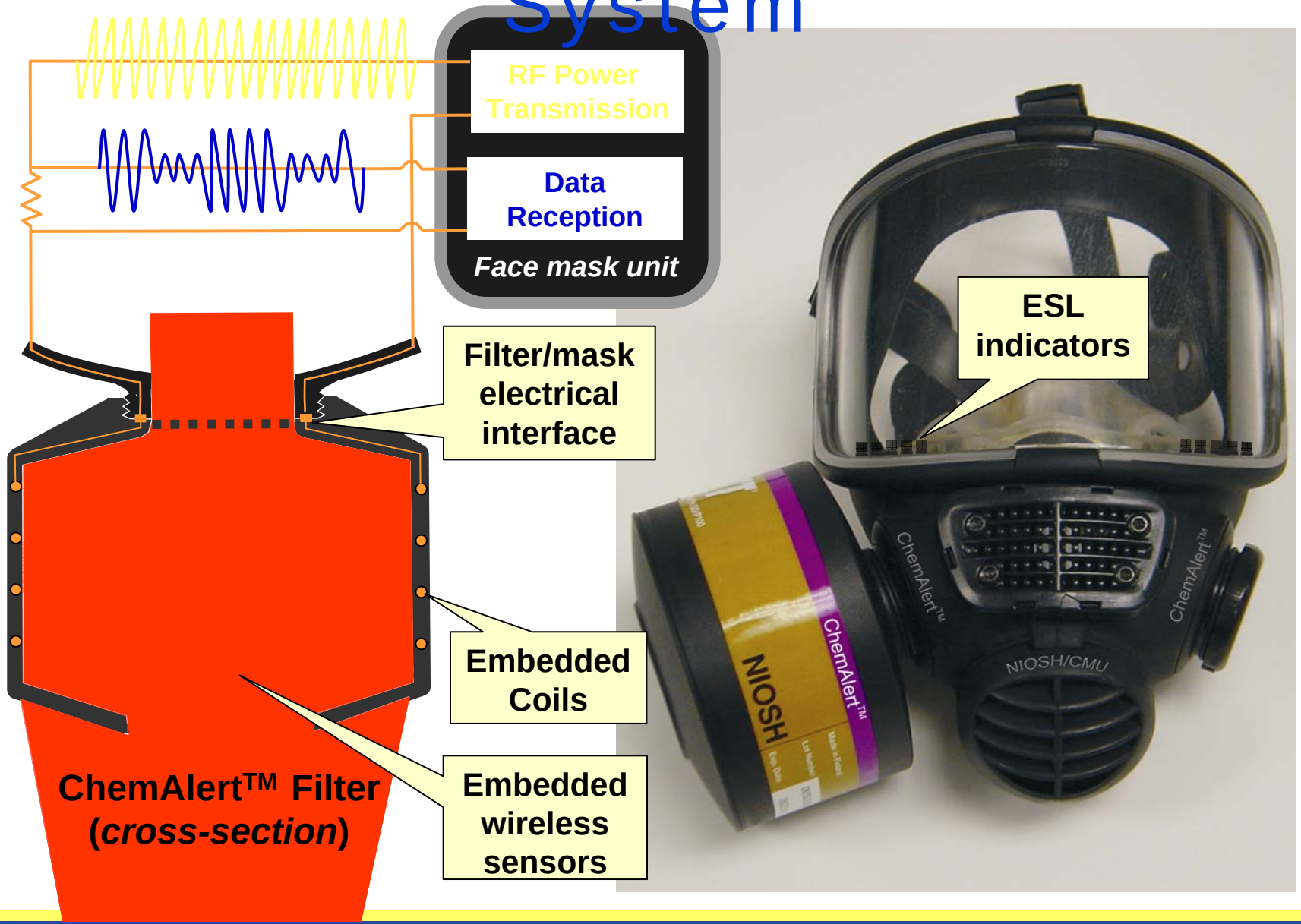


Sensor in TO-5 package, mounted on PCB with modulator/bridge circuit

Preliminary Sensor Data



End-of-Service-Life Detection System



Work with Respirator Manufacturers

- **3M**
- **Draeger**
- **Mine Safety Appliance**
- **Moldex-Metric Inc.**
- **North Safety Products**
- **Scott Health & Safety**
- **Sundstrom Safety AB**
- **Survivair**

Sensor Program Newsletter

NPPTL
Sensor Program Update

Progress during the past six months of the program has resulted in redesign. The sensor package and associated electronics have been changed to accommodate several problems identified during the evaluation of the 4x6 array package that had been used. The revised sensors have been configured in a six chemresistor system according to figure 1 at the bottom. The chemresistors are arranged in pairs to form voltage dividers, providing three independent sensor signals. Chemresistors in each divider will be covered with the same modified polythiophene. One chemresistor will be exposed to the environment to react to analyte in the gas stream. The other one will be sealed and used as a reference. This should reduce thermal and electrical interferences. The configuration will permit the use of up to three different polymers which can be compared side by side. This configuration will be packaged in an 8-pin TO-5 package which is shown in figure 2.

The electronics used to power and generate data from the sensor package has been redesigned. The new sensor circuit in the TO-5 packages has been changed in three primary ways. The voltage divider configuration nulls the temperature offset to first order. This is accomplished by placing a sensor reference (with the anlayte exposure blocked) in the divider. Second, the divider is driven in ac operation. Third, the ac modulation is driven in a bipolar arrangement so that the output with no analyte stimulus will result in a zero ac and dc output.

The polymer resistivity is a function of dc bias across the sensor, and gives rise to a drift in the baseline voltage output in a dc driven sensor system. By driving with ac modulated input, the sensors do not experience a dc voltage bias and therefore the baseline drift over time is decreased. A second motivation for the ac modulation is the ability to move the sensor signal to a modulation frequency that separates the signal from other environmental influences that occur near dc. These interfering disturbances at dc are then filtered.

A respirator cartridge simulator that accommodates these sensors has been constructed (figure3). It has a 2.5 or 5.0 cm bed depth and will be used to test and characterize sensor systems in a carbon bed prior to distribution to volunteer respirator manufacturers.

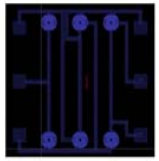


Figure 1

Figure 2

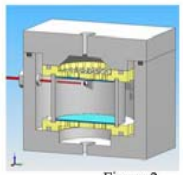
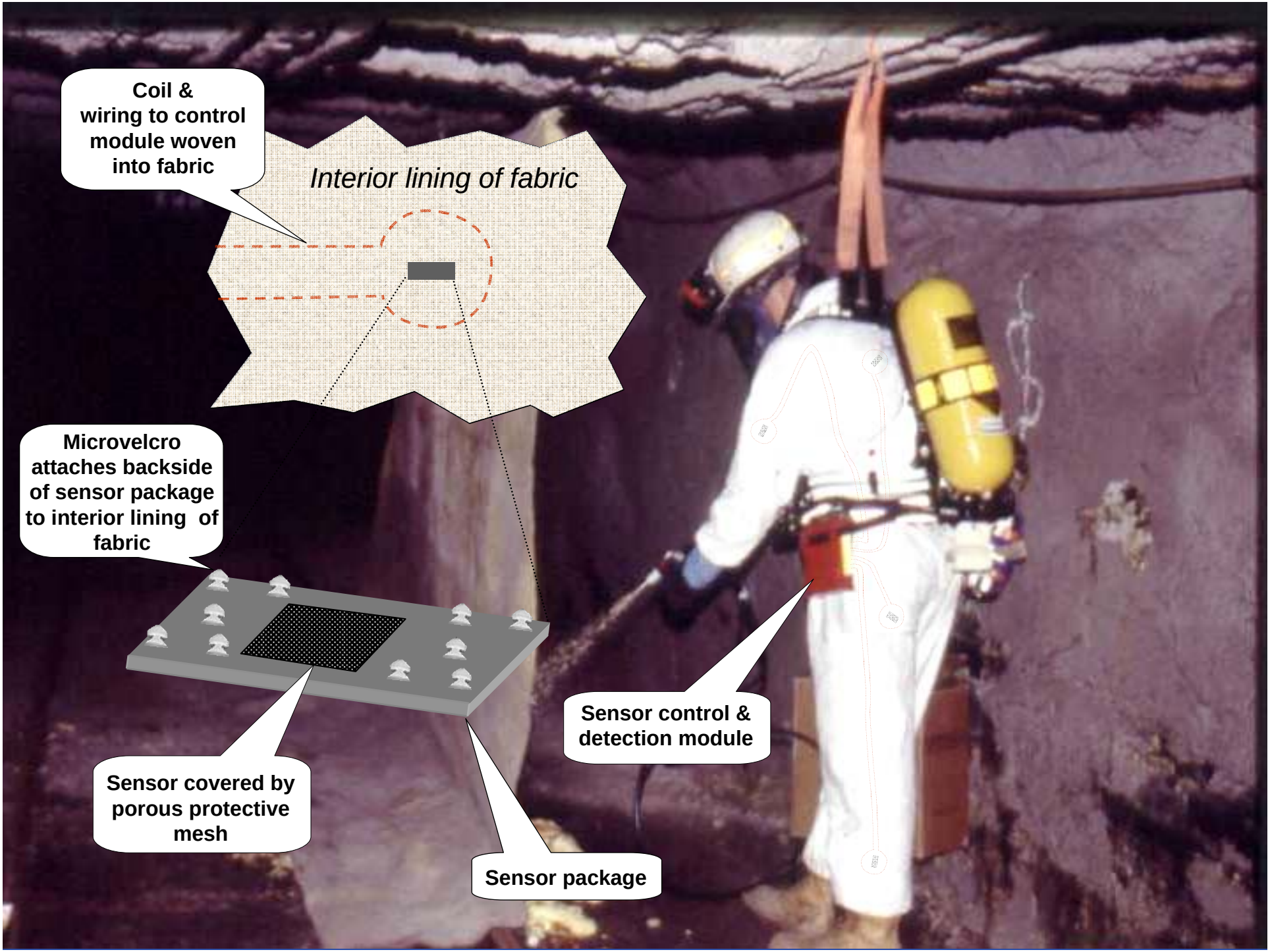


Figure 3


Coil &
wiring to control
module woven
into fabric
Interior lining of fabric
Microvelcro
attaches backside
of sensor package
to interior lining of
fabric
Sensor control &
detection module
Sensor covered by
porous protective
mesh
Sensor package

Personal Protective Equipment End-of-Service Life

- Questions?
- Comments!

Disclaimer

The findings and conclusions in this presentation are those of the author and do not necessarily represent the views of the National Institute for Occupational Safety and Health

NPPTL Respirator Fit Test Panels

Ziqing Zhuang, Ph.D.

National Institute for Occupational Safety and Health

NPPTL Public Meeting

October 13, 2006, Pittsburgh, PA

Acknowledgment

Ronald Shaffer, Ph.D.

Bruce Bradtmiller, Ph.D.

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Raymond Roberge, M.D.

Lauren Stein

Latoya Williams

Alex Reddington

Dennis Groce

Importance of Test Panels

- Anthropometric panels of facial dimensions are relied upon to provide sizing reference for respirators in many applications
  - **APF establishment**
  - **Respirator design and development**
  - **TIL certification and standards**
  - **Research standards**

History of LANL Panels

- **No survey of facial dimensions of the U.S. civilian workers**
- **The 1967 and 1968 US Air Force anthropometric survey**
- **The facial anthropometry was assumed to be representative of U.S. adults**
- **Face length, face width, and lip length**

LANL 25-Member Panel for Full-Facepiece Respirators

Face Length (mm) \ Face Width (mm)	117.5	126.5	135.5	144.5	153.5
133.5				2	2
123.5			2	5	2
113.5		2	4	2	
103.5	2	2			
93.5					

LANL 25-Member Panel for Half-Mask Respirators

Lip Length (mm)

Face Length (mm)	34.5	43.5	52.5	61.5
133.5			2	2
123.5	1	5	3	
113.5	3	4	1	
103.5	2	2		
93.5				

Panel Applicability Problem

- **Concern raised:**
  - Demographics of the U.S. population has changed over the last 30 years
  - Military data may not fairly represent the diversity of face sizes

Panel Applicability Problem

- **Scientific Evidence:**
  - Leigh measured 1,467 employees (1975)
  - Bureau of Mines surveyed 48 male mine rescue workers (1978)
  - Lip length is not appropriate (Oestenstad, 1990, 1992)
  - NIOSH found that 16% of Civilian American and European Surface Anthropometry Resources (CAESAR) subjects were outside the limits of the LANL panel for full-facepiece respirators (2002)

Background

- **NIOSH created an anthropometric database detailing the face-size distributions of the current U.S. respirator users**
- **The 1967-68 Air Force survey data is not reflective of the anthropometric distribution of the current U.S. workers (Zhuang et al., 2004)**
- **New respirator fit test panels need to be developed**

Objective

- **Develop respirator fit test panels representative of the current U.S. workforce**

Methods

- 2003 NIOSH anthropometric survey of respirator users (Zhuang and Bradtmiller, 2005)
- Stratified sampling plan
  - Two gender strata
  - Four race strata
  - Three age strata
- 3997 subjects
- Weighting factors (2000 U.S. census)
- 19 traditional measurements and 3D scanning

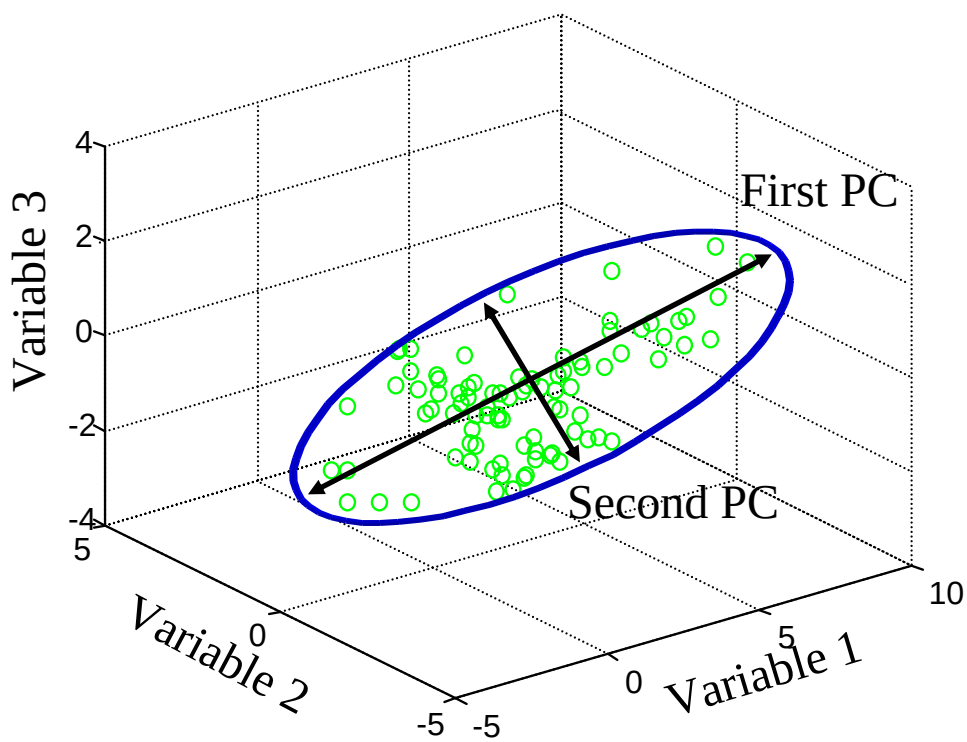
Two Approaches

- **Bivariate distribution (two dimensions)**
- **Principal component analysis**

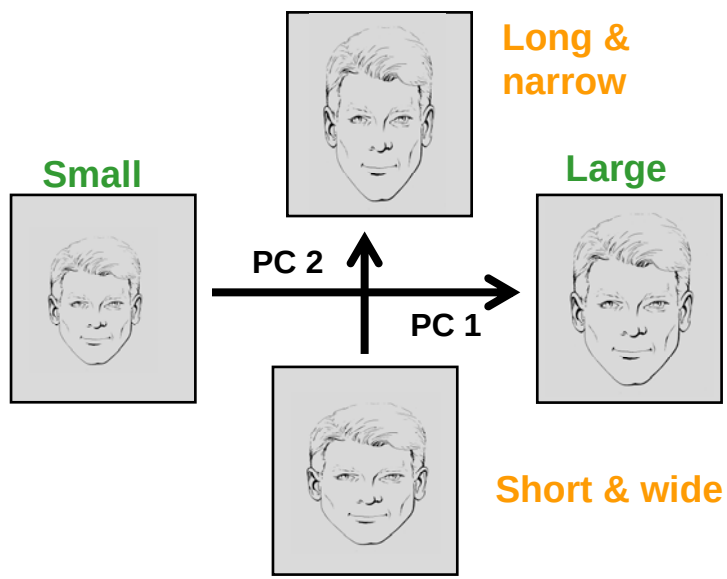
Criteria for Selecting Dimensions

- **The dimensions are relevant to respirator fit**
  - Literature review
  - Expert opinion
- **The dimensions excluded can be predicted by the dimensions included in the PCA**
- **The number of dimensions is reasonable**
- **Dimensions that are difficult to measure and/or highly variable are excluded**

Principal Component Analysis: Theory



PCA defines a new coordinate system using linear combinations of the original variables to describe trends in the data



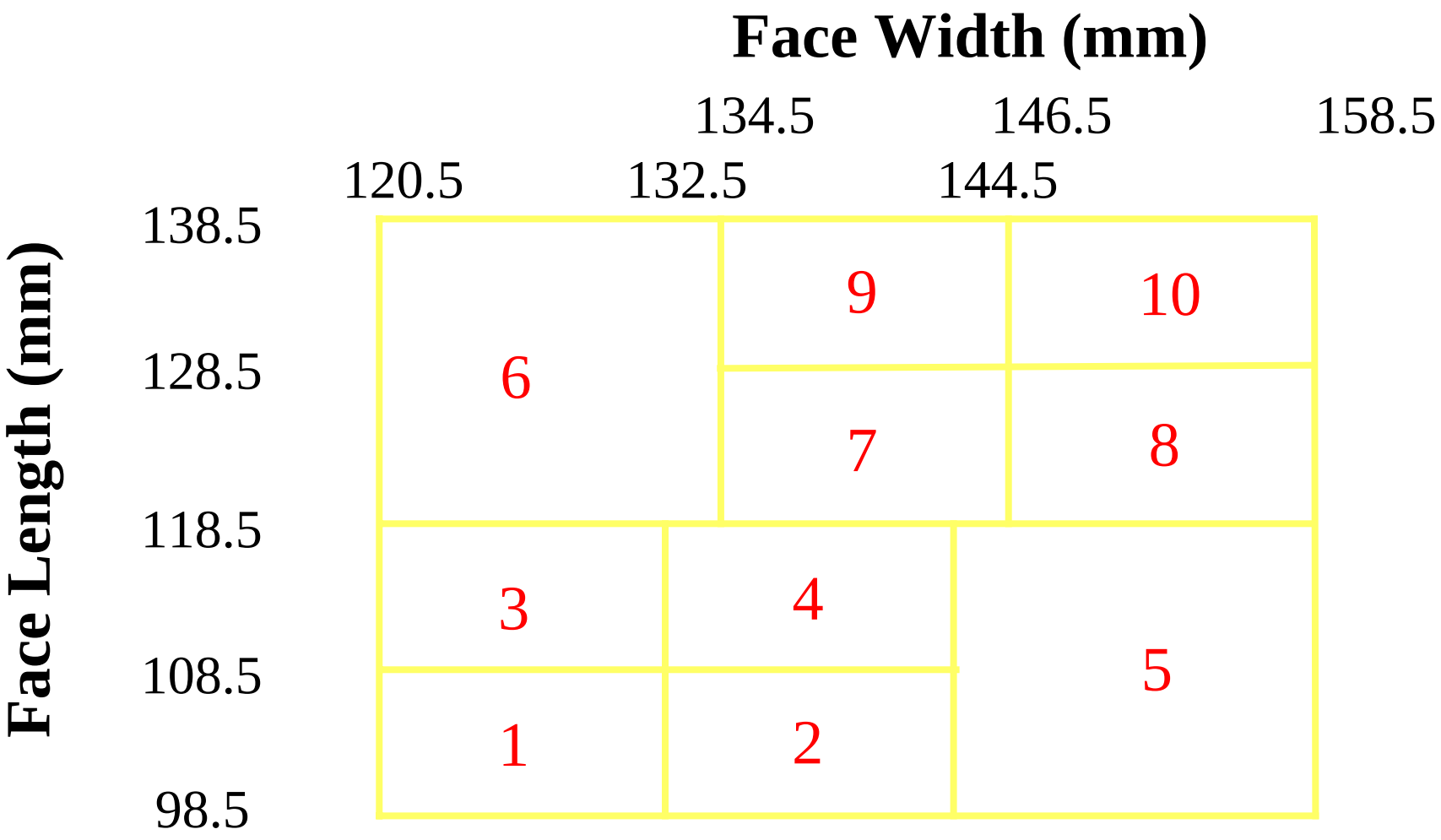
Results

- **Literature review revealed that several dimensions were found to have correlation with respirator fit (Zhuang et al., 2005)**
- **ISO Technical committee 94, Subcommittee 15, Working groups 2-3, joint project group 2 came up with a list of 9 dimensions**
- **Lip length is not appropriate for defining test panel for half-mask respirators**

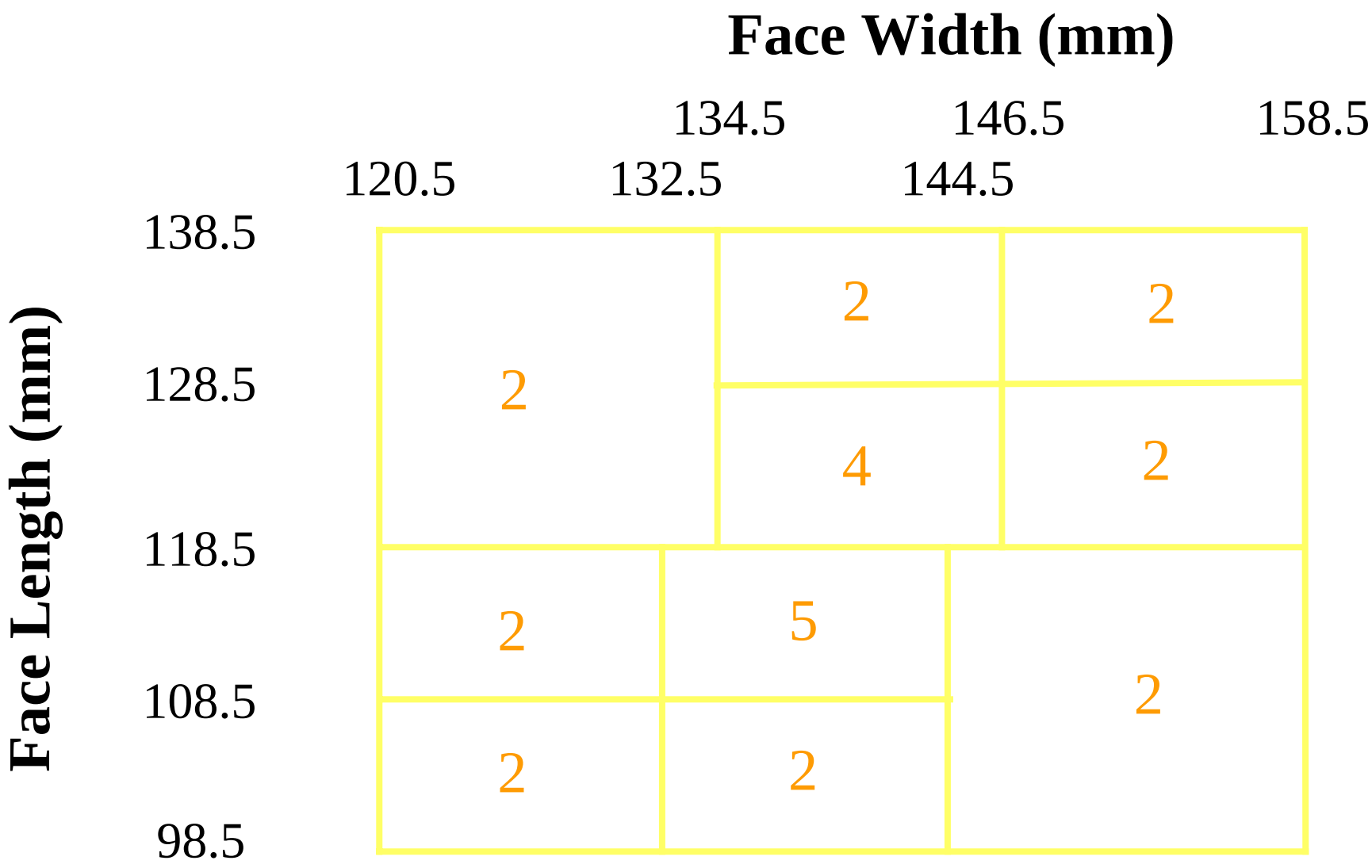
NIOSH Bivariate Panel

- **10-cell panel**
- **25 subjects**
- **At least two subjects for each cell**
- **Matching the distribution of the population**
- **Face length and face width were selected to define the bivariate panel for both half-masks and full-facepiece respirators**

NIOSH Bivariate Panel



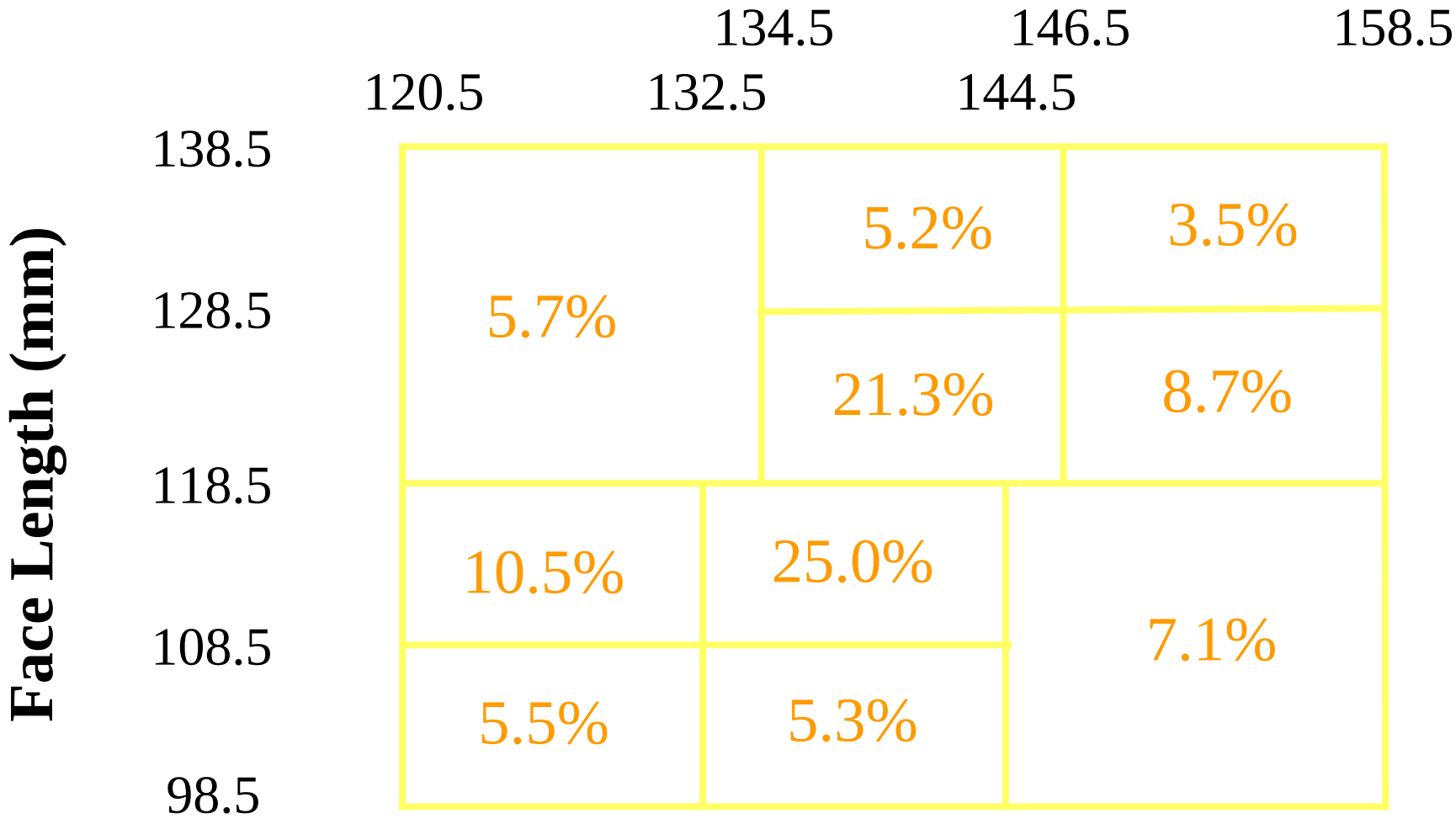
NIOSH Bivariate Panel



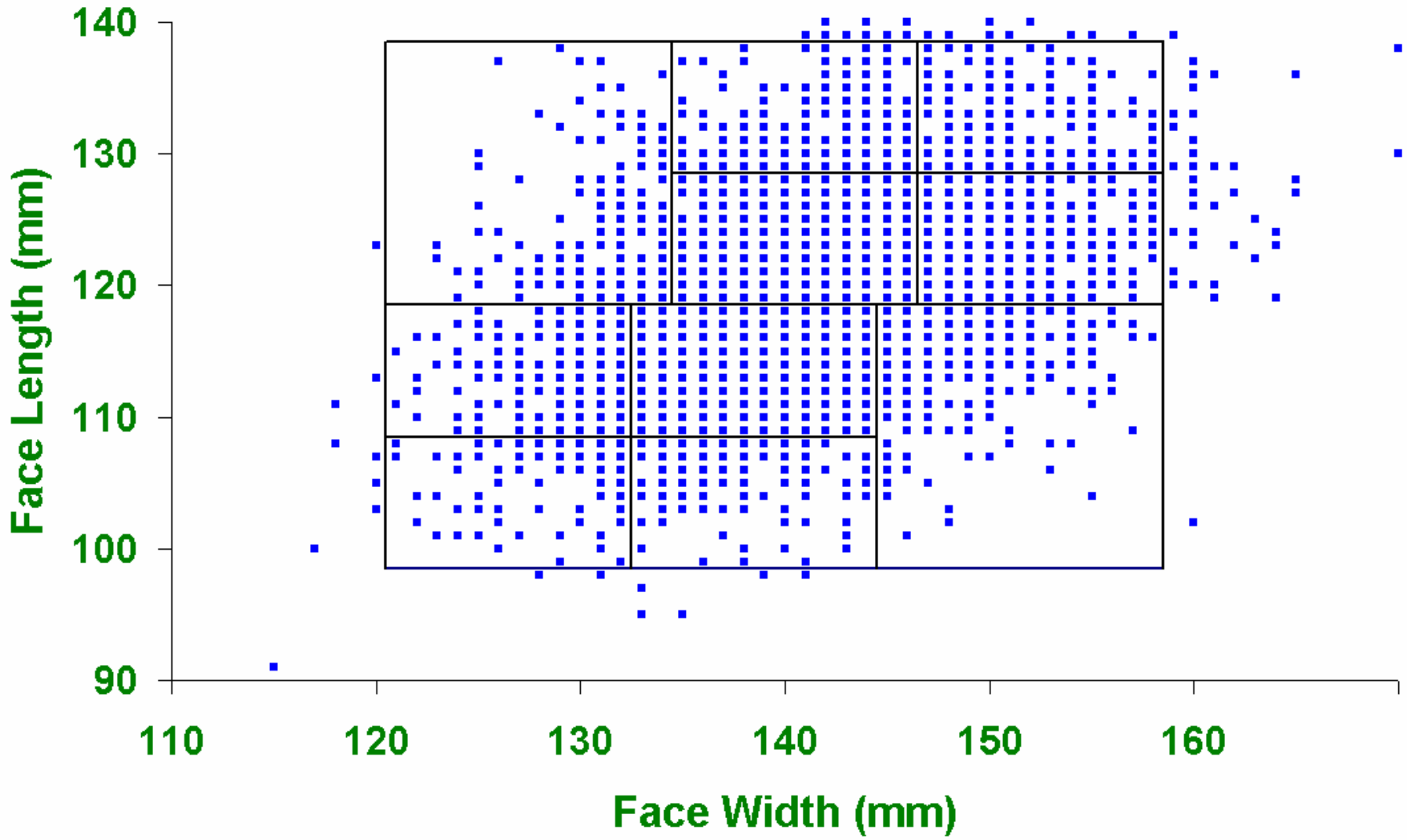
NIOSH Bivariate Panel

Total = 97.7%

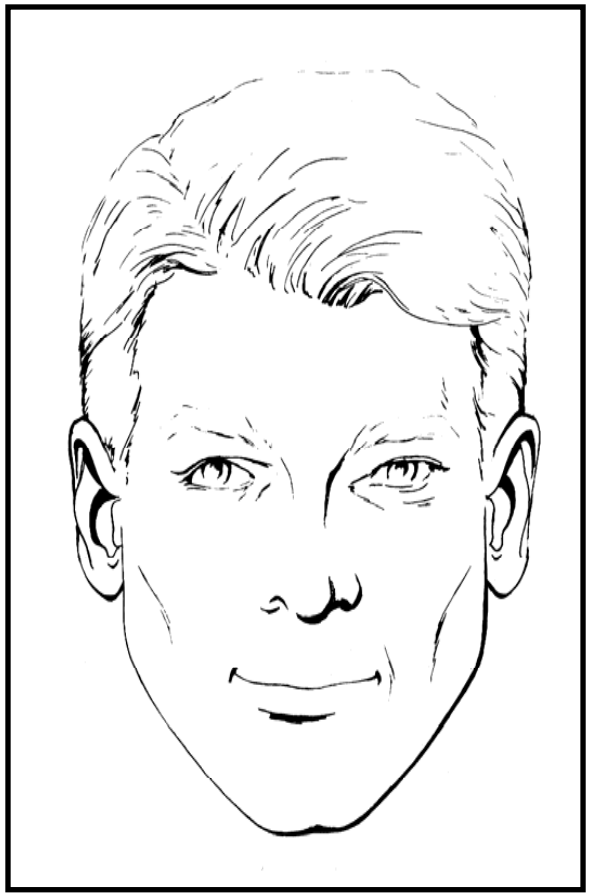
Face Width (mm)



NIOSH Panel - Bivariate Distribution



Dimensions Used in the PCA Panel



Minimum Frontal Breadth

Face Width

Bigonial Breadth

Face Length

Interpupillary Breadth

Head Breadth

Nose Protrusion

Nose Breadth

Nasal Root Breadth

Subnasale-Sellion Length

R^2 values for Multiple Regressions between Dimensions Excluded from the PCA Model and the 10 Dimensions Included in the PCA Model

Face Dimensions	R^2	p-value
Maximum Frontal Breath	0.83	< 0.01
Bitragion Chin Arc	0.69	< 0.01
Bitragion Subnasale Arc	0.66	< 0.01
Neck Circumference	0.66	< 0.01
Bitragion Frontal Arc	0.61	< 0.01
Head Circumference	0.44	<0.01
Lip Length	0.43	< 0.01
Head Length	0.42	< 0.01
Bitragion Coronal Arc	0.38	< 0.01

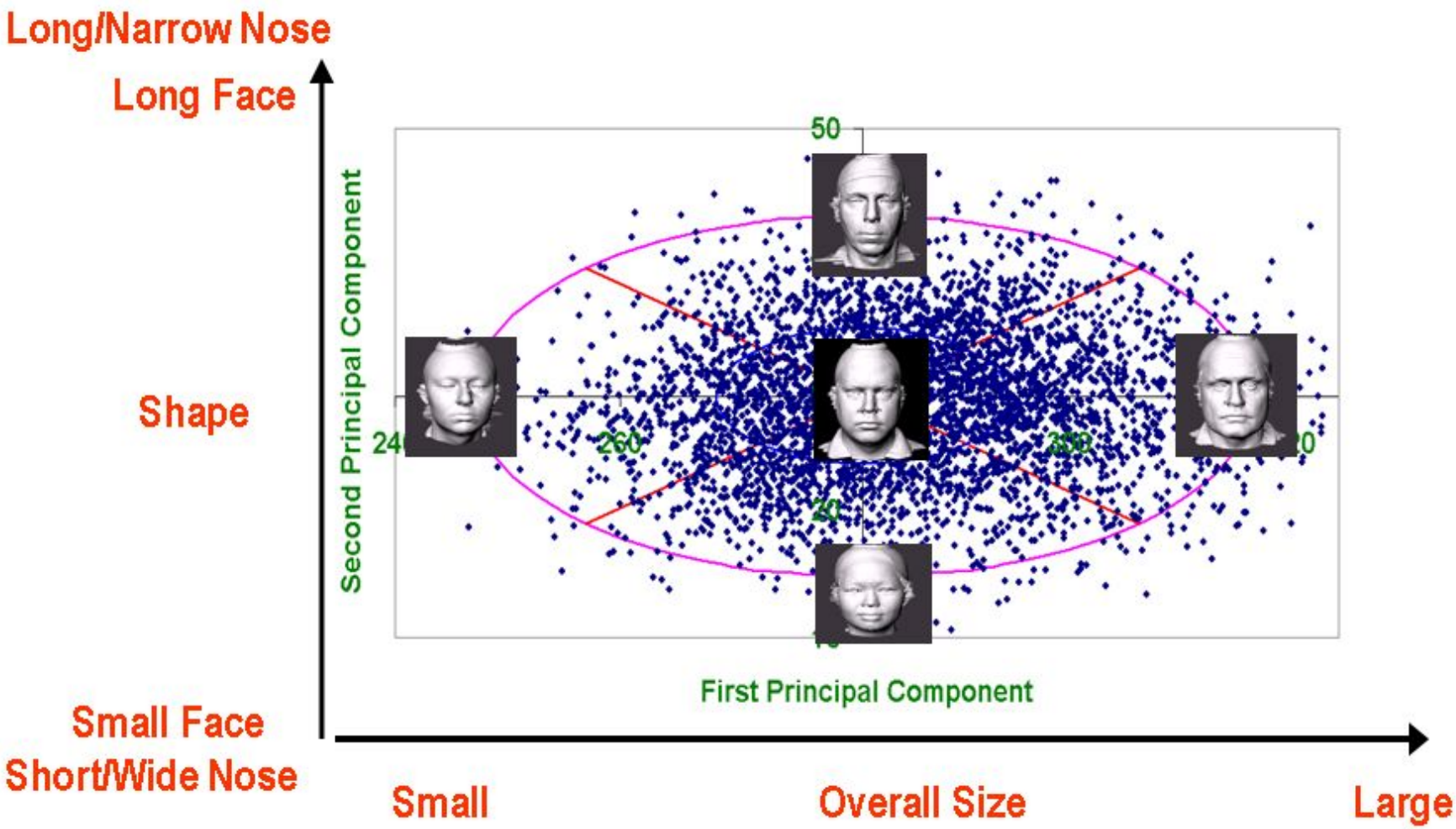
Principal Component Analysis (Males and Females)

PC	Eigenvalue	Cumulative Eigenvalue	% Total Variance	Cumulative %
1	4.205	4.205	42.1	42.1
2	1.640	5.845	16.4	58.5
3	0.859	6.705	8.6	67.0
4	0.804	7.509	8.0	75.1
5	0.634	8.142	6.3	81.4
6	0.598	8.741	6.0	87.4
7	0.419	9.159	4.2	91.6
8	0.356	9.515	3.6	95.2
9	0.302	9.818	3.0	98.2
10	0.182	10.000	1.8	100.0

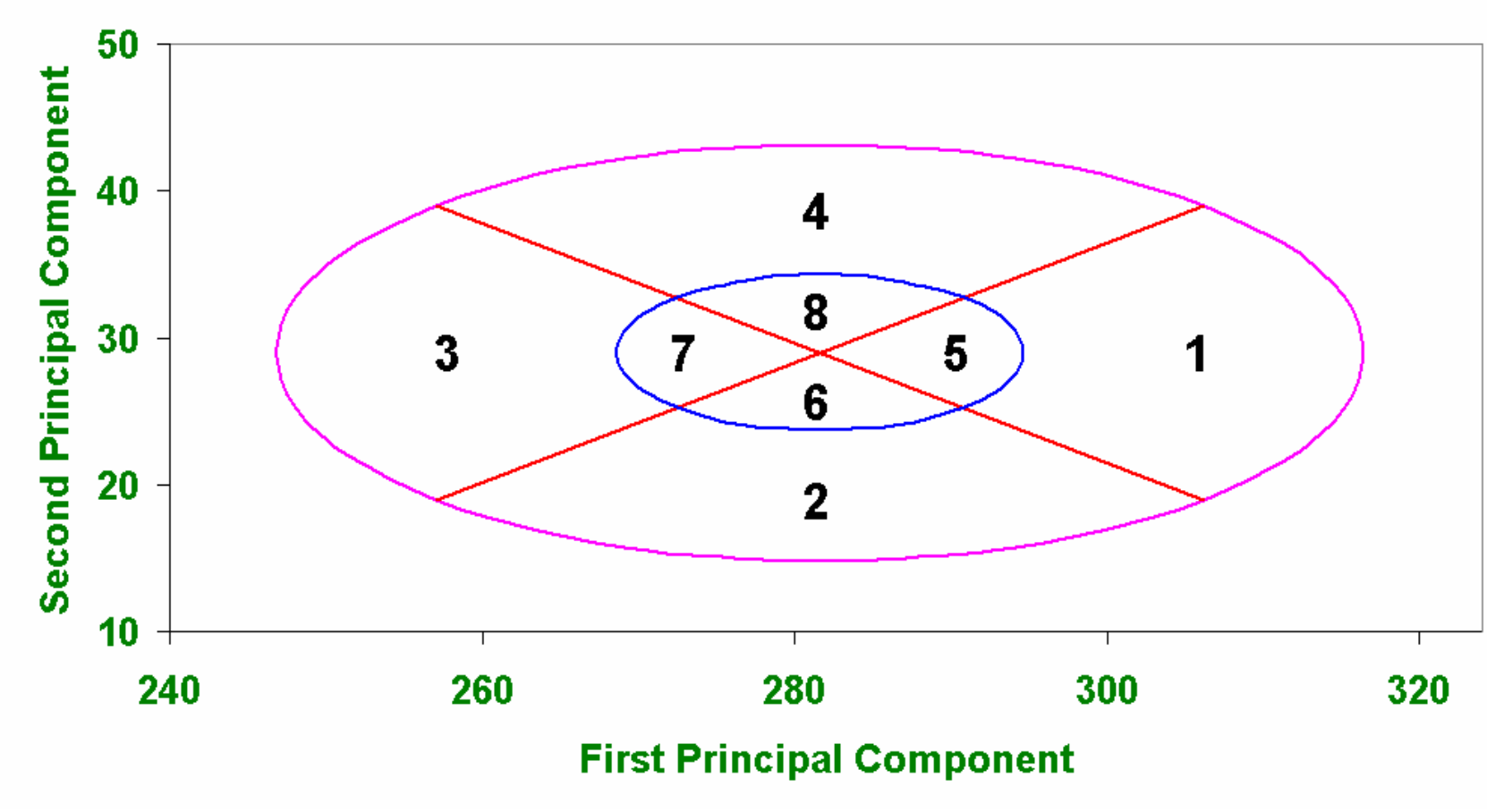
Principal Component Analysis (Males and Females)

Variables	Eigenvectors PC 1 (42%)	PC 2 (16%)
Minimum Frontal Breadth	0.3433	-0.1530
Face Width	0.4265	-0.0391
Bigonial Breadth	0.3727	-0.0933
Face Length	0.3296	0.3598
Interpupillary Breadth	0.3635	-0.1731
Head Breadth	0.3722	0.0133
Nose Protrusion	0.1136	0.5518
Nose Breadth	0.3011	-0.2108
Nasal Root Breadth	0.2023	-0.3412
Subnasale-Sellion Length	0.1937	0.5843

Scatter Plot of PC1 & PC2



NIOSH PCA Panel



25-Member PCA Panel

Cell	Male (%)	Female (%)	Total (%)
1	27.3	2.3	14.7
2	7.8	22.7	15.3
3	2.1	28.9	15.6
4	23.5	8.0	15.7
5	11.9	3.8	7.8
6	6.8	10.5	8.7
7	4.8	14.8	9.9
8	11.1	6.6	8.8
Total	95.3	97.6	96.8

25-Member PCA Panel

Cell	Male	Female	Total
1	4	0	4
2	1	3	4
3	0	4	4
4	3	1	4
5	2	0	2
6	1	1	2
7	1	2	3
8	1	1	2
Total	13	12	25

Comparison of the Two Panels

- **Bivariate Panel**
  - Easy to understand and use
  - May not exclude unusual faces, e.g., large nose
  - Need to measure 91 subjects on average to fill the panel (min=34 and max=264)
- **PCA Panel**
  - Complicated and more measurements
  - Likely to exclude unusual faces
  - Need to measure 58 subjects on average to fill the panel (min=28 and max=144)
  - Dimensions included in the model are correlated with those excluded

Conclusions

- Two panels were developed
- Respirators designed to fit these panels are expected to accommodate more than 95% of the current U.S. civilian workforce
- Both panels represent an improvement over the LANL panels used today
- Certification bodies, standards organizations, and manufacturers need to select the appropriate panel for their particular needs

Future Research

- **Differences among age, race and gender**
- **Comparison between the bivariate and PCA panels using NIOSH TIL data**
- **Headforms**
- **Chinese anthropometric database**
- **3-D parameters**

Journal Publications

1. Zhuang Z, Guan J, Hsiao H, and Bradtmiller B [2004]. Evaluating the Representativeness of the LANL Respirator Fit Test Panels for the Current U.S. Civilian Workers. Journal of the International Society for Respiratory Protection, 21(III-IV):83-93.
2. Zhuang Z and Bradtmiller B [2005]. Head-and-Face Anthropometric Survey of U.S. Respirator Users. J Occup. Environ. Hyg., 2, 567-577.
3. Zhuang Z, Coffey CC, and Berry Ann R [2005]. The effect of subject characteristics and respirator features on respirator fit. J Occup. Environ. Hyg. 2, 641-649.
4. Roberge R, Zhuang Z, Stein, L [2006] Association of Body Mass Index with Facial Dimensions for Defining Respirator Fit Panels. Journal of the International Society for Respiratory Protection, 23(I-II):44-52.
5. Zhuang Z, Bradtmiller B, and Shaffer RE [2006]. New Respirator Fit Test Panels Representing the Current U.S. Civilian Workforce. Currently undergoing NIOSH internal review. Submitted to the Journal of Occupational and Environmental Hygiene.
6. Zhuang Z, Roberge R, Williams LM, Viscusi DJ and Shaffer RE [2006]. Facial anthropometric differences among race/age groups. In preparation to submit to Journal of the International Society for Respiratory Protection.

Presentations

1. Zhuang Z, Coffey C, BerryAnn R, Lawrence RB, Viscusi D, The effect of subject characteristics and respirator features on respirator fit, American Industrial Hygiene Association Conference & Expo, Dallas, TX May 10-15, 2003.
2. Zhuang, et al. "Anthropometric Survey of Respirator Users" at the 2004 American Industrial Hygiene Conference and Exposition (AIHCE), Atlanta, Georgia, May 10, 2004.
3. Zhuang, et al. "Evaluating the Representativeness of the LANL Respirator Fit Test Panels for the Current U.S. Civilian Workers" at the ISRP 12th International Conference, Yokohama, Japan, November 9-12, 2004.
4. Zhuang, et al. "New Respirator Fit Test Panels Representing the Current U.S. Civilian Workforce" at the ISRP 12th International Conference, Yokohama, Japan, November 9-12, 2004.
5. Zhuang Z, Williams LM, Viscusi DJ and Shaffer RE. Facial anthropometric differences among race/age groups. American Industrial Hygiene Conference and Exposition, Anaheim, CA, May 18-26, 2005.
6. Roberge, R., Zhuang Z., Stein, L., Association of Body Mass Index with Facial Dimensions for Defining Respirator Fit Panels. American Industrial Hygiene Conference and Exposition, Chicago, IL, May 14-16, 2006.
7. Z. Zhuang, B. Bradtmiller, and R.E. Shaffer, New Respirator Fit Test Panel Based on Principal Component Analysis. American Industrial Hygiene Conference and Exposition, Chicago, IL, May 14-16, 2006.
8. Zhuang Z, Viscusi D, and Reddington A. "Anthropometrics for developing headforms for testing respiratory and eye protective devices" at the ISRP 13th International Conference, Toronto, Canada, Aug 27- Sep 1, 2006.

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

Any questions?

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412-386-4055

Penetration of Nanoparticles Through Respirators and Protective Clothing

Ron Shaffer, Pengfei Gao, and Samy Rengasamy

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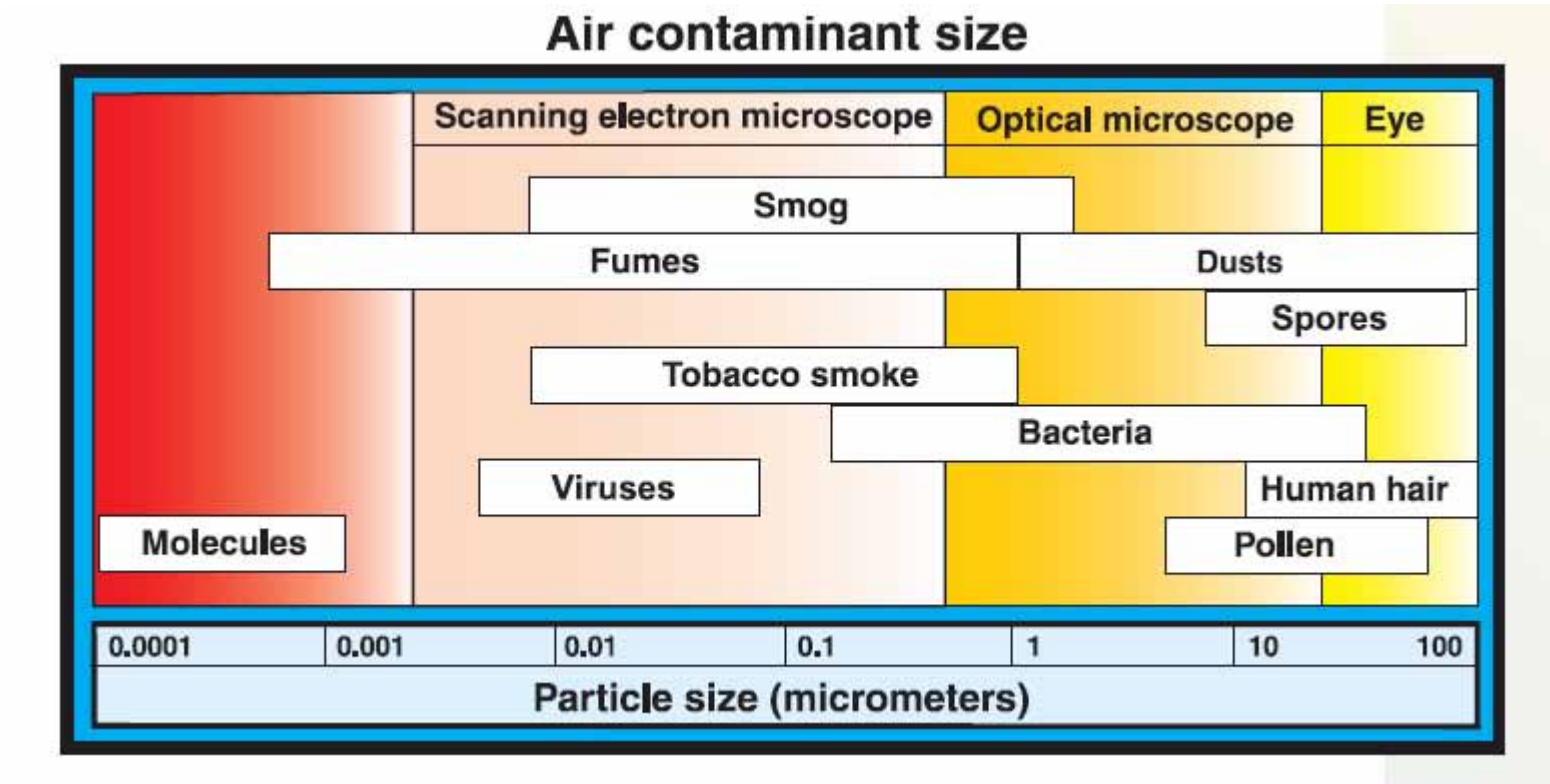
CDC Workplace Safety and Health | NIOSH | NPPTL Research to Practice through Partnerships

Overview

- **Nanotechnology**
- **NIOSH "Approaches to Safe Nanotechnology" Document**
- **Nanoparticle Penetration Through Respirators and Respirator Filter Media**
- **Nanoparticle Penetration Through Protective Clothing and Fabrics**

What are Nanoparticles?

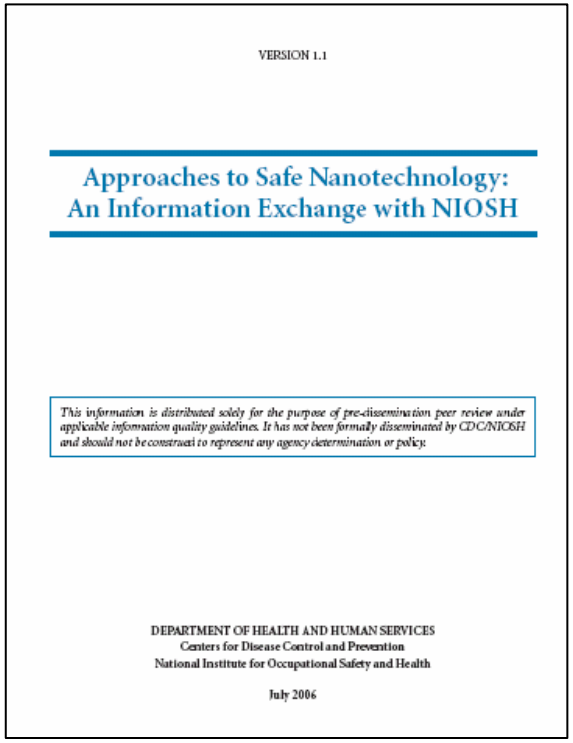
Nanoparticles are particles having a diameter between 1 and 100 nm (0.001-0.1 µm)



Adapted from: Guidance for Filtration and Air-Cleaning Systems to Protect Building Environments from Airborne Chemical, Biological, or Radiological Attacks, DHHS (NIOSH) Publication No. 2003-136.

Nanoparticles - Health Concerns

- Airborne nanomaterials can be inhaled and deposited in the respiratory tract
- Nanomaterials can enter the blood stream and translocate to other organs
- Mass doses of insoluble ultrafine particles (<100 nm) are more potent than larger particles of similar composition in causing pulmonary inflammation and lung tumors in laboratory animals
- Studies have shown that changes in the chemical composition, structure of the molecules, or surface properties of nanomaterials can influence their potential toxicity
- Workers exposed to fine and ultrafine particles have reported lung function decrements and adverse respiratory symptoms



VERSION 1.1

Approaches to Safe Nanotechnology: An Information Exchange with NIOSH

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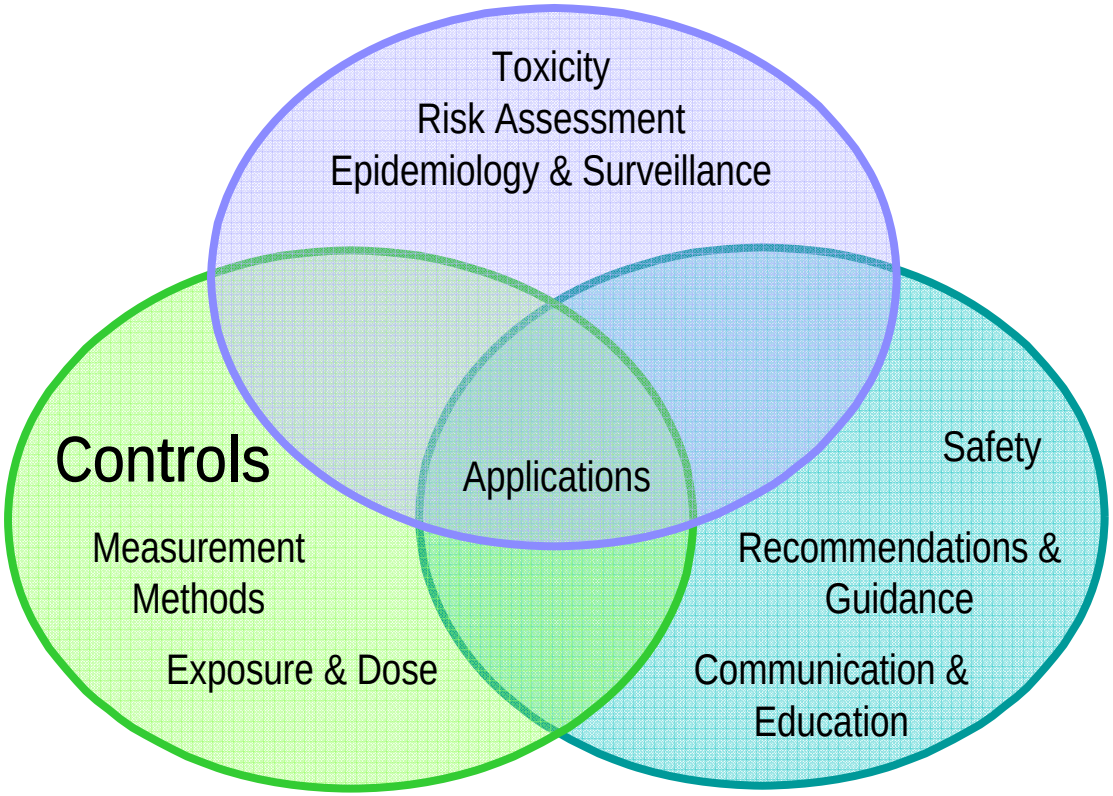
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

July 2006

http://www.cdc.gov/niosh/topics/nanotech/

NIOSH Nanotechnology Research Committee (NTRC)

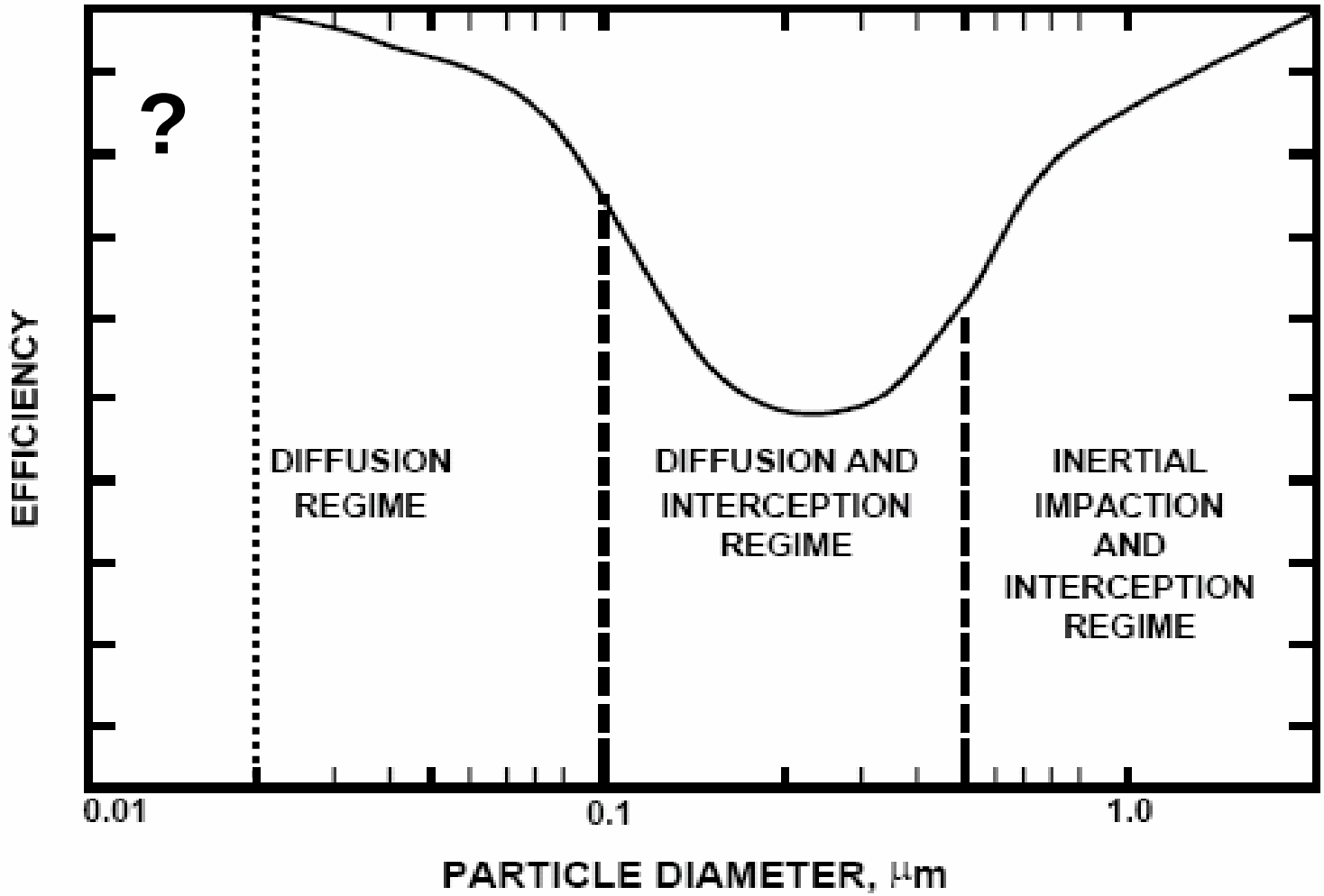


NIOSH has identified 10 critical topic areas to guide knowledge gaps, developing strategies, and providing recommendations

Impact on PPE

- **Concerns have been raised that nanoparticles could penetrate through PPE at higher rates than larger particles**
  - High priority need according to EPA, HSE, others
- **NIOSH/NPPTL initiated research to address these concerns for:**
  - Air purifying respirators (APR)
  - Protective clothing
- **NIOSH Partnerships**
  - MOU with DuPont; ASTM & ISO committee membership

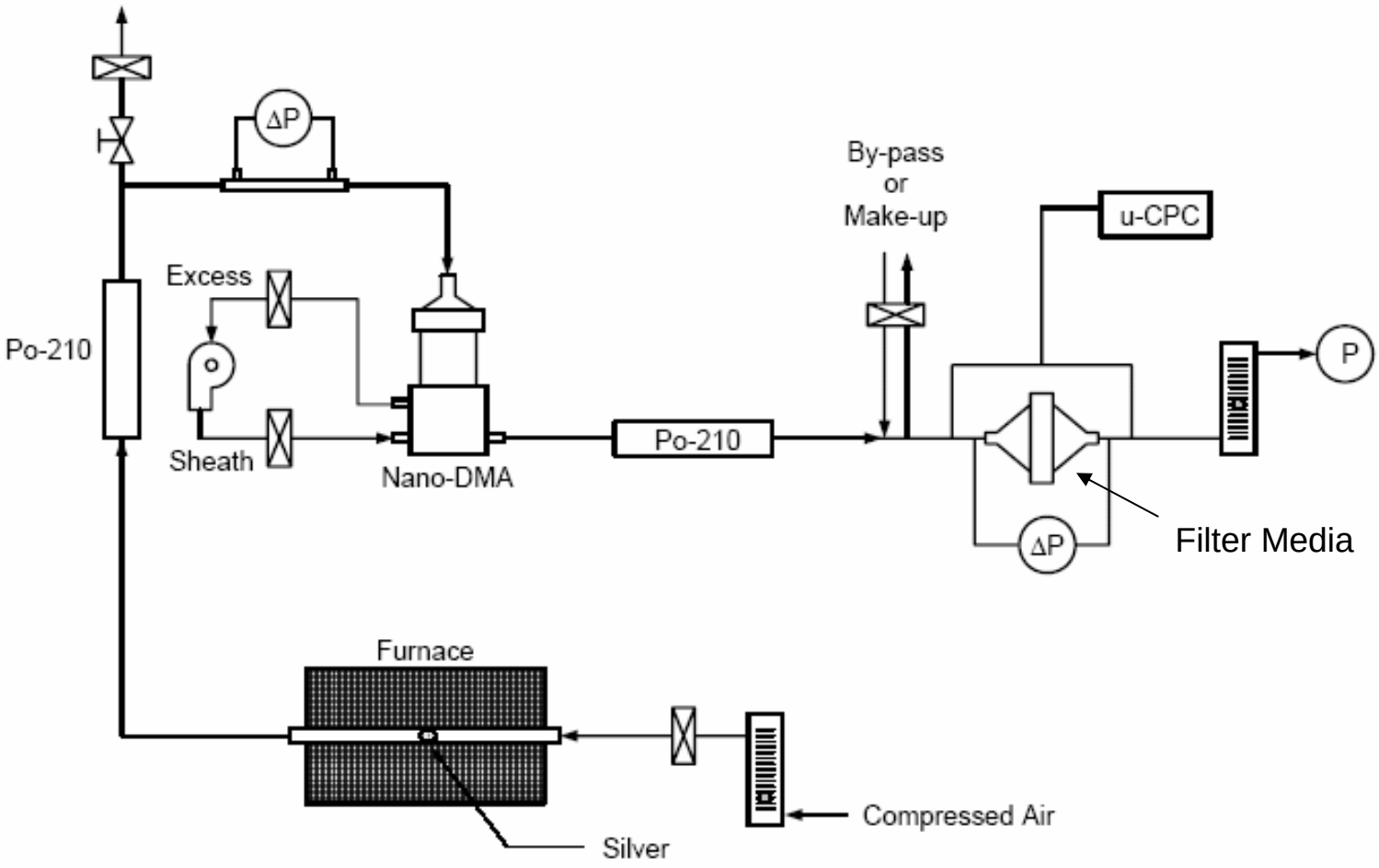
Filtration Theory



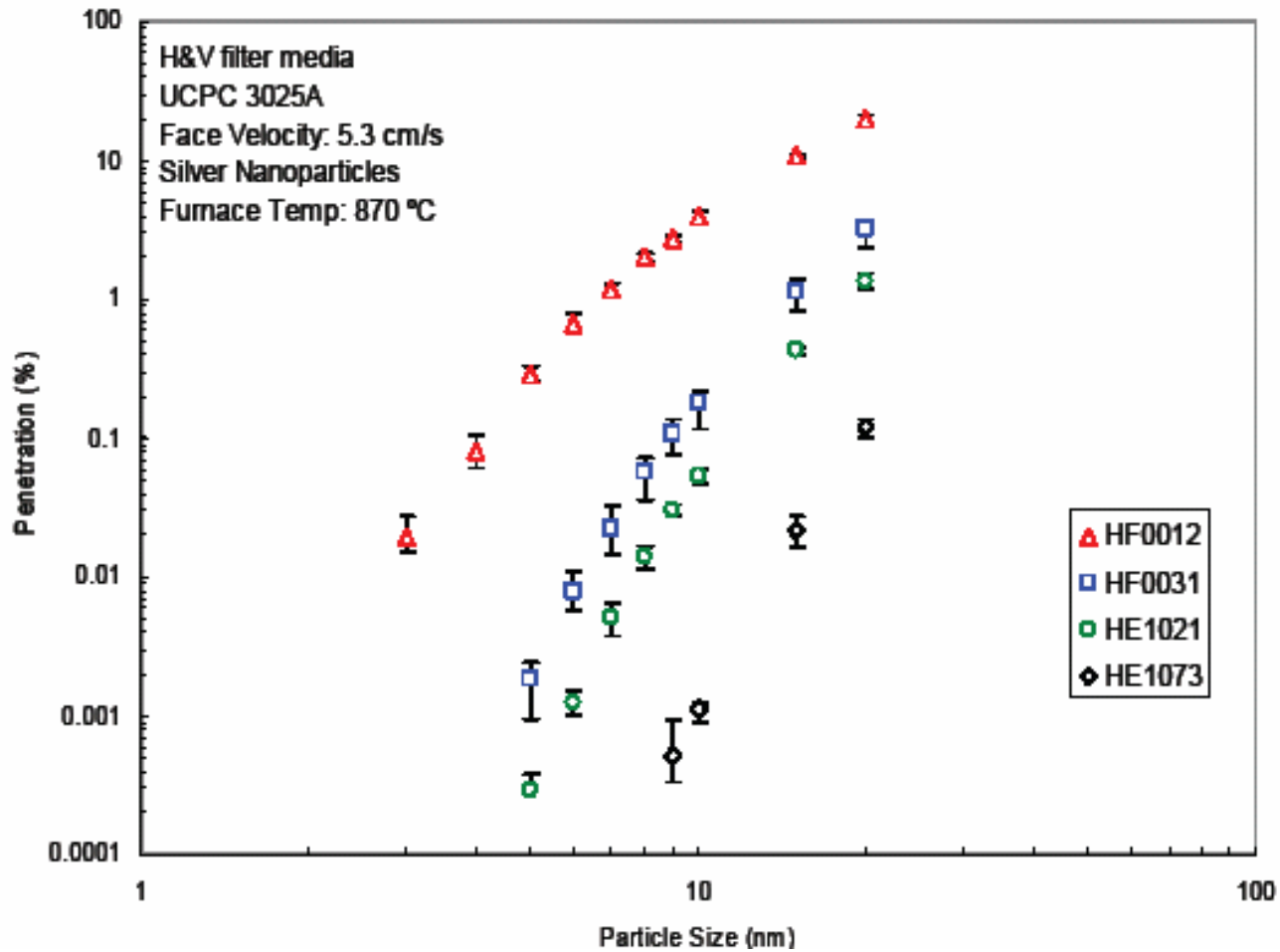
Project Overview

- **Contract awarded to University of Minnesota (March 2005)**
  - Construct a nanoparticle penetration test system
  - Measure penetration of particles (<300 nm) through various types of filter media
  - Verify that filtration theory holds for the smaller nanoparticles
- **Contract final report (April 2006)**
- **Follow-up NPPTL project plans (Oct 2006-Sept 2009)**
  - Construct nanoparticle test system at NPPTL
  - Validate previous work with NIOSH approved respirators
  - Effect of particle size on face seal leakage

Nanoparticle Penetration Test System

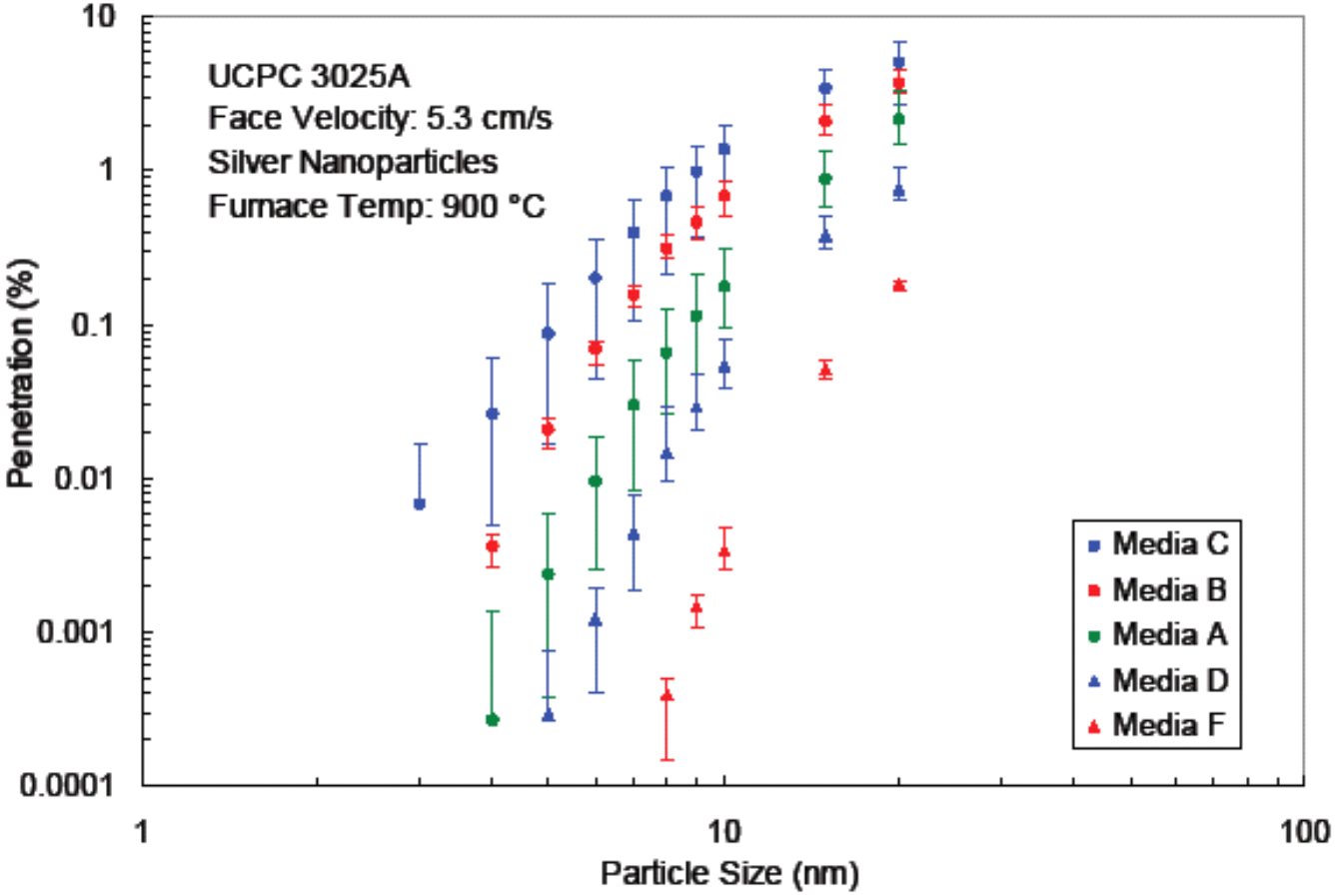


Filter Efficiency
H&V Fiberglass Filter Media



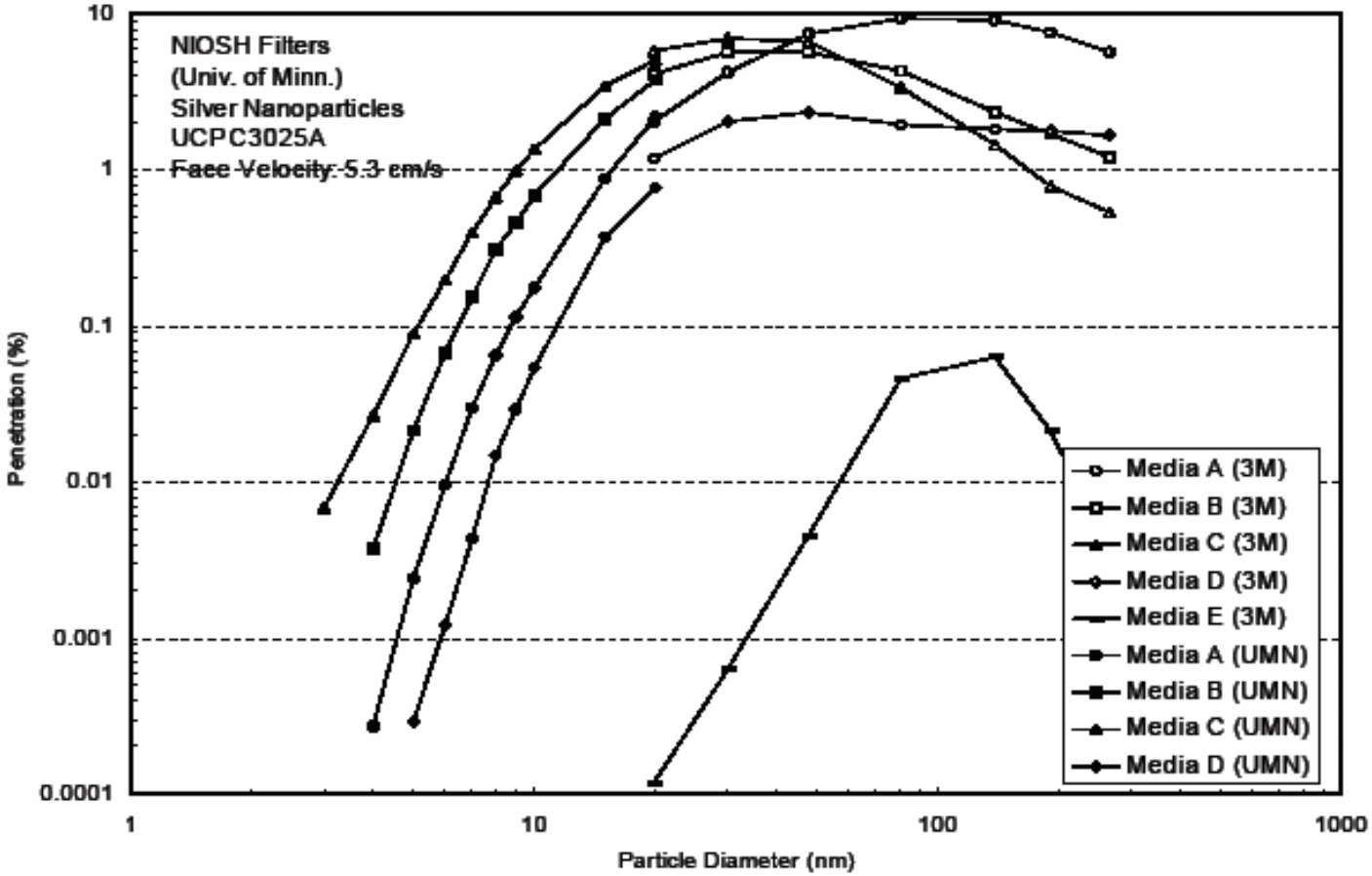
Seong Chan Kim, David Y.H. Pui, and Samy Rengasamy, Presented at 2nd Int. Symposium on Nanotechnology and Occupational Health, Minneapolis, MN, October 3-6, 2005.

Filter Efficiency
Electret Filter Media



Seong Chan Kim, David Y.H. Pui, and Samy Rengasamy, Presented at 2nd Int. Symposium on Nanotechnology and Occupational Health, Minneapolis, MN, October 3-6, 2005.

Filter Efficiency
Electret Filter Media – Combined Data



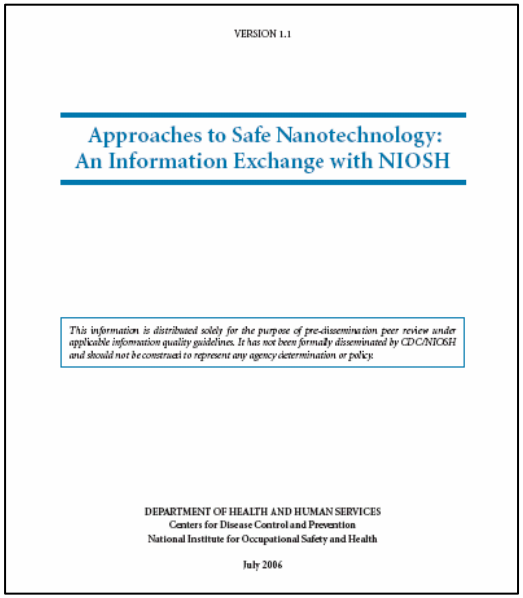
Seong Chan Kim, David Y.H. Pui, and Samy Rengasamy, Presented at 2nd Int. Symposium on Nanotechnology and Occupational Health, Minneapolis, MN, October 3-6, 2005.

Report Summary

- **Findings from the NIOSH contract with U. of Minnesota's Center for Filtration Research:**
  - Penetration through filter media decreased with decreasing particle size (< 20 nm)
  - Filtration data supported the classical single-fiber filtration theory down to 3 nm size
  - No evidence for thermal rebound

Interim Recommendations

- **Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures**
  - There are no specific exposure limits for airborne exposures to engineered nanoparticles
  - The decision to use respiratory protection should be based on professional judgment
  - Preliminary evidence shows that for respirator filter media there is no deviation from the classical single-fiber theory for particulates as small as 2.5 nm in diameter
  - It is likely that NIOSH certified respirators will be useful for protecting workers from nanoparticle inhalation



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Approaches to Safe Nanotechnology:
An Information Exchange with NIOSH

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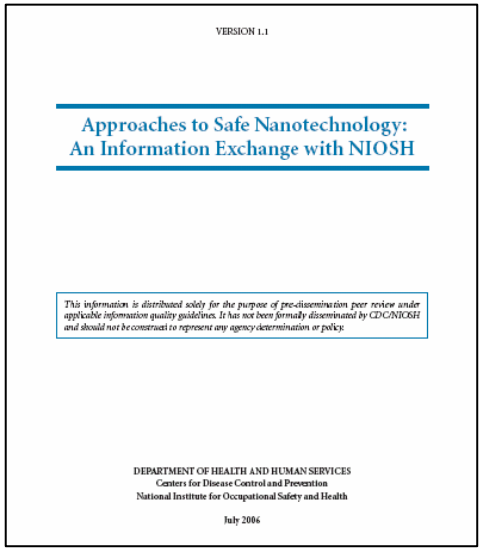
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

July 2006

http://www.cdc.gov/niosh/topics/nanotech/

Protective Clothing

- **No guidelines are currently available on the selection of clothing and gloves for the prevention of dermal exposure to nanomaterials**
- **Little data has been published on the penetration of nanoparticles through protective clothing**
  - ASTM standard F1671 uses 27 nm bacteriophage to evaluate penetration of bloodborne pathogens
  - Penetration of 0.48 µm particles through 8 fabrics ranged from 0-31% [Shalev et al. 2000]
- **NPPTL initiated research to develop methodology for standardizing bench-scale and man-in-simulant test (MIST) procedures for aerosol penetration (including nanoparticles)**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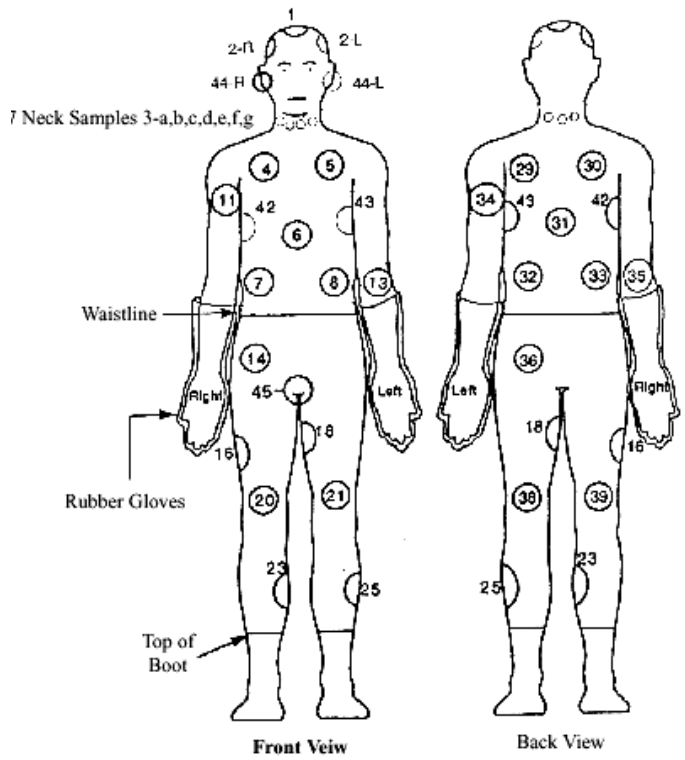
Recent Studies on Aerosol Penetration of Fabric Swatches

- **RTI (James Hanley)**
  - **Oleic acid & KCl test aerosols (15 nm - 3 µm)**
  - **Wind speeds 14, 32, and 64 mph; 90° F, 60% RH.**
  - **Aerosol penetration of permeable fabrics is particle size dependent.**
- **Battelle (Kent Hofacre)**
  - **Modified TOP 8-2-501 (aerosol penetration test method)**
  - **KCl test aerosol (10 nm - 10 µm); Wind speeds 8 & 23 mph; 90° F, 40% RH.**
  - **Penetration consistent with filtration theory**
    - **MPPS 100 to 400 nm; % penetration ranged < 5% to 60%**

Presented at Elevated Wind Studies International Conference, Arlington, VA, Sept. 25-26, 2006

Initial NPPTL Project Focus

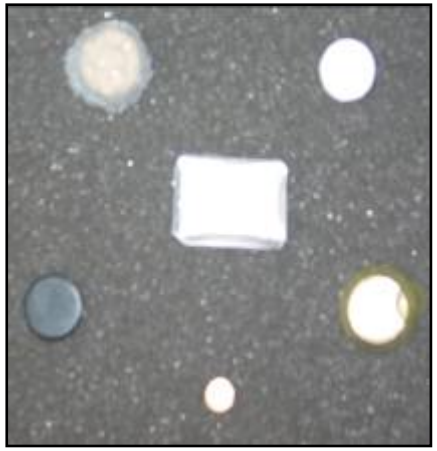
- **Develop a passive aerosol sampler (PAS) to determine penetration through protective clothing materials with minimal flow**
  - Active sampling methods may over-estimate particle penetration due to additional driving force
  - Samplers should not disturb PPE-wearer environment



Test Operations Procedure (TOP)-10-2-022 Chemical Vapor and Aerosol System-Level Testing of Chemical/Biological Protective Suits.

PAS Concept

- **Magnetic sampler (FeNdB magnet)**
  - Small size (18 mm diameter x 3 mm)
  - No sampling flow
  - Minimal particle loss during handling
- **Challenge particle--iron oxide (II, III)**
  - Magnetic susceptibility
  - Spherical particles
  - Low toxicity (OSHA PEL: 10 mg/m3)
  - Inexpensive
  - Wide range of particle sizes
- **Colorimetric method, SEM, TEM, or magnetic susceptibility**

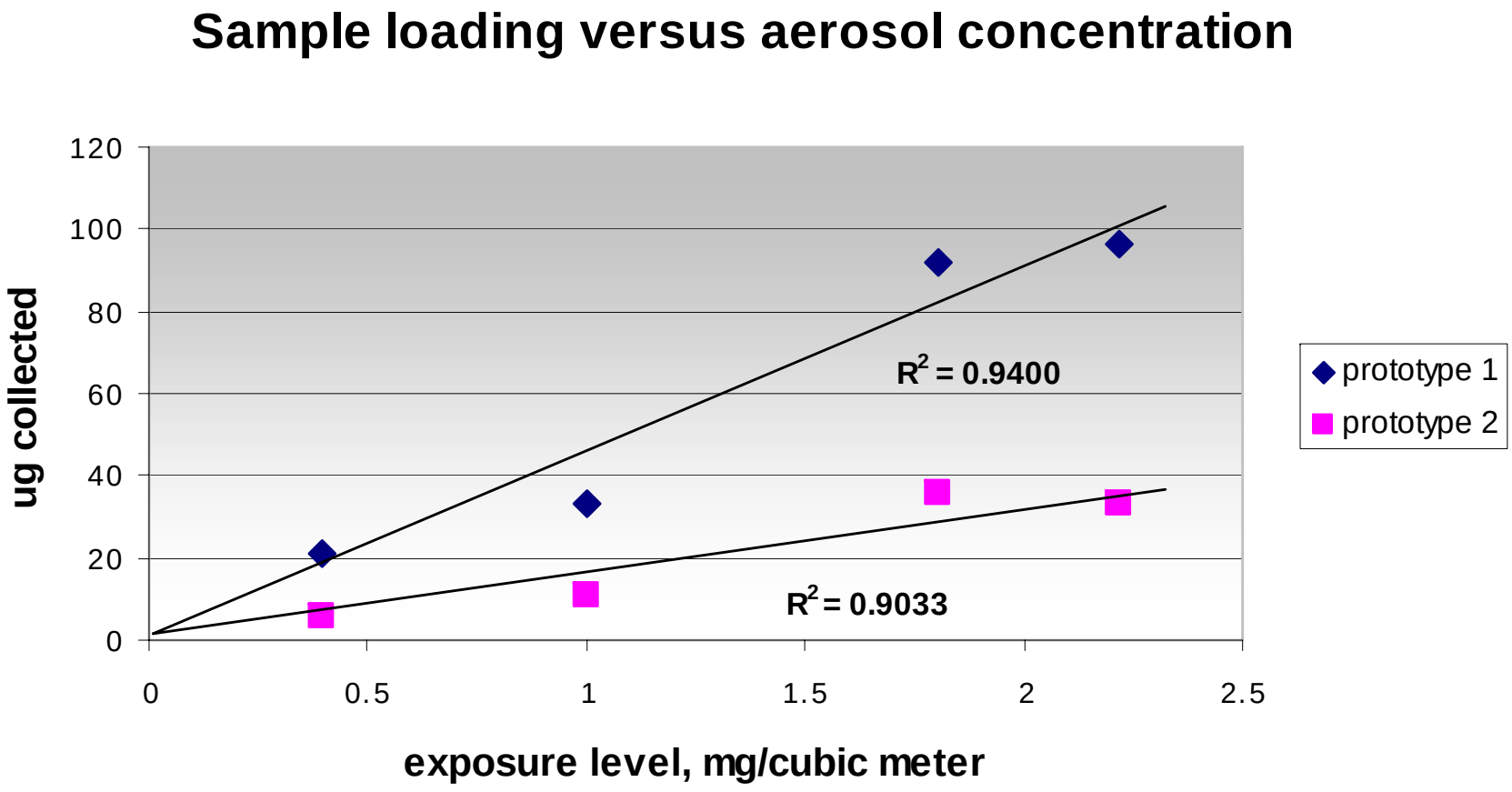


Characterization of PAS Response

Aerosol Test Chamber

- **Aerosol concentration measured by filter cassette sampling**
  - 0.3 to 2.5 mg/m^3, 45 minutes
- **Particle sizes estimated by light scattering (110 to 280 nm)**
- **Two sampler prototypes**
  - Prototype 1: 18 mm x 3 mm disc
  - Prototype 2: 6 mm x 2 mm disc

Sampler Response



King and Gao, A Passive Aerosol Sampler for Evaluation of Personal Protective Ensembles, Presented at the 2005 Advanced Personal Protective Equipment Conference, Blacksburg, VA.

Penetration Study using Swatch

ASTM F739 Cell

- **Glass cell conditions**
  - **30 minute exposure**
  - **≥ 50 mg/m3 iron oxide**
  - **Micron-sized particles**
  - **Ambient conditions**
- **Test fabric**
  - **Nomex (5 oz.) open weave**
- **Prototype 1**

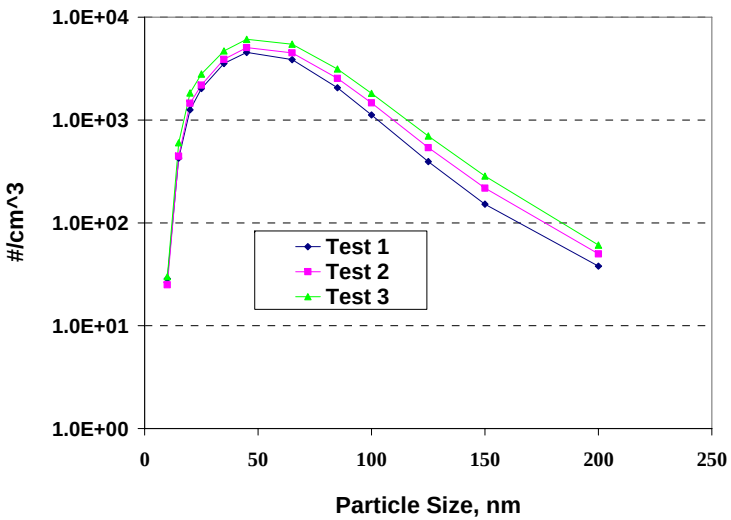
Protection Factor

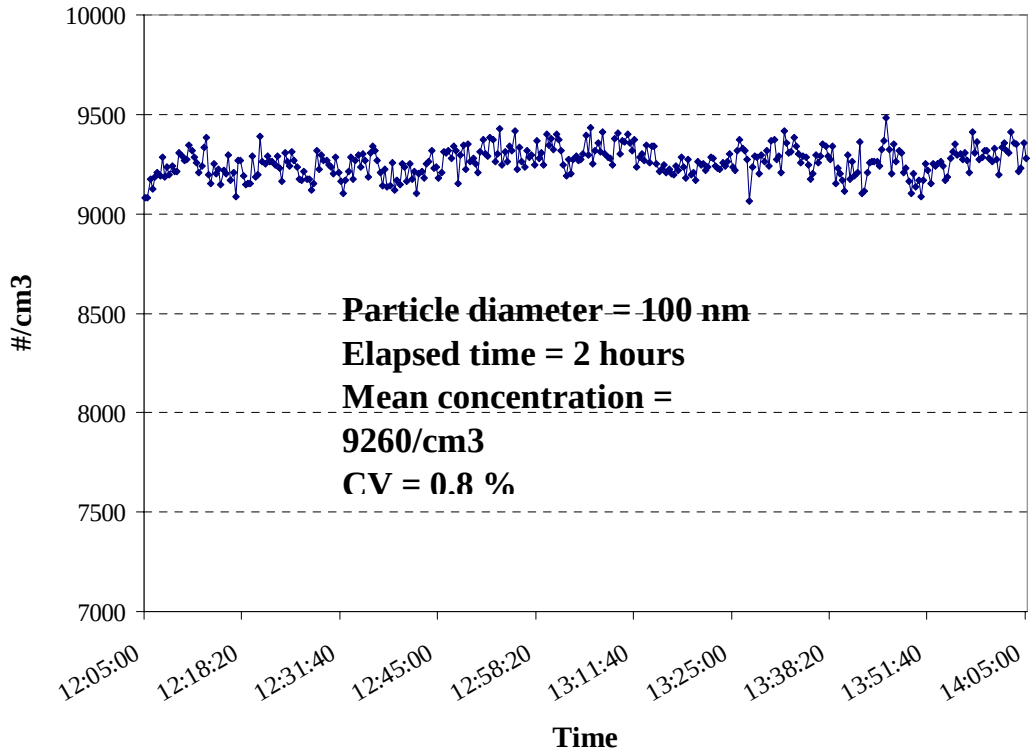
Cell	Average, µg	Std Dev	N
Nomex	5.4	6.2	5
Parafilm	1.7	2.5	5
Open (no fabric)	23	14.6	4

PF = (23-1.7) / (5.4-1.7) = 5.8

King and Gao, A Passive Aerosol Sampler for Evaluation of Personal Protective Ensembles, Presented at the 2005 Advanced Personal Protective Equipment Conference, Blacksburg, VA.

Generation of Monodisperse Nanoaerosols Using a Differential Mobility Analyzer (DMA)

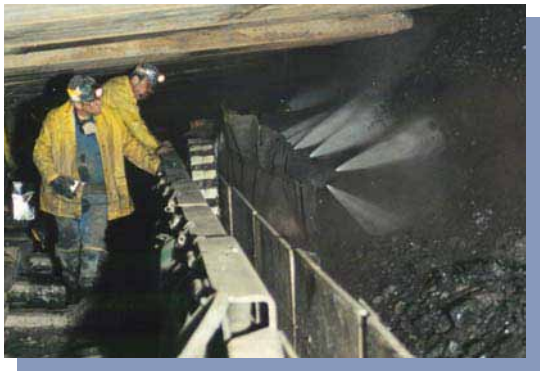




Summary of PAS Concept Development

- **The prototype PAS based on magnetic sampling allows zero-flow collection and sensitive detection of iron oxide aerosols**
- **PAS demonstrates proportional response, but additional characterization is necessary**
- **Applicability for bench-scale fabric penetration tests has been shown**
- **Further development is currently underway**
- **Need to analyze and incorporate results from military studies into NIOSH recommendations**

Quality Partnerships Enhance Worker Safety & Health



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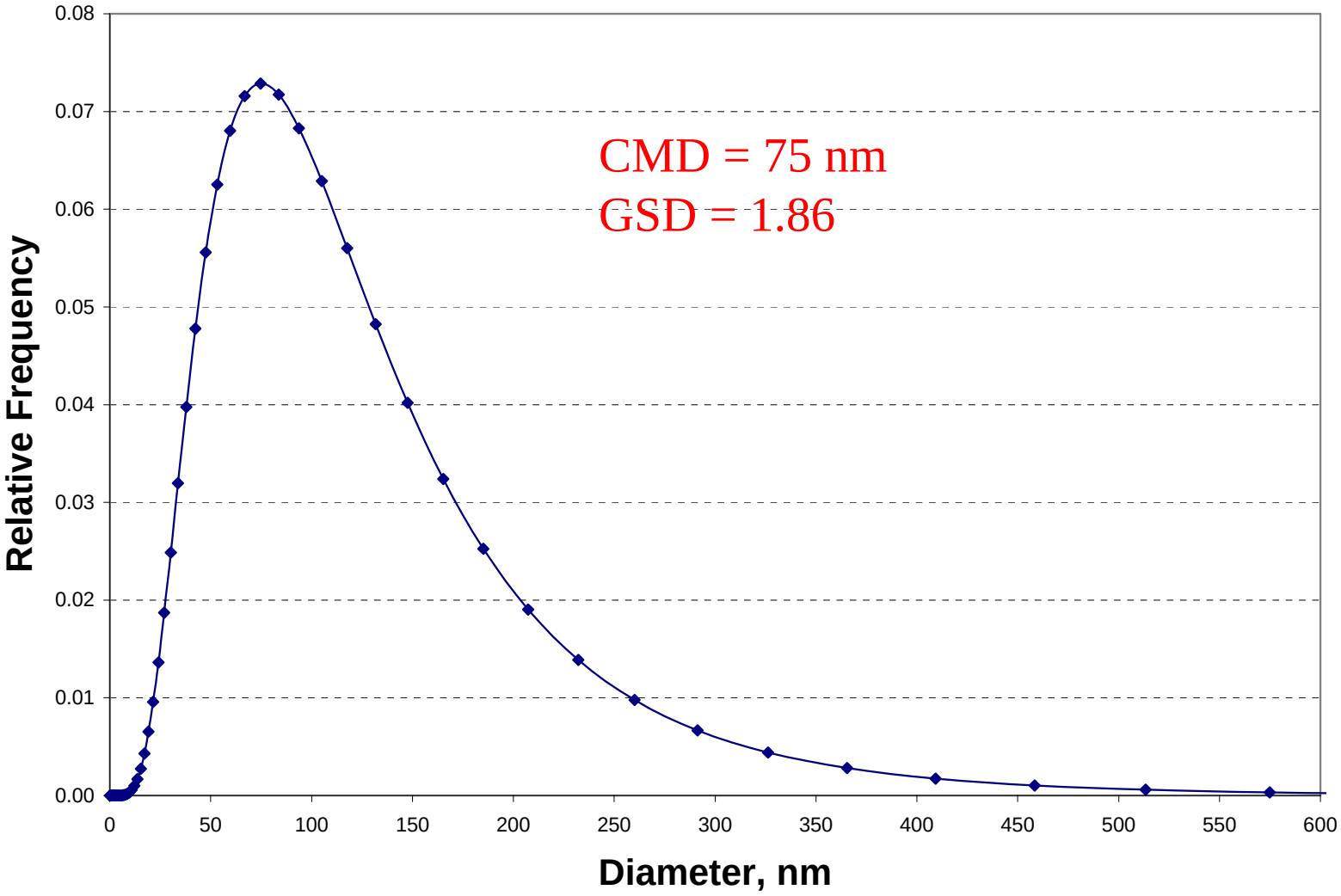
Thank you

NIOSH Certification Test

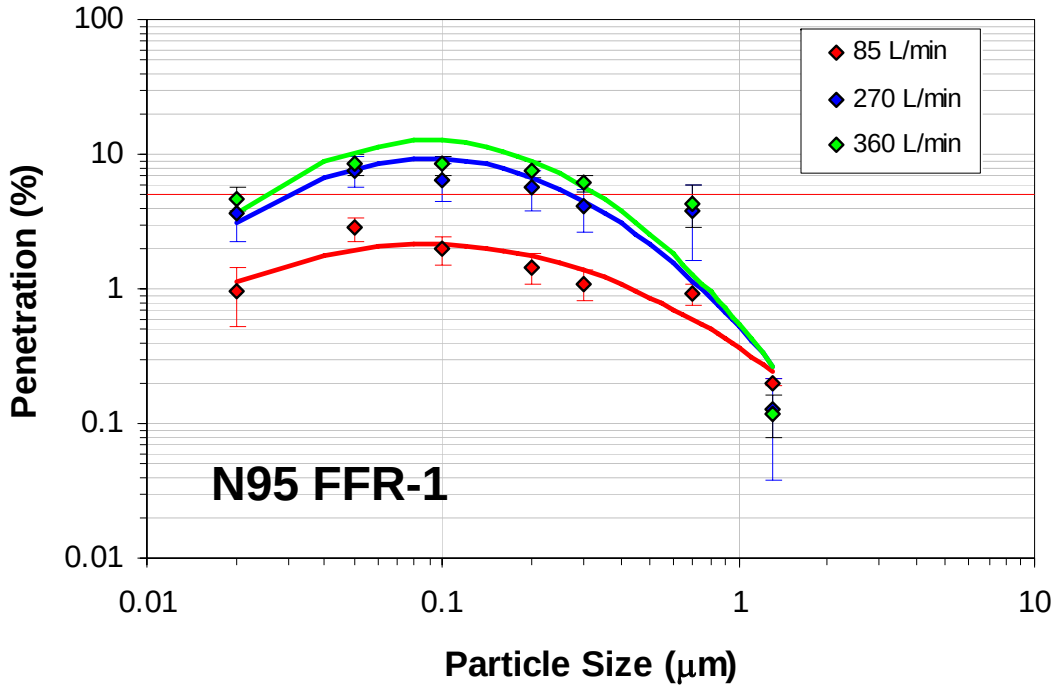
- **N- designated respirators:**
  - NaCl particles with a count median diameter (CMD) of 0.075 +/− 0.020 µm and a geometric standard deviation (GSD) of less than 1.86
  - 95% of the particles in the range of 22 nm – 259 nm
  - mass median diameter of ~240 nm
- **For R- and P- designated respirators:**
  - DOP particles with a CMD of 0.185 +/− 0.020 µm and a GSD of less than 1.60
- **Particles penetrating through the filter are measured simultaneously using a forward light scattering photometer**

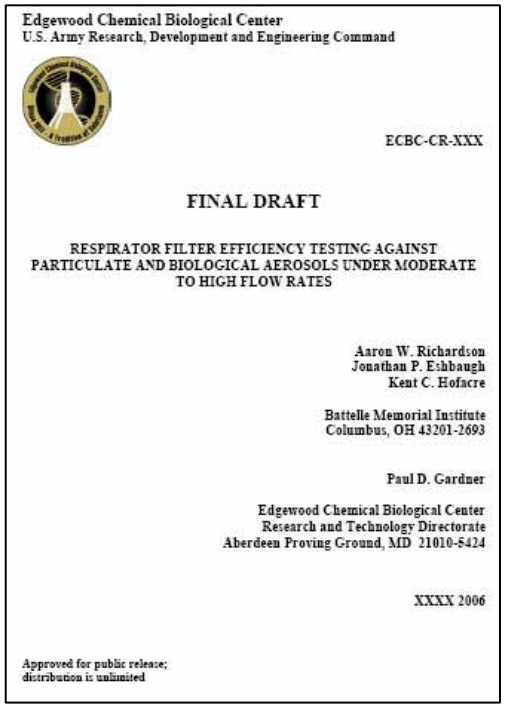
NaCl Particle Size Distribution



Studies at High Flow Rates

- NIOSH requirements were met at 85 L/min constant flow rate
- Penetration of particles in the 20 to 700 nm range tended to increase with increased flow rates
- Most penetrating particle size (MPPS) shifted to 50-100 nm for N95 respirators





Edgewood Chemical Biological Center
U.S. Army Research, Development and Engineering Command

ECBC-CR-XXX

FINAL DRAFT

RESPIRATOR FILTER EFFICIENCY TESTING AGAINST PARTICULATE AND BIOLOGICAL AEROSOLS UNDER MODERATE TO HIGH FLOW RATES

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XXXX 2006

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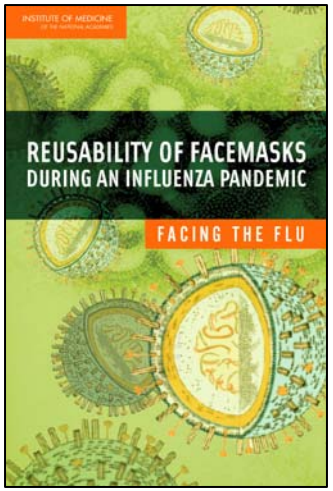
Reusability of Filtering Facepiece Respirators

Jon Szalajda, Samy Rengasamy, Raymond Roberge,
Ron Shaffer, Evanly Vo, Dennis Viscusi

October 13, 2006



Background – Planning Efforts

2005/2006 – CDC internal request for proposals related to influenza pandemic research

- **NPPTL develops Respiratory Protection Research for Infection Control Proposal and receives CDC program funding**

2006 – DHHS requests an IOM committee examine issues relative to the potential reuse of medical masks and N95 respirators in the event of an influenza pandemic

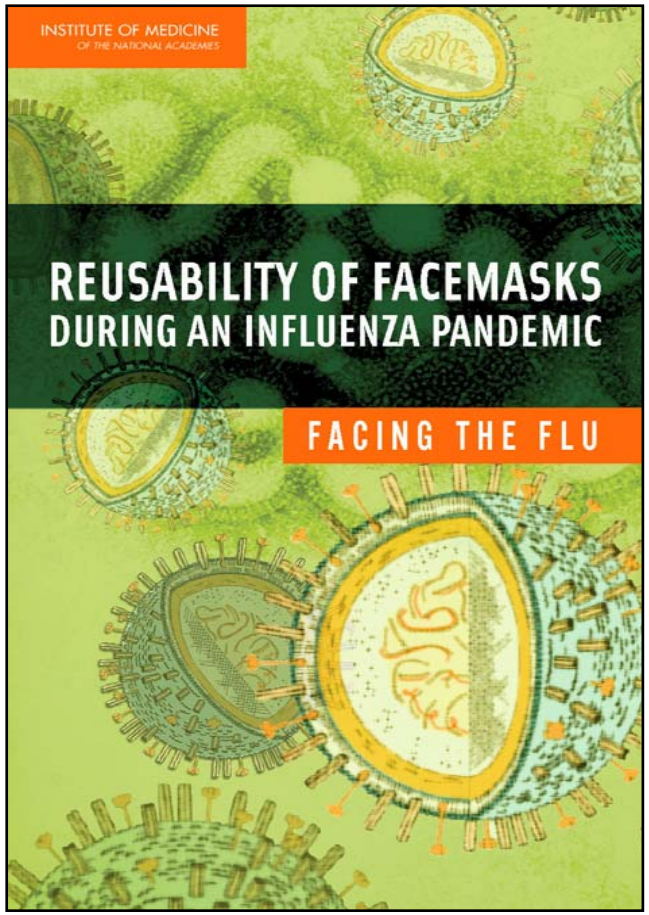
2006 – Senate Report 109-287, Appropriations Bill for 2007, recommends that NIOSH evaluate respirators for "effectiveness against transmission of avian influenza and other pathogens"

Background – Institute of Medicine Review

- During a pandemic, healthcare workers and the general public will have increased reliance on disposable N95 FFR for infection control

- According to a report from the National Academies' Institute of Medicine (IOM)*, during an influenza pandemic over 90 million N95 FFR will be needed to protect workers in the healthcare sector during a 42 day outbreak. Additional respirators would be needed by the general public

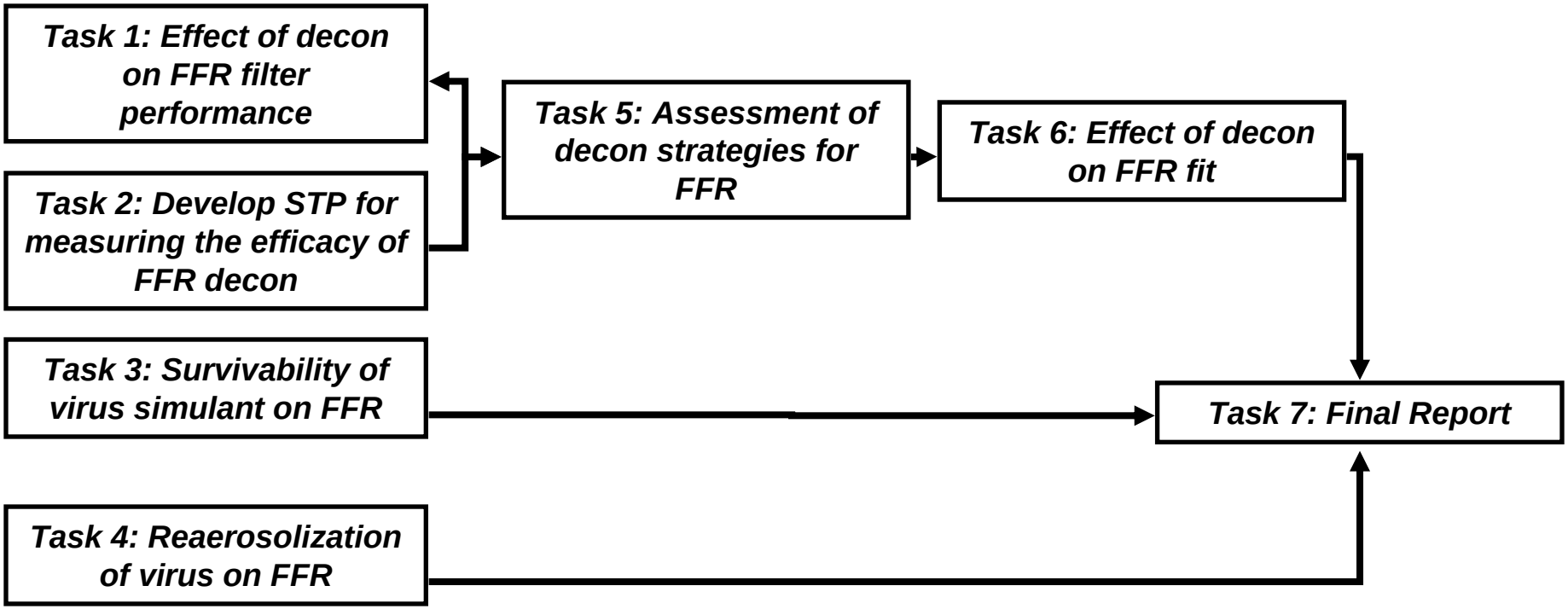
*http://www.iom.edu/CMS/3740/32033/34200.aspx



Background – IOM

- Some of the recommendations in the IOM report indicate that DHHS should conduct research to:
  - **understand the efficacy of simple decontamination methods that could be used without negative effects on respirator integrity**
  - **understand the risks associated with handling a respirator that has been used for protection against a viral threat (e.g., study the likelihood that the exterior surface of the respirator might harbor pathogenic microorganisms and thus serve as a fomite)**

Reusability of Filtering Facepiece Respirators



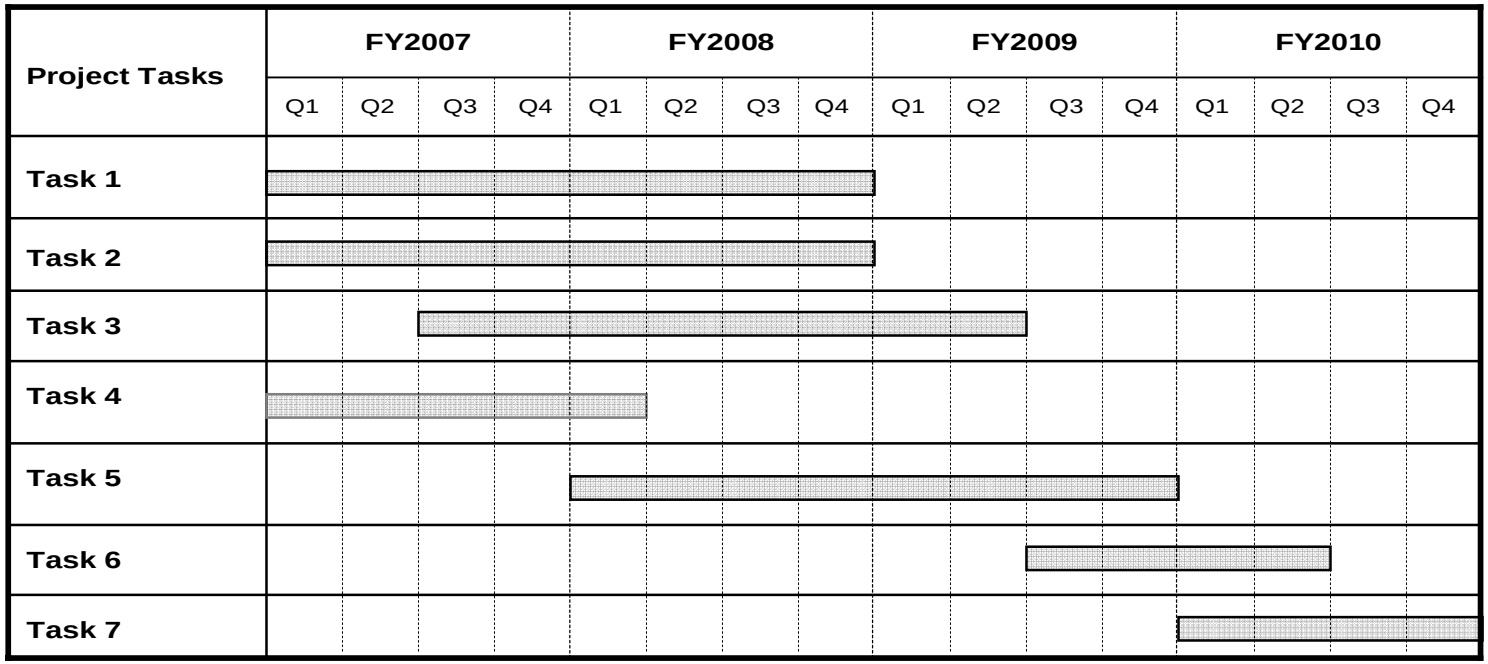
Reusability of Filtering Facepiece Respirators

NPPTL will give consideration to anti-viral technologies in this research study using the following hierarchy for selection of candidate FFR products and prototypes*:

- **FFR certified to 42 CFR 84 requirements,**
- **FFR in process of being certified to 42 CFR 84**
- **FFR is a prototype or a commercially available product that has not been submitted to NIOSH for certification from a manufacturer who has received NIOSH certification for other respiratory protection products**
- **FFR prototype contains a unique technology for disinfecting or sterilizing infectious aerosol particles trapped on the exterior surface of the FFR and complements the diversity of technologies already considered in the research design**

***Federal Register Notice, September 26, 2006, Vol. 71, Number 186, page 56151-56152**

Reusability of Filtering Facepiece Respirator – Project Schedule



Project Expected Outcomes

- **Improved guidelines and recommendations for respiratory protection against influenza and other infectious aerosols**
  - Performance data on FFR that incorporate decontamination capabilities
  - Potential modifications for NIOSH and CDC recommendations

- **Improved test methods and performance requirements for respiratory protection used by national and international standards development organizations**
  - ASTM Method of a decontamination procedure for FFR

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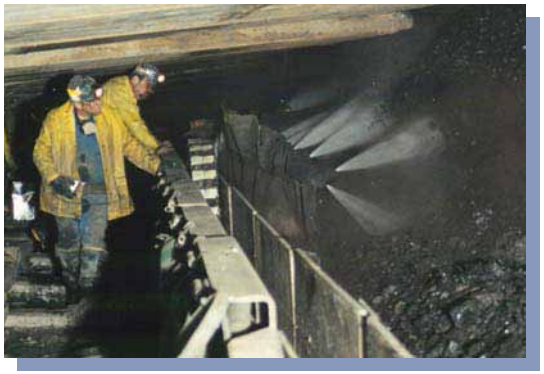

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National Personal Protective Technology Laboratory

Scientific Excellence Focus

Maryann D'Alessandro
Associate Director for Science

Academia - SDOs - Government Laboratories – Unions – Labor - Manufacturers

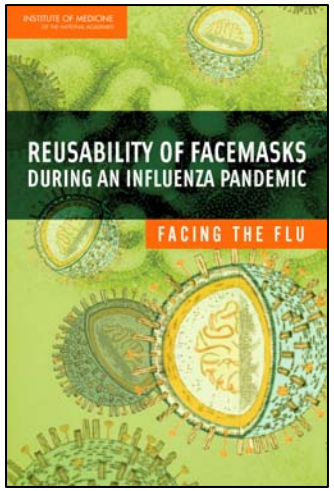
Quality Performance Initiatives

- **Evaluations**
  - National Academies involvement in NPPTL
  - Scientific information product review
  - Benchmarking
- **Customer and Market Knowledge**
  - Standards Development Committee Involvement
  - Public Meetings and feedback
  - Customer Satisfaction Groups (Focus Groups)
- **Customer Relationships and Satisfaction**
  - Customer Satisfaction Survey (CSS)
  - Direct Customer involvement

Academia - SDOs - Government Laboratories – Unions – Labor - Manufacturers

National Academies Involvement in NPPTL

- *Committee on PPE for the Workforce (COPPE)*
  - Three open meetings in FY06
  - Meeting 1 FY07: Oct 23-24, 2006
  - Workshop: Feb 2007 – **PPE during an Influenza Pandemic: Research, Standards, Certification and Testing Directions**
- *Review of Anthropometrics Survey and Respirator Panel Modifications*
  - Three open meetings in FY06
  - Final report due October 2006
  - Jan – Mar 2006 - *Support to HHS for Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic*
- *Review of BLS Survey of Respirator Use*
  - Three open meetings in FY06
  - Final report due October 2006
- *National Academies Evaluation of Personal Protective Technology (PPT) Cross Sector*
  - Evidence Package to National Academies Spring 2007
  - National Academies Evaluation June 2007



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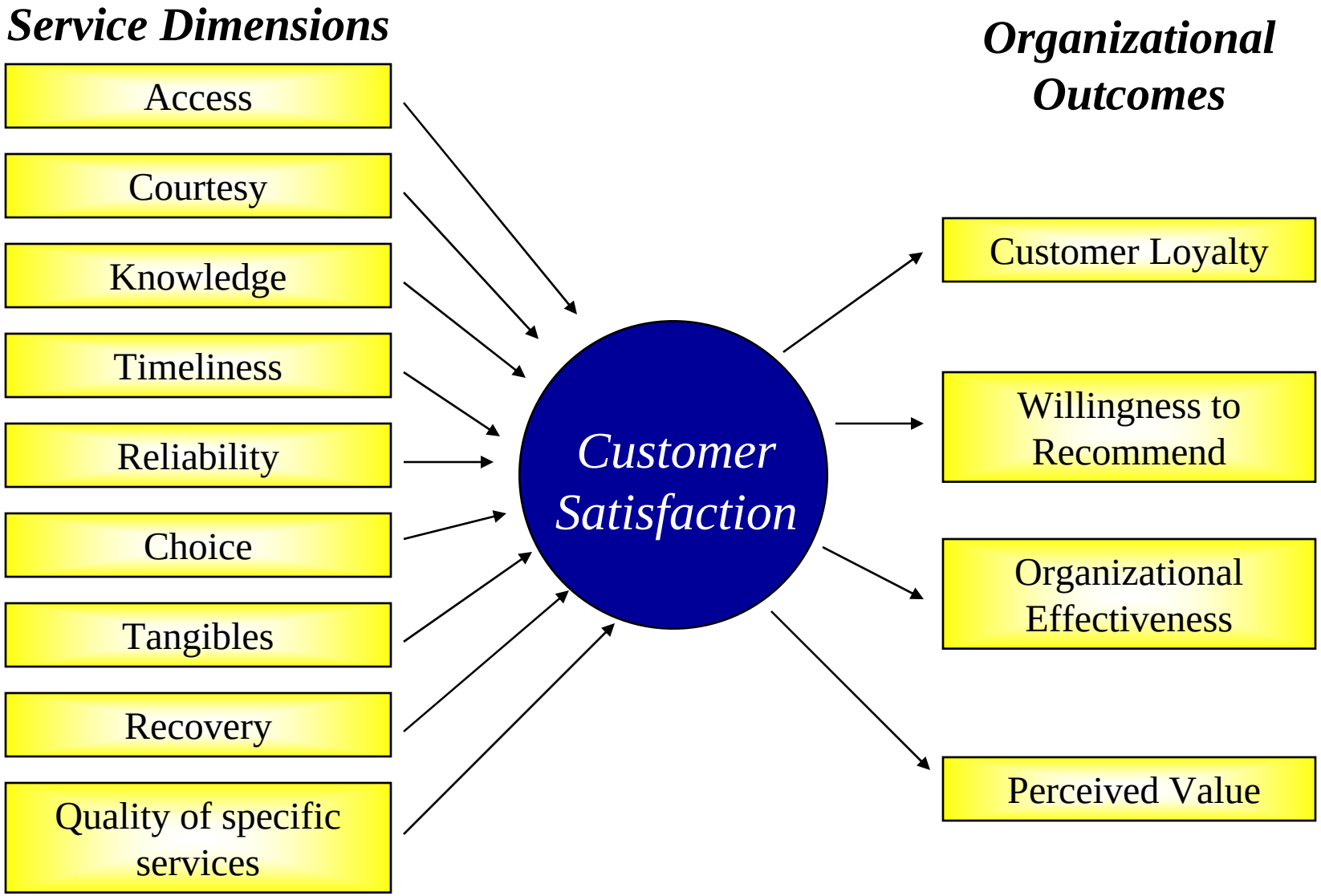
NPPTL Customer Satisfaction Survey
Method: The Surveys

- **Manufacturer & User Surveys**
- **Survey instruments include:**
  - demographic items
  - OPM's core customer satisfaction items
  - NPPTL-specific items
- **Surveys pilot-tested in October 2005**
- **OMB approval for distribution to public: Dec 2005**
- **Online administration: Dec 5 - 23, 2005**
- **Analyze results**
- **Act on results**
- **Monitor and evaluate progress**

Customer Service Dimensions and Outcomes



NPPTL Customer Satisfaction Survey Results

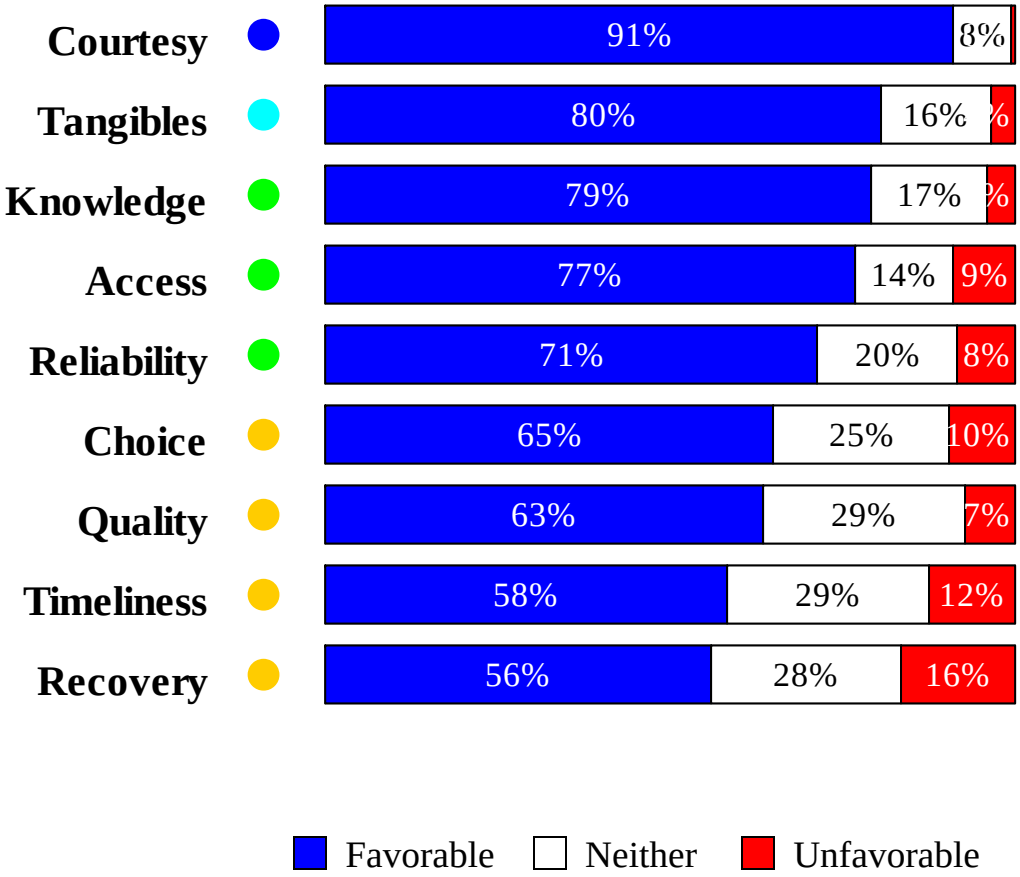
	Users	Manufacturers
Original Population	666	262
Undeliverables	44	19
Population	622	243
Responses	185	75
Final Response Rate	**30%**	**31%**

Guidelines for Interpreting Results

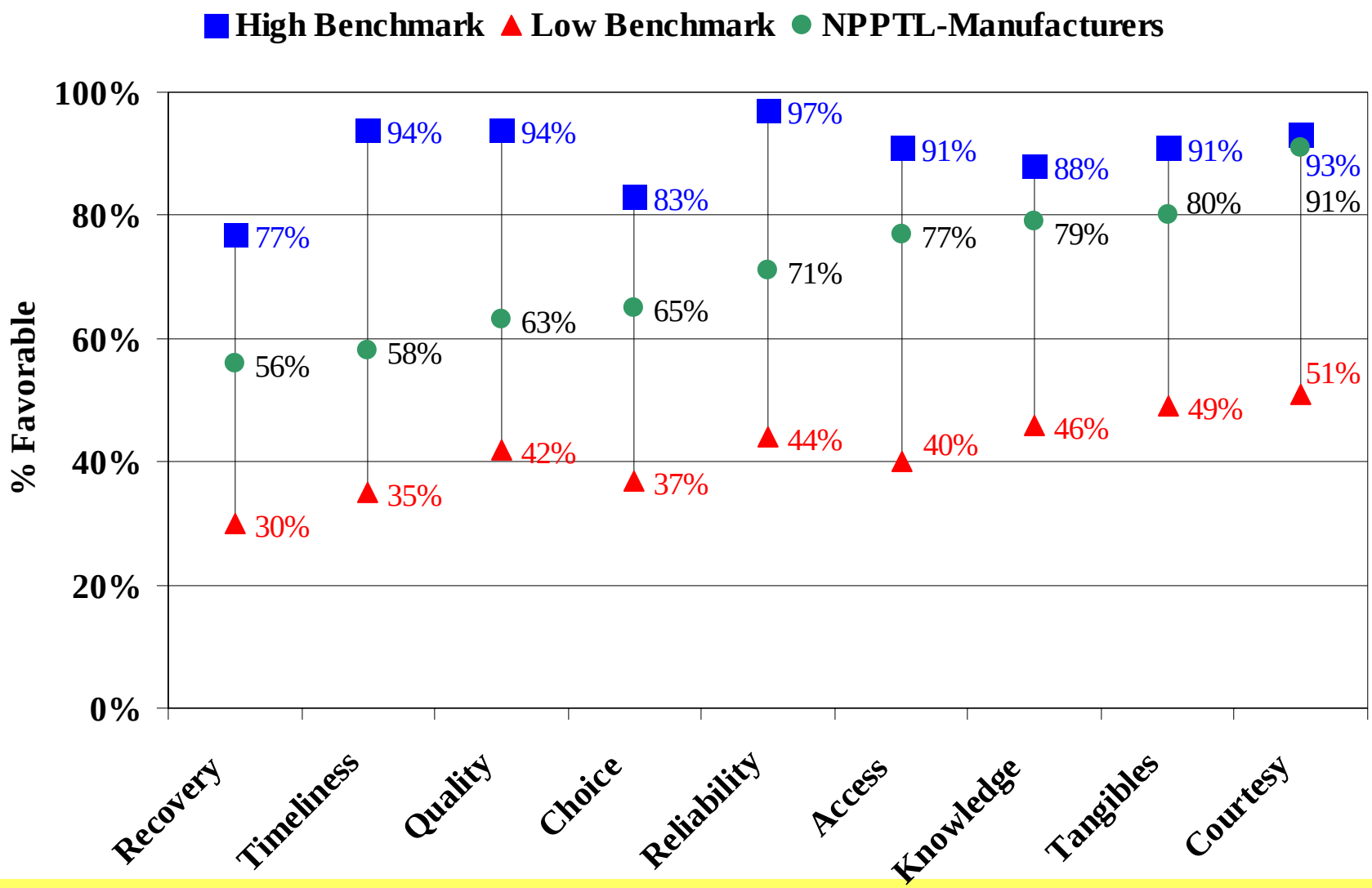
Favorability of Results

- Excellent: 90% - 100% favorable
- Good: 80% - 89% favorable
- Acceptable: 66% - 79% favorable
- Marginal: 50% - 65% favorable
- Critical: 0% - 50% favorable

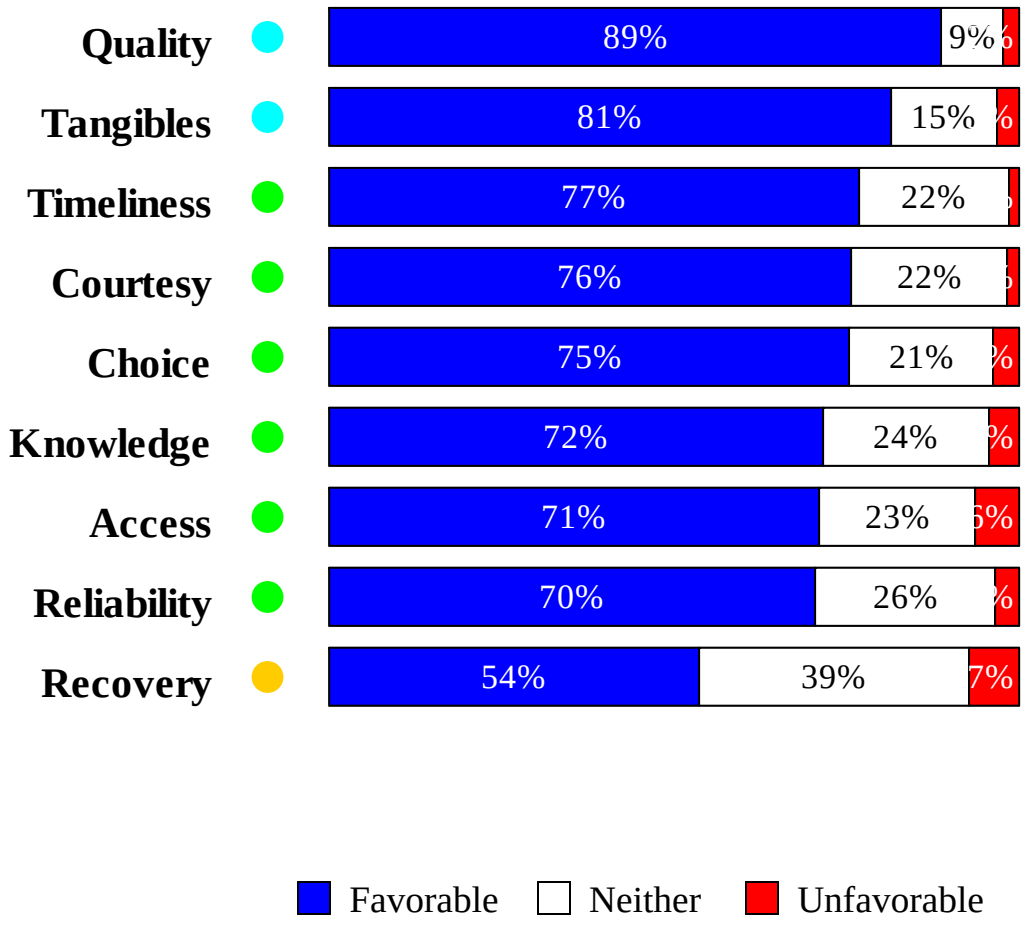
NPPTL CSS Results: Manufacturers



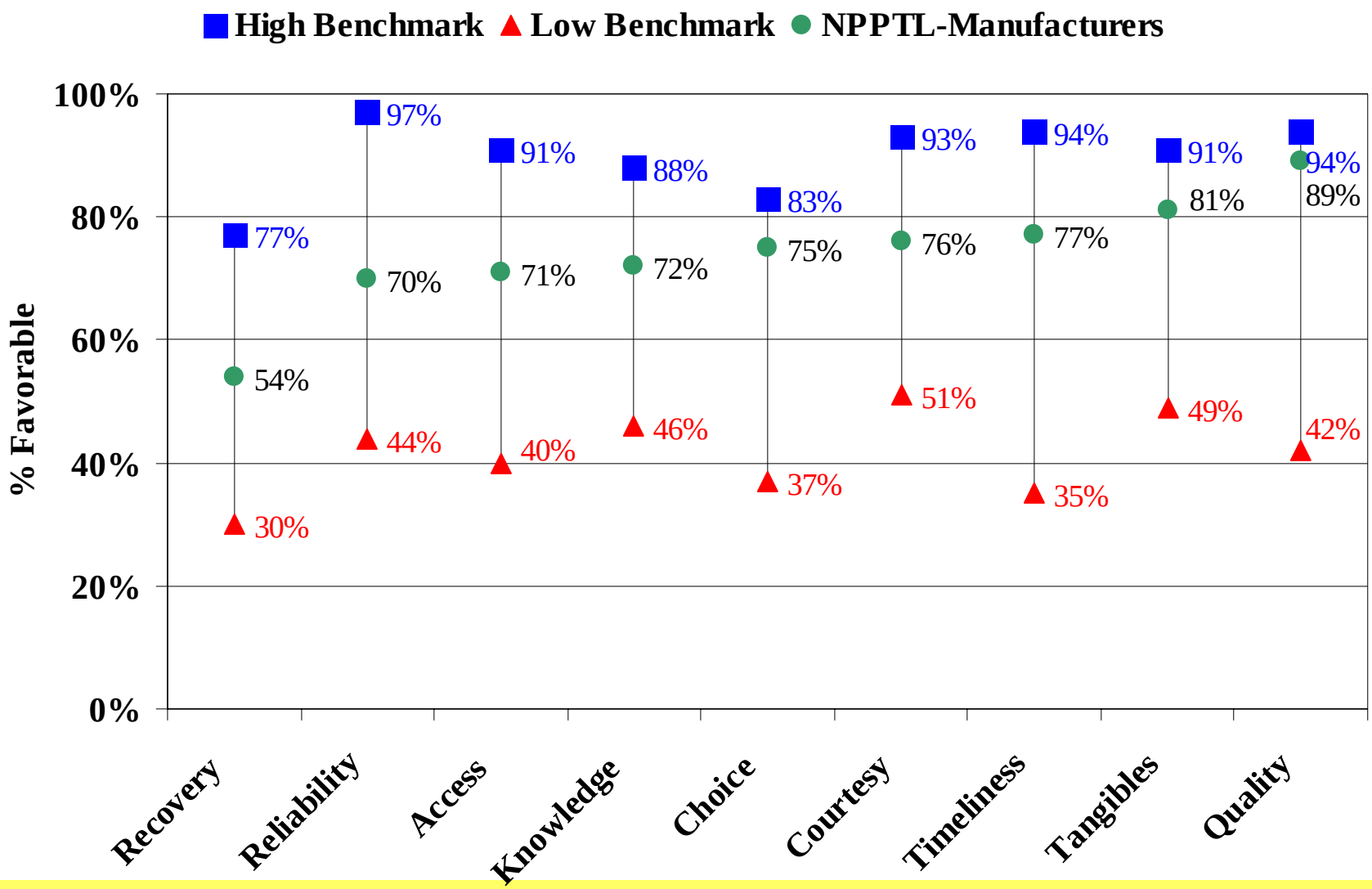
Benchmarks: Manufacturers



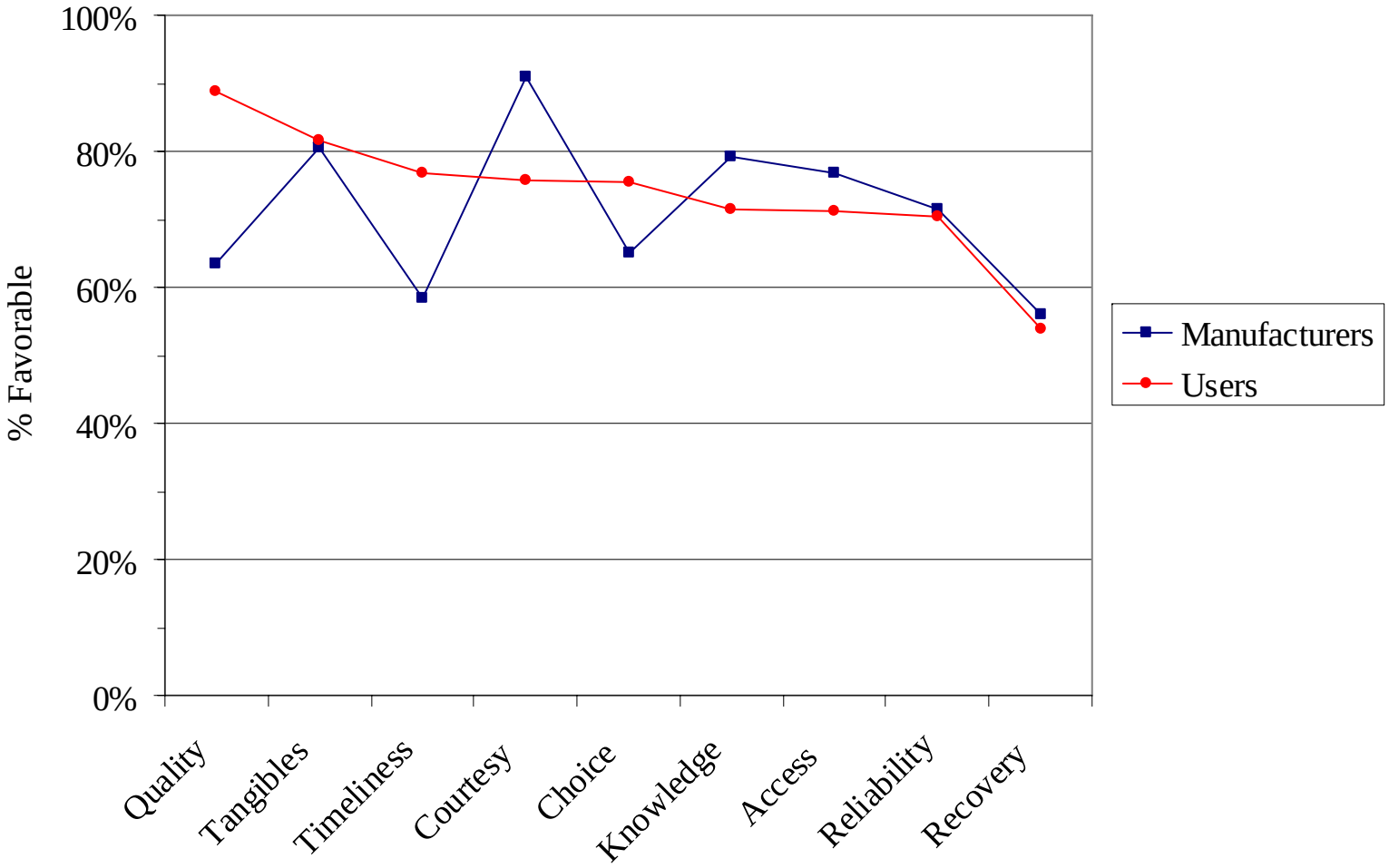
NPPTL CSS Results: Users



Benchmarks: Users



Results: Dimension Profiles



Now that we have the survey results where do we go from here?

- **Identify areas to improve within branches**
- **Create the Customer Satisfaction Groups**
  - Keep customers satisfied on an ongoing basis
  - Provide customers easy way to voice concerns/complaints
  - Provide customers easy way to seek more information

Customer Satisfaction Groups

- **Get Customer input on a regular basis**
  - Groups are a resource for direct customer contact
  - Allows for regular input in keeping up with the changing personal protective equipment market
- **Customer Satisfaction Group Results**
  - Verify NPPTL improvement areas
  - Verify marketplace opportunities
  - Recommend action plans on specific issues involving NPPTL

Customer Satisfaction Activity at NPPTL

Customer Satisfaction Groups

- **Three meetings in 2006**
  - Manufacturers – Washington, DC - Apr 2006
  - Fire Services – Pittsburgh, PA - Sept 2006
  - Fire Services – Arlington, VA – Oct 2006
- **Three meetings in 2007**
  - Health Care
  - Manufacturing
  - Manufacturers

Actions to Address Manufacturers' Issues

- **Quality**
  - ISO 17025 Certification Project
  - Improving standard application form (SAF)
  - Improving and posting standard test procedures (STPs)
  - Involvement in SDOs to address color coding issues
  - Input on Manufacturer's meeting agenda
- **Timeliness**
  - Streamlining certification process
  - Meeting lead time
  - Clarify meaning of 90 day approval
- **Recovery**
  - Improving methods for handling requests for additional information
  - Moving forward to install more CBRN testing at NIOSH
  - Adding additional filter penetration testing equipment
  - Manufacturers Arbitration Group
    - Composed of NPPTL experts not directly involved in issue of concern
- **Research updates**
  - Monthly updates on listserv and ENews

Next Steps

- **Continue to act on results**
- **Monitor and evaluate progress**
- **Conduct the Second NPPTL Customer Satisfaction Surveys for Manufacturers and PPE Users.**
  - JAN 2007 Finalize survey wording
  - FEB 2007 Obtain names and email addresses for customers
  - MAR 2007 Administer survey
  - APR 2007 Provide executive briefing and feedback reports

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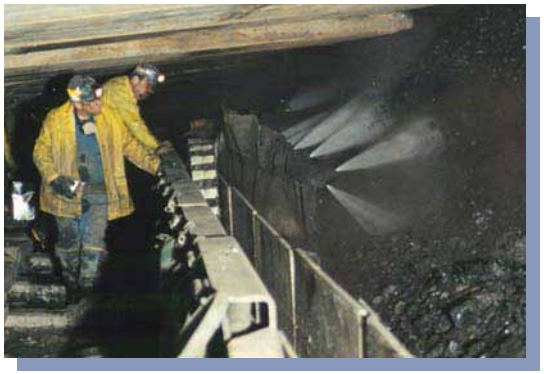

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Recovery

Problems and complaints are resolved quickly with minimal effort on the customer's part and problems do not recur.

- **Problems and complaints are resolved quickly.**
- **Problems and complaints are resolved with minimal effort on the customer's part.**
- **There are well-defined systems for linking customer feedback and complaints to employees who can act on this information.**
- **I am satisfied with the way the staff handles problems or mistakes.**
- **The staff is flexible in finding solutions to problems.**

Quality

What the customer receives from the service provider or the perception of excellence of the product or service received.

- **How would you rate the overall quality of service you received?**
- **From the list of services below, how would you rate the quality of each specific type of service?**

Timeliness

Promptness in receiving or providing promised materials and/or service.

- **Overall, NPPTL personnel provide timely service.**
- **(Other items were customized for this dimension. These items are not used to calculate a dimension score.)**