

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

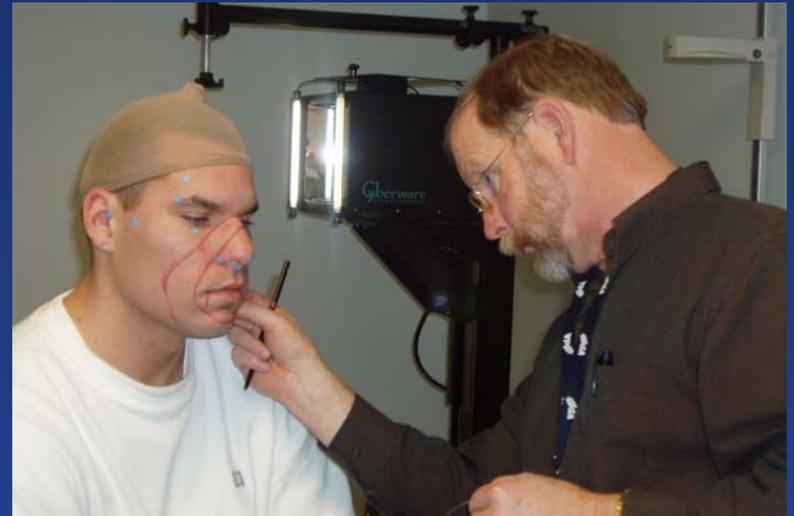
Meeting Objective

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



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** –

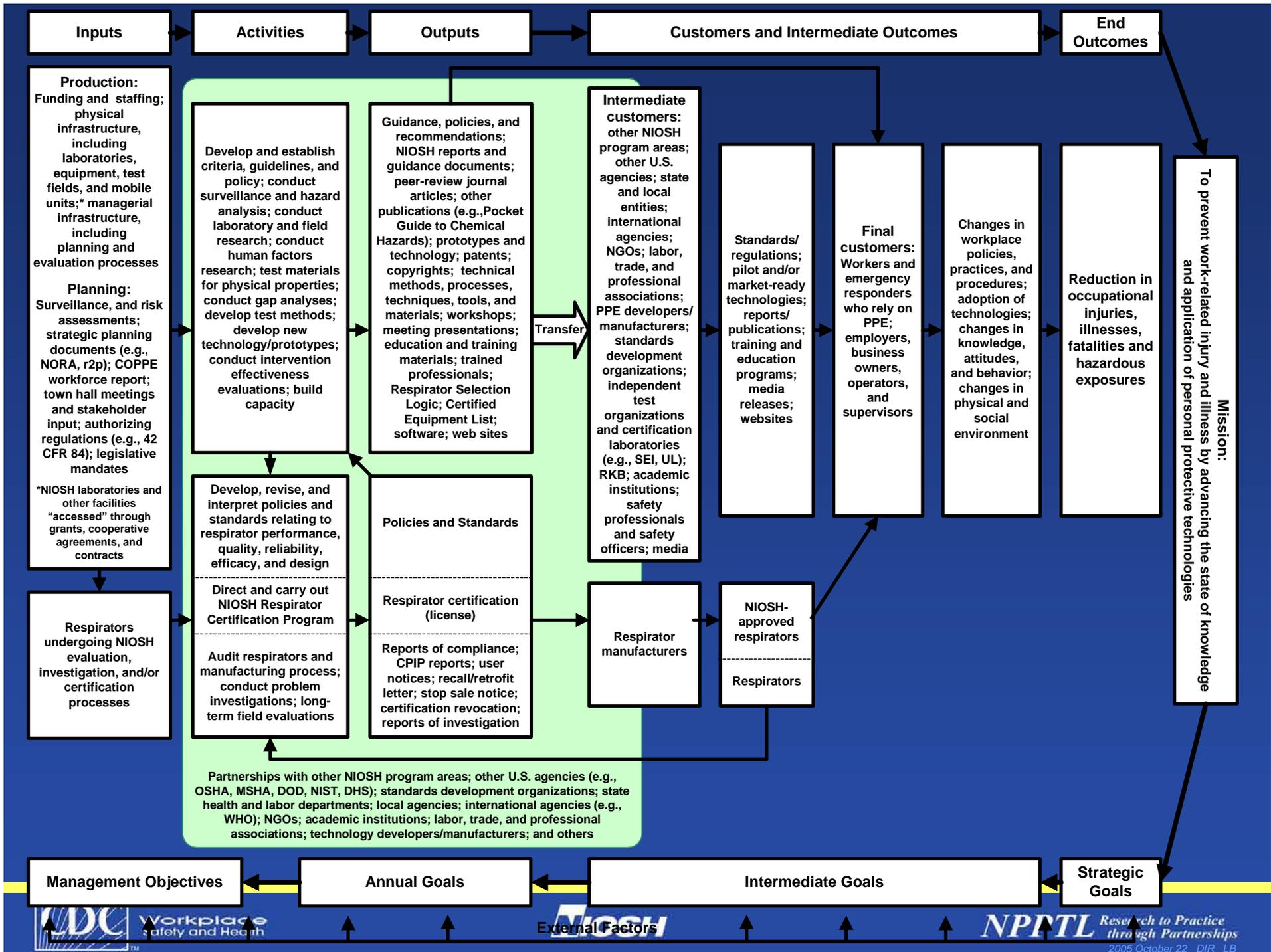
To prevent work-related injury and illness by advancing the state of knowledge and application of personal protective technologies.

- **Vision Statement** –

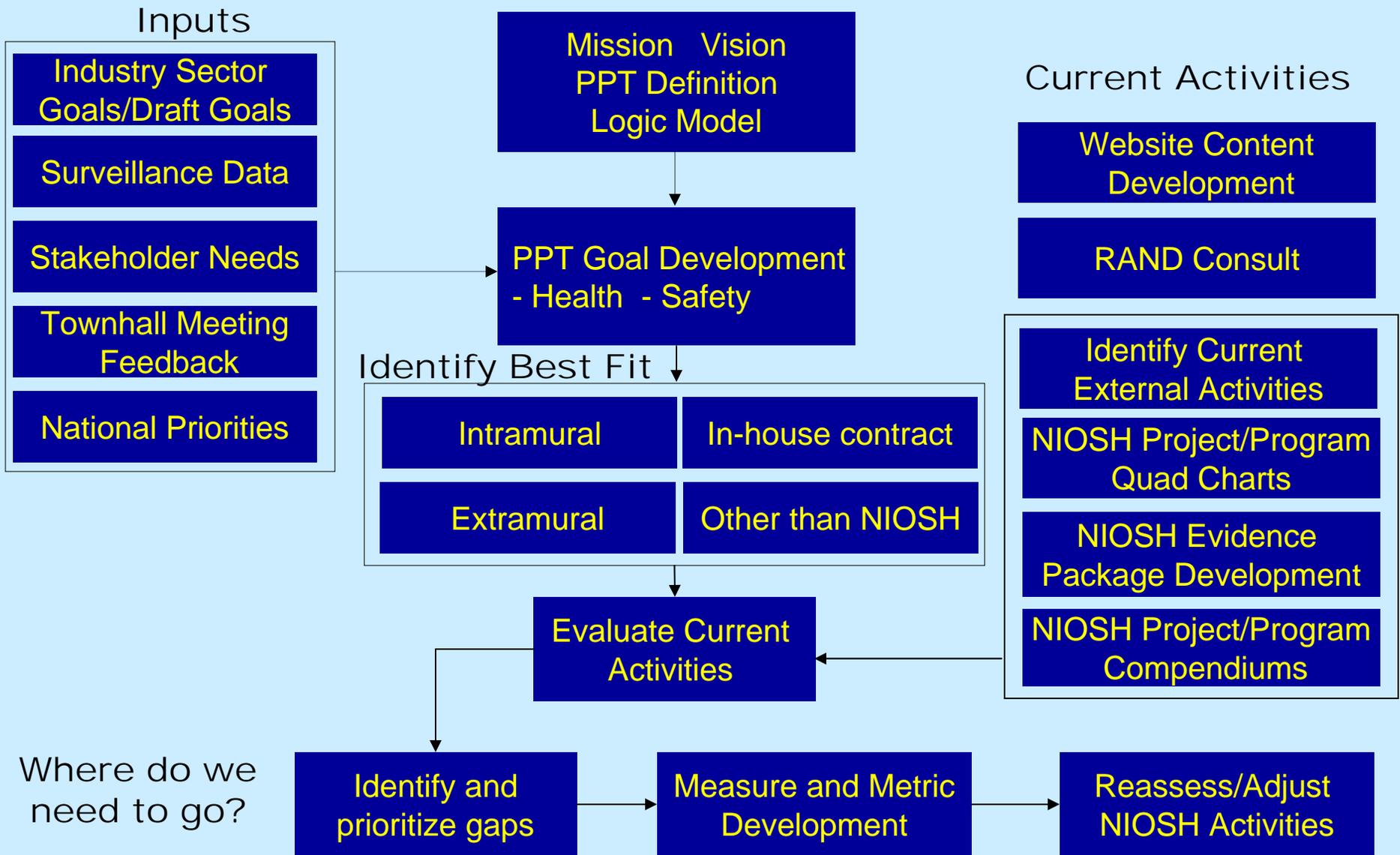
Be the leading provider of quality, relevant and timely PPT research, training and evaluation.

- **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.



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!!!



Workplace
Safety and Health



NPPTL *Research to Practice
through Partnerships*
2005 October 22 DIR LB

NPPTL RESEARCH

Ron Shaffer

Chief, Research Branch

NPPTL Public Meeting

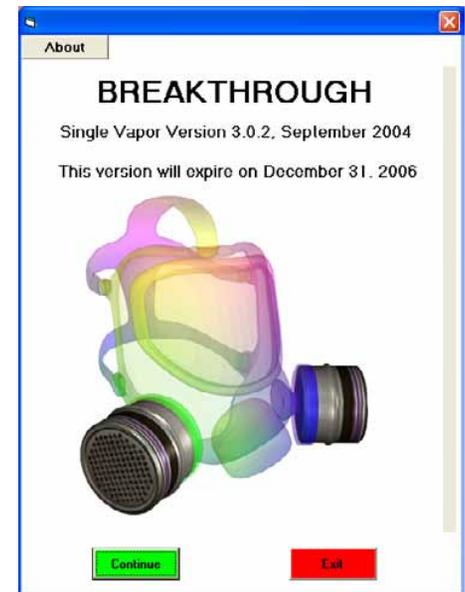
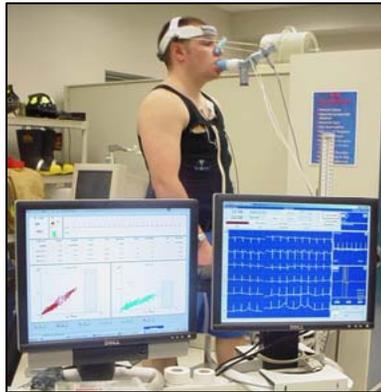
October 12, 2006



Research Focus Areas



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

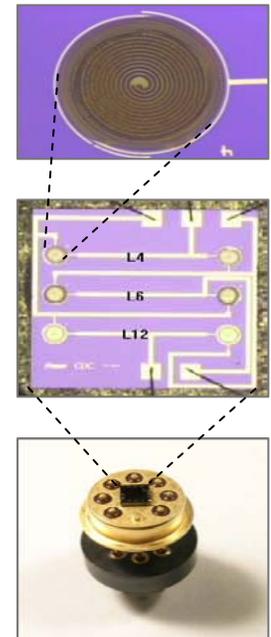
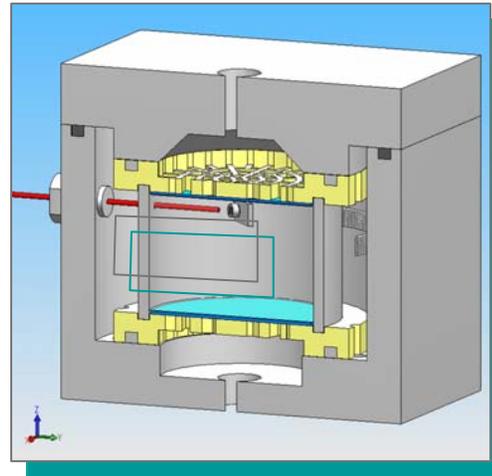
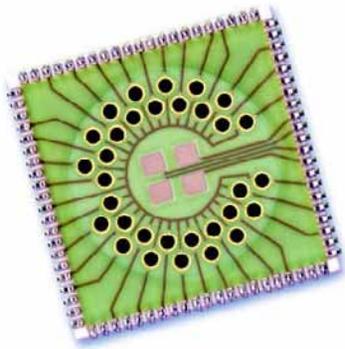


Poster Session

- 10 posters
- 5 minute overview presentation
- Posters on display until noon Friday
- More detailed presentation on 4 projects tomorrow

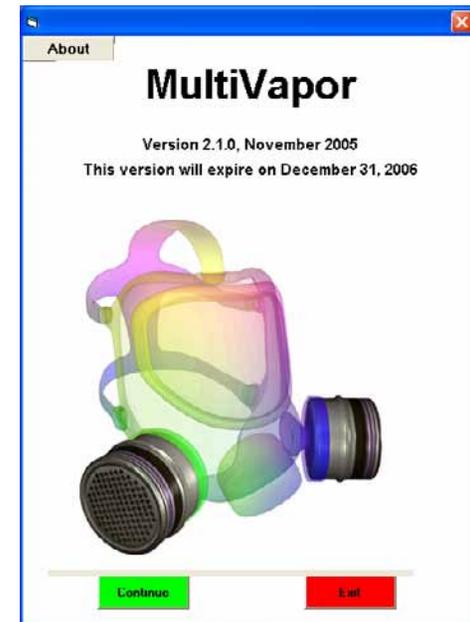
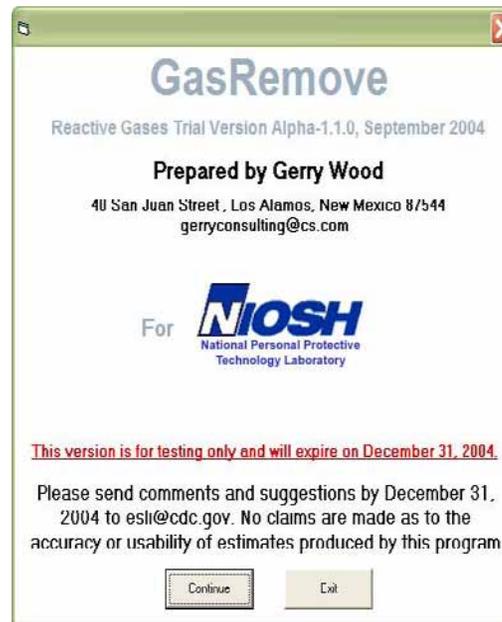
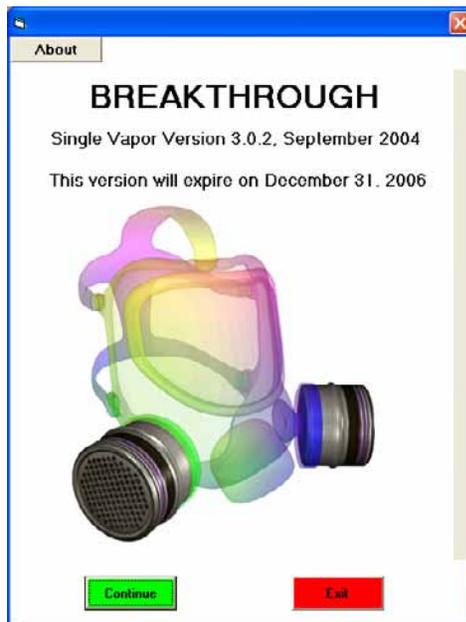
Polythiophene-Based Chemical Sensors for Detecting Respirator Cartridge End-of-Service Life

Jay Snyder



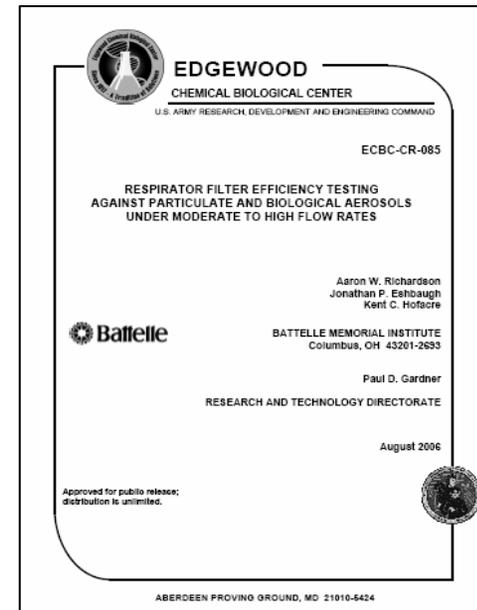
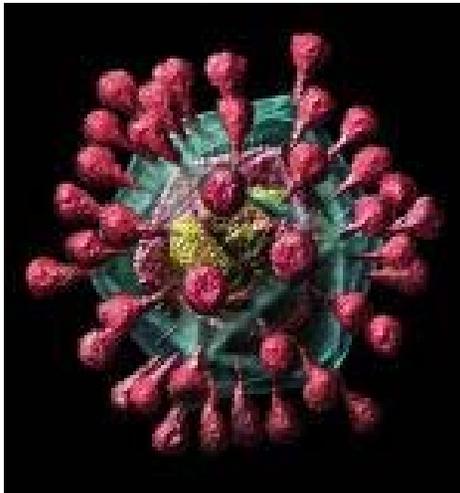
Development of Predictive Models for Respirator Service Life

Jay Snyder



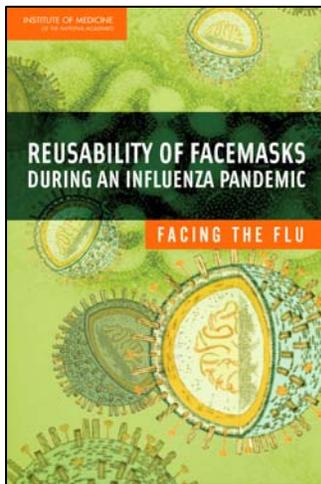
Respiratory Protection Against Bioaerosols Under High Flow Rate Conditions

Samy Rengasamy



Respiratory Protection Research for Infection Control

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



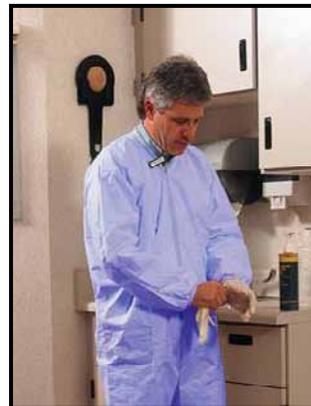
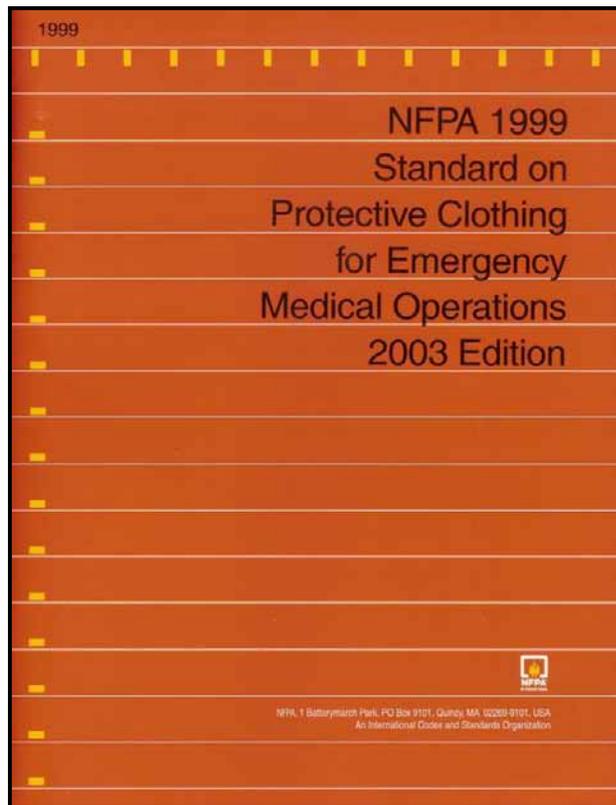
Development of Computer-Aided Face-Fit Evaluation Methods

Ziqing Zhuang, Dennis Viscusi,
and Ron Shaffer



Improved Criteria for Emergency Medical Protective Clothing

Angie Shepherd



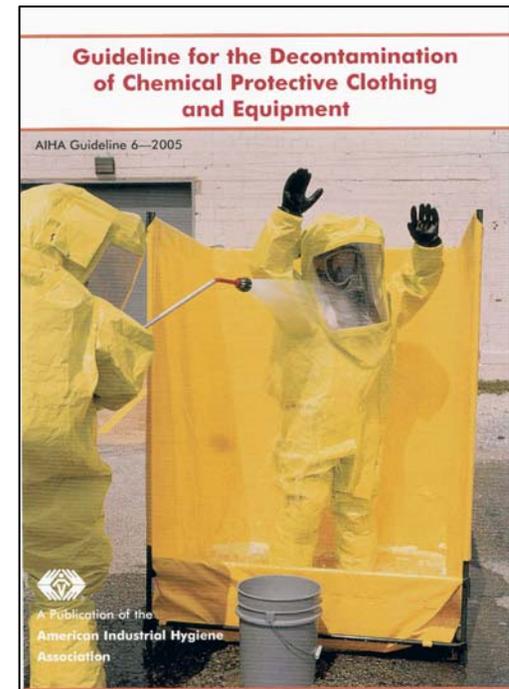
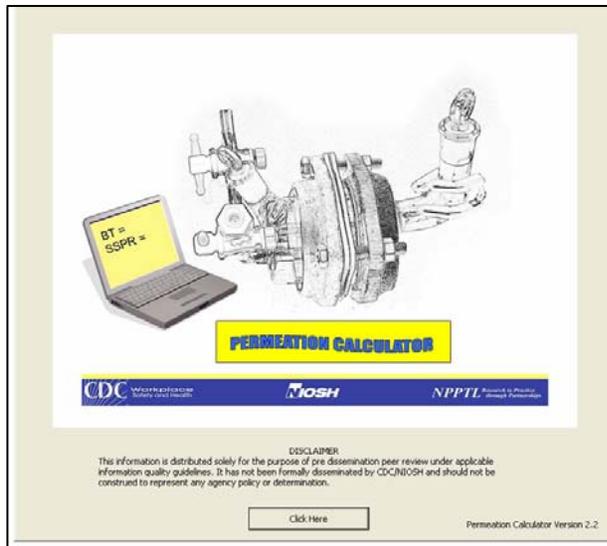
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Decontamination Strategies and Reusability of Chemical Protective Clothing (CPC)

Pengfei Gao



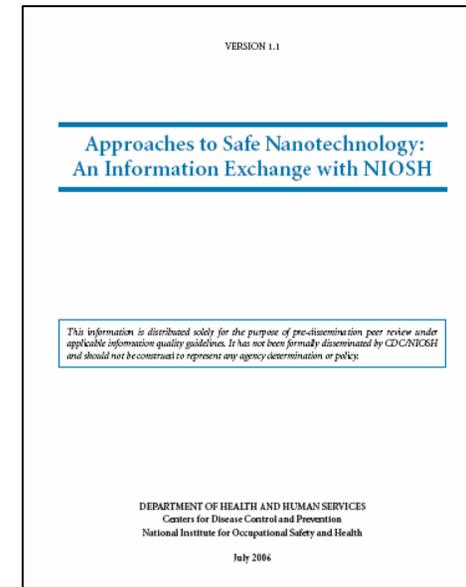
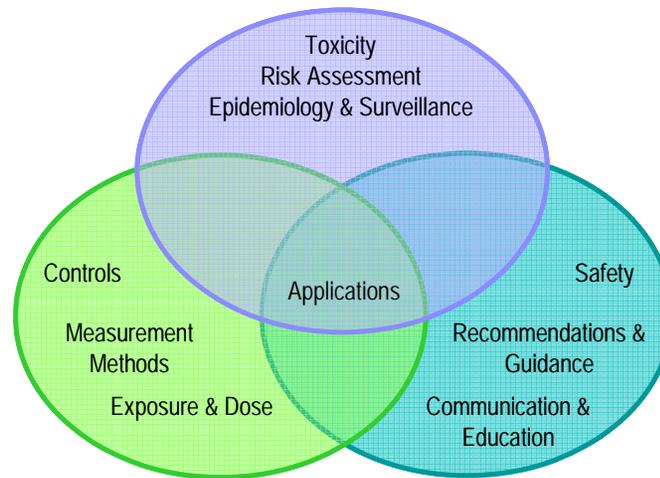
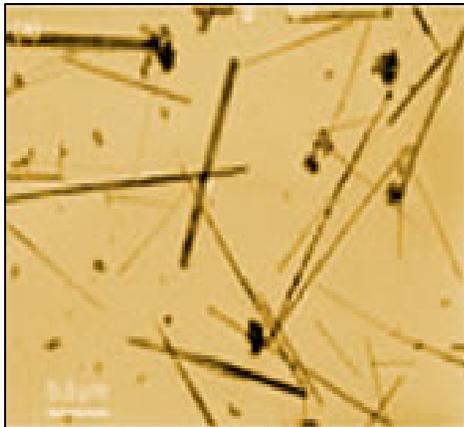
Workplace
Safety and Health

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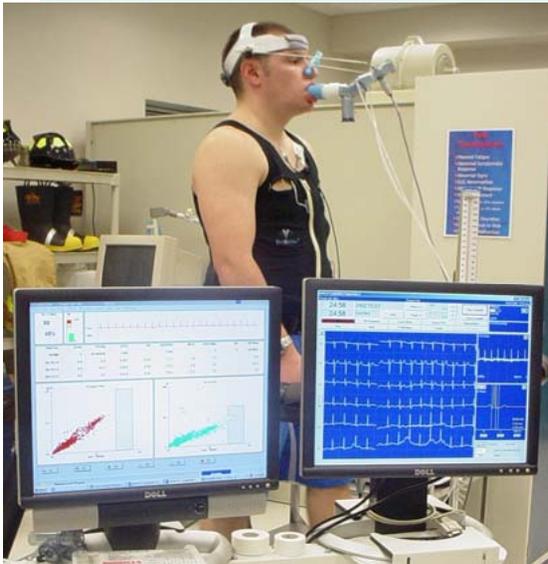
Nanotechnology: Performance of Personal Protective Equipment

Samy Rengasamy, Pengfei Gao and Ron Shaffer



Physiological Models and Countermeasures

Jon Williams, Raymond Roberge,
and Edward Sinkule



Workplace
Safety and Health



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Next Generation Structural Firefighting PPE – PROJECT HEROES



Jon Williams
Ron Shaffer
Angie Shepherd,
Raymond Roberge
Bill Haskell



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Safety and Health



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**National Personal Protective
Technology Laboratory**

**Multi-function Powered
Air Purifying Respirator
(PAPR)**

Crowne Plaza Pittsburgh South

Tim Rehak, General Engineer

October 12, 2006

Project Goals

- To develop new comprehensive test standards for certifying multifunction PAPR's (Powered Air Purifying Respirator).

Team/Resources

- NPPTL funded contract
- Human Performance Laboratory at the University of Maryland
 - Long history of research in all wearability issues of respirators
 - Bioengineering approach
- MSHA collaboration
- Stakeholders
 - Equipment manufacturers
 - BCOA
 - NMA
 - UMWA



Summary of Research



Exercise Performance While Wearing a Tight-Fitting PAPR with Limited Flow

- 16 subjects exercised at 80-85% VO_{2max} on a treadmill while wearing a tight fitting PAPR.
- Power supply was changed to produce 100%,94%,66%,30%,0% of 110 L/min.

Results: Inadequate blower flow rate decreased:

- performance time
- facial cooling
- respirator comfort

(Article published in the Journal of Occupational and Environmental Hygiene, July 2005)



Over Breathing a Loose-Fitting PAPR

- 16 subjects exercised at 80-85% VO_2 max on a treadmill while wearing a Loose Fitting PAPR in a Portable Breathing Chamber
- All subjects exceeded PAPR fan
- 17% of breathing volumes exceeded 1.4 L dead volume of the PAPR visor
- All instantaneous corrected flow rates were above 38L/min, 30% were above 120-158L/min range, and a small portion (above 1%) of flows were in 520-558 L/min range.
- Journal of the International Society for Respiratory Protection, Spring/Summer 2005, Vol. 22



Inhalation Flow Rates During Strenuous Exercise

- Instantaneous inhalation rates for subjects exercising on a treadmill were measured for the following conditions:
- 80-85% VO_2 max w/o respirator (n=24), Peak inhalation flow rate of 379 L/min (BTPS)
- 100% VO_2 max w/o respirator (n=9), Peak inhalation flow rate of 440 L/min (BTPS)
- 80-85% VO_2 max while wearing a breath-responsive PAPR (n=10), Peak inhalation flow rate of 679 L/min (BTPS)
- A linear relationship was found between peak flow rate and average minute volume, which can be used to produce peak flow rates expected at any given work rate.
- Journal of International Society for Respiratory Protection, Fall/Winter 2005, Vol.22



Effects of Helmet Weight on Volume Performance Time at 80-85% of Maximal Aerobic Capacity

- 10 subjects were tested with four weighed helmets of 0.54, 1.03, 1.85, and 3.36 kg while walking on a treadmill at 80-85% VO_2max .
- Results showed that performance time in minutes was linearly related to helmet mass.
- $T_{\text{perf}} = 21.63 - 3.073 * \text{kg}$
- Submitted to Journal of Occupational and Environmental Hygiene



Model of Exercise Performance While Wearing a Respiratory Protective Mask

- **A mathematical model to predict physiological and performance features of respirator mask wear.**
- **Model predicts**
 - Oxygen consumption
 - Minute volume
 - Performance time (work ongoing to improve accuracy)
- **Goal – predict performance times and physiological responses for respirators in the pre-prototype stage of development.**

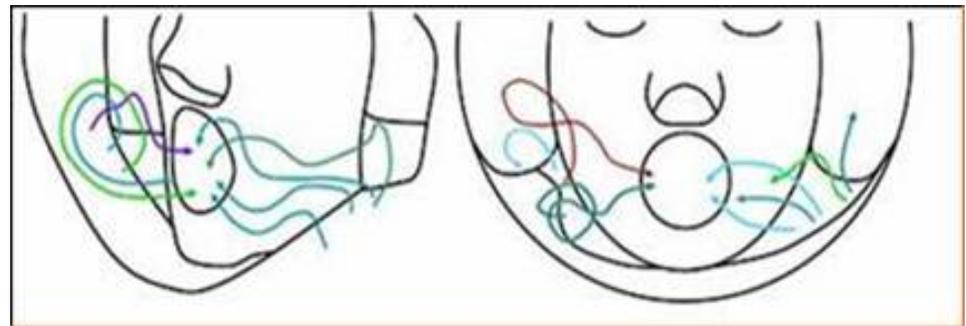
The Correlation Between Personality Type and Performance Time While Wearing a Respirator

- **Subjects performed on a treadmill at 80-85% VO_2 max while wearing a modified M40 respirator to create various inhalation resistances at 85L/min.**
- **31 subjects tested using Myers-Briggs Type Indicator (MBTI) and State-Trait Anxiety Inventory (STAI).**
- **Results- When air intake resistance is the highest, sensing-intuition (how one takes in information) and thinking-feeling (how one makes a decision) versus performance time was found to be statistically significant.**
- **Journal of Occupational and Environmental Hygiene, June 2006**



Flow Visualization Loose Fitting PAPR

- 2 Loose Fitting PAPRs were fitted on head form and connected to a breathing machine. A modified portable breathing chamber (PBC) contained the fog generated. Images were captured using a conventional video recorder.
- About 1.4 L of protective volume was observed to be inhaled before the fog reached the mouth.
 - Head tilt affects the protective volume.
 - Racal fog was present inside face shield at all times, even with no breathing
 - Fog reached the mouth quicker without the scarf (1.2 L of air was inhaled before fog reached the mouth without the scarf as compared with 1.4 L with scarf).
- Submitted to Journal of the International Society of Respiratory Protection



Protective Dead Volume Inside Loose Fitting Hood?

A full body chamber (FBC) was fabricated to test how much air must be inhaled before the fog reaches the mouth with the blower off.

Results:

2.0 L protective volume.

With the blower at 100LPM, the breathing machine set at 30BPM, tidal volume 2.21 L, total over breathed volume was measured at about 1 L. No fog was evidenced.



Tight Fitting PAPRs

- Tested 2-tight fitting PAPRs in a full body chamber (FBC)
- Bronchoscope used to observe fog entering the mouth
- Leak volumes were measured
- Results:
 - No fog was visualized
 - Leak volumes were detected
 - Unit A 0.26-.28 L (off or on)
 - Unit B 0.02 to .09L (on) and 0.26L-.28L (off)
 - Possible leak from face seal or exhalation valve
- Submitted to **Journal of Occupational and Environmental Hygiene**



Leak from Face Seal or Exhalation Valve?

- Both face seals leaked about .05L (comparison of with and without modeling clay)
- Unit A exhalation valve closed within .16s with about .01 L of air entering only when the blower is over breathed.
- Unit B exhalation valve opened and closed 3 times throughout the entire over breathing cycle.



Human Testing of Loose Fitting PAPR in the Full Body Chamber

- 12 subjects were tested.
- Preliminary data:
 - About 1.0 – 1.3 L needs to be inhaled before fog enters the mouth.
 - Over breathed pathways were similar to the head form/breathing machine data.



Remaining Work

- **CO₂ build up**
 - Full Body Chamber (FBC)
 - The breathing machine's inhaled air will be instantaneously analyzed for CO₂ concentration to determine actual over breathing of loose fitting PAPR and tight fitting PAPR.
- **Final Report – NIOSH numbered document**



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.

Industrial PAPR

Terry Thornton

**NIOSH/NPPTL Public Meeting
Crowne Plaza Pittsburgh South
Pittsburgh, Pa**

October 12, 2006

Industrial PAPR Concept

The project objective is to develop a PAPR Standard.

The project will prepare a new PAPR subpart for 42 CFR Part 84 that incorporates all PAPR requirements (including CBRN) into one area. This project will consolidate PAPR requirements in one subpart and allow for incorporation of new requirements and new technology. The project will be implemented using Formal Rulemaking processes.

Industrial PAPR Concept

Currently we are using the Concept paper process.

<http://www.cdc.gov/niosh/npptl/standardsdev/other/>

Comments to Docket # 008

NIOSH Docket Office, Reference: NIOSH DOCKET - 008

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Telephone 513-533-8303

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PAPR Concept

The module must be flexible enough to cover a potential wide range of applications while providing the desired respiratory protection to the user

The module must also have the flexibility to provide for specific tests associated with specific applications (like CBRN or Mining)

One size fits all approach may be too restrictive for some applications and not protective enough for others

PAPR Concept

Concept for consideration: Develop PAPR performance requirements using two categories

- 1. Base Requirements – Performance requirements that all PAPR exhibit**
 - A. Non – Respiratory**
 - B. Respiratory**

- 2. Use / Application Specific – Performance requirements based on the type of system being evaluated or on the workplace use of the system**

PAPR Concept

Use / Application Specific

CBRN Responder

**Additional Requirements
to Assess New Technology**

Hospital PAPR

**Eyepieces / Lens Impact
Resistance**

Clean Room PAPR

Law enforcement

Extreme Cold Weather Use

LCBRN Receiver

Field of View

Welding PAPR

Low Temperature Fogging

Multifunction PAPR

Flammability Resistance

Hydration Device

Intrinsic Safety

PAPR Concept

Do all PAPR need to be considered a Positive Pressure Device?

Many places in the Concept refer to PAPR as a positive pressure and many of the tests use the pressure inside the facepiece as a limit.

1. Low Flow / Pressure Indicator
2. Power requirement
3. Minimum airflow determination
4. Total Inward Leakage

PAPR Concept

Airflow determination

1. Single Power blower units
 - a. Traditional single “on/off” switch, constant speed, moderate work rate.
 - b. tight-fitting, average 115 Lpm while breathing at 40 Lpm (1.667 Liters @ 24 Respirations per minute)
 - c. loose-fitting, average 170 Lpm while breathing at 40 Lpm (1.667 Liters @ 24 Respirations per minute).

PAPR Concept

Airflow determination

2. Variable power blower units, multiple blower speed setting using manual selection.

tight-fitting:

Low	not allowed
Moderate	115 Lpm using 40 Lpm breathing
High	250 Lpm using 86 Lpm breathing

loose-fitting:

Low	100 Lpm using 21Lpm breathing
Moderate	170 Lpm using 40 Lpm breathing
High	370 Lpm using 86 Lpm breathing

PAPR Concept

Airflow determination

3. Variable power blower units, multiple blower speed setting using breathing pattern (breath responsive)

Tight-fitting or Loose-fitting

Maintain positive pressure inside the face and /or neck area during service time while breathing at each of the rates.

PAPR Concept

Minimum Airflow (not in Sept 19th paper)

The concept is not to require a minimum airflow in any PAPRs but to require a positive pressure device when tested against a specific breathing rate.

PAPR Concept

Breathing Rate	Minute Volume	Tidal Volume and Respirations
Low	21 Lpm	1.20 Liters @ 17.5 respirations per minute
Moderate	40 Lpm	1.67 Liters @ 24 respirations per minute
High	86 Lpm	2.867 Liters @ 30 respirations per minute

PAPR Concept

PAPR Power Requirements Battery Life

Manufacture will specify battery life.
(minimum be two hours) in increments of
one hour, i.e. 2-hour, 3-hour, etc.

What measurement will be used to determine the battery life? Positive pressure, flow requirements how do we test these?

PAPR Concept

PAPR Power Requirements

Allow for external power for tight-fitting and loose-fitting PAPR.

Tight-fitting PAPR with escape capacity must have a 15 minute emergency battery

1. What power limitations should there be; 12 V, 24 V, 110 V ?
2. What type of connection is needed to be allowed?

PAPR Concept

Power Indicators

Indicator must be readily visible and detectable to the user without manipulation.

Indicator must show when the status of the power supply. And alert the user when the battery has 15 minutes of charge left to operate the device with positive pressure. (lowest temperature and highest resistance).

What measurements will be used at the point to determine that the unit has insufficient power?
Positive pressure?

PAPR Concept

Low Flow / Pressure Indicator

Low flow / pressure indicators needs to alert user prior to the point where the flow / pressure is insufficient to maintain protection inside the facepiece.

What is this point? Positive pressure or specific flow according to work rate setting?

Pressure is much easier and accurate to measure inside the facepiece than is flow.

PAPR Concept

Respiratory Inlet Coverings

Lenses must meet
ANSI Z87.1 – 2003 “High Impact”
or be prominently and permanently labeled
that they are

“NOT IMPACT RESISTANT”

PAPR Concept

Service Life Testing
(capacity testing)

PAPR Concept

Service Life Testing

Manufacture will specify work rate of unit High, Moderate, Low (if allowed), or manual switch or breath responsive

Type respirator	Constant Flow: Low Work Rate	Constant Flow: Moderate Work Rate	Constant Flow: High	Breath response Low / Moderate / High Work Rate
Tight-fitting	Not Applicable	115 Lpm	270 Lpm	Average Flow at Highest Work Rate Requested
Loose-fitting	100 Lpm	170 Lpm	325 Lpm	Average Flow at Highest Work Rate Requested

PAPR Concept (non-CBRN)

TABLE 2-PAPR CARTRIDGE GAS/VAPOR BENCH TESTS AND REQUIREMENTS

Gas/vapor	Test Concentration (ppm)	Maximum Breakthrough (ppm)	Minimum allowable service life (min)
Ammonia	1000	12.5	50
Chlorine	500	5	35
Chlorine Dioxide	500	0.1	30
Organic Vapor (Cyclohexane)	1000	5	50
Formaldehyde	100	1	50
Hydrogen Chloride	500	5	50
Hydrogen Fluoride	70	3	30
Hydrogen Sulfide	1000	10	30
Methylamine	1000	10	25
Sulfur dioxide	500	5	30

PAPR Concept (non-CBRN)

TABLE 3-PAPR CANISTER GAS/VAPOR BENCH TESTS AND REQUIREMENTS

Gas/vapor	Test Concentration (ppm)	Maximum Break Through (ppm)	Minimum allowable service life (min)
Ammonia	2500	12.5	24
Chlorine	2500	5	24
Chlorine Dioxide	1000	0.1	60
Cyanogen Chloride	300	2	60
Organic Vapor (Cyclohexane)	2600	10	60
Ethylene Oxide	5000	1	60
Formaldehyde	500	1	60
Hydrogen Cyanide	940	4.7	60
Hydrogen Sulfide	5000	5	60
Methylamine	1000	10	12
Nitrogen Dioxide	200	1 NO₂ or 25 NO₅	60
Phosgene	250	1.25	60
Phosphine	300	0.3	60
Sulfur dioxide	1500	5	60

PAPR Concept

1. No temperature and humidity equilibration for testing
2. All service life to be run at low humidity and high humidity (25% and 80%)

PAPR Concept

Alternative Concepts of Service Life Testing

(capacity testing)

PAPR Concept

Capacity testing of all gas filtering elements

This would use one concentration for the chemical and a common flow rate for all testing. This would allow easy understanding of the test conditions between cartridge or canister and tight-fitting or loose-fitting PAPR.

PAPR Concept (non-CBRN)

		Low Capacity (cartridge)	High Capacity (canister)
Gas/vapor	Test Concentration (ppm)	Minimum allowable service life (min)	Minimum allowable service life (min)
Ammonia	2500	15	60
Chlorine	2500	15	60
Chlorine Dioxide	1000	15	60
Cyclohexane	2600	15	60
Formaldehyde	500	15	60
Hydrogen Chloride	1000	15	60
Hydrogen Cyanide	940	15	60
Hydrogen Fluoride	70	15	60
Hydrogen Sulfide	5000	15	60
Methylamine	1000	15	60
Nitrogen dioxide	200	15	60
Sulfur dioxide	5000	15	60

PAPR Concept

Approval of Families

(research continues)

1. Organic Vapor (cyclohexane)
2. Acid Gas (canisters and cartridges)
3. Other families created by CBRN
APR

PAPR Concept

Approval for Tear Gases

chloroacetophenone (CN)

o-chlorobenzylidene malononitrile (CS)

Full Facepiece Tight-Fitting Respirators

Canisters or cartridges meeting cyclohexane and PAPR P100 requirements may be approved for tear gas

PAPR Concept

- **Carbon Monoxide Testing –**
 - Not needed, no demand?
- **Additional Gases and Vapors not listed.**
 - Same traditional method as currently used
 - More detailed information regarding how testing will be done
 - NIOSH still retains the Final authority

PAPR Concept

Failure Mode and Effects Analysis (FMEA)

- **Manufacturers will conduct a system failure modes and effect analysis (FMEA) on each respirator protection system or components that have been developed and submitted for approval.**
- **The minimum for FMEA will include**
 - the probability that the occurrence will occur
 - the potential severity of the occurrence
 - the ability to detect the occurrence
 - specific instructions including cautions, limitations, and restrictions of use to assure product reliability

PAPR Concept

Application Specific

CBRN Responder

**Additional Requirements
to Assess New Technology**

Hospital PAPR

**Eyepieces / Lens of
Respiratory Inlet Coverings**

Clean Room PAPR

Law enforcement

Extreme Cold Weather Use

LCBRN Receiver

Field of View

Welding PAPR

Low Temperature Fogging

Multifunction PAPR

Flammability Resistance

Hydration Device

Intrinsic Safety

PAPR Concept

CBRN Responder requirements

Tight-fitting 14G approval

- Durability conditioning (tight-fitting)
- Chemical agent permeation and penetration resistance against Distilled Sulfur Mustard (HD) and Sarin (GB)
- Laboratory Respirator Protection Level (LRPL)
- Canister test challenge and test breakthrough concentrations against all 10 TRAs and DOP

PAPR Concept

LCBRN Responder requirements

Loose-fitting 23C approval

- Chemical agent permeation and penetration resistance against Distilled Sulfur Mustard (HD) and Sarin (GB)
- Laboratory Respirator Protection Level (LRPL)
- Cartridge test challenge and test breakthrough concentrations against all 10 TRAs and DOP

PAPR Concept

CBRN and LCBRN

Laboratory Respirator Protection Level (LRPL)

Further research in this area with drop the LRPL terminology and incorporate the Total Inward Leakage (TIL) Concept for this testing.

This testing may eliminate the isoamyl acetate (IAA) testing.

PAPR Concept

Multifunction PAPR

- PAPR that will incorporate all of these protections
 - Respiratory protection
 - Eyewear protection
 - Hearing protection
 - Head protection

Research is still under way for this section. As these Concepts are developed they will be incorporated into this module.

PAPR Concept

Other Application Specific Requirements

- Hospital
- Clean Room
- Welding
- Law Enforcement
- Mining

What specific requirements are needed in these areas? Or not needed?

PAPR Concept

Comments to Docket # 008

NIOSH Docket Office, Reference: NIOSH DOCKET - 008

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Chemical Warfare Agent (CWA) Simulant Project

Frank Palya

NIOSH/NPPTL Public Meeting

Crowne Plaza Pittsburgh South

Pittsburgh, Pa

12 Oct 2006

Purpose of CWA Simulant Project

- Stakeholder wanted NIOSH to Identify chemical compounds that can simulate the permeation effects of Sarin (GB) and Sulfur Mustard (HD) through barrier materials used in PPE
- Partnered with NIST and RDECOM
 - Experiments performed at RDECOM
 - Natick
 - Edgewood Chemical Biological Center

Project Goals (Phase I)

- Identify chemical compounds that simulate the permeation effect of GB and HD through low polarity, elastomeric barrier materials
- Develop a standardized, laboratory permeation method that can be used by stakeholders to measure simulant breakthrough times with the identical method that was employed with GB and HD
- Provide Stakeholders with a readily accessible, lower cost, and more rapid screening method for evaluating the permeation behavior of candidate materials using available, low toxicity simulants
- Allow the Stakeholders to rank their candidate materials based on simulant permeation performance and, therefore, submit fewer candidates for CWA permeation testing.

Accomplishments (Phase I)

1.) Obtained Test Data:

- 2 CWA: Sarin (GB) and Sulfur Mustard (HD)
- 4 Simulants
- 3 Barrier Materials: Silicone, EPDM and Butyl
- Experimental Design: 2 CWA x 4 Simulants x 3 Materials x 2 Tests (sorption and permeation)

2.) Based on correlations, identified four (4) simulants that can be used to estimate CWA permeation through three low polarity, elastomeric barrier materials:

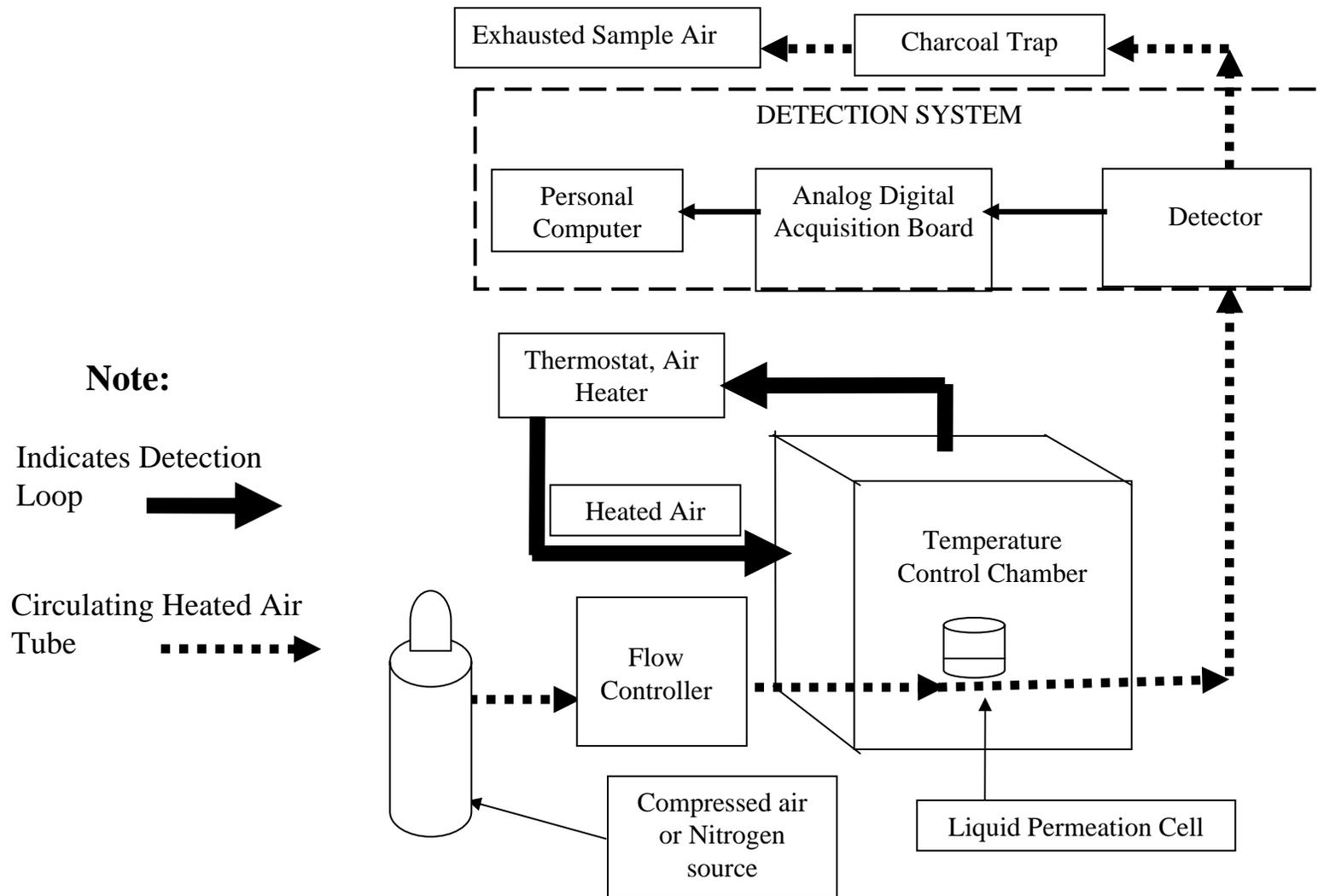
- Nominal HD simulants
 - DCH - 1,6-Dichlorohexane
 - CEPS - 2-Chloroethyl phenyl sulfide
- Nominal GB simulants
 - DEMP - Diethyl methylphosphonate
 - DIMP - Diisopropyl methylphosphonate

Accomplishments (Phase I)

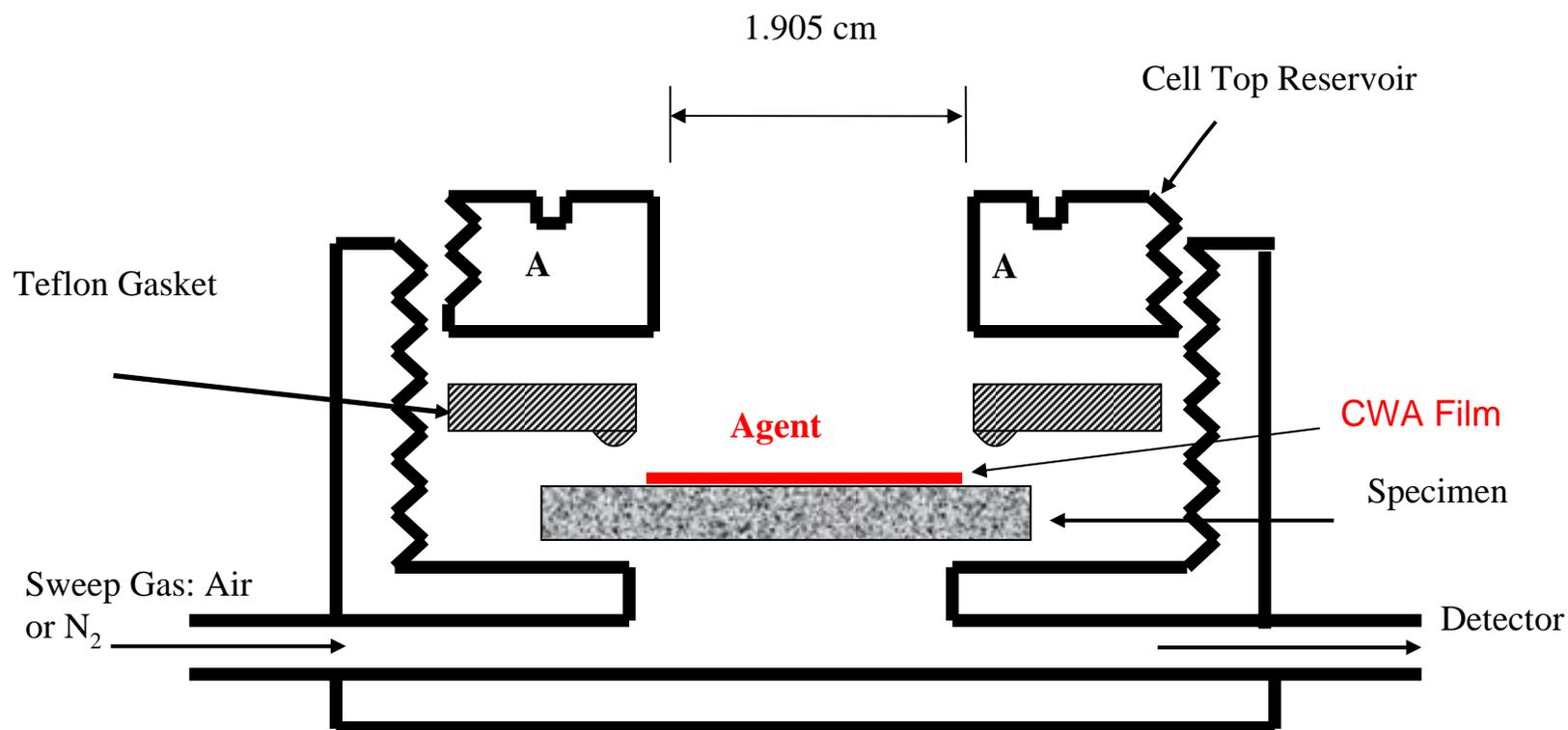
2.) Developed test method

- Capable of testing liquid permeation resistance through nonporous barrier polymers
- Capable of testing both hard and soft barrier materials, up to 0.7 cm thick
- Uses a new cell design, employing a liquid film to achieve the Flooded Cell Technique with minimal liquid volume. [in the Flooded Cell Technique the permeating chemical compound covers the entire surface area of the test specimen, rather than the partial surface coverage by droplets]

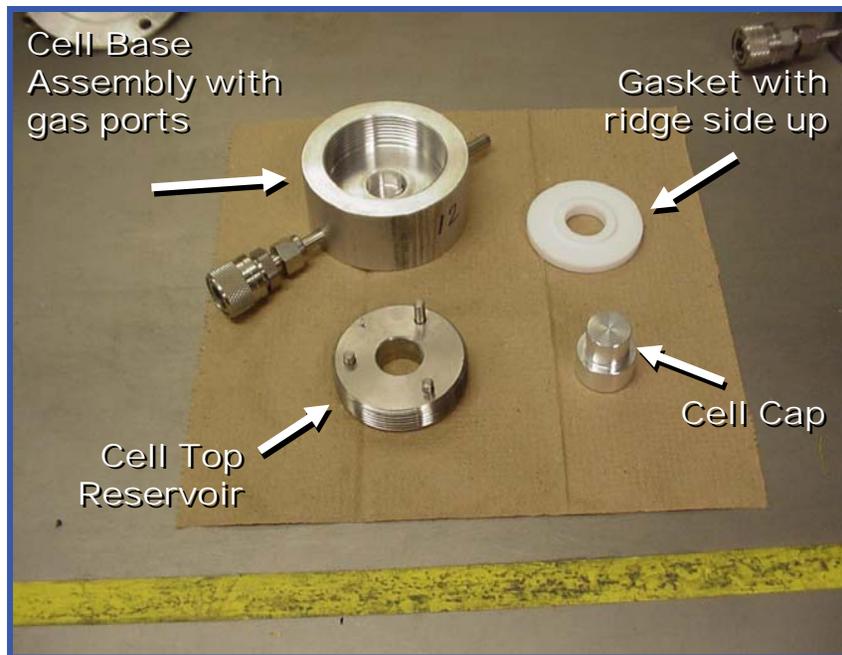
Permeation Test System



Liquid Permeation Cell



Permeation Cell Photographs



Accomplishments (Phase I)

3.) Journal Article published, emphasizing results, rather than detailed method: *Liquid Permeation Through Nonporous Barrier Materials*. Journal of Membrane Science. 246 (2005) 39-47

4.) Produced Document: *Estimating the Permeation Resistance of Nonporous Barrier Polymers to Sulfur Mustard [HD] and Sarin [GB] Chemical Warfare Agents Using Liquid Simulants*.

- Describes rationale for simulant and barrier material selection
- Contains 75 pages of detailed requirements needed to perform the testing, including equipment, procedures, data analysis techniques, permeation tables and plots, and discussion of applications. Also, includes detailed mechanical drawings of permeation cell to allow reproduction of the cell by Stakeholders
- Document will be published as an official NIOSH numbered document
- Status of document: Extensively reorganized after internal peer review. Approved by NIOSH Senior Management for external peer review process; review in progress.

Project Goals (Phase II)

- Broaden the estimation reliability of the Simulant Methodology by evaluating additional types of barrier materials with more polar structures, including thermoplastics.
- Develop additional simulants if the polar materials require specialized simulants
- Determine quantitative relationship between Flooded Cell Technique and conventional droplet test loading (at 10 g/m²)
- Determine CWA/simulant sorption/desorption of the same barrier materials and correlate to permeation results.

Project Goals (Phase II) (cont)

- Identify critical properties that control permeation of organophosphorus (G-agent type) and chloro-alkyl sulfide (mustard type) permeants through barrier materials
- Improve the capability to predict barrier permeation based on available chemical and physical properties of barrier polymers and the permeating CWA/simulants

Project Status (Phase II)

Examples of the >10 candidate materials screened by permeation testing at one or more thicknesses:

- **Thermoplastics:**

- PVDF [Poly(vinylidene fluoride)], polar
- PP [Polypropylene]; nonpolar
- PET [Poly(ethylene terephthalate)] polar

- **Elastomers:**

- Neoprene [polychloroprene, chlorinated butadiene] from the ASTM F23 archived standard material used for permeation round-robin testing for the ASTM F739 permeation test; polar
- Poly(tetrafluoroethylene-co-propylene) AFLAS™ rubber; polar

Project Status (Phase II) (cont)

Comparison tests

- Flooded cell vs. conventional droplet contamination (10 gm/m²)
 - w/DIMP and DCH on butyl
 - Breakthrough times essentially equal for flooded cell and different numbers of drops in simulant testing; permeation flux and steady state permeation vary.
- Inter-lab comparisons of simulant permeation results scheduled.
- HD and GB permeation testing of ASTM Neoprene scheduled
- 17 Sorption-Desorption experiments completed for Simulants DCH and CEPS in EPDM, Butyl, Silicone, and Neoprene.

Summary/Conclusion

- **Developed a rapid, relatively low cost laboratory procedure that can be used by manufacturers to estimate CWA permeation through candidate barrier materials using simulants.**
- **Identified four (4) CWA simulants that were useful for estimating CWA permeation resistance**
- **Contributed a peer reviewed Journal Article evaluating sorption and permeation results**
- **NIOSH Scientific Information Product developed**
 - External peer review in progress
 - Comments due by end of Oct.
 - Publication anticipated in FY07

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National Personal Protective Technology Laboratory (NPPTL)

Identifying Alternate Laboratories for

Qualification to Perform NIOSH Chemical Warfare Live Agent Tests (LAT) for Certification of Chemical, Biological, Radiological, and Nuclear (CBRN) Respirators

Frank Palya

12 Oct 2006

Background

- Since NIOSH Live Agent Testing (LAT) began in 2001, only one laboratory has ever been qualified to perform the work
- Two CWA used in the NIOSH LAT: Sarin (GB) and Sulfur Mustard (HD)
- NIOSH LAT includes: 1.) NIOSH standard and test procedure development testing; 2.) CBRN respirator certification testing and 3.) Manufacturers' R&D testing for product development
- **Benefits for NIOSH to qualify alternate laboratories:**
 - Expand test capacity base in the case of a National Emergency
 - Capability is needed to accommodate a surge in CBRN respirator applications
 - Increase lab availability for PPE manufacturers to perform research and development testing for product development
- **NIOSH/NPPTL began Initiative to identify Alt. Labs in February 2006**

Goals of the Project

- **To identify and qualify alternate laboratories that are capable of performing NIOSH CBRN LAT (GB and HD) testing of CBRN Air-Purifying types of respirators**
- **To select alternate laboratories based on stated criteria established by NPPTL**
- **To ensure that NIOSH CBRN certification testing continues without interruption**



Workplace
Safety and Health



NPPTL *Research to Practice
Through Partnerships*

To ensure that candidate laboratories

Contract Services

- **EG&G Technical Services, Inc. was contracted to identify and evaluate candidate laboratories**
- **A technical expert in chemical warfare agents (CWA) testing from Georgia State University was contracted by EG&G to assist in the effort**

Identified Candidate Laboratories

- **Two: Government-Owned / Government-Operated (GOGO) labs were surveyed**
 - Dugway Proving Ground; Dugway, UT
 - Pine Bluff Arsenal; Pine Bluff, AK
- **Five Contractor-Owned / Contractor-Operated (COCO) labs were surveyed**
 - Battelle Memorial Institute
 - Calspan-UB Research Center
 - GEOMET Technologies, LLC
 - Midwest Research Institute
 - Southwest Research Institute

Selection Criteria Candidate Labs

- Does a COCO Lab have a Bailment Agreement with the Army (**Primary**)
- Bailment Agreement is a negotiated Contract Agreement between the U.S. Army and a Laboratory
 - Bailment Agreement establishes terms and conditions:
 - Incorporates such documents as AR 50-6, AR 385-61, AR 190-59 and DA PAM 385-61
 - Addresses Safety, Training, PPE, Inspection, Accountability, Decon/Disposal, Agent Monitoring, Agent Shipping and Storage, Incident Response, Medical Surveillance, Diagnosis and Treatment of Agent Intoxication, Security Response Forces, etc.



Workplace
Safety and Health



NPPTL *Research to Practice
through Partnerships*

Selection Criteria Candidate Labs Cont.

- Bailment agreement allow for NIOSH LAT (Non-DOD Testing)
- Bailment limitations on the amount of agent stored at lab (Adequate supply for additional NIOSH LAT)
- Quality assurance to ensure that test agents (GB and HD) meet purity requirements and certification as *CASARM agents
- Life cycle cost (one-time costs and recurring costs)
- Convenience of laboratory: location for delivery of agent and for NIOSH and PPE manufacturers to visit
- Laboratory capacity to meet NIOSH demand for alternative (NIOSH CBRN Development) tests.

* Chemical Agent Standard Analytical Reference Material (CASARM)

Projected Milestones

- **Status:**

- Initial draft of the report is being written by EG&G
 - Initial draft will be sent to NIOSH/NPPTL for review and approval for release to Participating Laboratories

- **Steps to Project Finalization**

- Draft report will be sent to Participating Laboratories for solicitation of comments
- Revise report based on Laboratory comments
- Provide report to senior NIOSH/NPPTL management to make decision whether to activate an alternate lab and select the lab

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Hazard Assessment of First Receivers in Medical Facilities Responding to a CBRN Terrorist Incident

Frank Palya
NIOSH/NPPTL Public Meeting
Crowne Plaza Pittsburgh South
Pittsburgh, Pa

12 Oct 2006

Issues

- **What degree of individual protection is required for First Receivers (FR) in the Emergency Department (ED) following a Chemical, Biological, Radiological or Nuclear (CBRN) terrorist incident?**
- **What is the extent of Chemical and Biological (CB) secondary hazard in an ED during treatment of contaminated casualties?**

Definitions

- **First Receivers (FR):**
 - **Emergency Department (ED) staff to include:**
 - **Emergency Physicians, Emergency Nurses, Patient Care Associates, Clerical Staff, House Cleaning Staff and Security Staff**
- **Secondary hazard:**
 - **Residual contamination from chemical or biological agents on the clothing and bodies of casualties/victims of CB incident**



STUDY GROUP: “FIRST RECEIVERS”

- “First Receivers typically include personnel in the following roles: clinicians (e.g., physicians, nurses, nurse practitioners, physicians’ assistants, etc.), and other hospital staff who have a role in receiving and treating contaminated victims (e.g., triage, decontamination, medical treatment, and security) and those whose roles support these functions (e.g., set up and patient tracking)



OSHA BEST PRACTICES for HOSPITAL-BASED FIRST RECEIVERS OF VICTIMS from Mass Casualty Incidents Involving the Release of Hazardous Substances, OSHA, January, 2005



Background

- Chemical and biological agents are orders of magnitude more toxic than Toxic Industrial Chemicals (TIC)
- FR have suffered effects of secondary exposures in previous CB terrorism event responses (e.g., Tokyo and Matsumoto sarin incidents) and following some TIC HAZMAT responses
- The potential levels of contamination and hazard that might be encountered by FR in terrorism scenarios have not been determined
- Effort performed primarily by OptiMetrics, Inc. through a NIOSH collaboration with U.S. Army Research, Development and Engineering Command (RDECOM)
 - NIST/DHS funded the effort under an IAA with NIOSH and U.S. Army RDECOM (ECBC) to develop CBRN Respirator Standards

Objectives

- **Identify potential CB hazards inside a typical emergency medical facility**
- **Estimate levels of potential vapor concentration to enable development of standards for NIOSH CBRN Non-Tight Fitting PAPR appropriate for Emergency Departments**
- **Use sound rationale and assumptions based on previous studies, published documents and mathematical modeling to obtain estimated hazard concentrations**
 - Infinite number of venues and scenarios can be modeled yielding an infinite set of hazard concentration values so assumptions had to be made

Effort

- **Medical facility is not the primary attack point (ground zero): Contamination source is from incoming victims**
- **Selected 9 Chemicals to model from NIOSH list of Chemicals based on toxicity and most likely to be encountered in an ED:**
 - 7 TIC: Ammonia, Chlorine, Formaldehyde, Nitrogen Dioxide, Phosgene, Phosphine and Sulfuric acid;
 - 2 CWA: Sarin (GB) and Sulfur Mustard (HD)
- **Hot Zone Modeling and Processing Scheme.**
 - **Hot Zone Venues:**
 - Meeting Room: 350 people / 1 Liter of CWA Chemical
 - Auditorium / Theater: 800 People / 1 and 4 Liters of CWA Chemical
 - Airport Concourse 300 Occupants: 300 people / 25 lbs, 50 lbs, and 100 lbs

Effort (Cont)

– Hot Zone Scenario Selected:

- Auditorium / Theater
- 50 Gallons for TIC; 1 and 4 Liters for CWA
- Explosively released model: Agent to Explosive (5 : 1) Ratio produces fine aerosol
- 10 minute elapse time from explosion to when victims enter ED

– Hot Zone Device Modeling:

- Used the Non-Uniform Simple Surface Evaporation (NUSSE4) Model for liquid-filled explosive device that estimated Vapor Fraction, Liquid Fraction and Pool Fraction of the CWA or TIC
- Liquid Deposition on to victims and vapor adsorbed on victims and clothing
- InDeVap Model (In-Door eVaporation model for liquid spills, sprays and explosive dispersions)

Effort (Cont)

Identified 4 scenarios that can result at the ED in response to a potential terrorist CB attack.

- 1. Confirmed Event – EMS Transported:** Victims have undergone partial decontamination; ED staff implements CBRN protocol procedures and don PPE: lock-down of facility
- 2. Confirmed Event – Self-Referred:** Same as above, but victims will not be Warm Zone decontaminated and arrive by private or public transportation or ambulatory (St. Luke's Hospital during Tokyo GB event)
- 3. Unannounced Event- BW:** Generally biological event; victims will arrive days after the event and not have undergone pre-entry decontamination; First Receivers will not have implemented CBRN protocol procedures
- 4. Unannounced Event-CW:** Mass casualties arrive at ED contaminated with a CWA or TIC: FR may not have been notified and may not have a chance to institute CBRN protocol procedures including decontamination

Note: Scenario 4 considered to be worst case condition and the parameters of this scenario were used in the computational modeling

Effort (Cont)

- **ED Modeling and Processing Scheme**

- Used the InDeVap Model again for the ED with the following scenario combinations

- **Decontamination Scenarios used:**

- No Doffing of contaminated clothing
- Doffing with 10%, 25%, 50% and 90% Efficacy of Decontamination at ED

- **Air Changes Per Hour (ACH) in the ED**

- Power on 6 ACH / Power Off 0.3 ACH

- **Used the following room sizes for a Representative Hospital ED Determined from surveying 5 different hospitals and evaluating the HVAC systems**

- Individual Treatment Room 15' (L) x 10' (W) x 10' (H) [1,500 ft³]
- Center-Console Area 52' (L) x 52' (W) x 10' (H) [27,040 ft³]



STUDY SITES



- **Five hospitals visited in three states (Virginia, Maryland, Pennsylvania)**
 - 1) Inova Fairfax Hospital – 833 bed community, teaching hospital, 70,000 ED visits/yr.**
 - 2) Inova Alexandria Hospital – 339 bed community hospital, 46,000 ED visits/yr**
 - 3) U. of Maryland Medical Center – 655 bed university teaching hospital, 63,000 ED visits/yr.**
 - 4) U. of Pittsburgh Medical Center, 1228 bed university teaching hospital, 40,000 ED visits/yr.**
 - 5) U. of Pittsburgh Shadyside Hospital, 490 bed, community teaching hospital, 36,000 ED visits/yr.**

INTERIOR ED CONFIGURATIONS

- **Central Console Station**



- **Waiting Area**



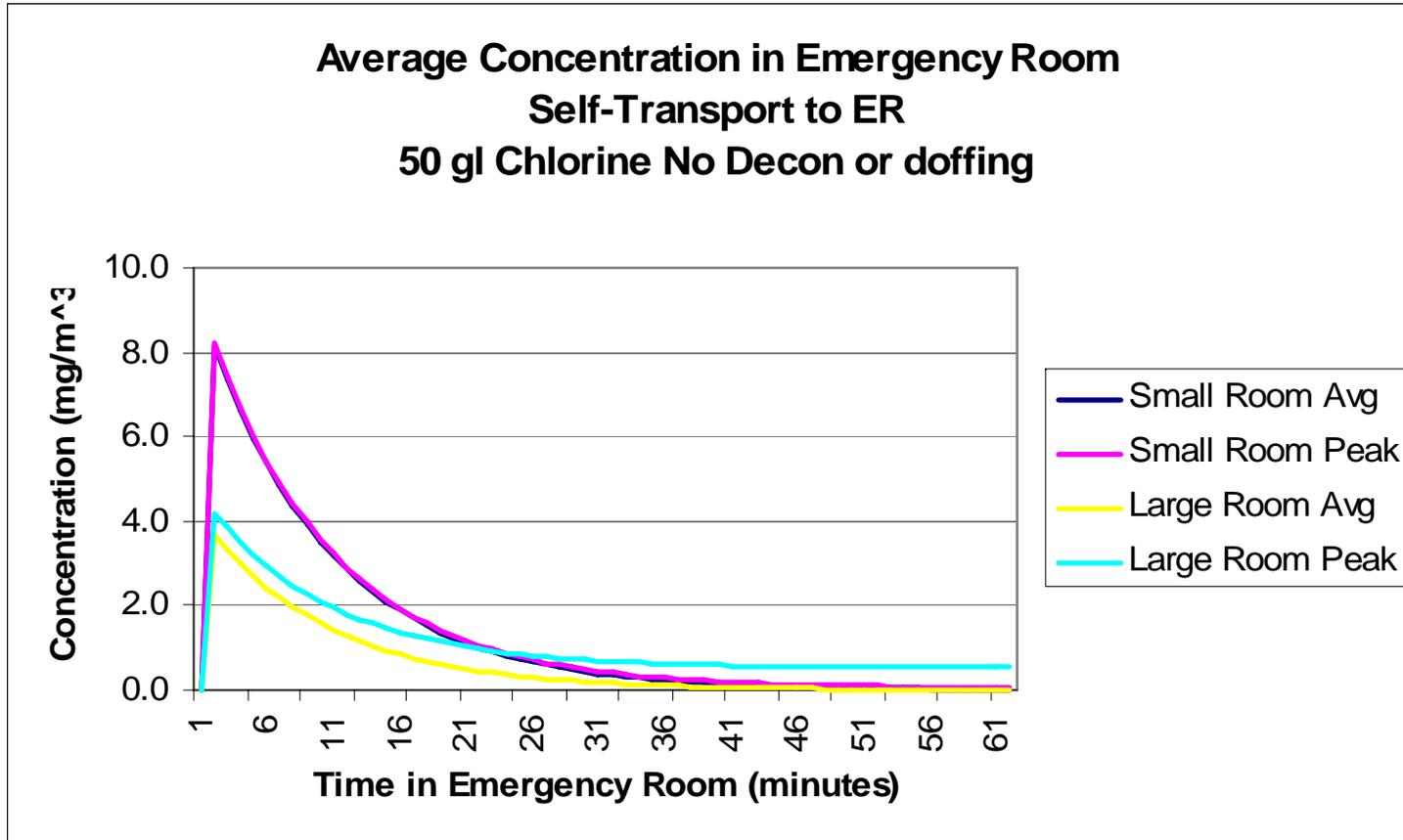
- **Individual Rooms and Bays**



Results

- **Determined the Following**

- Peak Hazard Concentrations for:
 - Individual Treatment Room
 - Center-Console Area
 - † Patient Bubble in Individual Treatment Room
 - † Patient Bubble in Console Area
- † Patient Bubble is an artificially constructed as though a casualty were on a stretcher with medical personnel providing care to the individual: the volume surrounding a patient is $3 \text{ m}^3 \sim (1 \text{ m} \times 1.5\text{m} \times 2\text{m})$



- Vapor hazard remaining on the victim upon entry into the emergency room
- Arrival at Emergency Room 10 minutes after initial contamination
- No reduction due to Doffing or Decontamination
- Chlorine explosively released in an Auditorium, 50 gallons, with 5:1 Agent to Burster Emergency room 0.3
- ACH, 150 CFM from AC
 - Single room (1 victim)
 - Large room (8 victims)
- Results both within the patient bubble, and over entire room
- Time of peak concentration the same for both the patient bubble and entire room

TIC Estimated Concentrations

ENTRY OF ONE CASUALTY INTO ED

TIC	Vapor Amount Remaining after 10 minutes to ED Arrival (mg)	Amount Remaining After Doffing (mg)	Doffing and 90% Decon:	Doffing and 10% Decon:	No Doffing No Decon
			Peak Patient Bubble Concentration (mg/m ³)	Peak Patient Bubble Concentration (mg/m ³)	Peak Patient Bubble Concentration (mg/m ³)
Ammonia	292	161	0.32	7.27	14.7
Chlorine	721	397	0.28	4.50	9.07
Formaldehyde	328	180	0.25	5.72	11.5
Nitrogen Dioxide	951	528	0.22	2.52	10.7
Phosgene	551	303	0.20	3.60	6.35
Phosphine	2,296	1,359	1.10	22.0	41.8
Sulfuric Acid	296	163	0.053	0.163	0.163

GB and HD Estimated Concentrations: ENTRY OF ONE CASUALTY INTO ED

CWA GB = Sarin HD= Sulfur Mustard	Vapor Amount Remaining after 10 minutes to ED Arrival (mg)	Amount Remaining After Doffing (mg)	Doffing and 90% Decon:	Doffing and 10% Decon:	No Doffing No Decon
			Peak Patient Bubble Concentration (mg/m ³)	Peak Patient Bubble Concentration (mg/m ³)	Peak Patient Bubble Concentration (mg/m ³)
GB – 1L, 2:1 A/B	68.65	37.34	0.0261	0.5463	0.9186
GB – 1L, 20:1 A/B	44.90	24.39	0.0174	0.3825	(ND) Not Determined
GB – 1L, 200:1 A/B	40.39	21.99	0.0174	0.3484	ND
GB – 4L, 2:1 A/B	43.72	23.84	0.0174	0.3735	ND
GB – 4L, 20:1 A/B	38.48	20.90	0.0146	0.3321	ND
GB – 4L, 200:1 A/B	37.09	20.14	0.0146	0.3228	ND
HD – 1L, 20:1 A/B	14.7	7.86	0.0038	0.0518	0.0624
HD – 4L, 20:1 A/B	7.6	4.19	0.0020	0.0371	ND

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National Personal Protective Technology Laboratory

Benchmark Testing for CBRN, Full Facepiece, Closed Circuit, Self- Contained Breathing Apparatus (SCBA)

Crowne Plaza Pittsburgh South

Tim Rehak, General Engineer

October 12, 2006

Previous Benchmark Tests Conducted

- LRPL
- Heat and Flame
- Salt Fog
- Sand and Dust



Previous Heat and Flame Resistance

- **Procedures**

- Section 8.11.5 of NFPA 1981, 2002 Edition
 - Exposed to 95°C for 15-minutes
 - Exposed to direct flame contact for 10-seconds
 - Raised 150 mm and dropped freely
 - Note: Tests conducted without live oxygen cylinder

- **Problems noted**

- After flame beyond 2.2 seconds at:
 - Hoses
 - Harness
 - Facepiece hose connector
- Backpack fell off the mannequin



Follow Up Heat and Flame Resistance

- **Planned tests**

- Follow same procedures
- Exception:
 - Tests will be conducted with live oxygen cylinder
- Status
 - Modified flame resistant CC-SCBA's have been purchased
 - Requisitions to Intertek have been issued
 - Waiting for the design/construction of safety barrier



Vibration Endurance

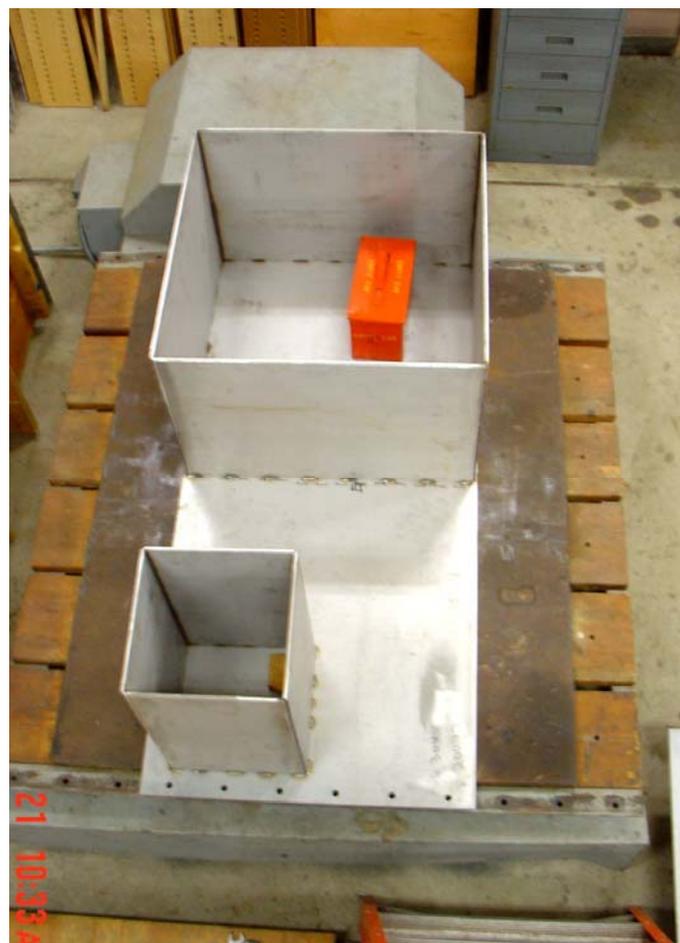
- **Procedures**

- Draft NIOSH STP (CET-CC-SCBA-STP-CBRN-0611)
- NFPA 1981, Section 8.3.5.3, 2nd Edition
- Tests conducted by US Army Research, Development and Engineering Command
- Tested two units



Vibration Endurance

- **Results**
 - Both CC-SCBA showed signs of external wear
 - Two latching mechanisms became disconnected
 - One internal fitting fractured
- **Conclusions**
 - One system passed follow-up operational test
 - The other unit required replacement of the fractured fitting before passing the follow-up operational test



Environmental Temperature Operational Performance

Tested Two Units

(CC-SCBA not rated for requirement)



- Hot Test at 71°C
 - Both units were hot soaked for 12 hours
 - Operation tests were conducted (Testing was stopped when CO₂ rose above 4%)
 - Test Duration Results
 - Unit A -191 min
 - Unit B -11 min

Environmental Temperature Operational Performance

Tested Two Units

(CC-SCBA not rated for requirement)

- Cold Test at -30° C
 - Both units were cold soaked for 12 hours
 - Operation tests were conducted (Testing was stopped when CO₂ rose above 4%)
 - Test Duration Results
 - Unit A - 7 min
 - Unit B - 84 min



Chemical Agent Permeation and Penetration Resistance Against HD and GB

- **Closed Circuit-SCBA will be held to the same performance requirements as Open Circuit-SCBA systems**
- **Currently working to develop a system that will simulate the CO₂ and humidity to activate the CC-SCBA without requiring ABMS**
 - Activate the sorbent bed
 - Control test costs
 - Eliminate the need for a walk-in test hood
 - Minimize decon exposure risks



Develop NIOSH STPs to Test Requirements

- **Testing will be conducted IAW NIOSH STPs that will be based on NFPA 1981 Standard, 2002 edition for the following requirements:**
 - Accelerated Corrosion Resistance
 - Particulate Resistance
 - Facepiece Lens Haze, Luminous Transmittance, and Abrasion Resistance
 - Communications Performance Requirement
 - Vibration Endurance
- **Rationale: NIOSH STPs can be updated to reflect the latest changes of the NFPA 1981 Standard**

Remaining Benchmark Testing

- Heat and Flame Resistance
- Chemical Agent Permeation and Penetration Resistance Against HD and GB



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Conceptual Requirements for the Combination CBRN Open-Circuit SCBA with Tight-Fitting Full Facepiece APR/PAPR

Jon Szalajda

**NIOSH/NPPTL Public Meeting
Crowne Plaza Pittsburgh South
Pittsburgh, Pa**

October 12, 2006

Conceptual Requirements for the Combination CBRN Open-Circuit SCBA with Tight-Fitting Full Facepiece APR/PAPR

- Initial concept considers established performance and design criteria from 42 CFR Part 84, consensus standards, and CBRN statements of standard
- The Combination CBRN standard will be developed using rulemaking processes
- Concept paper addresses General Requirements, Combination Unit Specific Requirements, and CBRN Performance

Conceptual Requirements for the Combination CBRN Open-Circuit SCBA with Tight-Fitting Full Facepiece APR/PAPR

General Requirements:

- Protection of breathing circuit by not allowing disconnection/connection
- No backflow can occur from one mode to the other



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Powered air-purifying units must function

Conceptual Requirements for the Combination CBRN Open-Circuit SCBA with Tight-fitting Full Facepiece APR/PAPR

Combination Unit Specific Requirements:

- Each unit must have an indicator which identifies to the user the mode of operation (air-purifying or air-supplied)
- The indicator must be distinguished and readily apparent to the user without manipulation of the respirator by the user

Conceptual Requirements for the Combination CBRN Open-Circuit SCBA with Tight-fitting Full Facepiece APR/PAPR

CBRN Performance Requirements:

- Criteria established in accordance with CBRN SCBA, CBRN APR, and CBRN PAPR Statements of Standard

Information Docket

- **Mail:**

**NIOSH Docket Office
Robert A. Taft Laboratories, M/S C 34
Combination Units – NIOSH 082
4676 Columbia Parkway
Cincinnati, OH 45226**

- **Email: niocindocket@cdc.gov**

- **Fax: (513) 533-8285**

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Conceptual Requirements for the CBRN Type C and CE Positive Pressure, Pressure Demand, Full Facepiece Supplied Air Respirator (SAR)

Bill Hoffman

**NIOSH/NPPTL Public Meeting
Crowne Plaza Pittsburgh South
Pittsburgh, Pa**

October 12, 2006



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Conceptual Requirements for the CBRN Type C and CE Positive Pressure, Pressure Demand, Full Facepiece Supplied Air Respirator (SAR)

- Initial concept considers established performance and design criteria from 42 CFR Part 84, consensus standards, and CBRN statements of standard
- The SAR CBRN standard will be developed using rulemaking processes



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Concept paper addresses full facepiece.

Conceptual Requirements for the CBRN Type C and CE Positive Pressure, Pressure Demand, Full Facepiece Supplied Air Respirator (SAR)

Requirements from 42 CFR Part 84:

- Includes Appropriate requirements from Subpart J for Type C and Type CE respirators
- Includes Subparts A, B, D, E, F, and G



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requirements



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Conceptual Requirements for the CBRN Type C and CE Positive Pressure, Pressure Demand, Full Facepiece Supplied Air Respirator (SAR)

Requirements based on Consensus Standards:

- Uses Criteria identified in existing CBRN standards for Durability; Communications; Low Temperature/Fogging; Hydration; CO₂; Lens Material Haze, Luminous Transmittance, and Abrasion; Field of

Conceptual Requirements for the CBRN Type C and CE Positive Pressure, Pressure Demand, Full Facepiece Supplied Air Respirator (SAR)

CBRN Performance Requirements:

- Criteria established in accordance with CBRN Open-Circuit SCBA and CBRN APR Statements of Standard

Information Docket

- **Mail:**

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Proposed Total Inward Leakage Testing in NIOSH Certification

William Newcomb

NIOSH/NPPTL PUBLIC MEETING
October 12, 2006

NIOSH certification fit test history

- **Schedule 21C**

- Circa 1972
- Coal dust test abolished
- Isoamyl acetate test
 - Configuration issues



- **42 CFR Part 84**

- Circa 1995
- Isoamyl acetate test eliminated for particulate respirators
- Unchanged for other respirators
- Individual fit tests still needed (OSHA program)



Lack of Fit Testing

- ***Respirator Usage in Private Sector Firms, 2001***
 - Only 53% of respondents conduct fit tests
- **OSHA public hearing on the proposed revision to 29 CFR 1910.134**
 - Table for assigned protection factors
 - Maximum use concentrations
- **NPPTL committed to add fit criteria to respirator certification requirements for all respirators**



Total Inward Leakage Program

- **Consistent with NIOSH's unique modular approach to Standards Development, the plan would be:**
 - Develop requirements for half-mask particulate respirators, including filtering facepieces first
 - Modify regulations for half masks
 - Full facepiece, Hoods, Helmets and other respirators to be addressed later



TIL Certification Performance Criteria

- **Not a substitute for OSHA mandated individual fit-testing**
 - Only method of accessing individual fit is a fit test
 - No respirator can be certified to fit
 - Respirators are to be evaluated for the potential to fit a given population

Total Inward Leakage Program

- **Phase 1: Concept development**
- **Phase 2: Establish test facility, conduct benchmark testing, and establish criteria concepts**
- **Phase 3: Finalize requirements and implementation plan**

Total Inward Leakage Program

- **Guidelines for Establishing TIL certification performance criteria**
 - Not based on OSHA's APF
 - Based on actual fit factor results
 - Inappropriate to use previously obtained fit-test data
 - Conduct benchmark testing on state-of-the-art respirators within class
 - Use entire panel for TIL evaluation

Total Inward Leakage Program

- **For the half-mask project the following test method characteristics were compared:**
 - Ability to be used to measure TIL on all styles of halfmasks, quartermasks and filtering facepieces regardless of air purifying element
 - Required sensitivity for the desired results
 - Ability to give accurate, repeatable results
 - Ability to do required test exercises without disturbing the fit due to test equipment, probes, etc
 - Ease of duplication (i.e., intra-lab reproducibility)
 - Cost of equipment
 - Need for a test chamber
 - Ease of preparation, use, clean up, etc

Total Inward Leakage Program

- **Best choice for measuring half-mask respirator TIL is PortaCount® Plus with Companion™ in a direct reading mode**
- **Most reproducible exercise methods were found to be the OSHA fit test protocol (slightly modified)**



Total Inward Leakage Program

NIOSH Bivariate Panel

Face Width (mm)

		120.5	132.5	144.5	158.5
Face Length (mm)	138.5		9 (n=2)	10 (n=2)	
	128.5	6 (n=2)	7 (n=4)	8 (n=2)	
	118.5	3 (n=2)	4 (n=5)	5 (n=2)	
	108.5	1 (n=2)	2 (n=2)	5 (n=2)	
	98.5				
		$\Sigma n=25$			

Total Inward Leakage Program

Half mask benchmark tests completed

- 57 Filtering Facepiece Respirators
- 43 Elastomeric Half-Mask Respirators
- 1 Quarter-Mask Respirator (also included)
- 25 Subjects per model
- Three donnings per respirator per subject
- 8250 Fit Factor data points

Total Inward Leakage Program

- **Summary**

- Phase 2 is complete
- The study was designed to assess the overall capabilities of individual respirators
- The Benchmark Data was derived by testing across the complete panel regardless of respirator size designation and therefore does not represent actual field use
- The Data is being analyzed in several different ways, and no conclusions have been reached concerning proposed requirements for Certification

TIL Docket Information

- Mail:
 - NIOSH Docket Office
 - Robert A. Taft Laboratories, M/S C 34
 - **TIL - NIOSH 036**
 - 4676 Columbia Parkway
 - Cincinnati, OH 45226
- Email: niocindocket@cdc.gov
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National Personal Protective Technology Laboratory

TIL Criteria Development

Doug Landsittel

Statistician/Senior Fellow

**NIOSH NPPTL Public Meeting
Crowne Plaza Pittsburgh South**

October 12, 2006



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NPPTL 04 August 3

Outline

- **Focus: statistical issues**
- **Main considerations**
 - Definition of a performance criteria
 - Strategy for subject selection
- **Approaches, strengths and limitations for subject selection strategies**
- **Existing data collection**
- **Statistical considerations for different criteria**
- **Summary of current progress and challenges**
- **Subsequent impact of results**

Definition of a Performance Criteria

Two Basic Approaches:

1. Require a fraction of subjects to meet a penetration cut-off

- Cut-off penetration (e.g. 1%, 10%, etc.)
- Fraction needing to meet that cut-off (e.g. 60%, 80%, etc.)
- Adequate sample size

2. Tolerance limit

- % of subjects within some range of penetrations
- % confidence
- Adequate sample size

Strategy for Subject Selection

- **Testing every respirator on every subject**
- **Specifying a restricted range of face sizes for a given respirator size**
- **For models with different sizing, only require the subject pass for one size**

Strategy for Subject Selection

Testing Every Respirator on Every Subject

- **Approach**
 - Randomly select N subjects for each respirator
 - Based on the NPPTL or other panel regardless of respirator sizing
- **Strengths and Limitations**
 - Most straightforward approach
 - Limiting for respirators designed for specific face sizes
- **Eliminated from consideration for the final criteria**

Strategy for Subject Selection

Specifying a Restricted Range of Face Sizes

- **Approach**
 - Based on respirator size, sample is restricted to a subset of face sizes
 - Randomly select N subjects for each respirator
- **Strengths and Limitations**
 - Requires a definition of how respirator sizes specifically relate to cells of the test panel
 - Choice of panel and size definitions become critical
 - Intuitive, but most complex approach in practice
- **Current analysis is assessing the relationship between size of the face and respirator model**

Strategy for Subject Selection

Require a Given Subject Pass for Only One Size

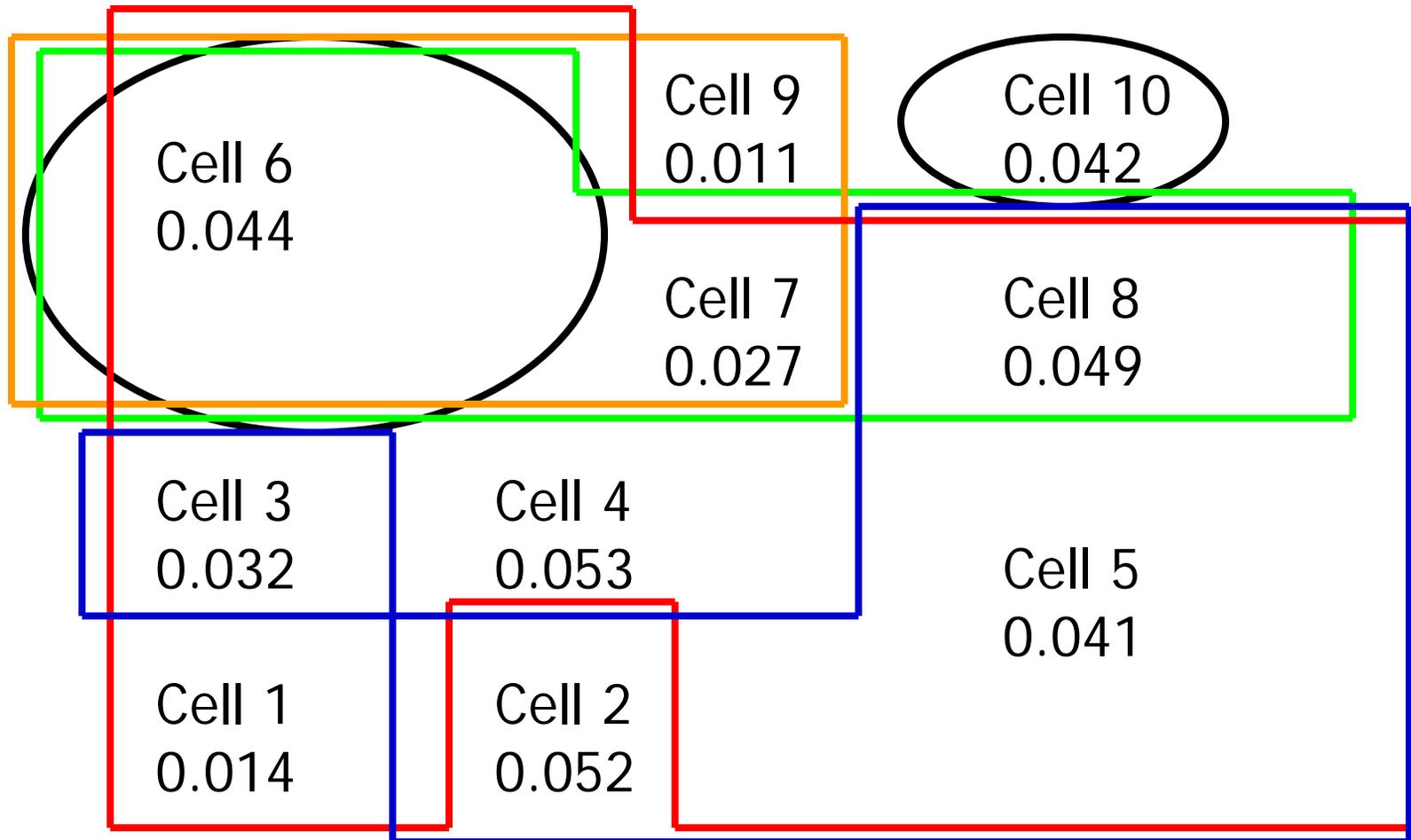
- **Approach**
 - Consider a ‘family’ of respirators as a whole
 - Randomly select N subjects for each respirator
 - Flexibility to determine which subject is assigned to a given respirator size
- **Strengths and Limitations**
 - Subject selection is still correlated to model size
 - Less straightforward but more flexible approach
- **Currently assessing optimal approach for practical implementation**

Existing Data Collection

- **59 different models, some with multiple sizing**
 - 100 total different elastomeric and FF respirators
- **25 subjects tested (on each of 100 respirators)**
 - Sampled from 87 total subjects
- **Fixed number per NPPTL cell**
 - Representative of the population
 - Irrelevant of respirator size
- **2 main concerns**
 - Criteria feasibility
 - Relationship between face dimensions, model size and fit

Mean Penetrations by NPPTL Cell

Medium-Sized Elastomeric Models



Statistical Considerations

- **Statistical properties for different options**
 - % of subjects meeting a given penetration cut-off
 - Sample size
- **Analysis across multiple measurements**
 - Donning 3 times per subject
 - Multiple tasks
 - Currently averaging
- **Consider jointly with scientific and feasibility considerations**

Statistical Properties of Different Criteria

- **Goal: Select a required % of subjects (meeting a given penetration cut-off) and sample size with “good statistical properties”**
- **Scenario 1:**
 - Given: model that passes for a high % of the population
 - Optimal result: high probability it passes for the specified % of the given sample size
- **Scenario 2:**
 - Given: model that passes for a low % of the population
 - Optimal result: high probability it fails for the specified % of the given sample size

Statistical Properties for Different Criteria

- **Example 1: require 24/25 to meet the cut-off**
 - Leads to less optimal statistical properties
 - A respirator or model that truly meets the cut-off for 96% of the population → fails the test over 25% of the time
- **Example 2: require 15/25 to meet the cut-off**
 - Leads to less optimal statistical properties
 - A respirator or model that truly meets the cut-off for 60% of the population → fails over 40% of the time
- **Example 3: require 20/25 to meet the cut-off**
 - A respirator or model that truly meets the cut-off for $\geq 90\%$ of the population → almost never fails the test
 - A respirator or model that truly meets the cut-off for $\leq 60\%$ of the population → almost always fails the test

Statistical Properties and Sample Size

- **Increasing the sample size to 50 per test improves some statistical properties**
- **Given: respirator that truly meets the penetration cut-off for 90% of the population**
 - Using a requirement of 20/25, will pass 96.7% of tests
 - Using a requirement of 40/50, will pass 99.1% of tests
- **Given: respirator that truly meets the penetration cut-off for 96% of the population**
 - Using a requirement of 24/25, will pass 73.6% of tests
 - Using a requirement of 48/50, will pass 67.7% of tests
- **Need to assess other sample sizes such as 30-40**

Current Progress and Challenges

- **Statistical assessment of sample size and % of sample required to pass**
 - Completed some analyses for $n = 25$ and 50 , and a wide range of required sample percentages
 - Need to assess other variations and tolerance limits
- **Determining the appropriate penetration cut-off value**
 - Completed some analyses to assess feasibility across different types of respirators and model sizes
 - Currently re-analyzing respirator fit relative to face and respirator size
 - Considering finite sampling

Current Progress and Challenges

- **Analysis of individual versus average penetration values**
 - Donning-to-donning and task-to-task variability
- **Determination of optimal strategy for subject selection and testing**
 - Complex and integral part of the criteria
 - 3 possible approaches:
 1. every subject with every size (not considering for the criteria)
 2. define sizing a-priori with set panel and size definition
 3. consider size with a more flexible approach

Impact of Subsequent Results

- **Each model and size to be tested on 25 subjects**
 - Appropriate number of subjects and statistical approach for specifying the criteria still under analysis
- **Strategy for subject selection and testing**
 - Unlikely to affect the total number being tested
 - Will affect how subjects are divided between different sizes of the same model
- **Complexity of the analysis and criteria development is dependent on subject selection**
 - 2nd approach represents the most complex approach

TIL Criteria Development

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Thank you

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Quality Assurance Module

William Newcomb

NIOSH/NPPTL PUBLIC
MEETING

October 12, 2006

Quality Assurance Module

- **History**

- Under discussion since 1995
- Manufacturers Meeting, March 22, 2000
- Public Meetings, August 8 & 16, 2000
- Public Meeting , June 25, 2003
- Public Meeting, October 6, 2003
- Public Meeting, Today

Quality Assurance Module

- **Status**

- Concept for Proposed Modifications to 42 CFR Part 84 written
- Preamble written
- Ready for Internal Review

Quality Assurance Module

- **What's in the Concept?**

- Paradigm shift from the Manufacturer's Benefit to Consumers' Benefit
- Mandatory Quality Management System
- Clarification of Audit Procedures
- Modifications to the Application Procedure
- Codified Procedure for Use of External Auditors

Quality Assurance Module

- **What's in the Concept?**

- Quality Assurance Requirements rather than Quality Control Procedures
- Procedure for Revocation of Approval for QA Deficiencies
- Clarification of Procedure for Reporting Changes in Ownership
- Modifications to the Quality Control Plan Content

Quality Assurance Module

- **What's in the Concept?**

- Replacing Classification of Defects with Critical to Quality Characteristics
- Replacing Mandatory Sampling Plans with Flexible Plans Suited to Each Manufacturer
- Clarification of Procedure for Reporting Consumer/User Complaints
- Requirements for Retention of Quality System Records

Quality Assurance Module

- **What's next?**

- NIOSH/NPPTL Internal Review
- NIOSH Review
- CDC Review
- HHS Review
- OMB Review
- Publish Notice of Proposed Rule in the FR

Quality Assurance Module

Time line

Jun / Jul / Aug / Sept / Oct / Nov / Dec / Jan / Feb / Mar / April / May /

Drafting Concept

Public Meeting

NPPTL

NIOSH HQ.

CDC

HHS

OMB

FR

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Docket Information

- **Mail:**
 - **NIOSH Docket Office**
 - **Robert A. Taft Laboratories, M/S C 34**
 - **QA - NIOSH 001**
 - **4676 Columbia Parkway**
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National Personal Protective Technology Laboratory

Scientific Excellence Focus

Maryann D'Alessandro
Associate Director for Science

NIOSH NPPTL Public Meeting
Crowne Plaza Pittsburgh South
October 12, 2006

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Advisers to the Nation on Science, Engineering, and Medicine



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



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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

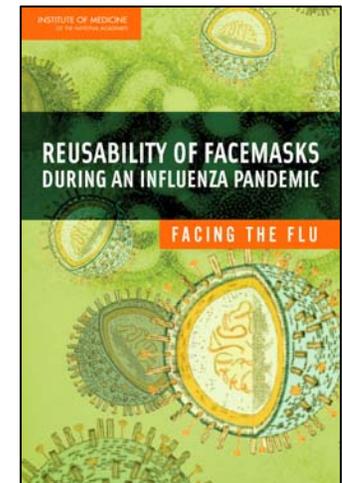
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Academia - SDOs - Government Laboratories – Unions – Labor - Manufacturers

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

Service Dimensions

Access

Courtesy

Knowledge

Timeliness

Reliability

Choice

Tangibles

Recovery

Quality of specific services



Organizational Outcomes

Customer Loyalty

Willingness to Recommend

Organizational Effectiveness

Perceived Value

NPPTL Customer Satisfaction Survey Results

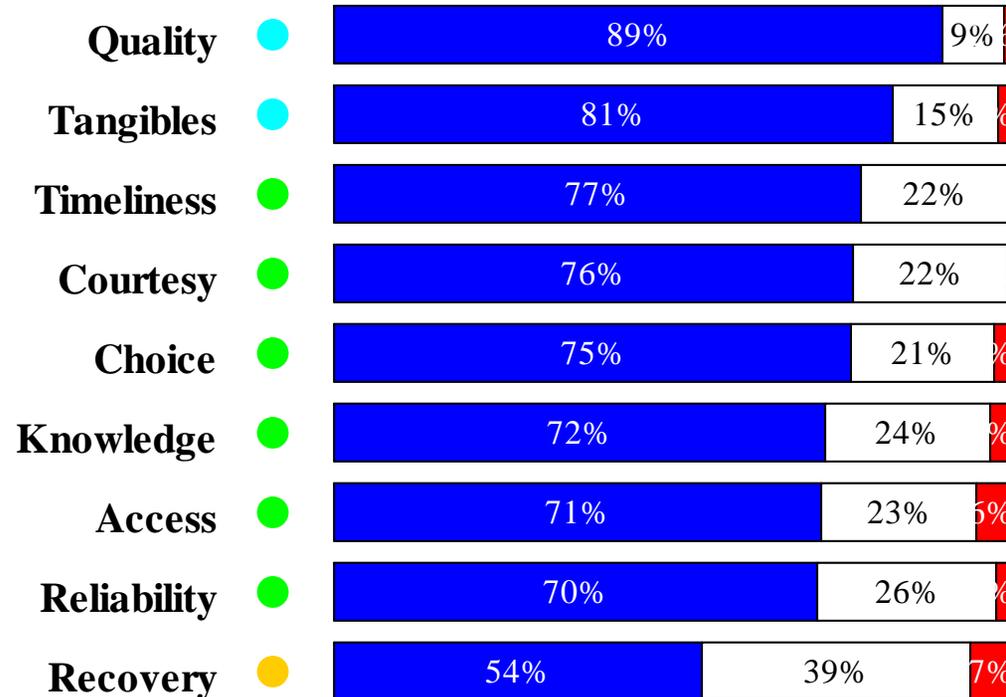
	Users	Manufacturers
Original Population	666	262
Undeliverables	44	19
Population	622	243
Responses	185	75
Final Response Rate	30%	31%

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: Users



■ Favorable □ Neither ■ Unfavorable

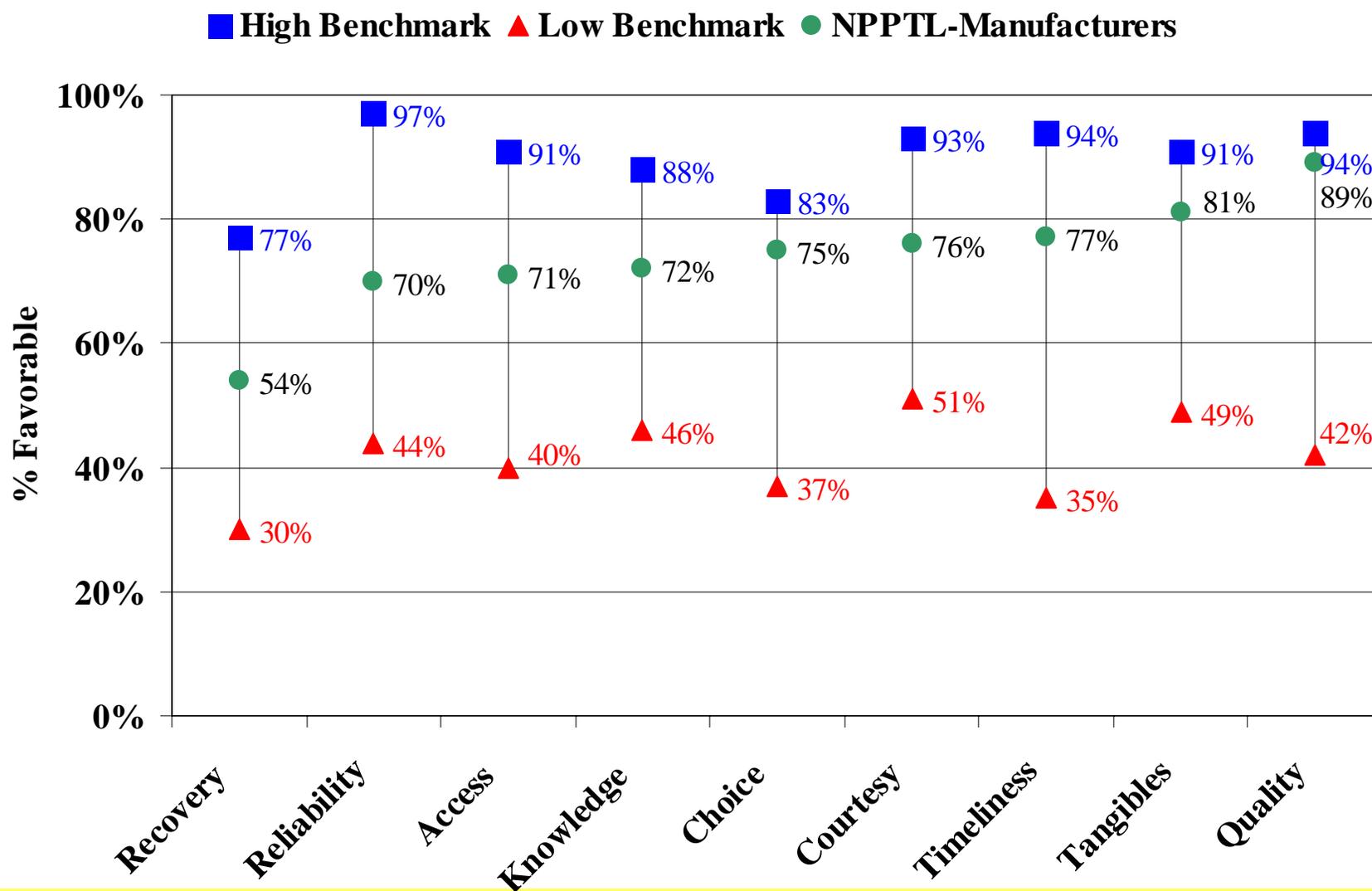


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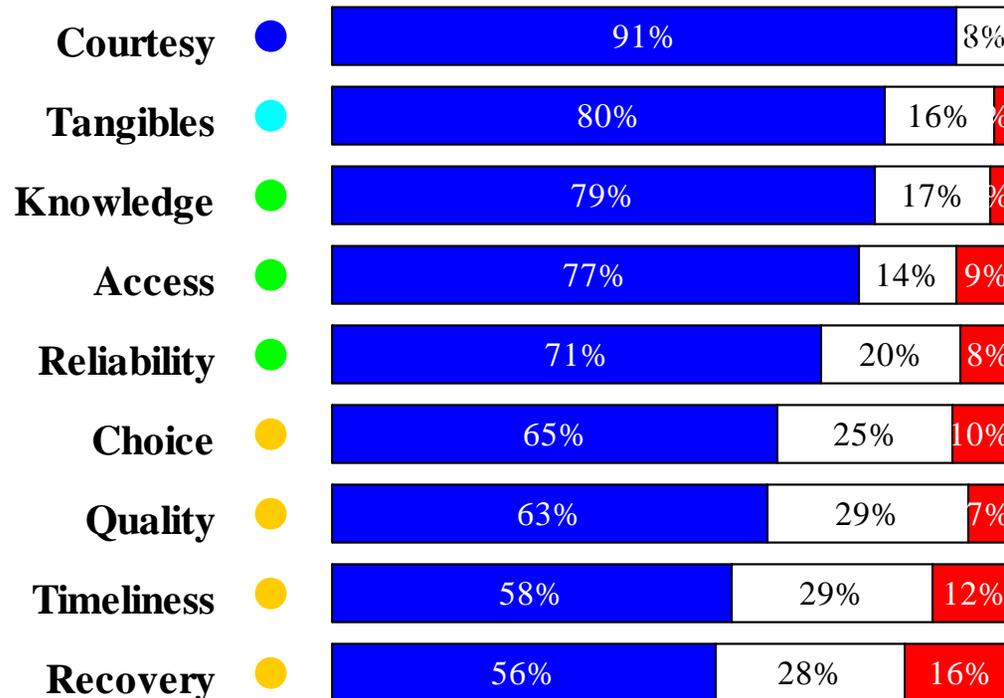


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Benchmarks: Users

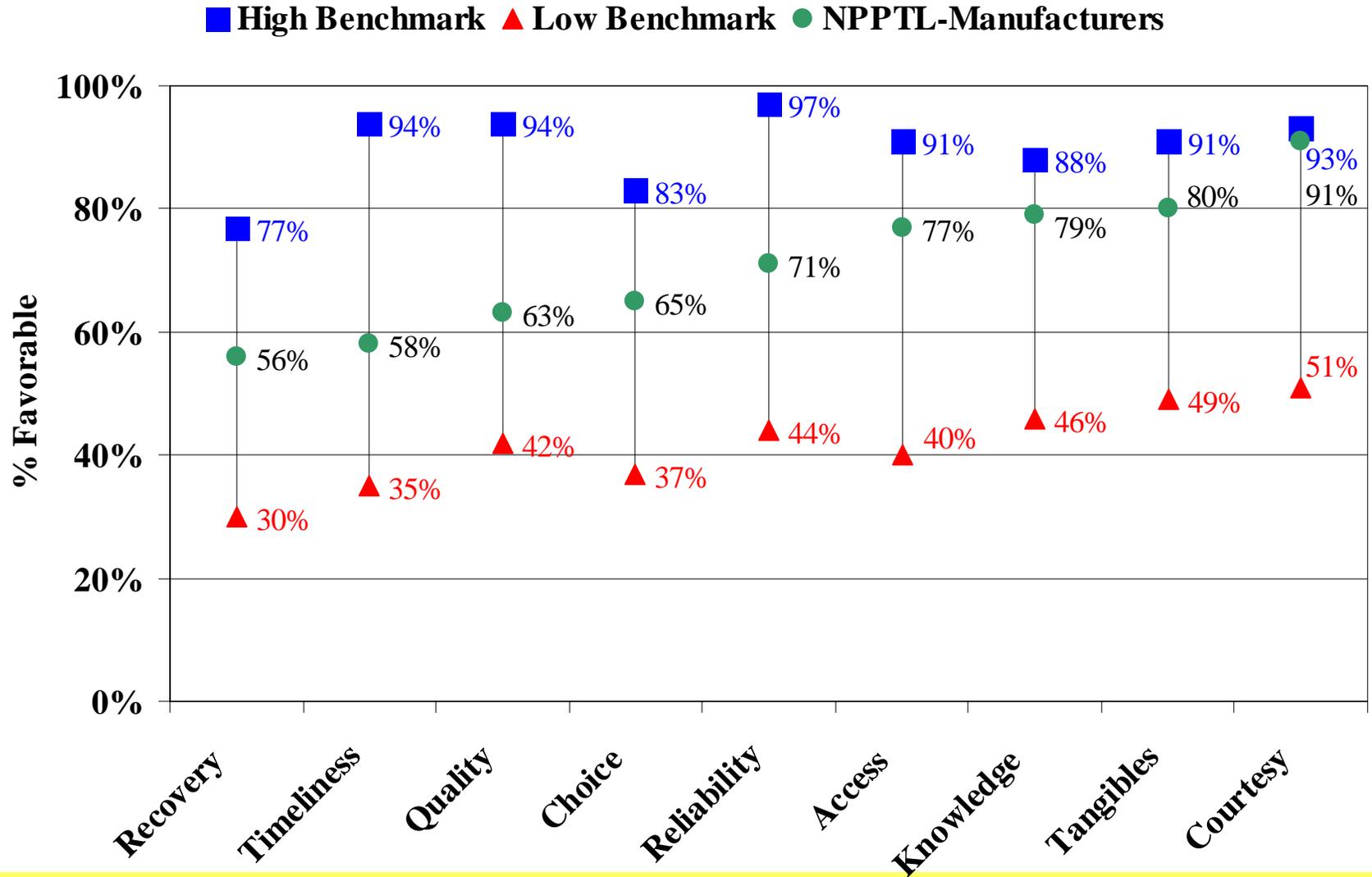


NPPTL CSS Results: Manufacturers

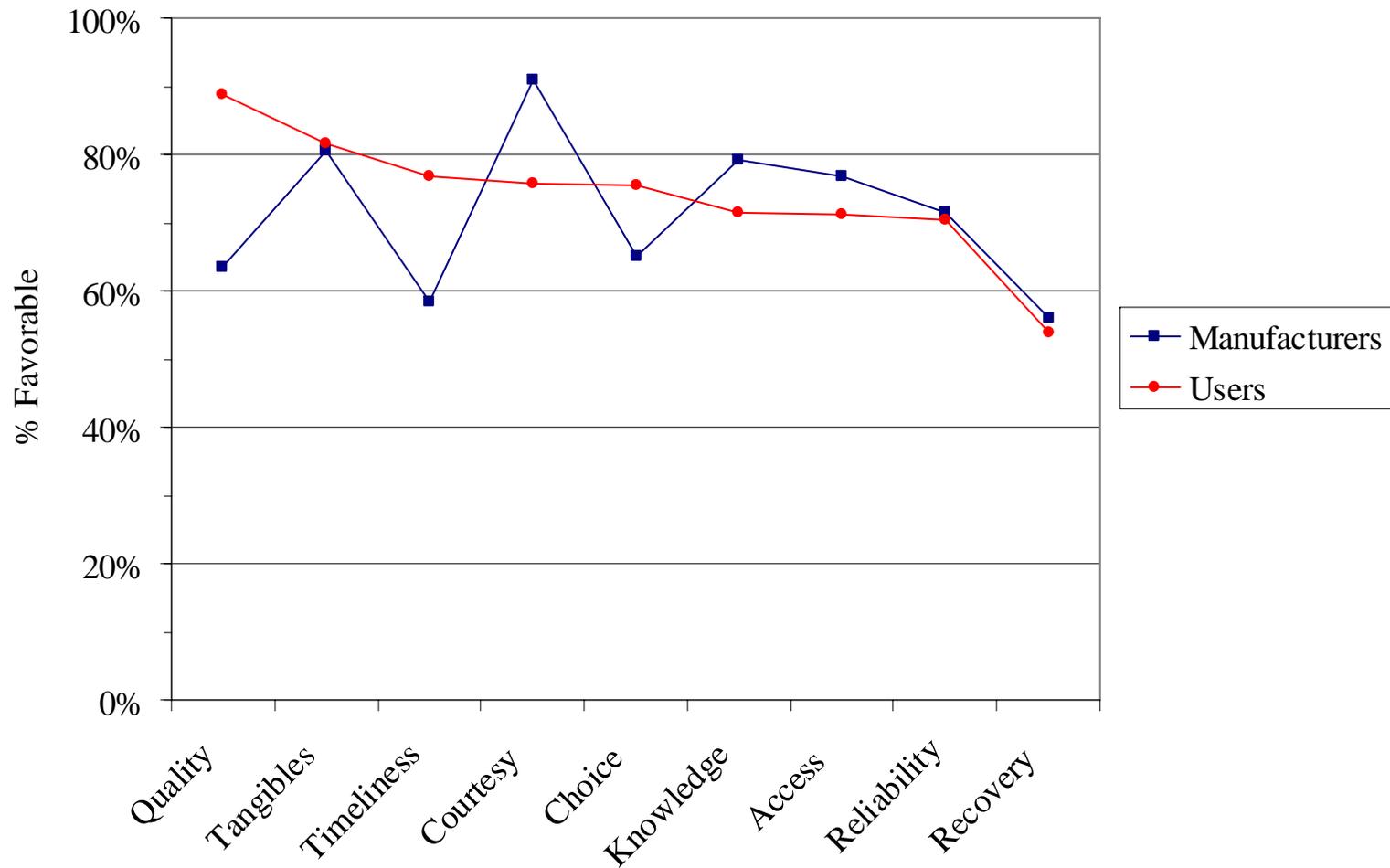


■ Favorable □ Neither ■ Unfavorable

Benchmarks: Manufacturers



Results: Dimension Profiles



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

- **Validate/resolve NPPTL improvement areas**
 - Identify areas to improve within branches
- **Create the Customer Satisfaction Groups**
 - ◆ Benefit to customers
 - ◆ Keep customers satisfied on an ongoing basis
 - ◆ Provide customers easy way to voice concerns/complaints
 - ◆ Provide customers easy way to seek more information
 - ◆ Benefit to NPPTL
 - ◆ Provide a resource for direct customer contact
 - ◆ Obtain regular input in keeping up with the changing personal protective equipment market

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 User Issues

- **Recovery**
 - Focus groups with multiple fire services groups to understand concerns
 - Focus groups with other industry customers
 - Improve methods for handling requests for additional information
- **Reliability**
 - Improve review processes
 - Involve stakeholders up front
- **Access**
 - Explore potential avenues to disseminate information
 - Post reports
 - Video tape public meetings
 - Disseminate findings as quickly as possible
- **Research updates**
 - Monthly updates on listserv and Enews
 - Update research activities at Public meetings

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

Quality Partnerships Enhance Worker Safety & Health



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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.)**