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.
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)
• **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.
Customers and Intermediate Outcomes

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; PPE developers/manufacturers; certification laboratories (e.g., SEI, UL); RKB; academic institutions; safety professionals and safety officers; media

Outputs

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

Activities

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

Inputs

Funding and staffing; physical infrastructure, including laboratories, equipment, test fields, and mobile units; managerial infrastructure, including planning and evaluation processes

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

External Factors

Reduction in occupational injuries, illnesses, fatalities and hazardous exposures

Strategic Goals

Intermediate Goals

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

End Outcomes

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

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

Respirators undergoing NIOSH evaluation, investigation, and/or certification processes

Audit respirators and manufacturing process; conduct problem investigations; long-term field evaluations

Develop, revise, and interpret policies and standards relating to respirator performance, quality, reliability, efficacy, and design

Direct and carry out NIOSH Respirator Certification Program

Policies and Standards

Respirator certification (license)

Reports of compliance; CPIP reports; user notices; recall/retrofit letter; stop sale notice; certification revocation; reports of investigation

Respirator manufacturers

NIOSH-approved respirators

Respirators

Transfer

Management Objectives

Annual Goals

Intermediate Goals

Transfer

STD
PPT Cross Sector Strategy

**Inputs**
- Industry Sector Goals/Draft Goals
- Surveillance Data
- Stakeholder Needs
- Townhall Meeting Feedback
- National Priorities

**Mission**
- **Vision**
- **PPT Definition**
- **Logic Model**

**PPT Goal Development**
- Health - Safety

**Identify Best Fit**
- Intramural
- In-house contract
- Extramural
- Other than NIOSH

**Evaluate Current Activities**

**Where do we need to go?**
- Identify and prioritize gaps
- Measure and Metric Development
- Reassess/Adjust NIOSH Activities

**Current Activities**
- Website Content Development
- RAND Consult
- Identify Current External Activities
- NIOSH Project/Program Quad Charts
- NIOSH Evidence Package Development
- NIOSH Project/Program Compendiums
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

  - 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 2007 – 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!!!
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 Renganasamy
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
Decontamination Strategies and Reusability of Chemical Protective Clothing (CPC)

Pengfei Gao
Nanotechnology: Performance of Personal Protective Equipment

Samy Rengasamy, Pengfei Gao and Ron Shaffer
Physiological Models and Countermeasures

Jon Williams, Raymond Roberge, and Edward Sinkule
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$_2$max 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% VO₂ 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.
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.
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$_2$max.

• Results showed that performance time in minutes was linearly related to helmet mass.

• $T_{perf} = 21.63 - 3.073 \times \text{kg}$

• 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% VO₂ 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
Robert A. Taft Laboratories, M/S C34
4676 Columbia Parkway
Cincinnati, Ohio 45226
Telephone 513-533-8303
Fax 513/533-8285
Email: niocindocket@cdc.gov
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 Extreme Cold Weather Use
- Law enforcement Field of View
- LCBRN Receiver Low Temperature Fogging
- Welding PAPR Flammability Resistance
- Multifunction PAPR Intrinsic Safety
- Hydration Device
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.

<table>
<thead>
<tr>
<th>tight-fitting:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>not allowed</td>
</tr>
<tr>
<td>Moderate</td>
<td>115 Lpm using 40 Lpm breathing</td>
</tr>
<tr>
<td>High</td>
<td>250 Lpm using 86 Lpm breathing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>loose-fitting:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>100 Lpm using 21Lpm breathing</td>
</tr>
<tr>
<td>Moderate</td>
<td>170 Lpm using 40 Lpm breathing</td>
</tr>
<tr>
<td>High</td>
<td>370 Lpm using 86 Lpm breathing</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Breathing Rate</th>
<th>Minute Volume</th>
<th>Tidal Volume and Respirations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>21 Lpm</td>
<td>1.20 Liters @ 17.5 respirations per minute</td>
</tr>
<tr>
<td>Moderate</td>
<td>40 Lpm</td>
<td>1.67 Liters @ 24 respirations per minute</td>
</tr>
<tr>
<td>High</td>
<td>86 Lpm</td>
<td>2.867 Liters @ 30 respirations per minute</td>
</tr>
</tbody>
</table>
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 were 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

<table>
<thead>
<tr>
<th>Type respirator</th>
<th>Constant Flow: Low Work Rate</th>
<th>Constant Flow: Moderate Work Rate</th>
<th>Constant Flow: High</th>
<th>Breath response Low / Moderate / High Work Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tight-fitting</td>
<td>Not Applicable</td>
<td>115 Lpm</td>
<td>270 Lpm</td>
<td>Average Flow at Highest Work Rate Requested</td>
</tr>
<tr>
<td>Loose-fitting</td>
<td>100 Lpm</td>
<td>170 Lpm</td>
<td>325 Lpm</td>
<td>Average Flow at Highest Work Rate Requested</td>
</tr>
</tbody>
</table>
### PAPR Concept (non-CBRN)

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

<table>
<thead>
<tr>
<th>Gas/vapor</th>
<th>Test Concentration (ppm)</th>
<th>Maximum Breakthrough (ppm)</th>
<th>Minimum allowable service life (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonia</td>
<td>1000</td>
<td>12.5</td>
<td>50</td>
</tr>
<tr>
<td>Chlorine</td>
<td>500</td>
<td>5</td>
<td>35</td>
</tr>
<tr>
<td>Chlorine Dioxide</td>
<td>500</td>
<td>0.1</td>
<td>30</td>
</tr>
<tr>
<td>Organic Vapor (Cyclohexane)</td>
<td>1000</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>100</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Hydrogen Chloride</td>
<td>500</td>
<td>5</td>
<td>50</td>
</tr>
<tr>
<td>Hydrogen Fluoride</td>
<td>70</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>Hydrogen Sulfide</td>
<td>1000</td>
<td>10</td>
<td>30</td>
</tr>
<tr>
<td>Methylamine</td>
<td>1000</td>
<td>10</td>
<td>25</td>
</tr>
<tr>
<td>Sulfur dioxide</td>
<td>500</td>
<td>5</td>
<td>30</td>
</tr>
</tbody>
</table>
# PAPR Concept (non-CBRN)

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

<table>
<thead>
<tr>
<th>Gas/vapor</th>
<th>Test Concentration (ppm)</th>
<th>Maximum Break Through (ppm)</th>
<th>Minimum allowable service life (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonia</td>
<td>2500</td>
<td>12.5</td>
<td>24</td>
</tr>
<tr>
<td>Chlorine</td>
<td>2500</td>
<td>5</td>
<td>24</td>
</tr>
<tr>
<td>Chlorine Dioxide</td>
<td>1000</td>
<td>0.1</td>
<td>60</td>
</tr>
<tr>
<td>Cyanogen Chloride</td>
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<td>Formaldehyde</td>
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<td>60</td>
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<tr>
<td>Sulfur dioxide</td>
<td>1500</td>
<td>5</td>
<td>60</td>
</tr>
</tbody>
</table>
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)

<table>
<thead>
<tr>
<th>Gas/vapor</th>
<th>Test Concentration (ppm)</th>
<th>Low Capacity (cartridge)</th>
<th>High Capacity (canister)</th>
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<tbody>
<tr>
<td>Ammonia</td>
<td>2500</td>
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<td>Chlorine Dioxide</td>
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<td>60</td>
</tr>
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<td>Cyclohexane</td>
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</tr>
<tr>
<td>Formaldehyde</td>
<td>500</td>
<td>15</td>
<td>60</td>
</tr>
<tr>
<td>Hydrogen Chloride</td>
<td>1000</td>
<td>15</td>
<td>60</td>
</tr>
<tr>
<td>Hydrogen Cyanide</td>
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<tr>
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<tr>
<td>Nitrogen dioxide</td>
<td>200</td>
<td>15</td>
<td>60</td>
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<tr>
<td>Sulfur dioxide</td>
<td>5000</td>
<td>15</td>
<td>60</td>
</tr>
</tbody>
</table>
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
<table>
<thead>
<tr>
<th>PAPR Concept</th>
<th>Application Specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBRN Responder</td>
<td>Additional Requirements to Assess New Technology</td>
</tr>
<tr>
<td>Hospital PAPR</td>
<td>Eyepieces / Lens of Respiratory Inlet Coverings</td>
</tr>
<tr>
<td>Clean Room PAPR</td>
<td>Extreme Cold Weather Use</td>
</tr>
<tr>
<td>Law enforcement</td>
<td>Field of View</td>
</tr>
<tr>
<td>LCBRN Receiver</td>
<td>Low Temperature Fogging</td>
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<tr>
<td>Welding PAPR</td>
<td>Flammability Resistance</td>
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<tr>
<td>Multifunction PAPR</td>
<td>Intrinsic Safety</td>
</tr>
<tr>
<td>Hydration Device</td>
<td></td>
</tr>
</tbody>
</table>
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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Cincinnati, Ohio 45226
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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

Note:
Indicates Detection Loop
Circulating Heated Air Tube

Exhausted Sample Air
Charcoal Trap

DETECTION SYSTEM

Personal Computer
Analog Digital Acquisition Board
Detector

Thermostat, Air Heater
Heated Air
Temperature Control Chamber

Flow Controller
Compressed air or Nitrogen source
Liquid Permeation Cell
Liquid Permeation Cell

- Teflon Gasket
- Agent
- Specimen
- Detector
- Sweep Gas: Air or N₂
- CWA Film
- Cell Top Reservoir
- 1.905 cm
Permeation Cell Photographs

- Cell Base Assembly with gas ports
- Gasket with ridge side up
- Cell Top Reservoir
- Cell Cap
- Cell Top Reservoir
Accomplishments (Phase I)


- 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.
• 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
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, chloronated 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
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
Quality Partnerships Enhance Worker Safety & Health

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Thank you

Visit NPPTL at: http://www.cdc.gov/niosh/npptl/default.html
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
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.
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
Quality Partnerships Enhance Worker Safety & Health

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Thank you

Visit NPPTL at: http://www.cdc.gov/niosh/npptl/default.html
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
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 elapsed 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)
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

<table>
<thead>
<tr>
<th>TIC</th>
<th>Vapor Amount Remaining after 10 minutes to ED Arrival (mg)</th>
<th>Amount Remaining After Doffing (mg)</th>
<th>Doffing and 90% Decon: Peak Patient Bubble Concentration (mg/m³)</th>
<th>Doffing and 10% Decon: Peak Patient Bubble Concentration (mg/m³)</th>
<th>No Doffing No Decon: Peak Patient Bubble Concentration (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ammonia</td>
<td>292</td>
<td>161</td>
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<td>9.07</td>
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<td>296</td>
<td>163</td>
<td>0.053</td>
<td>0.163</td>
<td>0.163</td>
</tr>
</tbody>
</table>
## GB and HD Estimated Concentrations: ENTRY OF ONE CASUALTY INTO ED

<table>
<thead>
<tr>
<th>CWA</th>
<th>Vapor Amount Remaining after 10 minutes to ED Arrival (mg)</th>
<th>Amount Remaining After Doffing (mg)</th>
<th>Doffing and 90% Decon: Peak Patient Bubble Concentration (mg/m³)</th>
<th>Doffing and 10% Decon: Peak Patient Bubble Concentration (mg/m³)</th>
<th>No Doffing No Decon: Peak Patient Bubble Concentration (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GB = Sarin HD= Sulfur Mustard</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GB – 1L, 2:1 A/B</td>
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<td>37.34</td>
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<td>GB – 1L, 20:1 A/B</td>
<td>44.90</td>
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<td>0.0174</td>
<td>0.3825</td>
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<tr>
<td>GB – 1L, 200:1 A/B</td>
<td>40.39</td>
<td>21.99</td>
<td>0.0174</td>
<td>0.3484</td>
<td>ND</td>
</tr>
<tr>
<td>GB – 4L, 2:1 A/B</td>
<td>43.72</td>
<td>23.84</td>
<td>0.0174</td>
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<td>GB – 4L, 20:1 A/B</td>
<td>38.48</td>
<td>20.90</td>
<td>0.0146</td>
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<tr>
<td>GB – 4L, 200:1 A/B</td>
<td>37.09</td>
<td>20.14</td>
<td>0.0146</td>
<td>0.3228</td>
<td>ND</td>
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<tr>
<td>HD – 1L, 20:1 A/B</td>
<td>14.7</td>
<td>7.86</td>
<td>0.0038</td>
<td>0.0518</td>
<td>0.0624</td>
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<tr>
<td>HD – 4L, 20:1 A/B</td>
<td>7.6</td>
<td>4.19</td>
<td>0.0020</td>
<td>0.0371</td>
<td>ND</td>
</tr>
</tbody>
</table>
Quality Partnerships Enhance Worker Safety & Health

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Thank you

Visit NPPTL at: http://www.cdc.gov/niosh/npptl/default.html
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\(^\circ\) C
  – Both units were cold soaked for 12 hours
  – Operation tests were conducted (Testing was stopped when CO\(_2\) 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
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.
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

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

– Phone:  (513) 533-8303

– NPPTL Web Site:  http://www.cdc.gov/niosh(npptl)
Quality Partnerships Enhance Worker Safety & Health

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

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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
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 requirements
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 View
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:**
  NIOSH Docket Office
  Robert A. Taft Laboratories, M/S C 34
  SAR – NIOSH 083
  4676 Columbia Parkway
  Cincinnati, OH 45226

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

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

- **Phone:** (513) 533-8303

- **NPPTL Web Site:** http://www.cdc.gov/niosh(npptl)
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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)

<table>
<thead>
<tr>
<th>Face Length (mm)</th>
<th>120.5</th>
<th>132.5</th>
<th>144.5</th>
</tr>
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<tr>
<td>138.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>128.5</td>
<td>6 (n=2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>118.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>108.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>98.5</td>
<td>1 (n=2)</td>
<td>2 (n=2)</td>
<td></td>
</tr>
</tbody>
</table>

\[ \sum n = 25 \]
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
• Fax: (513) 533-8285
• Phone: (513) 533-8303
• NPPTL Web Site: http://www.cdc.gov/niosh/npptl

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TIL Criteria Development

Doug Landsittel
Statistician/Senior Fellow

NIOSH NPPTL Public Meeting
Crowne Plaza Pittsburgh South

October 12, 2006
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

- Cell 3: 0.032
- Cell 4: 0.053
- Cell 5: 0.041
- Cell 6: 0.044
- Cell 7: 0.027
- Cell 8: 0.049
- Cell 9: 0.011
- Cell 10: 0.042
- Cell 1: 0.014
- Cell 2: 0.052
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 ≥90% of the population → almost never fails the test
  – A respirator or model that truly meets the cut-off for ≤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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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

CDC Workplace Safety and Health

NIOSH

NPPTL Research to Practice through Partnerships
Quality Partnerships Enhance Worker Safety & Health

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Thank you

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Docket Information

- Mail:
  - NIOSH Docket Office
  - Robert A. Taft Laboratories, M/S C 34
    - QA - NIOSH 001
  - 4676 Columbia Parkway
  - Cincinnati, OH 45226
- Email: niocindocket@cdc.gov
- Fax: (513) 533-8285
- Phone: (513) 533-8303
- NPPTL Web Site: http://www.cdc.gov/niosh/npptl
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
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
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

*Customer Satisfaction*
## NPPTL Customer Satisfaction Survey Results

<table>
<thead>
<tr>
<th></th>
<th>Users</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original Population</td>
<td>666</td>
<td>262</td>
</tr>
<tr>
<td>Undeliverables</td>
<td>44</td>
<td>19</td>
</tr>
<tr>
<td>Population</td>
<td>622</td>
<td>243</td>
</tr>
<tr>
<td>Responses</td>
<td>185</td>
<td>75</td>
</tr>
<tr>
<td>Final Response Rate</td>
<td>30%</td>
<td>31%</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Favorable</th>
<th>Neither</th>
<th>Unfavorable</th>
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<tr>
<td>Quality</td>
<td>89%</td>
<td></td>
<td>9%</td>
</tr>
<tr>
<td>Tangibles</td>
<td>81%</td>
<td></td>
<td>15%</td>
</tr>
<tr>
<td>Timeliness</td>
<td>77%</td>
<td></td>
<td>22%</td>
</tr>
<tr>
<td>Courtesy</td>
<td>76%</td>
<td></td>
<td>22%</td>
</tr>
<tr>
<td>Choice</td>
<td>75%</td>
<td></td>
<td>21%</td>
</tr>
<tr>
<td>Knowledge</td>
<td>72%</td>
<td></td>
<td>24%</td>
</tr>
<tr>
<td>Access</td>
<td>71%</td>
<td></td>
<td>23%</td>
</tr>
<tr>
<td>Reliability</td>
<td>70%</td>
<td></td>
<td>26%</td>
</tr>
<tr>
<td>Recovery</td>
<td>54%</td>
<td></td>
<td>39%</td>
</tr>
</tbody>
</table>
Benchmarks: Users

High Benchmark ▲ Low Benchmark □ NPPTL-Manufacturers

Quality: 42%, 35%, 49%, 81%, 94%
Tangibles: 89%, 77%, 46%, 40%, 54%
Timeliness: 77%, 75%, 37%, 51%, 83%
Choice: 88%, 72%, 40%, 37%, 83%
Knowledge: 72%, 71%, 75%, 46%, 54%
Access: 44%, 40%, 30%, 26%, 70%
Reliability: 91%, 97%, 77%, 44%, 70%
Recovery: 77%, 70%, 71%, 44%, 30%
**NPPTL CSS Results: Manufacturers**

- **Courtesy**: 91% Favorable, 8% Unfavorable, 8% Neither
- **Tangibles**: 80% Favorable, 16% Neither, 4% Unfavorable
- **Knowledge**: 79% Favorable, 17% Neither, 4% Unfavorable
- **Access**: 77% Favorable, 14% Neither, 9% Unfavorable
- **Reliability**: 71% Favorable, 20% Neither, 8% Unfavorable
- **Choice**: 65% Favorable, 25% Neither, 10% Unfavorable
- **Quality**: 63% Favorable, 29% Neither, 7% Unfavorable
- **Timeliness**: 58% Favorable, 29% Neither, 12% Unfavorable
- **Recovery**: 56% Favorable, 28% Neither, 16% Unfavorable

Legend: 
- Favorable
- Neither
- Unfavorable
Benchmarks: Manufacturers

- High Benchmark
- Low Benchmark
- NPPTL-Manufacturers

- Recovery
  - 77%
  - 56%
  - 30%

- Timeliness
  - 94%
  - 83%
  - 42%
  - 63%
  - 42%
  - 35%

- Quality
  - 94%
  - 97%
  - 91%
  - 91%
  - 91%
  - 93%

- Choice
  - 83%
  - 71%
  - 44%

- Reliability
  - 77%
  - 79%
  - 46%

- Access
  - 77%
  - 80%
  - 49%

- Knowledge
  - 91%
  - 88%
  - 51%

- Tangibles

- Courtesy

- NPPTL-Manufacturers

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NPPTL 04 July 19

Recovery Timeliness Quality Choice Reliability Access Knowledge Tangibles Courtesy

% Favorable

0% 20% 40% 60% 80% 100%
Results: Dimension Profiles

- Quality
- Tangibles
- Timeliness
- Courtesy
- Choice
- Knowledge
- Access
- Reliability
- Recovery

% Favorable

Manufacturers

Users
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

• 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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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
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.)