Issues and Criteria for Air-Fed Protective Ensembles

Angie M. Shepherd
William E. Haskell

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
Public Meeting

December 2, 2008
Docket 148
Air-Fed Protective Ensembles

A protective ensemble with respiratory protective equipment that provides a source of air directly into the ensemble without the use of a tight-fitting facepiece worn by the individual inside the ensemble.

Air-Fed Ensemble

Tight-fitting facepiece respirator and separate suit
Air-Fed Protective Ensembles

The respiratory protective equipment is either an airline or a powered air-purifying respirator (PAPR) that is connected to the suit wall of the ensemble.

Both designs can have a means for distributing air inside the ensemble.
History - Air-Fed Protective Ensembles

- Supplied-air suits were developed in 1960s to protect nuclear workers
- Protection from respiratory and skin hazards, primarily plutonium and tritium
- Replaced airline respirators used inside protective suits
- Provided better comfort, mobility and visibility with high protection factors
- Atomic Energy Commission set up a testing facility at Los Alamos National Laboratory for air-supplied suits in 1973
Current Use - Government

- **Department of Energy**
  - 11 Nuclear Facilities including Savannah River Site, Idaho National Laboratory, and Miamisburg Environmental Management Program

- **Department of Defense**
  - U.S. Army Medical Research Institute of Infectious Diseases - Biosafety Level 4 (BSL-4) biological hazards in accordance with 32 CFR 627 "The Biological Defense Safety Program, Technical Safety Requirements"

- **Centers for Disease Control and Prevention**
  - BSL-4 laboratories for work conducted in Class II biological safety cabinets
Current Use - Industrial

- **Nuclear Industry**
  - Prevents against radioactive contamination during operation, maintenance, and decommissioning activities

- **Pharmaceutical Industry**
  - Protection from inhalation, dermal contact and contamination during manufacturing and handling of toxic compounds

---

Photo Credits: Jim Gathany/CDC
Current Use – Industrial (cont’d)

• Chemical Industry
  – Used in manufacturing and laboratory testing for dermal and inhalation protection from chemicals such as indelible paints and dyes

• Laboratories
  – Any lab that utilizes BSL-4 biological hazards

Photo Credits: Jim Gathany/CDC
Background – Issues

- Is an air-fed ensemble a respirator or protective clothing?
- No U.S. nationally recognized consensus based standards exist
- Federal organizations including DOE, CDC, and DOD have requested an air-fed ensemble standard
- Currently manufacturers can make claims of performance without third party certification
Background – Issues

- Ensembles are used in a wide range of applications
- Test methods need to be selected, modified or developed
- Appropriate design and performance criteria need to be established
- Certification and manufacturer quality assurance must be addressed
Background – Existing Standards

- **Title 42 CFR Part 84**, Approval of Respiratory Protective Devices, Under federal law, respiratory protective devices must be certified by NIOSH
  - Does not contain specific approval for air-fed ensembles

  - Only applicable to ensembles used by the DOE

- **EN1073-1:1998**, Protective Clothing Against Radioactive Contamination
  - Focuses on use in nuclear industry and contains no information on quality assurance or certification program

  - No provision for airline; intended for emergency response
Project Objectives

- To develop standard(s) for air-fed protective ensembles that will result in appropriate respiratory and dermal protection for wearers during a variety of uses

- To determine how to effectively apply NIOSH requirements for respiratory protection under the CFR in conjunction with requirements for dermal protection under a separate standard
Project Approach

- Dual standard approach initiated parallel efforts within NIOSH and an outside standards development organization (SDO)

- Partnership with a consensus SDO
  - ASTM International F23 Committee on Protective Clothing and Equipment

- NIOSH liaison to manage efforts to prevent gaps and overlaps in requirements
ASTM Ensemble Certification – Key Issues

- Development of design, performance, classification, documentation, labeling and certification requirements for ensemble and ensemble elements
- Determination of appropriate criteria for limited use and multiple use ensembles using an airline, PAPR or both
- Selection of appropriate inward leakage test – Man-in-Simulant (MIST) or Sulfur Hexafluoride (SF6)
- Prevention of duplication or mutually exclusive requirements with CFR
- Provision for permeation performance
ASTM Ensemble Certification – Approach

- Working within subcommittees on chemical (F23.30), biological (F23.60), and radiological (F23.70) hazards
- Submitted drafts for four ballot cycles
- Input from a range of interests inside and outside of ASTM
  - Notice in *ASTM Standardization News*
  - Meetings and conference calls of interested parties
  - Presentation at AIHce 2008
- Initial requirements were primarily based on NFPA 1991, as well as the DOE and EN standards
## Proposed ASTM Ensemble Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Application</th>
<th>Test Method</th>
<th>Performance Property</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ending pressure ≤ 80 mm water gauge pressure</td>
<td>All ensemble classes</td>
<td>ASTM F 1052</td>
<td>Maintenance of positive pressure</td>
</tr>
<tr>
<td>- Test subjects complete all tasks</td>
<td>All ensemble classes</td>
<td>ASTM F 1154</td>
<td>Ergonomic impact on wearer</td>
</tr>
<tr>
<td>- Test subjects are able to read eye chart to 20/35 through visor</td>
<td>All ensemble classes</td>
<td>N/A</td>
<td>Air flow capacity</td>
</tr>
<tr>
<td>- Test subject are able to withdraw and reinsert hands into gloves or glove system</td>
<td>All ensemble classes</td>
<td>ASTM F 1359</td>
<td>Liquid inward leakage</td>
</tr>
<tr>
<td>- Test subjects are able to execute emergency doffing within 60 seconds</td>
<td>All ensemble classes</td>
<td>ISO 17491</td>
<td>Sulfur hexafluoride inward leakage</td>
</tr>
<tr>
<td>- Ensemble internal pressure ≤ 100 mm water gauge pressure</td>
<td>All ensemble classes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Ending pressure after evaluation ≥ 80 mm water gauge pressure</td>
<td>All ensemble classes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No liquid penetration to interior of ensemble</td>
<td>All ensemble classes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No liquid accumulation in outer gloves or outward</td>
<td>All ensemble classes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Inward leakage ≤ 0.2%</td>
<td>All ensemble classes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performance Property</td>
<td>Test Item</td>
<td>ASTM F 903</td>
<td>ASTM D 5034</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------</td>
<td>---------------</td>
<td>--------------</td>
</tr>
<tr>
<td></td>
<td>Multiple Use</td>
<td>PASS</td>
<td>≥ 225 N</td>
</tr>
<tr>
<td></td>
<td>Limited Use</td>
<td>PASS</td>
<td>≥ 100 N</td>
</tr>
<tr>
<td></td>
<td>Test Item</td>
<td>Material only</td>
<td>Material only</td>
</tr>
<tr>
<td></td>
<td>Performance</td>
<td>Liquid penetration resistance</td>
<td>Tensile strength</td>
</tr>
<tr>
<td></td>
<td>Property</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* After 5 industrial launderings
# Proposed ASTM Hardware Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Performance Property</th>
<th>Test Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt; 135 N</td>
<td>Mounting strength</td>
<td>Exhaust valve</td>
</tr>
<tr>
<td>≥ 10 N</td>
<td>Pull-out strength</td>
<td>External fittings</td>
</tr>
<tr>
<td>Performance Property</td>
<td>Test Item</td>
<td>Test Method</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Liquid penetration resistance</td>
<td>Material and seams</td>
<td>ASTM F 903</td>
</tr>
<tr>
<td></td>
<td>Material only</td>
<td>ASTM D 3787</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ASTM D 2582</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ASTM D 751</td>
</tr>
<tr>
<td>Burst strength</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Puncture propagation tear resistance</td>
<td>Material only</td>
<td></td>
</tr>
<tr>
<td>Seam strength</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Proposed ASTM Glove Criteria

<table>
<thead>
<tr>
<th>Performance Property</th>
<th>Test Item</th>
<th>Test Method</th>
<th>Limited Use</th>
<th>Multiple Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid leakage</td>
<td>Whole gloves</td>
<td>ASTM D 5151</td>
<td>PASS</td>
<td>PASS *</td>
</tr>
<tr>
<td>Liquid penetration</td>
<td>Seams only</td>
<td>ASTM F 903</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>resistance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cut resistance</td>
<td>Material only</td>
<td>ASTM D 1790</td>
<td>≥ 50 g</td>
<td>≥ 200 g</td>
</tr>
<tr>
<td>Puncture resistance</td>
<td>Material only</td>
<td>ASTM D 1342</td>
<td>≥ 10 N</td>
<td>≥ 30 N</td>
</tr>
<tr>
<td>Abrasion resistance</td>
<td>Material only</td>
<td>ASTM D 3884</td>
<td>≥ 500 cycles</td>
<td>≥ 2,000 cycles</td>
</tr>
<tr>
<td>Hand function</td>
<td>Whole gloves</td>
<td>ASTM D 2010</td>
<td>≤ 150%</td>
<td>≤ 300%</td>
</tr>
</tbody>
</table>

* After 5 industrial launderings
# Proposed ASTM Footwear Criteria

<table>
<thead>
<tr>
<th>Performance Property</th>
<th>Test Item</th>
<th>Test Method</th>
<th>Limited Use</th>
<th>Multiple Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid leakage</td>
<td>Whole footwear</td>
<td>ASTM D 5151</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>Liquid penetration resistance</td>
<td>Seams only</td>
<td>ASTM F 903</td>
<td>PASS</td>
<td>PASS</td>
</tr>
<tr>
<td>Cut resistance</td>
<td>Upper material only</td>
<td>ASTM D 1790</td>
<td>≥ 200 g</td>
<td>≥ 400 g</td>
</tr>
<tr>
<td>Puncture resistance</td>
<td>Upper material only</td>
<td>ASTM D 1342</td>
<td>≥ 20 N</td>
<td>≥ 50 N</td>
</tr>
<tr>
<td>Abrasion resistance</td>
<td>Upper material only</td>
<td>ASTM D 3884</td>
<td>≥ 1,000 cycles</td>
<td>≥ 4,000 cycles</td>
</tr>
<tr>
<td>Slip resistance</td>
<td>Sole material only</td>
<td>ASTM F 489</td>
<td>≥ 0.75</td>
<td>≥ 0.75</td>
</tr>
<tr>
<td>Abrasion resistance</td>
<td>Sole material only</td>
<td>ASTM D 1630</td>
<td>≥ 65 Index</td>
<td>≥ 65 Index</td>
</tr>
</tbody>
</table>

_CDC Workplace Safety and Health_  
_NIOSH_  
_NPPTL Research to Practice through Partnerships_
Proposed ASTM Labeling Requirements

- Certification organization’s mark
- Airline or PAPR protective ensemble designation
- Limited Use or Multiple Use statement
- Manufacturer’s detailed information
  - Name and address
  - Country of manufacture
  - Serial or garment identification number
  - Principal materials composition
  - Model and size
- Cleaning and decontamination information
- Required ensemble elements

Photo Credit: Jim Gathany/CDC
Proposed ASTM User Guide and Technical Information

- **User Information Guide**
  - Required to be attached to the ensemble
  - Information on warnings and instructions for use such as donning and doffing

- **Technical Information**
  - Supplied upon request
  - Results of all required tests
  - Test data for any additional claims including chemical and viral resistance
  - Detailed cleaning, decontamination and storage instructions

*Photo Credits: Jim Gathany/CDC*
Proposed ASTM Certification Program

- NIOSH certification to 42 CFR 84 as a prerequisite
- Mandatory third party certification
- Required quality assurance program (ISO 9001)
- Initial testing and inspection
- Annual verification of continued compliance through testing and site visits
- Complaint investigation program
- Safety alert and product recall system
Timeline

- ASTM Air-fed Ensemble Specification
- Fourth ballot cycle will be complete in January 2009
- Could be published as early as 2009
- Submission of products for certification could begin as soon as the ASTM standard is published with NIOSH approval under the CFR
Summary

- NIOSH NPPTL supported effort to develop standards and criteria for a specific area of personal protective technology that is not currently addressed
  - Standards and certification for manufacturers
  - Certified air-fed protective ensembles that have been evaluated by NIOSH and a third party certification organization
  - More readily available and improved information for users
  - Reduction of exposures to biosafety Level 4 biological hazards, radioactive contamination, and other dangerous substances
Quality Partnerships Enhance Worker Safety & Health

Acknowledgements
Jim Gathany, CDC
Delta Protection/Spherian

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.