

Issues and Criteria for Air-Fed Protective Ensembles

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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.



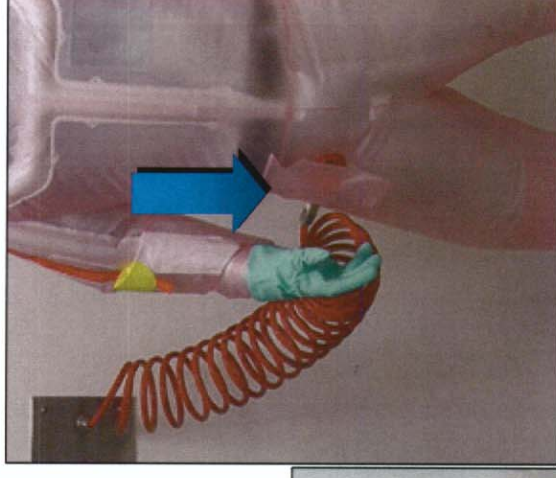
Air-Fed Ensemble



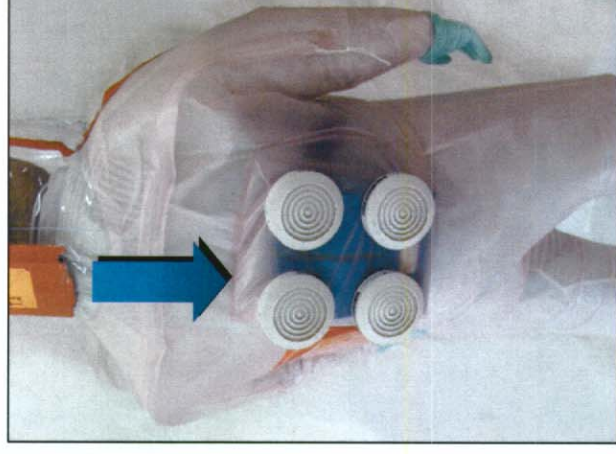
Tight-fitting facepiece respirator and separate suit

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.



Airline Ensemble



PAPR Ensemble

Photos courtesy of Delta Protection

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

Photo courtesy of Delta Protection

Current Use - Government

- **Department of Energy**



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

- **Department of Defense**



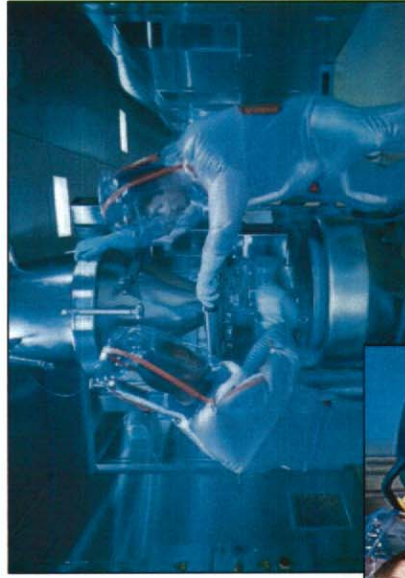
- U.S. Army Medical Research Institute of Infectious Diseases - Biosafety Level 4 (BSL-4) biological hazards in accordance with 32 CFR 627 "The Biological Defense Safety Program, Technical Safety Requirements"

- **Centers for Disease Control and Prevention**



- BSL-4 laboratories for work conducted in Class II biological safety cabinets

Current Use - Industrial



Courtesy of Delta Protection



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- **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

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



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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
- **DOE-STD-1167-2003**, The Department of Energy Respiratory Acceptance Program for Supplied-Air Suits
 - 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
- **NFPA 1991-2005**, Standard on Vapor-Protective Ensembles for Hazardous Materials Emergencies
 - 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

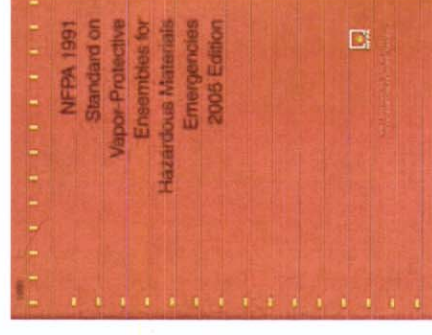


ASTM Ensemble Certification – Key Issues

- 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, PAPER 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

- Initiated ASTM Work Item WK14247 *Standard Specification for Air-Fed Protective Ensembles* at January 2007 ASTM meeting
- 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

Performance Property	Test Method	Application	Criteria
Maintenance of positive pressure	ASTM F 1052	All ensemble classes	Ending pressure \leq 80 mm water gauge pressure
Ergonomic impact on wearer	ASTM F 1154	All ensemble classes	<ul style="list-style-type: none"> • Test subjects complete all tasks • Test subjects are able to read eye chart to 20/35 through visor • Test subject are able to withdraw and reinsert hands into gloves or glove system • Test subjects are able to execute emergency doffing within 60 seconds
Air flow capacity	N/A	All ensemble classes	<ul style="list-style-type: none"> • Ensemble internal pressure \leq 100 mm water gauge pressure • Ending pressure after evaluation \geq 80 mm water gauge pressure
Liquid inward leakage	ASTM F 1359	All ensemble classes	<ul style="list-style-type: none"> • No liquid penetration to interior of ensemble • No liquid accumulation in outer gloves or outer boots
Sulfur hexafluoride inward leakage	ISO 17491	All ensemble classes	Inward leakage \leq 0.2%

Proposed ASTM Suit Material Criteria

Performance Property	Test Item	Test Method	Limited Use	Multiple Use
Liquid penetration resistance	Material and seams	ASTM F 903	PASS	PASS *
Tensile strength	Material only	ASTM D 5034	≥ 100 N	≥ 225 N
Tear resistance	Material only	ASTM D 5587	≥ 20 N	≥ 40 N
Burst strength	Material only	ASTM D 3787	≥ 150 N	≥ 300 N
Puncture Propagation Tear resistance	Material only	ASTM D 2582	≥ 10 N	≥ 25 N
Abrasion resistance	Material only	ASTM D 3884	≥ 500 cycles	≥ 2,000 cycles
Seam strength	Seams only	ASTM D 751	≥ 100 N	≥ 225 N
Closure strength	Closure only	ASTM D 751	≥ 100 N	≥ 225 N

* After 5 industrial launderings

Proposed ASTM Hardware Criteria

Performance Property	Test Item	Criteria
Mounting strength	Exhaust valve	> 135 N
Pull-out strength	External fittings	≥ 10 N

Proposed ASTM Visor Criteria

Performance Property	Test Item	Test Method	Limited Use	Multiple Use
Liquid penetration resistance	Material and seams	ASTM F 903	PASS	PASS *
Burst strength	Material only	ASTM D 3787	≥ 150 N	≥ 300 N
Puncture propagation tear resistance	Material only	ASTM D 2582	≥ 10 N	≥ 25 N
Seam strength	Seams only	ASTM D 751	≥ 100 N	≥ 225 N

* After 5 industrial launderings

Proposed ASTM Glove Criteria

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

* After 5 industrial launderings

Proposed ASTM Footwear Criteria

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

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



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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

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www.cdc.gov/niosh/npptl/default.html

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