

# NFPA 1999

## Standard on Protective Clothing for Emergency Medical Operations

### 2003 Edition



NFPA, 1 Batterymarch Park, PO Box 9101, Quincy, MA 02269-9101  
An International Codes and Standards Organization

NFPA License Agreement

This document is copyrighted by the National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02269-9101 USA.  
All rights reserved.

NFPA grants you a license as follows: The right to download an electronic file of this NFPA document for temporary storage on one computer for purposes of viewing and/or printing one copy of the NFPA document for individual use. Neither the electronic file nor the hard copy print may be reproduced in any way. In addition, the electronic file may not be distributed elsewhere over computer networks or otherwise. The hard copy print may only be used personally or distributed to other employees for their internal use within your organization.

## IMPORTANT NOTICES AND DISCLAIMERS CONCERNING THIS DOCUMENT

### Notice and Disclaimer of Liability Concerning the Use of NFPA Documents

NFPA codes, standards, recommended practices, and guides, of which the document contained herein is one, are developed through a consensus standards development process approved by the American National Standards Institute. This process brings together volunteers representing varied viewpoints and interests to achieve consensus on fire and other safety issues. While the NFPA administers the process and establishes rules to promote fairness in the development of consensus, it does not independently test, evaluate, or verify the accuracy of any information or the soundness of any judgments contained in its codes and standards.

The NFPA disclaims liability for any personal injury, property or other damages of any nature whatsoever, whether special, indirect, consequential or compensatory, directly or indirectly resulting from the publication, use of, or reliance on this document. The NFPA also makes no guaranty or warranty as to the accuracy or completeness of any information published herein.

In issuing and making this document available, the NFPA is not undertaking to render professional or other services for or on behalf of any person or entity. Nor is the NFPA undertaking to perform any duty owed by any person or entity to someone else. Anyone using this document should rely on his or her own independent judgment or, as appropriate, seek the advice of a competent professional in determining the exercise of reasonable care in any given circumstances.

The NFPA has no power, nor does it undertake, to police or enforce compliance with the contents of this document. Nor does the NFPA list, certify, test or inspect products, designs, or installations for compliance with this document. Any certification or other statement of compliance with the requirements of this document shall not be attributable to the NFPA and is solely the responsibility of the certifier or maker of the statement.

Important Notices and Disclaimers continued on inside back cover.

## IMPORTANT NOTICES AND DISCLAIMERS CONCERNING NFPA DOCUMENTS

(Continued from inside front cover)

### ADDITIONAL NOTICES AND DISCLAIMERS

#### Updating of NFPA Documents

Users of NFPA codes, standards, recommended practices, and guides should be aware that these documents may be superseded at any time by the issuance of new editions or may be amended from time to time through the issuance of Tentative Interim Amendments. An official NFPA document at any point in time consists of the current edition of the document together with any Tentative Interim Amendments and any Errata then in effect. In order to determine whether a given document is the current edition and whether it has been amended through the issuance of Tentative Interim Amendments or corrected through the issuance of Errata, consult appropriate NFPA publications such as the National Fire Codes Subscription Service, visit the NFPA website at [www.nfpa.org](http://www.nfpa.org), or contact the NFPA at the address listed below.

#### Interpretations of NFPA Documents

A statement, written or oral, that is not processed in accordance with Section 6 of the Regulations Governing Committee Projects shall not be considered the official position of NFPA or any of its Committees and shall not be considered to be, nor be relied upon as, a Formal Interpretation.

#### Patents

The NFPA does not take any position with respect to the validity of any patent rights asserted in connection with any items which are mentioned in or are the subject of NFPA codes, standards, recommended practices, and guides, and the NFPA disclaims liability for the infringement of any patent resulting from the use of or reliance on these documents. Users of these documents are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, is entirely their own responsibility.

NFPA adheres to applicable policies of the American National Standards Institute with respect to patents. For further information, contact the NFPA at the address listed below.

#### Laws & Regulations

Users of these documents should consult applicable federal, state, and local laws and regulations. NFPA does not, by the publication of its codes, standards, recommended practices, and guides, intend to urge action that is not in compliance with applicable laws, and these documents may not be construed as doing so.

#### Copyrights

This document is copyrighted by the NFPA. It is made available for a wide variety of both public and private uses. These include both use, by reference, in laws and regulations, and use in private self-regulation, standardization, and the promotion of safe practices and methods. By making this document available for use and adoption by public authorities and private users, the NFPA does not waive any rights in copyright to this document.

**Adoption by Reference.** Use of NFPA documents for regulatory purposes should be accomplished through adoption by reference. The term “adoption by reference” means the citing of title, edition and publishing information only. Any deletions, additions, and changes desired by the adopting authority should be noted separately in the adopting instrument. In order to assist NFPA in following the uses made of its documents, adopting authorities are requested to notify the NFPA (Attention: Secretary, Standards Council) in writing of such use. For technical assistance and questions concerning adoption of NFPA documents, contact NFPA at the address below.

#### For Further Information

All questions or other communications relating to NFPA codes, standards, recommended practices, and guides and all requests for information on NFPA procedures governing its codes and standards development process, including information on the procedures for requesting Formal Interpretations, for proposing Tentative Interim Amendments, and for proposing revisions to NFPA documents during regular revision cycles, should be sent to NFPA headquarters, addressed to the attention of the Secretary, Standards Council, NFPA, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101.

For more information about NFPA, visit the NFPA website at [www.nfpa.org](http://www.nfpa.org).

Copyright © 2003, National Fire Protection Association, All Rights Reserved

## NFPA 1999

### Standard on

## Protective Clothing for Emergency Medical Operations

### 2003 Edition

This edition of NFPA 1999, *Standard on Protective Clothing for Emergency Medical Operations*, was prepared by the Technical Committee on Emergency Medical Services Protective Clothing and Equipment, released by the Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment, and acted on by NFPA at its November Association Technical Meeting held November 16–20, 2002, in Atlanta, GA. It was issued by the Standards Council on January 17, 2003, with an effective date of February 6, 2003, and supersedes all previous editions.

This edition of NFPA 1999 was approved as an American National Standard on January 17, 2003.

### Origin and Development of NFPA 1999

This standard was developed to address protective garments, gloves, and facewear designed to protect persons providing emergency medical care against exposure to liquid-borne pathogens during emergency medical operations. NFPA 1999 defines minimum performance for protective clothing as required by the Occupational Safety and Health Administration (OSHA) Final Rule (29 CFR 1910.1030) *Protecting Health Care Workers from Occupational Exposure to Bloodborne Pathogens*. The Final Rule states:

When there is occupational exposure, the employer shall provide at no cost to the employee, appropriate personal protective equipment, such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks, and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered “appropriate” only if it does not permit blood or other potential infectious materials to pass through to or reach the employee’s work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

NFPA 1999 offers specific performance criteria that involve exposing protective clothing materials to surrogate virus challenge utilizing a specific time and pressure protocol. This procedure has been documented to discriminate between current protective clothing materials and to correlate with visual penetration results that are obtained with a human factors evaluation. Each type of clothing must resist penetration to blood-borne pathogens as determined by this test.

Additional garment requirements cover overall liquidtight integrity, material strength, physical hazard resistance, seam strength, and closure strength.

Additional requirements for gloves cover minimum performance for tensile and elongation properties in an “as received” condition as well as following heat aging and isopropyl alcohol immersion, minimum sizing, and liquidtight integrity for intended areas of penetration.

Additional requirements for facewear or face protection devices cover adequate visibility and integrity, in addition to resisting penetration of blood-borne pathogens.

The selection of test methods and performance requirements was based on surveys of emergency medical services (EMS) personnel and a technical study supported by the U.S. Fire Administration.

The Subcommittee on Hazardous Chemicals Protective Clothing began its work on the first edition of this document in 1990 and passed its work on to the Technical Committee on Fire Service Protective Clothing and Equipment in January 1991. The first edition was presented to the Association at the 1992 Annual Meeting in New Orleans, LA.

Since the first edition in 1992, the entire project for fire service protective clothing and equipment was reorganized in January 1995 by the Standards Council. The new project has a Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment and eight technical committees operating within it. The Technical Committee on Emergency Medical Services Protective Clothing and Equipment is now responsible for NFPA 1999.

In 1997, the second edition incorporated single-use and reusable items of EMS protective clothing. Prior to that edition, there was no differentiation between single-use and reusable items. Items that were reused may not have continued to provide biopenetration barrier protection. Reusable items could be advantageous and cost-effective for certain items of EMS clothing such as garments. Durability conditioning was added to the test methods of items that would be identified as not for single use only. EMS gloves remain single-use items only. This was consistent with NFPA 1581, *Standard on Fire Department Infection Control Program*. EMS gloves were also newly required to be an FDA registered medical device.

The first edition allowed partial body garments, such as sleeve covers or apron-type gowns, and also allowed the biopenetration barrier protection to be less in area than the area covered by the garment (such as only the front of a smock or jacket having the biopenetration barrier protection). The second edition continued to permit partial body garments, but did *not* allow partial biopenetration barrier protection in a garment. Biopenetration barrier protection was required for the full area covered by the garment.

Test methods were completely reformatted to present consistency in test methods and to assure that all key elements of a test were given within the method.

This third edition of NFPA 1999 has been reformatted into the new style for all NFPA codes and standards and, therefore, the chapter titles and numbering, as well as paragraph numbering, have changed. In this edition, the Committee added new requirements for emergency medical work gloves, emergency medical footwear, and cleaning gloves.

Emergency medical work gloves will provide the barrier protection from blood and liquid-borne pathogens that all EMS PPE provides, and a higher level of physical protection for incidents where rough or sharp surfaces could be contacted, such as during extrication operations. The emergency medical footwear can be configured either as a single-use, disposable bootie to pull over work shoes or as normal footwear designed for multiple uses. Both would provide the same barrier protection from blood and liquid-borne pathogens as other items of EMS PPE. The cleaning gloves are single-use items to protect wearers during cleaning and decontamination of EMS equipment.

This third edition was acted on by the NFPA membership at the November Association Technical Meeting in Atlanta, GA, on 20 November 2002.

#### **In Memoriam, 11 September 2001**

We pay tribute to the 343 members of FDNY who gave their lives to save civilian victims on September 11, 2001, at the World Trade Center. They are true American heroes in death, but they were also American heroes in life. We will keep them in our memory and in our hearts. They are the embodiment of courage, bravery, and dedication. May they rest in peace.

## Technical Correlating Committee on Fire and Emergency Services Protective Clothing and Equipment (FAE-AAC)

**Richard M. Duffy**, *Chair*

International Association of Fire Fighters, DC [L]  
Rep. International Association of Fire Fighters

**William M. Lambert**, *Secretary*

Mine Safety Appliances Company, PA [M]  
Rep. Compressed Gas Association

**Leslie Anderson**, U.S.D.A. Forest Service, MT [E]

**Richard W. Blocker, Jr.**, The DuPont Company, VA [M]

**Nicholas J. Curtis**, Lion Apparel, Inc., OH [M]

**Robert A. Freese**, Globe Manufacturing Company,  
NH [M]

**Bill Grilliot**, Total Fire Group/Morning Pride  
Manufacturing, LLC, OH [M]

Rep. Fire and Emergency Manufacturers and Services  
Association Inc.

**William E. Haskell III**, U.S. Army SBCCOM, MA [U]

**Virgil Hathaway**, San Diego Fire Department, CA [U]  
Rep. Southern Area Fire Equipment Research

**James S. Johnson**, Lawrence Livermore National Labs,  
CA [RT]

**Cy Long**, Texas Commission on Fire Protection, TX [E]

**David G. Matthews**, Fire & Industrial (P.P.E.) Ltd.,  
England [SE]

**Jim Minx**, Oklahoma State Firefighters Association,  
OK [C]

Rep. Oklahoma State Firefighters Association

**Stephen R. Sanders**, Safety Equipment Institute (SEI),  
VA [RT]

**Denise N. Statham**, Southern Mills, Inc., GA [M]

**Jeffrey O. Stull**, International Personnel Protection, Inc.,  
TX [SE]

**David Trivette**, Scott Health and Safety, NC [M]

Rep. Industrial Safety Equipment Association

**Robert D. Tutterow, Jr.**, Charlotte Fire Department, NC [U]

Rep. Fire Industry Equipment Research Organization

**Bruce H. Varner**, City of Carrollton Fire Department, TX  
[U]

Rep. International Fire Service Training Association

**Harry Winer**, U.S. Department of the Navy, MA [RT]

**Thomas L. Wollan**, Underwriters Laboratories Inc.,  
NC [RT]

### Alternates

**Janice C. Bradley**, Industrial Safety Equipment  
Association, VA [M]

(Alt. to D. Trivette)

**Gregory S. Copeland**, Celanese AG, NC [M]

(Alt. to R. W. Blocker, Jr.)

**Patricia A. Freeman**, Globe Manufacturing Company, NH  
[M]

(Alt. to R. A. Freese)

**Patricia A. Gleason**, Safety Equipment Institute (SEI),  
VA [RT]

(Alt. to S. R. Sanders)

**Mary I. Grilliot**, Total Fire Group/Morning Pride  
Manufacturing, LLC, OH [M]

(Alt. to B. Grilliot)

**Steven B. Lumry**, Oklahoma City Fire Department,  
OK [C]

(Alt. to J. Minx)

**Daniel Ryan**, Underwriters Laboratories Inc., NC [RT]

(Alt. to T. L. Wollan)

**Frank P. Taylor**, Lion Apparel, Inc., VA [M]

(Alt. to N. J. Curtis)

### Nonvoting

**Donna P. Brehm**, Virginia Beach Fire Department,  
VA [U]

**Don R. Forrest**, United Firefighters of Los Angeles City,  
CA [L]

**Bryan C. Heirston**, Oklahoma City Fire Department,  
OK [L]

**William R. Hutfilz**, Clark County Fire Department,  
NV [U]

**George M. Jackson**, U.S.D.A. Forest Service, MT [E]

**Richard Mangan**, U.S.D.A. Forest Service, MT [RT]

**Kirk Owen**, Plano Fire Department, TX [U]

**Ray F. Reed**, Dallas Fire Department, TX [U]

**Bruce W. Teele**, NFPA Staff Liaison

**Committee Scope:** This Committee shall have primary responsibility for documents on the design, performance, testing, and certification of protective clothing and protective equipment manufactured for fire and emergency services organizations and personnel, to protect against exposures encountered during emergency incident operations. This Committee shall also have the primary responsibility for documents on the selection, care, and maintenance of such protective clothing and protective equipment by fire and emergency services organizations and personnel.

## Technical Committee on Emergency Medical Services Protective Clothing and Equipment (FAE-EMS)

**Donna P. Brehm**, *Chair*  
Virginia Beach Fire Department, VA [U]

**Karen E. Strumlock**, *Secretary*  
Lion Apparel, Inc., OH [M]

**Sherri-Lynne Almeida**, Houston Fire Department, TX [U]  
**James M. Baker**, National Safety Clean, Inc., PA [IM]  
**Stacy Lynn Carey**, Intertek Testing Services NA, Inc., NY [RT]  
**Ira B. Dyer II**, Louisville Division of Fire, KY [U]  
**Michael Garrobo**, Best Manufacturing Company, GA [M]  
**Daniel Gohlke**, W. L. Gore & Associates, MD [M]  
**Zachary Goldfarb**, New York City Fire Department, NY [E]

**Guillermo “Bill” Herrera**, Miami Dade County Fire Department, FL [L]  
Rep. International Association of Fire Fighters  
**Alton J. Lovingood**, Hall County Fire Services, GA [U]  
**John Murray**, Corpus Christi Fire Department, TX [E]  
**Gregg A. Skelly**, Underwriters Laboratories Inc., NC [RT]  
**Michael Spiewak**, I. Spiewak & Sons, Inc., NY [M]  
**Jeffrey O. Stull**, International Personnel Protection, Inc., TX [SE]

### Alternates

**Nicholas J. Curtis**, Lion Apparel, Inc., OH [M]  
(Alt. to K. E. Strumlock)  
**Stephen L. Derynck**, Underwriters Laboratories Inc., NC [RT]  
(Alt. to G. A. Skelly)

**Andy Gbur**, Intertek Testing Services NA, Inc., OH [RT]  
(Alt. to S. L. Carey)  
**Grace G. Stull**, International Personnel Protection, Inc., TX [SE]  
(Alt. to J. O. Stull)

**Bruce W. Teele**, NFPA Staff Liaison

**Committee Scope:** This Committee shall have primary responsibility for documents on protective clothing and protective equipment, except respiratory protective equipment, that provides hand, torso, limb, and face protection for fire fighters or other emergency services responders during incidents that involve emergency medical operations. These operations include first aid, cardiopulmonary resuscitation, basic life support, advanced life support, and other medical procedures provided to patients prior to arrival at a hospital or other health care facility.

Additionally, this committee shall have primary responsibility for documents on the selection, care, and maintenance of emergency medical protective clothing and protective equipment by fire and emergency services organizations and personnel.

*These lists represent the membership at the time the Committees were balloted on the final text of this edition. Since that time, changes in the membership may have occurred. A key to classifications is found at the back of the document.*

NOTE: Membership on a committee shall not in and of itself constitute an endorsement of the Association or any document developed by the committee on which the member serves.

## Contents

|                                                                                |         |                                                                        |         |
|--------------------------------------------------------------------------------|---------|------------------------------------------------------------------------|---------|
| <b>Chapter 1 Administration</b> .....                                          | 1999– 6 | 7.5 Emergency Medical Footwear Cover<br>Performance Requirements ..... | 1999–20 |
| 1.1 Scope .....                                                                | 1999– 6 | 7.6 Cleaning Glove Performance<br>Requirements .....                   | 1999–21 |
| 1.2 Purpose .....                                                              | 1999– 6 | 7.7 Emergency Medical Work Gloves<br>Performance Requirements .....    | 1999–21 |
| 1.3 Application .....                                                          | 1999– 6 |                                                                        |         |
| 1.4 Units .....                                                                | 1999– 6 |                                                                        |         |
| <b>Chapter 2 Referenced Publications</b> .....                                 | 1999– 6 | <b>Chapter 8 Test Methods</b> .....                                    | 1999–21 |
| 2.1 General .....                                                              | 1999– 6 | 8.1 Sample Preparation Procedures .....                                | 1999–21 |
| 2.2 NFPA Publications .....                                                    | 1999– 7 | 8.2 Liquidtight Integrity Test One .....                               | 1999–22 |
| 2.3 Other Publications .....                                                   | 1999– 7 | 8.3 Biopenetration Test One .....                                      | 1999–23 |
| <b>Chapter 3 Definitions</b> .....                                             | 1999– 8 | 8.4 Tensile Strength Test .....                                        | 1999–24 |
| 3.1 General .....                                                              | 1999– 8 | 8.5 Burst Strength Test .....                                          | 1999–24 |
| 3.2 NFPA Official Definitions .....                                            | 1999– 8 | 8.6 Puncture Propagation Tear Resistance<br>Test .....                 | 1999–24 |
| 3.3 General Definitions .....                                                  | 1999– 8 | 8.7 Tear Resistance Test .....                                         | 1999–25 |
| <b>Chapter 4 Certification</b> .....                                           | 1999–10 | 8.8 Seam/Closure Breaking Strength Test ...                            | 1999–25 |
| 4.1 General .....                                                              | 1999–10 | 8.9 Liquidtight Integrity Test Two .....                               | 1999–25 |
| 4.2 Certification Program .....                                                | 1999–10 | 8.10 Biopenetration Test Two .....                                     | 1999–26 |
| 4.3 Inspection and Testing .....                                               | 1999–11 | 8.11 Ultimate Tensile Strength Test .....                              | 1999–26 |
| 4.4 Recertification .....                                                      | 1999–11 | 8.12 Ultimate Elongation Test .....                                    | 1999–26 |
| 4.5 ISO Registration for Manufacturers .....                                   | 1999–12 | 8.13 Puncture Resistance Test One .....                                | 1999–27 |
| 4.6 Hazards Involving Compliant Product ...                                    | 1999–12 | 8.14 Dexterity Test One .....                                          | 1999–27 |
| 4.7 Manufacturers' Investigation of<br>Complaints and Returns .....            | 1999–13 | 8.15 Protein Content Test .....                                        | 1999–28 |
| 4.8 Manufacturers' Safety Alert and Product<br>Recall Systems .....            | 1999–13 | 8.16 Visual Acuity Test .....                                          | 1999–28 |
| <b>Chapter 5 Labeling and Information</b> .....                                | 1999–13 | 8.17 Liquidtight Integrity Test Three .....                            | 1999–28 |
| 5.1 Product Label Requirements .....                                           | 1999–13 | 8.18 Cut Resistance Test .....                                         | 1999–29 |
| 5.2 User Information .....                                                     | 1999–16 | 8.19 Abrasion Resistance Test One .....                                | 1999–29 |
| <b>Chapter 6 Design Requirements</b> .....                                     | 1999–16 | 8.20 Puncture Resistance Test Two .....                                | 1999–30 |
| 6.1 Emergency Medical Garment Design<br>Requirements .....                     | 1999–16 | 8.21 Flex Fatigue Test .....                                           | 1999–30 |
| 6.2 Emergency Medical Examination Glove<br>Design Requirements .....           | 1999–16 | 8.22 Slip Resistance Test .....                                        | 1999–30 |
| 6.3 Emergency Medical Face Protection<br>Device Design Requirements .....      | 1999–16 | 8.23 Eyelet and Stud Post Attachment Test ....                         | 1999–30 |
| 6.4 Emergency Medical Footwear Design<br>Requirements .....                    | 1999–17 | 8.24 Impact and Compression Resistance<br>Test .....                   | 1999–30 |
| 6.5 Emergency Medical Footwear Cover<br>Design Requirements .....              | 1999–17 | 8.25 Corrosion Resistance Test .....                                   | 1999–31 |
| 6.6 Cleaning Glove Design Requirements ....                                    | 1999–17 | 8.26 Overall Liquid Integrity Test Four .....                          | 1999–31 |
| 6.7 Emergency Medical Work Glove Design<br>Requirements .....                  | 1999–17 | 8.27 Chemical Permeation Resistance Test ....                          | 1999–31 |
| <b>Chapter 7 Performance Requirements</b> .....                                | 1999–19 | 8.28 Abrasion Resistance Test Two .....                                | 1999–32 |
| 7.1 Emergency Medical Garment<br>Performance Requirements .....                | 1999–19 | 8.29 Dexterity Test Two .....                                          | 1999–32 |
| 7.2 Emergency Medical Examination Glove<br>Performance Requirements .....      | 1999–20 | 8.30 Grip Test .....                                                   | 1999–32 |
| 7.3 Emergency Medical Face Protection<br>Device Performance Requirements ..... | 1999–20 | 8.31 Liner Retention Test .....                                        | 1999–33 |
| 7.4 Emergency Medical Footwear<br>Performance Requirements .....               | 1999–20 | 8.32 Overall Liquid Integrity Test Three .....                         | 1999–33 |
|                                                                                |         | 8.33 Tactility Test .....                                              | 1999–33 |
|                                                                                |         | 8.34 Water Repellency Test .....                                       | 1999–34 |
|                                                                                |         | 8.35 Total Heat Loss Test .....                                        | 1999–34 |
|                                                                                |         | 8.36 Label Durability and Legibility Test .....                        | 1999–34 |
|                                                                                |         | <b>Annex A Explanatory Material</b> .....                              | 1999–35 |
|                                                                                |         | <b>Annex B Informational References</b> .....                          | 1999–38 |
|                                                                                |         | <b>Index</b> .....                                                     | 1999–39 |

**NFPA 1999****Standard on****Protective Clothing for Emergency Medical Operations****2003 Edition**

NOTICE: An asterisk (\*) following the number or letter designating a paragraph indicates that explanatory material on the paragraph can be found in Annex A.

Information on referenced publications can be found in Chapter 2 and Annex B.

**Chapter 1 Administration****1.1 Scope.**

**1.1.1\*** This standard shall specify the minimum documentation, design, performance, testing, and certification requirements for new single-use and new multiple-use emergency medical protective clothing, including garments, gloves, footwear, and face protection devices, used by fire and emergency services personnel during emergency medical operations.

**1.1.2\*** This standard shall not be interpreted as providing criteria for protection from radiological agents, from hazardous chemicals, from flammable or explosive atmospheres, or from thermal hazards associated with fire fighting.

**1.1.3\*** This standard shall not be interpreted as providing criteria for protection from blood and body fluid-borne pathogens that are airborne.

**1.1.4** This standard shall not be interpreted as providing criteria for respiratory protection.

**1.1.5** This standard shall not be interpreted as providing criteria for protection from chemical and biological terrorism agents.

**1.1.6** Certification of emergency medical garments, emergency medical examination gloves, emergency medical work gloves, emergency medical footwear, emergency medical footwear covers, or emergency medical face protection devices, or cleaning gloves to the requirements of this standard shall not preclude certification to additional appropriate standards where the garments, gloves, footwear, or face protection devices meet all applicable requirements of each standard.

**1.1.7** This standard shall not be construed as addressing all of the safety concerns, if any, associated with its use. It shall be the responsibility of the persons and organizations that use this standard to establish safety and health practices and determine the applicability of regulatory limitations prior to use of this standard.

**1.1.8** Nothing herein shall restrict any jurisdiction or manufacturer from exceeding these minimum requirements.

**1.2 Purpose.**

**1.2.1\*** The purpose of this standard shall be to establish a minimum level of protection from contact with blood and body fluid-borne pathogens for personnel performing patient care during emergency medical operations.

**1.2.2** To achieve this purpose, this standard shall establish minimum requirements for garments, gloves, footwear, and face protection devices to minimize skin and mucous membrane contact with blood and body fluid-borne pathogens for fire and emergency services personnel.

**1.2.3** Controlled laboratory tests used to determine compliance with the performance requirements of this standard shall not be deemed as establishing performance levels for all situations to which personnel can be exposed.

**1.2.4** This standard shall not be interpreted or used as a detailed manufacturing or purchase specification but shall be permitted to be referenced in purchase specifications as minimum requirements.

**1.3 Application.**

**1.3.1** This standard shall apply to the design, manufacturing, and certification of new emergency medical garments, emergency medical examination gloves, emergency medical work gloves, emergency medical footwear and footwear covers, emergency medical face protection devices, and cleaning gloves.

**1.3.2** This edition of NFPA 1999 shall not apply to any emergency medical operations protective clothing manufactured to previous editions of this standard.

**1.3.3** This standard shall not apply to any emergency medical operations protective clothing manufactured to the requirements of any other standard.

**1.3.4** This standard shall not apply to respiratory protection for emergency medical operations as such requirements are specified by NIOSH in 42 CFR 84 and OSHA in 29 CFR 1910.134 and 29 CFR 1910.1030.

**1.3.5** This standard shall not apply to protective clothing for chemical and biological terrorism incidents as such requirements are specified in NFPA 1994, *Standard on Protective Ensembles for Chemical/Biological Terrorism Incidents*.

**1.3.6** This standard shall not apply to the use of emergency medical protective clothing; such use requirements are specified in NFPA 1500, *Standard on Fire Department Occupational Safety and Health Program*, and NFPA 1581, *Standard on Fire Department Infection Control Program*.

**1.3.7** The requirements of this standard shall not apply to accessories that could be attached to any emergency medical protective clothing unless specifically addressed herein.

**1.4 Units.**

**1.4.1** In this standard, values for measurement are followed by an equivalent in parentheses, but only the first stated value shall be regarded as the requirement.

**1.4.2** Equivalent values in parentheses shall not be considered as the requirement as these values might be approximate.

**Chapter 2 Referenced Publications**

**2.1 General.** The documents or portions thereof listed in this chapter are referenced within this standard and shall be considered part of the requirements of this document.

**2.2 NFPA Publications.** National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101.

NFPA 1500, *Standard on Fire Department Occupational Safety and Health Program*, 2002 edition.

NFPA 1581, *Standard on Fire Department Infection Control Program*, 2000 edition.

NFPA 1994, *Standard on Protective Ensembles for Chemical/Biological Terrorism Incidents*, 2001 edition.

NFPA 1999, *Standard on Protective Clothing for Emergency Medical Operations*, 1997 edition.

### 2.3 Other Publications.

**2.3.1 AATCC Publications.** American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, NC 27709.

AATCC 22, *Water Repellency: Spray Test*, 1996.

AATCC 70, *Test Method for Water Repellency: Tumble Jar Dynamic Absorption Test*, 1988.

**2.3.2 ANSI Publication.** American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036.

ANSI Z41, *Standard for Personal Protection — Protective Footwear*, 1999.

**2.3.3 ASTM Publications.** American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959.

ASTM B 117, *Standard Practice for Operating Salt Spray (Fog) Apparatus*, 1997.

ASTM D 412a, *Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers — Tension*, 1998.

ASTM D 573, *Standard Test Method for Rubber-Deterioration in an Air Oven*, 1999.

ASTM D 751, *Standard Test Methods for Coated Fabrics*, 2000.

ASTM D 1630, *Test Method for Rubber Property-Abrasion Resistance (Footwear Abrader)*, 2000.

ASTM D 2582, *Standard Test Method for Puncture-Propagation Tear Resistance of Plastic Film and Thin Sheetings*, 2000.

ASTM D 3884, *Standard Test Method for Abrasion Resistance of Textile Fabrics (Rotary Platform, Double-Head Method)*, 1992.

ASTM D 4966, *Standard Test Method for Abrasion Resistance of Textile Fabrics (Martindale Abrasion Test Method)*, 1998.

ASTM D 5151, *Standard Test Method for Detection of Holes in Medical Gloves*, 1999.

ASTM D 5598, *Standard Test Method for the Tearing of Fabrics by Trapezoid Procedure*, 1996.

ASTM D 5712, *Standard Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method*, 1999.

ASTM D 5733, *Standard Test Method for the Tearing of Nonwoven Fabrics by the Trapezoidal Procedure*, 1999.

ASTM F 489, *Standard Test Method for Static Coefficient of Friction of Shoe Sole and Heel Materials as Measured by the James Machine*, 1996.

ASTM F 739a, *Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases Under Conditions of Continuous Contact*, 1999.

ASTM F 1342, *Standard Test Method for Protective Clothing Material Resistance to Puncture*, 1996.

ASTM F 1359a, *Standard Test Method for Liquid Penetration Resistance Integrity of Protective Clothing or Protective Ensembles Under a Shower Spray While on a Mannequin*, 1999.

ASTM F 1671, *Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System*, 1997.

ASTM F 1790, *Test Methods for Measuring Cut Resistance of Materials Used in Protective Clothing*, 1997.

ASTM F 1862, *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*, 2000.

ASTM F 1868, *Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate*, 1998.

ASTM F 2010, *Standard Test Method for Evaluation of Glove Effects on Wearer Hand Dexterity Using a Modified Pegboard Test*, 2000.

**2.3.4 EN Publications.** European Standard, BSI, Linford Wood, Milton Keynes MK14 6LE, U.K.

EN 420, *General requirements for gloves*, 1994.

EN 455-2, *Medical gloves for single use — Part 2: Requirements and testing for physical properties*, 2000.

**2.3.5 FIA Publication.** Footwear Industries of America, 1420 K Street, NW, Suite 600, Washington, DC 20005.

FIA Standard 1209, *Whole Shoe Flex*, 1984.

**2.3.6 GSA Publication.** General Services Administration, Specifications Activity, Printed Materials Supply Division, Building 197, Naval Weapons Plant, Washington, DC 20407.

Federal Test Method Standard 191A, *Textile Test Methods*, 20 July 1978.

**2.3.7 ISO Publications.** International Standards Organization, 1 rue de Varembe, Case Postale 56, CH-1211 Genève 20, Switzerland.

ISO 27, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*, 1983.

ISO 65, *General requirements for bodies operating product certification systems*, 1996.

ISO 2859-1, *Sampling procedures for inspection by attributes. Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*, 1999.

ISO 9001, *Quality management systems — requirements*, 2000.

ISO 9001, *Quality systems — model for quality assurance in design, development, production, installation, and servicing*, 1994.

ISO 9002, *Quality systems — model for quality assurance in production, installation, and servicing*, 1994.

ISO 17025, *General requirements for the competence of testing and calibration laboratories*, 1999.

**2.3.8 Psychological Corporation Publication.** Psychological Corporation, 555 Academic Court, San Antonio, TX 78204.

*Crawford Small Parts Dexterity Test*, 1981.

**2.3.9 U.S. Government Publications.** Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Title 21, Code of Federal Regulations, Part 880, “Medical Devices; Patient Examination Glove; Revocation of Exemptions from the Premarket Notification Procedures and the Current Good Manufacturing Practice Regulations; Final Rule,” 13 January 1989.

Title 29, Code of Federal Regulations, Part 1910.13, “General Requirements of Subpart I, Personal Protective Equipment,” 27 August 1971.

Title 29, Code of Federal Regulations, Part 1910.1030, “Protecting Health Care Workers from Occupational Exposure to Blood-Borne Pathogens,” 6 March 1992.

### Chapter 3 Definitions

**3.1 General.** The definitions contained in this chapter shall apply to the terms used in this standard. Where terms are not included, common usage of the terms shall apply.

#### 3.2 NFPA Official Definitions.

**3.2.1\* Approved.** Acceptable to the authority having jurisdiction.

**3.2.2\* Authority Having Jurisdiction (AHJ).** The organization, office, or individual responsible for approving equipment, materials, an installation, or a procedure.

**3.2.3 Labeled.** Equipment or materials to which has been attached a label, symbol, or other identifying mark of an organization that is acceptable to the authority having jurisdiction and concerned with product evaluation, that maintains periodic inspection of production of labeled equipment or materials, and by whose labeling the manufacturer indicates compliance with appropriate standards or performance in a specified manner.

**3.2.4\* Listed.** Equipment, materials, or services included in a list published by an organization that is acceptable to the authority having jurisdiction and concerned with evaluation of products or services, that maintains periodic inspection of production of listed equipment or materials or periodic evaluation of services, and whose listing states that either the equipment, material, or service meets appropriate designated standards or has been tested and found suitable for a specified purpose.

**3.2.5 Shall.** Indicates a mandatory requirement.

**3.2.6 Should.** Indicates a recommendation or that which is advised but not required.

**3.2.7 Standard.** A document, the main text of which contains only mandatory provisions using the word “shall” to indicate requirements and which is in a form generally suitable for mandatory reference by another standard or code or for adoption into law. Nonmandatory provisions shall be located in an appendix or annex, footnote, or fine-print note and are not to be considered a part of the requirements of a standard.

#### 3.3\* General Definitions.

**3.3.1 Accessories.** An item, or items, that are attached to the certified product that are not necessary to meet the requirements of the standard.

**3.3.2 Arch.** The bottom curve of the foot from the heel to the ball.

**3.3.3 Barrier Layer.** The layer of garment material, glove material, footwear material, or face protection device material designated as providing blood and body fluid-borne pathogen resistance.

**3.3.4 Biological Terrorism Agents.** Biological materials that are capable of causing an acute disease or long-term damage to the human body.

**3.3.5 Blood and Body Fluid-Borne Pathogen.** An infectious bacteria or virus carried in human, animal, or clinical body fluids, organs, or tissues.

**3.3.6 Body Fluids.** Fluids that are produced by the body, including, but not limited to, blood, semen, mucus, feces, urine, vaginal secretions, breast milk, amniotic fluid, cerebrospinal fluid, synovial fluid, and pericardial fluid.

**3.3.7 Certification/Certified.** A system whereby a certification organization determines that a manufacturer has demonstrated the ability to produce a product that complies with the requirements of this standard, authorizes the manufacturer to use a label on listed products that comply with the requirements of this standard, and establishes a follow-up program conducted by the certification organization as a check on the manufacturer to determine compliance with the requirements of this standard.

**3.3.8 Certification Organization.** An independent, third-party organization that determines product compliance with the requirements of this standard with a labeling/listing/follow-up program.

**3.3.9\* Cleaning Glove.** Multipurpose glove, not intended for emergency patient care, that provides a barrier against body fluids, cleaning fluids, and disinfectants and limited physical protection to the wearer during cleaning or care of emergency medical clothing and equipment.

**3.3.10 Compliance/Compliant.** Meeting or exceeding all applicable requirements of this standard.

**3.3.11 Compliant Product.** Product that is covered by this standard and has been certified as meeting all applicable requirements of this standard that pertain to the product.

**3.3.12 Component(s).** Any material, part, or subassembly used in the construction of the compliant product.

**3.3.13 Emergency Medical Examination Glove.** An item of emergency medical protective clothing that is designed and configured to provide barrier protection to the wearer’s hand to at least the wrist. (*See also Emergency Medical Work Glove.*)

**3.3.14 Emergency Medical Face Protection Device.** An item of emergency medical protective clothing that is designed and configured to provide barrier protection to the wearer’s face or head.

**3.3.15 Emergency Medical Footwear.** An item of emergency medical protective clothing that is designed and configured to provide barrier protection to the wearer’s feet.

**3.3.16 Emergency Medical Footwear Cover.** An item of emergency medical protective clothing designed and configured to be worn over standard footwear to provide barrier and physical protection to the wearer's feet.

**3.3.17\* Emergency Medical Garment.** An item of emergency medical protective clothing designed and configured as a single garment or an assembly of multiple garments to provide barrier protection to the wearer's upper and lower torso, excluding the hands, face, and feet.

**3.3.18 Emergency Medical Operations.** Delivery of emergency patient care and transportation prior to arrival at a hospital or other health care facility.

**3.3.19 Emergency Medical Protective Clothing.** Multiple items of protective clothing, including garments, examination gloves, work gloves, cleaning gloves, footwear and footwear covers, and face protection devices designed and configured to provide limited physical protection and barrier protection against blood and body fluid-borne pathogens contact with the wearer's body during delivery of emergency patient care and other emergency medical functions. (See also *Cleaning Glove*, *Emergency Medical Examination Glove*, *Emergency Medical Face Protection Device*, *Emergency Medical Footwear*, *Emergency Medical Footwear Cover*, *Emergency Medical Garment*, and *Emergency Medical Work Glove*.)

**3.3.20 Emergency Medical Work Glove.** An item of emergency medical protective clothing that is designed and configured to provide physical and barrier protection to the wearer's hand and wrist. (See also *Emergency Medical Examination Glove*.)

**3.3.21 Emergency Patient Care.** The provision of treatment to patients, including first aid, cardiopulmonary resuscitation, basic life support, advanced life support, and other medical procedures that occur prior to arrival at a hospital or other health care facility.

**3.3.22 Examination Glove.** An abbreviated term for emergency medical examination glove. (See *definition for Emergency Medical Examination Glove*.)

**3.3.23 Face Protection Device.** An abbreviated term for emergency medical face protection device. (See *definition for Emergency Medical Face Protection Device*.)

**3.3.24 Follow-Up Program.** The sampling, inspections, tests, or other measures conducted by the certification organization on a periodic basis to determine the continued compliance of labeled and listed products that are being produced by the manufacturer to the requirements of this standard.

**3.3.25 Footwear.** An abbreviated term for emergency medical footwear (See *definition for Emergency Medical Footwear*.)

**3.3.26 Footwear Cover.** An abbreviated term for emergency medical footwear cover. (See *definition for Emergency Medical Footwear Cover*.)

**3.3.27 Garment.** An abbreviated term for emergency medical garment. (See *definition for Emergency Medical Garment*.)

**3.3.28 Garment Closure.** The garment component designed and configured to allow the wearer to enter (don) and exit (doff) the garment.

**3.3.29 Garment Closure Assembly.** The combination of the garment closure and the seam attaching the garment closure to the garment, excluding any protective flap or cover.

**3.3.30 Garment Material.** All material layers used in the construction of emergency medical garments other than patches, reinforcements, and visibility markings.

**3.3.31 Glove.** See *Cleaning Glove*, *Emergency Medical Examination Glove*, and *Emergency Medical Work Glove*.

**3.3.32 Glove Body.** The part of the glove that extends from the tip of the fingers to 25 mm (1 in.) beyond the wrist crease.

**3.3.33 Glove Material.** All material layers used in the construction of gloves.

**3.3.34 Hazardous Materials.** Any solid, liquid, gas, or mixture thereof that can potentially cause harm to the human body through respiration, ingestion, skin absorption, or contact.

**3.3.35 Insole.** The inner part of the protective footwear upon which the foot rests and that conforms to the bottom of the foot.

**3.3.36 Manufacturer.** The person or persons, company, firm, corporation, partnership, or other organization responsible for turning the raw materials or components into a certified product for use.

**3.3.37 Model.** The collective term used to identify a group of individual elements or items of the same basic design and components from a single manufacturer produced by the same manufacturing and quality assurance procedures that are covered by the same certification.

**3.3.38 Package.** The wrapping or enclosure directly containing a glove or face protection device.

**3.3.39 Package Product Label.** The product label that is printed on or attached to a package containing one or more compliant products. (See also *Product Label*.)

**3.3.40 Product Label.** A label or marking affixed to each compliant garment, glove, or face protection device by the manufacturer. Such labels contain compliance statements, certification statements, general information, care, maintenance, or similar data. The product label is not the certification organization's label, symbol, or identifying mark; however, the certification organization's label, symbol, or identifying mark is attached to or a part of the product label. (See also *Labeled and Package Product Label*.)

**3.3.41 Safety Alert.** The action by which a manufacturer identifies a specific compliant product or a compliant product component, provides notice to users of the compliant product, and informs the marketplace and distributors of potential safety concerns regarding the product or component.

**3.3.42 Sample.** An amount of the material, product, or assembly to be tested that is representative of the item as a whole. (See also *Specimen*.)

**3.3.43 Seam.** Any permanent attachment of two or more materials in a line formed by joining the separate material pieces.

**3.3.44\* Single-Use Item.** Items that are designed to be used one time and then disposed of.

**3.3.45 Specimen.** The conditioned element, item, component, or composite that is tested. Specimens are taken from samples. (See also *Sample*.)

**3.3.46 Splash-Resistant Eyewear.** Safety glasses, prescription eyewear with protective side shields, goggles, or chin-length face shields that, when worn properly, provide limited protection against splashes, spray, spatters, or droplets of body fluids.

**3.3.47 Trace Number.** A code that can be used to retrieve the production history of a product (e.g., a lot or serial number).

**3.3.48 Upper.** That part of the protective footwear including, but not limited to, the toe, vamp, quarter, shaft, collar, and throat; but not including the sole with heel, puncture-resistant device, and insole.

**3.3.49 Wear Surface.** A footwear term for the bottom of the sole, including the heel.

**3.3.50 Work Glove.** An abbreviated term for emergency medical work glove. (*See definition for Emergency Medical Work Glove.*)

## Chapter 4 Certification

### 4.1 General.

**4.1.1** The process of certification for emergency medical operations protective clothing as being compliant with NFPA 1999 shall meet the requirements of Section 4.1, General; Section 4.2, Certification Program; Section 4.3, Inspection and Testing; Section 4.4, Recertification; Section 4.5, ISO Registration for Manufacturers; Section 4.6, Hazards Involving Compliant Product; Section 4.7, Manufacturers' Investigation of Complaints and Returns; and Section 4.8, Manufacturers' Safety Alert and Product Recall Systems.

**4.1.2** All compliant emergency medical operations protective clothing items that are labeled as being compliant with this standard shall meet or exceed all applicable requirements specified in this standard and shall be certified.

**4.1.3** All certification shall be performed by a certification organization that meets at least the requirements specified in Section 4.2, Certification Program, and that is accredited for personal protective equipment in accordance with ISO 65, *General requirements for bodies operating product certification systems*.

**4.1.4** Manufacturers shall not claim compliance with a portion(s) or segment(s) of the requirements of this standard and shall not use the name or identification of this standard, NFPA 1999, in any statements about their respective product(s) unless the product(s) is certified as compliant to this standard.

**4.1.5** All compliant emergency medical operations protective clothing items shall be labeled and listed.

**4.1.6** All compliant emergency medical operations protective clothing items shall also have a product label that meets the requirements specified in Chapter 5.

**4.1.7\*** The certification organization's label, symbol, or identifying mark shall be attached to the product label, shall be part of the product label, or shall be immediately adjacent to the product label.

**4.1.8** The certification organization shall not certify any emergency medical operations protective clothing to the 1997 edition of this standard on or after 1 September 2003.

**4.1.9** The certification organization shall not permit any manufacturer to label any emergency medical operations protective clothing as compliant with the 1997 edition of this standard on or after 1 September 2003.

**4.1.10** The certification organization shall require manufacturers to remove all certification labels and product labels in-

dicating compliance with the 1997 edition of this standard from all emergency medical operations protective clothing that are under the control of the manufacturer on 1 September 2003. The certification organization shall verify this action is taken.

### 4.2 Certification Program.

**4.2.1\*** The certification organization shall not be owned or controlled by manufacturers or vendors of the product being certified.

**4.2.2** The certification organization shall be primarily engaged in certification work and shall not have a monetary interest in the product's ultimate profitability.

**4.2.3** The certification organization shall be accredited for personal protective equipment in accordance with ISO 65, *General requirements for bodies operating product certification systems*.

**4.2.4** The certification organization shall refuse to certify products to this standard that do not comply with all applicable requirements of this standard.

**4.2.5\*** The contractual provisions between the certification organization and the manufacturer shall specify that certification is contingent on compliance with all applicable requirements of this standard.

**4.2.5.1** The certification organization shall not offer or confer any conditional, temporary, or partial certifications.

**4.2.5.2** Manufacturers shall not be authorized to use any label or reference to the certification organization on products that are not compliant with all applicable requirements of this standard.

**4.2.6** The certification organization shall have laboratory facilities and equipment available for conducting proper tests to determine product compliance.

**4.2.6.1** The certification organization's laboratory facilities shall have a program in place and functioning for calibration of all instruments, and procedures shall be in use to ensure proper control of all testing.

**4.2.6.2** The certification organization's laboratory facilities shall follow good practice regarding the use of laboratory manuals, form data sheets, documented calibration and calibration routines, performance verification, proficiency testing, and staff qualification and training programs.

**4.2.7** The certification organization shall require the manufacturer to establish and maintain a quality assurance program that meets the requirements of Section 4.5, ISO Registration for Manufacturers.

**4.2.7.1\*** The certification organization shall require the manufacturer to have a product recall system as part of the manufacturer's quality assurance program.

**4.2.7.2** The certification organization shall audit the manufacturer's quality assurance program to ensure that the quality assurance program provides continued product compliance with this standard.

**4.2.8** The certification organization and the manufacturer shall evaluate any changes affecting the form, fit, or function of the compliant product to determine its continued certification to this standard.

**4.2.9\*** The certification organization shall have a follow-up inspection program of the manufacturing facilities of the com-

pliant product, with at least two random and unannounced visits per 12-month period.

**4.2.9.1** As part of the follow-up inspection program, the certification organization shall select sample product at random from the manufacturer's production line, from the manufacturer's in-house stock, or from the open market.

**4.2.9.2** Sample product shall be inspected and tested by the certification organization to verify the product's continued compliance.

**4.2.10** The certification organization shall have in place a series of procedures, as specified in Section 4.6, Hazards Involving Compliant Product, that address report(s) of situation(s) in which a compliant product is subsequently found to be hazardous.

**4.2.11** The certification organization's operating procedures shall provide a mechanism for the manufacturer to appeal decisions. The procedures shall include the presentation of information from both sides of a controversy to a designated appeals panel.

**4.2.12** The certification organization shall be in a position to use legal means to protect the integrity of its name and label. The name and label shall be registered and legally defended.

### 4.3 Inspection and Testing.

**4.3.1** For both initial certification and recertification of protective clothing, the certification organization shall conduct both inspection and testing as specified in this section.

**4.3.2** All inspections, evaluations, conditioning, and testing for certification or for recertification shall be conducted by the certification organization or a facility accredited by the certification organization for inspections, evaluations, conditioning, and testing in accordance with all requirements pertaining to testing laboratories in ISO 17025, *General requirements for the competence of testing and calibration laboratories*.

**4.3.3** All inspections, evaluations, conditioning, or testing conducted by a product manufacturer shall not be used in the certification or recertification process unless the facility for inspections, evaluations, conditioning, or testing has been accredited by the certification organization in accordance with all requirements pertaining to testing laboratories in ISO 17025, *General requirements for the competence of testing and calibration laboratories*.

**4.3.4** Sampling levels for testing and inspection shall be established by the certification organization and the manufacturer to ensure a reasonable and acceptable reliability at a reasonable and acceptable confidence level that products certified to this standard are compliant, unless such sampling levels are specified herein. This information shall be included in the manufacturer's technical data package.

**4.3.5** Inspection by the certification organization shall include a review of all product labels to ensure that all required label attachment, compliance statements, certification statements, and other product information are at least as specified for the respective protective clothing item in 5.1.1 through 5.1.7.

**4.3.6** Inspection by the certification organization shall include an evaluation of any graphic representations used on product labels as permitted by in 5.1.1 through 5.1.7 to ensure that the symbols are consistent with the worded statements, readily understood, and clearly communicate the intended message.

**4.3.7** Inspection by the certification organization shall include a review of the user information required by Section 5.2, User Information, to ensure that the information has been developed and is available.

**4.3.8** Inspection by the certification organization for determining compliance with the design requirements specified in Chapter 6 shall be performed on whole or complete products.

**4.3.9** Testing conducted by the certification organization in accordance with the testing requirements of Chapter 8, for determining product compliance with the applicable performance requirements specified in Chapter 7, shall be performed on samples representative of materials and components used in the actual construction of the emergency medical protective clothing. The certification organization also shall be permitted to use sample materials cut from a representative product.

**4.3.10** Where certification testing includes a protective clothing item with one or more accessories, the item with each accessory shall be certified as complying with 6.1.7 and 6.1.8, 6.2.4 and 6.2.5, 6.3.5 and 6.3.6, or 6.6.4 and 6.6.5, as applicable.

**4.3.11** Any change in the design, construction, or material of a compliant product shall necessitate new inspection and testing to verify compliance to all applicable requirements of this standard that the certification organization determines can be affected by such change. This recertification shall be conducted before labeling the modified product as being compliant with this standard.

**4.3.12** The certification organization shall not allow any modifications, pretreatment, conditioning, or other such special processes of the product or any product component prior to the product's submission for evaluation and testing by the certification organization.

**4.3.13** The certification organization shall accept from the manufacturer, for evaluation and testing for certification, only product or product components that are the same in every respect to the actual final product or product component.

**4.3.14** The certification organization shall not allow the substitution, repair, or modification, other than as specifically permitted herein, of any product or any product component during testing.

**4.3.15** The certification organization shall not allow test specimens that have been conditioned and tested for one method to be reconditioned and tested for another test method unless specifically permitted in the test method.

**4.3.16** The manufacturer shall maintain all design and performance inspection and test data from the certification organization used in the certification of the manufacturer's compliant product. The manufacturer shall provide such data, upon request, to the purchaser or the AHJ.

### 4.4 Recertification.

**4.4.1** All individual items of emergency medical protective clothing that are labeled as being compliant with this standard shall undergo recertification on an annual basis. This recertification shall include inspection and evaluation to all design requirements and testing to all performance requirements as required by this standard on all manufacturer models and components.

**4.4.1.1** Any change that affects the item's performance under the design or performance requirements of this standard shall constitute a different model.

**4.4.1.2** For the purpose of this standard, models shall include each unique pattern, style, or design of an individual item.

**4.4.2** Samples of manufacturer models and components for recertification shall be acquired from the manufacturer or component supplier during random and unannounced visits as part of the follow-up inspection program.

**4.4.3** The manufacturer shall maintain all design and performance inspection and test data from the certification organization used in the recertification of manufacturer models and components. The manufacturer shall provide such data, upon request, to the purchaser or the AHJ.

#### **4.5 ISO Registration for Manufacturers.**

**4.5.1** The manufacturer shall be registered to ISO 9001, *Quality management systems — requirements*, 2000 edition.

**4.5.1.1** Where the manufacturer is already registered to the 1994 edition of ISO 9001, *Quality systems — model for quality assurance in design, development, production, installation, and servicing*, the manufacturer shall be permitted to be registered to the 1994 edition of ISO 9001 until 15 December 2003.

**4.5.1.2** Where the manufacturer is already registered to the 1994 edition of ISO 9002, *Quality systems — model for quality assurance in production, installation, and servicing*, the manufacturer shall be permitted to be registered to the 1994 edition of ISO 9002 until 15 December 2003.

**4.5.1.3** Manufacturers who are currently registered to either the 1994 edition of ISO 9001, *Quality systems — model for quality assurance in design, development, production, installation, and servicing*, or the 1994 edition of ISO 9002, *Quality systems — model for quality assurance in production, installation, and servicing*, shall be permitted to be registered to the 2000 edition of ISO 9001, specified in 4.5.1, at any time prior to 15 December 2003.

**4.5.1.4** Effective not later than 15 December 2003, all manufacturers of compliant emergency medical protective clothing shall be registered to the 2000 edition of ISO 9001, *Quality management systems — requirements*.

**4.5.2** The manufacturer shall provide and operate a quality assurance program.

**4.5.3** The manufacturer's quality assurance program shall include a safety alert and product recall systems that shall meet the requirements specified in Section 4.8, Manufacturers' Safety Alert and Product Recall Systems.

#### **4.6 Hazards Involving Compliant Product.**

**4.6.1\*** The certification organization shall establish procedures to be followed where situation(s) are reported in which a compliant product is subsequently found to be hazardous. These procedures shall comply with the provisions of ISO 27, *Guidelines for corrective action to be taken by a certification body in the event of misuse of its mark of conformity*, and as modified herein.

**4.6.2\*** Where a report of a hazard involved with a compliant product is received by the certification organization, the validity of the report shall be investigated.

**4.6.3** With respect to a compliant product, a hazard shall be a condition, or create a situation, that results in exposing life, limb, or property to an imminently dangerous condition or dangerous condition.

**4.6.4** Where a specific hazard is identified, the determination of the appropriate action for the certification organization

and the manufacturer to undertake shall take into consideration the severity of the hazard and its consequences to the safety and health of users.

**4.6.5** Where it is established that a hazard is involved with a compliant product, the certification organization shall determine the scope of the hazard including products, model numbers, serial numbers, factory production facilities, production runs, and quantities involved.

**4.6.6** The certification organization's investigation shall include, but not be limited to, the extent and scope of the problem as it might apply to other compliant product or compliant product components manufactured by other manufacturers or certified by other certification organizations.

**4.6.7** The certification organization shall also investigate reports of a hazard where compliant product is gaining widespread use in applications not foreseen when the standard was written, such applications in turn being ones for which the product was not certified, and no specific scope of application has been provided in the standard, and no limiting scope of application was provided by the manufacturer in written material accompanying the compliant product at the point of sale.

**4.6.8** The certification organization shall require the manufacturer of the compliant product or the manufacturer of the compliant product component, if applicable, to assist the certification organization in the investigation and to conduct its own investigation as specified in Section 4.7, Manufacturers' Investigation of Complaints and Returns.

**4.6.9** Where the facts indicating a need for corrective action are conclusive and the certification organization's appeal procedures referenced in 4.2.11 have been followed, the certification organization shall initiate corrective action immediately, provided there is a manufacturer to be held responsible for such action.

**4.6.10** Where the facts are conclusive and corrective action is indicated, but there is no manufacturer to be held responsible, such as when the manufacturer is out of business or the manufacturer is bankrupt, the certification organization shall immediately notify relevant government and regulatory agencies and issue a notice to the user community about the hazard.

**4.6.11\*** Where the facts are conclusive and corrective action is indicated, the certification organization shall take one or more of the following corrective actions:

- (1) Notification of parties authorized and responsible for issuing a safety alert when, in the opinion of the certification organization, such a notification is necessary to inform the users
- (2) Notification of parties authorized and responsible for issuing a product recall when, in the opinion of the certification organization, such a recall is necessary to protect the users
- (3) Removal of the mark of certification from the product

**4.6.11.1** Where a hazardous condition exists and it is not practical to implement 4.6.11(1), (2), or (3) or the responsible parties refuse to take corrective action, the certification organization shall notify relevant government and regulatory agencies and issue a notice to the user community about the hazard.

**4.6.12** The certification organization shall provide a report to the organization or individual identifying the reported hazardous condition and notify them of the corrective action indicated, if corrective action is indicated.

**4.6.13\*** Where a change to an NFPA standard(s) is felt to be necessary, the certification organization shall also provide a copy of the report and corrective actions indicated to the NFPA, and submit either a public proposal for a proposed change to the next revision of the applicable standard or a proposed Temporary Interim Amendment (TIA) to the current edition of the applicable standard.

#### **4.7 Manufacturers' Investigation of Complaints and Returns.**

**4.7.1** Manufacturers shall provide corrective action in accordance with ISO 9001, *Quality management systems — requirements*, for investigating written complaints and returned products.

**4.7.2** Manufacturers' records of returns and complaints related to safety issues shall be retained for at least 5 years.

**4.7.3** Where the manufacturer discovers, during the review of specific returns or complaints, that a compliant product or compliant product component can constitute a potential safety risk to end users that is possibly subject to a safety alert or product recall, the manufacturer shall immediately contact the certification organization and provide all information about their review to assist the certification organization with its investigation.

#### **4.8 Manufacturers' Safety Alert and Product Recall Systems.**

**4.8.1** Manufacturers shall establish a written safety alert system and a written product recall system that describes the procedures to be used in the event that it decides, or is directed by the certification organization, to either issue a safety alert or conduct a product recall.

**4.8.2** The manufacturers' safety alert and product recall systems shall provide the following:

- (1) Establishment of a coordinator and responsibilities by the manufacturer for the handling of safety alerts and product recalls
- (2) A method of notifying all dealers, distributors, purchasers, users, and the NFPA about the safety alert or product recall that can be initiated within 1 week following the manufacturer's decision to issue a safety alert or to conduct a product recall, or after the manufacturer has been directed by the certification organization to issue a safety alert or conduct a product recall
- (3) Techniques for communicating accurately and understandably the nature of the safety alert or product recall and, in particular, the specific hazard or safety issue found to exist
- (4) Procedures for removing product that is recalled and documenting the effectiveness of the product recall
- (5) A plan for either repairing, replacing, or compensating purchasers for returned product

## **Chapter 5 Labeling and Information**

### **5.1 Product Label Requirements.**

#### **5.1.1 Emergency Medical Garments Product Label Requirements.**

**5.1.1.1** Each garment shall have a product label or labels permanently and conspicuously located inside each garment

when the garment is properly assembled with all layers and components in place.

**5.1.1.2** Multiple label pieces shall be permitted in order to carry all statements and information required to be on the product label; however, all label pieces comprising the entire product label shall be located adjacent to each other.

**5.1.1.3** All worded portions of the required product label shall be at least in English.

**5.1.1.4** Symbols and other pictorial graphic representations shall be permitted to be used to supplement worded statements on the product label(s).

**5.1.1.5** The product label of each garment that has been designated by the manufacturer as a single-use garment, in accordance with 6.1.1, shall have the following statement printed in letters that are at least 2 mm ( $\frac{1}{16}$  in.) high:

**“THIS GARMENT IS FOR SINGLE USE ONLY.”**

**5.1.1.6** The certification organization's label, symbol, or identifying mark and at least the following statement shall be legibly printed on the product label. All letters shall be at least 2 mm ( $\frac{1}{16}$  in.) high.

**“THIS (insert name of garment type) MEETS THE EMERGENCY MEDICAL GARMENT REQUIREMENTS OF NFPA 1999, STANDARD ON PROTECTIVE CLOTHING FOR EMERGENCY MEDICAL OPERATIONS, 2003 EDITION. DO NOT REMOVE THIS LABEL.”**

**5.1.1.7** The following information shall also be printed legibly on the product label. All letters shall be at least 2 mm ( $\frac{1}{16}$  in.) high.

- (1) Manufacturer's name, identification, or designation
- (2) Manufacturer's address
- (3) Country of manufacture
- (4) Garment model and style
- (5) Trace number
- (6) Materials of construction
- (7) Month and year of manufacture, not coded
- (8) Size

#### **5.1.2 Emergency Medical Examination Gloves Product Label Requirements.**

**5.1.2.1** The package containing the smallest number of glove items from which the user withdraws the product for use shall have a package product label.

**5.1.2.2** The package product label shall be permanently and conspicuously located on the outside of the package or printed on the package. This label shall not be removed, obscured, or otherwise mutilated by the opening of the package when the package is opened as intended.

**5.1.2.3** The certification organization's label, symbol, or identifying mark and at least the following statement shall be legibly printed on the product label in letters at least 3 mm ( $\frac{3}{16}$  in.) high.

**“THIS GLOVE MEETS THE EMERGENCY MEDICAL EXAMINATION GLOVE REQUIREMENTS OF NFPA 1999, STANDARD ON PROTECTIVE CLOTHING FOR EMERGENCY MEDICAL OPERATIONS, 2003 EDITION. THIS GLOVE IS FOR SINGLE USE ONLY.”**