1. Revise the title to read as follows:

New Title: Standard on Protective Clothing and Ensembles for Emergency Medical Operations

2. Add new sections to read as follows:

1.1.2 This standard shall also specify additional minimum design, performance, testing, documentation, and certification as requirements for single-use and multiple-use emergency medical protective ensembles comprising the protective clothing items described in 1.1.1 for protection from airborne and liquid-borne pathogens. [renumber current 1.1.2 and successive paragraphs]

1.2.2 The purpose of this standard shall also be to establish a minimum level of whole body protection for emergency services personnel and medical first receivers from airborne and liquid-borne pathogens. [renumber current 1.2.2 and successive paragraphs]

3. Revise 1.3.1 and 1.3.4 to read as follows:

1.3.1* This standard shall apply to the design, performance, testing, and certification of new emergency medical garments; emergency medical examination gloves; emergency medical helmets; emergency medical cleaning/utility gloves; emergency medical work gloves; emergency medical facemasks; emergency medical face protection devices; emergency medical footwear and footwear covers; medical care facility footwear; and single-use and multiple-use emergency protective ensembles; and shall apply to ensembles and ensemble elements for the additional [C]BRN protection from specified biological and radiological terrorism agents.

1.3.4* Other than the certification of emergency medical protective ensembles to the single-use, multiple-use, and [C]BRN ensemble requirements of this standard, this standard shall not apply to respiratory protection in emergency medical operations as such requirements are specified by NIOSH in 42 CFR 84, and by OSHA in 29 CFR 1910.134 and 29 CFR 1910.1030.

4. Add new referenced publications to Section 2.2:


5. Add new referenced publication to 2.3.3:


6. Revise Section 3.3 General Definitions and associated Annex items to read as follows:
3.3.8 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, sweat, vomit, and pericardial fluid.

3.3.23* Emergency Medical Cleaning/Utility Glove. Multipurpose glove, not for emergency patient care, that provides a barrier against body fluids, cleaning fluids, and disinfectants and limited physical protection to the wearer.

A.3.3.23 Emergency Medical Cleaning/Utility Glove. Emergency medical cleaning/utility gloves are not intended to be used as emergency medical examination gloves or emergency medical work gloves. Emergency medical cleaning/utility gloves are moderately thick rubber gloves and are not intended and should not be used have limited application for emergency patient care because these gloves might not provide adequate hand function in terms of dexterity and tactility for some medical tasks, such as palpitation of a pulse or setting an IV. Emergency medical cleaning/utility gloves also do not provide the necessary levels of physical protection that are met by emergency medical work gloves, which are suitable for extrication and other emergency medical operations where significant physical hazards might be faced. However, emergency medical cleaning/utility gloves are more robust and provide greater resistance to physical hazards compared to emergency medical examination gloves and can be suitable for body recovery and other medical functions where blood and other body fluids could be encountered outside the provision of emergency patient care.

3.3.28 Emergency Medical Footwear Cover. An element or item of emergency medical protective ensemble or protective clothing designed and configured to be worn over standard footwear to provide barrier and limited physical protection to the wearer’s feet.

7. Add new definitions and associated Annex items to Section 3.3 as follows:

3.3.XX Elements(s). See 3.3.XX, Ensemble Elements.

3.3.XX Ensemble Elements. The compliant products that provide protection to the upper and lower torso, arms, legs, head, hands, and feet.

3.3.XX* Single-Use Emergency Medical Protective Ensemble. Multiple elements of compliant protective clothing and equipment providing full body coverage, intended for a single use, that when worn together provide protection from some risks, but not all risks, of emergency medical operations.

A.3.3.XX Single-Use Emergency Medical Protective Ensemble. Single-use medical protective ensembles are intended for applications where no exposed skin is permitted and the majority of the elements, including the garment, gloves, footwear covers, and certain eye and face protection devices are disposable after use. These ensembles include a single-use medical protective garment that may be a coverall with or without a hood, or separate garments that can include a hood. These ensembles include two pairs of any NFPA 1999-certified single-use emergency medical examination gloves. The use of double gloving is a precaution intended to offer additional protection and minimize the risk of cross-contamination during doffing. The effect of the double glove system on hand function is not evaluated as part of this standard. These ensembles are also either configured with multiple-use emergency medical or multiple-use medical care facility footwear or single-use emergency medical footwear covers worn over standard footwear. Footwear certified to NFPA 1951, NFPA 1971, NFPA 1991, NFPA 1992, or NFPA 1994 may be substituted since these items have demonstrated material, seam, and overall product biopenetration resistance, integrity, and physical hazard resistance that is equivalent or greater than multiple-use emergency medical footwear specified in NFPA 1999. If single-use footwear covers are used as part of the ensemble, then it is recommended that additional physical foot protection be achieved by the use of footwear that complies with ASTM F2413. Garments that include bootie foot extensions as part of their construction can be used with any footwear that meets ASTM F2413. Eye and face protection is provided by a combination of emergency medical eye and face protection devices that may include goggles and faceshields that comply with ANSI Z87.1 requirements and respirators that are approved by NIOSH as N95 filtering facepieces that further demonstrate fluid resistance. Single-use medical protective ensembles may also be configured with the types of respirators established for multiple-use protective ensembles.
### 3.3.XX* Multiple-Use Emergency Medical Protective Ensemble

Multiple elements of compliant protective clothing and equipment providing full body coverage, intended for multiple use, that when worn together provide protection from some risks, but not all risks, of emergency medical operations.

### A.3.3.XX Multiple-Use Emergency Medical Protective Ensemble

Multiple-use medical protective ensembles are intended for high-risk applications where no exposed skin is permitted and the majority of the elements can be reused, if properly cleaned and decontaminated. High-risk applications include situations where there is an increased likelihood of contacting individuals or contaminated items where exposure to contaminated fluids can occur. The risk of exposure increases based on the amount and reliability of information available if an individual is infected with a liquid-borne pathogen, the expected proximity of the wearer to the affected individuals, the duration for which the wearer may be in proximity with an infected individual, and the likelihood for any exposure with contaminated liquids or waste as part of the operations. Multiple-use protective ensembles further offer a higher degree of ruggedness and resistance to physical hazards. These ensembles consist of a multiple-use emergency medical garment that may be a coverall with or without a hood, or multiple garments that can include a hood. Hand protection is provided by the combination of a single-use examination glove worn underneath either a single-use emergency medical cleaning/utility glove or a multiple-use emergency medical work glove. Foot protection is provided by multiple-use emergency medical or multiple-use medical care facility footwear. Footwear certified to NFPA 1951, NFPA 1971, NFPA 1991, NFPA 1992, or NFPA 1994 may be substituted since these items have demonstrated material, seam, and overall product biopenetration resistance, integrity, and physical hazard resistance that is equivalent or greater than multiple-use emergency medical footwear specified in NFPA 1999. Garments that include bootie foot extensions as part of their construction can be used with any footwear that meets ASTM F2413. Single-use emergency medical footwear covers may be provided but are not required for the certification of these ensembles. These covers are suggested for minimizing contamination to more durable, reusable footwear. Eye or face protection is provided by either (1) a NIOSH-approved full facepiece air-purifying respirator (APR) with P100 filters, or (2) a NIOSH-approved appropriate tight or loose fitting powered air-purifying respirator (PAPR) with a protection level of HE. Alternative respiratory protective equipment can include CBRN APR, CBRN PAPR, or SCBA that is certified to NFPA 1981.

### 3.3.XX Storage Life

The life expectancy of protective clothing and ensemble elements from the date of manufacture when it is only stored and inspected and has undergone proper care and maintenance in accordance with the manufacturer’s instructions, but not used, donned, doffed, or repaired.

8. In Table 4.4.1, change first row first column to read “Multiple-use emergency medical garments and ensembles”, and first two instances of “Garment” in fourth column to “Garment or Ensemble”

9. In Table 4.4.1, change second row first column to read “Single-use emergency medical garments and ensembles”, and first two instances of “Garment” in fourth column to “Garment or Ensemble”; change the ninth line in the second row second column from “Total Heat Loss Test (8.32)” to “Moisture Vapor Transmission Rate Test (8.28)”.

10. In Table 4.4.1, delete ninth line starting “Glove Donning Test (8.28)” from fifth row.

11. Revise 5.1.2 and 5.1.2.2 to read as follows:

#### 5.1.2 Single-Use Emergency Medical Protective Garment and Ensemble Product Label Requirements

5.1.2.2 The product label shall have the certification organization’s label, symbol, or identifying mark and at least the following statement legibly printed on the product label:

“THIS GARMENT [insert the term GARMENT or ENSEMBLE here] IS FOR SINGLE USE ONLY!”
12. Add a new 5.1.2.4 as follows:

5.1.2.4 Where the garment is certified as part of a single-use emergency medical protective ensemble, the following additional language shall be provided:

**TO PROVIDE FULL BODY PROTECTION, THE FOLLOWING ADDITIONAL ITEMS MUST BE WORN AS PART OF THIS ENSEMBLE.**
[insert items including manufacturer name and model or style number.]

13. Revise 5.1.3 to read as follows:

5.1.3 Multiple-Use Emergency Medical Protective Garment and Ensemble Product Label Requirements.

5.1.3.2 The product label shall have the certification organization’s label, symbol, or identifying mark and at least the following statement legibly printed on the product label:

**“THIS GARMENT [insert the term GARMENT or ENSEMBLE here] MEETS THE MULTIPLE-USE EMERGENCY MEDICAL GARMENT [insert the term GARMENT or ENSEMBLE here] REQUIREMENTS OF NFPA 1999, STANDARD ON PROTECTIVE CLOTHING AND ENSEMBLES FOR EMERGENCY MEDICAL OPERATIONS, 2013 EDITION.**

**DO NOT REMOVE THIS LABEL!”**

14. Add a new 5.1.3.6 as follows:

5.1.3.6 Where the garment is certified as part of a multiple-use emergency medical protective ensemble, the following additional language shall be provided:

**TO PROVIDE FULL BODY PROTECTION, THE FOLLOWING ADDITIONAL ITEMS MUST BE WORN AS PART OF THIS ENSEMBLE.**
[insert items including manufacturer name and model or style number.]

15. Revise 5.2.2 to read as follows:

5.2.2 For protective ensembles, or protective ensembles certified to the [C]BRN requirements, the manufacturer shall provide the following additional instruction and information with each ensemble:

(1) A statement that only the ensemble and the specific items with which the ensemble has been certified shall be worn together to ensure that the [C]BRN protection is provided.

(2) A list of the specific items and interface components that shall be worn as part of the [C]BRN ensemble, including each type of NIOSH CBRN APR, CBRN PAPR, or CBRN SCBA, or approved breathing system(s) that the ensemble has been certified with.

(3) Specific limitations associated with the use of the ensemble for a response involving biological threats or [C]BRN hazards, including but not limited to a statement that protection against radiological and nuclear hazards is limited to particulates only.

(4) Specific care and maintenance provisions associated with properly maintaining the unique performance properties of the ensemble, its items, or interface components.
(5) A statement that, if the ensemble is used in an emergency involving biological or [C]BRN hazards, the ensemble shall be retired from use and not be further used.

16. Add a new 5.2.3, A.5.2.3 and 5.2.4 as follows

5.2.3* For single-use or multiple-use protective ensembles, the following additional instructions and information shall be provided:
   (1) The specific sequence and requirements for donning each item of the ensemble.
   (2) The specific type of tape and detailed instructions for its application if specified for single-use protective ensembles only.
   (3) Specific recommended methods for cleaning each element where elements are combined or attached.
   (4) Specific considerations for decontamination to be employed during the doffing of ensemble elements.
   (5) The specific sequence, precautions, and requirements for doffing each item of the ensemble, when contaminated with body fluids, for the avoidance of cross-contamination of the individual wearer, other ensemble items, and the outside environment.

A.5.2.3 The use of protective ensembles for protection against liquid-borne pathogens requires further information from the manufacturer that describes the order for putting on and taking off ensemble elements and how individual items should be put on and taken off to create and preserve protection to interface areas. Where tape is used as part of single-use ensembles, only specific tapes recommended by the manufacturers should be used and its application should be consistent with detailed manufacturer instructions, including how it is removed. This information is important for avoiding cross-contamination of the individual wearer, ensemble elements, and the environment. When elements are integrated through interfaces, specific instructions should be provided that address whether specific care is needed for cleaning of these items. For example, if gloves are attached, then any variation in the cleaning procedures for this type of interface should be addressed. Similarly, considerations for decontamination of the ensemble should be provided that address any restrictions for how ensemble elements should be decontaminated, such as whether bleach or liquid-based disinfectants should be used. The manufacturer should indicate that their procedures may need to be adapted for specific missions and applications.

5.2.4 The manufacturer shall state the storage life for all single-use and multiple-use protective elements that have been certified as part of an ensemble, and shall include the storage life and the basis for recommended storage life as part of the user information.

17. Add a new section 6.1.1.8 and associated Annexitems as follows:

6.1.1.8* Where the garment is certified as part of a single-use emergency medical protective ensemble to meet the requirements of Section 7.1.1.1, the manufacturer shall specify the use of any NFPA 1999-certified single-use emergency medical examination gloves (2 pairs – inner and outer), specific emergency medical footwear or emergency medical footwear covers, specific eye and face protection devices, and specific filtering facepiece respirator.


6.1.1.8.2 If the garment is configured with a bootie that is constructed of garment material and covers the wearer’s foot and ankle, then any footwear meeting ASTM F2413 shall be permitted to be specified in conjunction with the garment.

6.1.1.8.3* Eye and face protection devices shall be permitted to include goggles and faceshields that only meet ANSI Z87.1 requirements when marked for splash/droplet use.

6.1.1.8.4* The filtering facepiece respirator shall be a NIOSH-approved filtering facepieces in accordance with Title 42, Code of Federal Regulations, Part 84, “Approval of Respiratory Protective Devices” that also meets the requirements of
ASTM F2100, *Standard Specification for Performance of Materials Used in Medical Face Masks* or a surgical N95 filtering facepiece respirator that is a NIOSH-approved N95 respirator that has also been cleared by the U.S. Food and Drug Administration as a surgical mask.

### 6.1.1.8.5
The manufacturer shall be permitted to specify respirators that meet the requirements in 6.1.2.9.2.

### 6.1.1.8.6*
The use of a specific tape specified by the manufacturer shall be permitted for securing items in interface areas.

A.6.1.1.8 See A.3.3.XX, Single-Use Emergency Medical Protective Ensemble.

A.6.1.1.8.3 Multiple-use emergency medical eye and face protective devices are already required to meet the respective requirements of ANSI Z87.1, *Occupational and Educational Personal Eye and Face Protection Devices*. The ANSI Z87.1 standard already includes criteria that address other areas of performance such as ignition and droplet/splash protection. Goggles and faceshields meeting these requirements are marked for splash/droplet use using the “D3” marking.


A.6.1.1.8.6 Tape is permitted only where the manufacturer identifies a specific tape, where the tape is used to secure interface areas and the tape does not serve as the primary liquid or viral penetration resistance barrier, and the manufacturer provides detailed instructions for its application as part of the required user information.

18. Add a new section 6.1.2.9 and associated Annex item as follows:

### 6.1.2.9*
Where the garment is certified as part of a multiple-use emergency medical protective ensemble to meet the requirements of Section 7.1.2.1, the manufacturer shall specify the use of specific emergency medical cleaning/utility or work gloves worn over any NFPA 1999-certified single-use medical emergency examination gloves, specific multiple-use emergency medical footwear, and specific full facepiece respirator(s).


6.1.2.9.2 If the garment is configured with a bootie that is constructed of garment material and covers the wearer’s foot and ankle, then any footwear meeting ASTM F2413 shall be permitted to be specified in conjunction with the garment.

6.1.2.9.3 Full face respirators shall be NIOSH approved as either full facepiece air-purifying respirator with minimum protection level of P100 or an appropriate tight or loose fitting NIOSH-approved powered air-purifying respirator with a protection level of HE. All respirators shall be approved in accordance with Title 42, Code of Federal Regulations, Part 84, “Approval of Respiratory Protective Devices.”

6.1.2.9.4 Where a loose fitting powered air-purifying respirator is specified, the materials used in the construction of the hood shall meet the garment material performance requirements specified in either 7.1.1.1 with the exception of the requirement in 7.1.1.8, or 7.1.1.2 with the exception of 7.1.2.9.
A.6.1.2.9 See A.3.3.XX, Multiple-Use Emergency Medical Protective Ensemble.

19. Revise 6.2.3.6 to read as follows:

6.2.3.6 In order to label or otherwise represent a glove as compliant with the requirements of this standard, the manufacturer shall provide gloves in not less than five separate and distinct sizes, as specified in Table 6.2.3.6(a) through Table 6.2.3.6(e). The manufacturer shall provide gloves in each size that at least fit the hand dimension ranges specified in those tables.

20. Move asterisk from 6.2.3.6 to paragraph 6.2.3.7.

21. Revise 6.3.3.3 through 6.3.3.5 to read as follows:

6.3.3.3 Where the eye and face protection device is configured as safety glasses, the safety glasses shall meet the respective requirements for spectacles in Section 7 of, and be marked “Z87++” at least “Z87 D3” in accordance with ANSI Z87.1, Occupational and Educational Personal Eye and Face Protection Devices.

6.3.3.4 Where the eye and face protection device is configured as goggles, the goggles shall meet the respective requirements for goggles in Section 8 of, and be marked “Z87++” at least “Z87 D3” in accordance with ANSI Z87.1, Occupational and Educational Personal Eye and Face Protection Devices.

6.3.3.5 Where the eye and face protection device is configured as a faceshield, the faceshield shall meet the respective requirements for faceshields in Section 9 of, and be marked “Z87++” at least “Z87 D3” in accordance with ANSI Z87.1, Occupational and Educational Personal Eye and Face Protection Devices.

22. Revise 7.1.1.1 and 7.1.1.8 to read as follows:

7.1.1.1 Full body or full torso garments, including, but not limited to, ensembles, coveralls, coats, jackets, pants, and overalls, shall be tested for liquidtight integrity as specified in Section 8.2, Liquidtight Integrity Test One, and shall allow no water penetration.

7.1.1.8 Garment materials for full body garments including, but not limited to, ensembles, coveralls, and full torso and limb encapsulating garments shall be tested for total heat loss as specified in Section 8.32, Total Heat Loss Test, and shall have a total heat loss value of at least 450 W/m² or greater moisture vapor transmission rate as specified in Section 8.28, Moisture Vapor Transmission Rate Test, and shall have a moisture vapor transmission rate of at least 650 g/m²-24 hr or greater.

23. Revise 7.1.2.1 to read as follows:

7.1.2.1 Garments or ensembles shall be tested for liquidtight integrity as specified in Section 8.2, Liquidtight Integrity Test One, and shall allow no water penetration.

24. Revise 7.2.1.6 to read as follows:

7.2.1.6 Examination gloves shall be tested for dexterity as specified in Section 8.14, Dexterity Test One, and shall have test times no greater than 106 percent of baseline test measurements.

24. Revise 7.2.2.4 and 7.2.2.5 to read as follows:

7.2.2.4 Cleaning/utility glove materials shall be tested for tensile strength as specified in Section 8.11, Ultimate Tensile Strength Test, and shall have an ultimate tensile strength of greater than 12.5 MPa (1813 psi) or greater than 10.3 MPa (1500 psi).
7.2.2.5 Cleaning/utility glove materials shall be tested for puncture resistance as specified in Section 8.13, Puncture Resistance Test One, and shall have a puncture resistance of greater than 10 9 N (2.3 2 lbf).

25. Revise 7.2.3 to read as follows:

7.2.3.3 Work glove body materials shall be tested for puncture resistance as specified in Section 8.13, Puncture Resistance Test One, and shall have a puncture resistance of greater than 22 9 N (5 2 lbf).

7.2.3.6 Gloves shall be tested for hand function as specified in Section 8.26, Dexterity Test Two, and shall have an average percent of barehanded control not exceeding 170 200 percent.

7.2.3.8 Work gloves shall be tested for ease of donning as specified in Section 8.28, Glove Donning Test, and shall not have a baseline donning time exceeding 10 seconds, a final donning time not to exceed the baseline donning time plus 20.0 seconds, shall have no detachment of the inner liner, shall have no detachment of the moisture barrier, and shall allow full insertion of all digits.

26. Revise 7.4.2.3 to read as follows:

7.4.2.3 Footwear soles and heels shall be tested for abrasion resistance as specified in Section 8.19, Abrasion Resistance Test One, and the relative volume loss shall not be greater than 200 250 mm³.

27. Revise 7.4.3.3 to read as follows:

7.4.3.3 Footwear soles and heels shall be tested for abrasion resistance as specified in Section 8.19, Abrasion Resistance Test One, and the relative volume loss shall not be greater than 200 250 mm³.

28. Revise 8.1.3.7 and 8.1.3.12 to read as follows:

8.1.3.7 Garments shall be washed and dried for a total of 25 10 washing and 25 10 drying cycles.

8.1.3.12 Where work gloves used in conjunction with multiple-use ensembles consist of two separate gloves with the inner glove attached to the garment, the outer glove shall not be required to be washed and dried in accordance with 8.1.3.11.

29. Revise 8.1.4 to read as follows:

8.1.4 Flexural Fatigue Procedure for Gloves. Sample gloves shall be subjected to one full cycle of testing for dexterity testing as specified in Section 8.14 for emergency medical examination gloves and as specified in Section 8.27 for emergency medical cleaning/utility gloves.

30. Add a new 8.2.2.3 as follows:

8.2.2.3 When ensembles are tested, specimens shall include all items that are specified as part of the ensemble in 6.1.1.8 or 6.1.2.9.

31. Revise 8.2.3 to read as follows:

8.2.3.1 Samples for conditioning shall be complete garments or ensembles.

8.2.3.2 Single-use garment and ensemble samples shall be conditioned as specified in 8.1.2.
8.2.3.3 Multiple-use garment and ensemble garment samples shall be conditioned as specified in 8.1.3 and then conditioned as specified in 8.1.2. All other ensemble elements shall be conditioned as specified in 8.1.2.

32. Revise 8.2.4.2 to read as follows:

8.2.4.2 In the testing of garments, the mannequin used in testing shall have straight arms and legs, with the arms positioned downward at the mannequin’s side.

33. Add a new 8.2.4.3 as follows:

8.2.4.3 In the testing of ensembles, the mannequin used in testing shall have straight legs, means for supporting gloves as intended to be worn, a straight right arm positioned downward at the mannequin’s side, and a bent left arm, with the left arm bent upward at a 135-degree angle at the elbow from the mannequin’s side.

34. Add a new 8.2.5.4 as follows:

8.2.5.4 The use of tape shall be permitted when testing single-use ensembles. The tape shall be applied using the instructions supplied by the manufacturer as required in 5.2.3(2).

35. Renumber old 8.2.5.4 as 8.2.5.5 and revise as follows:

8.2.5.5 For single-use garments and ensembles, the suited mannequin shall be exposed to the liquid spray for a total of 8 minutes — 2 minutes 30 seconds in each of the four specified mannequin orientations. For multiple-use garments and ensembles, the suited mannequin shall be tested for a total of 8 minutes with 2 minutes in each of the four specified mannequin orientations.

36. Renumber old 8.2.5.5 and 8.2.5.6 as follows:

8.2.5.6 At the end of the liquid spray exposure period, excess liquid shall be removed from the surface of the specimen.

8.2.5.7 Inspection of the liquid-absorptive garment on the mannequin shall be completed within 10 minutes of the end of the liquid spray exposure period.

37. Revise 8.10.3.2 to read as follows:

8.10.3.2 Specimens shall be conditioned as specified in 8.1.4 8.1.2.

38. Revise 8.13.4 to read as follows:

8.13.4.1 Specimens shall be tested in accordance with ASTM F1342, Standard Test Method for Protective Clothing Material Resistance to Puncture, using Test Method A with the following modification:

8.13.4.2 The modifications specified in 8.13.4.2.1 through 8.13.4.2.3 shall apply.

8.13.4.2.1 A 0.025 mm (0.01 in.) thick, ultrahigh molecular weight high-density polyethylene shall be used as a standard reference material.

8.13.4.2.2 Puncture probes shall be qualified first before use in testing by showing an average puncture resistance of 10.3 N (2.3 lbf).
8.13.4.2.3 (1) The compression load cell shall be capable of discerning 0.5 N (0.1 lbf) of force in the range suitable for the glove material being tested. The upper limit of the load cell shall not be more than 10 times the actual puncture resistance measured for the glove specimens.

39. Revise 8.18.8.3 to read as follows:

8.18.8.3 Cut resistance testing shall be performed under a load of 450 75 g (5.3 2.5 oz).

40. Delete current Section 8.24.1 through 8.24.7 and replace with:

**8.24 Chemical Permeation Resistance Test.**

**8.24.1 Application.** This test method shall apply to cleaning/utility glove materials.

**8.24.2 Specimens.** A minimum of three specimens shall be tested.

**8.24.3 Sample Preparation.** Specimens shall be conditioned as specified in 8.1.2.

**8.24.4 Procedure.**

8.24.4.1 Permeation resistance shall be measured in accordance with ASTM F739a, *Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids or Gases Under Conditions of Continuous Contact*, at 25°C, ±2°C (77°F, ±3°F), using the following test parameters and modifications:

(1) A test duration of 1 hour shall be used.
(2) The test shall be done in the closed loop configuration, using distilled water as the collection medium.
(3) The selected method of detection shall have a sensitivity for measuring a cumulative permeation of 0.1 μg/cm² over the 1-hour test period. The actual sensitivity of the selected method of detection shall be determined.
(4) The total cumulative permeation over 1 hour shall be measured in lieu of breakthrough time and permeation rate.

8.24.4.2 Permeation resistance shall be separately evaluated against the following chemicals:

(1) 40 percent weight-for-weight (w/w) solution of glutaraldehyde
(2) 70 percent w/w isopropanol
(3) 5 percent solution of sodium hypochlorite

41. Renumber current 8.24.8 and 8.24.9 as 8.24.5 and 8.24.6, respectively.

42. Revise 8.25.8.1 to read as follows:

**8.25.8.1 Specimens.** Specimens shall be taken from the palm area of the gloves representative of the glove body composite construction at the following glove areas as described in 8.1.9 and shall not include seams: A-P, B-P, D-P, E-P, F-P, G-P, H-P, and I-P, A-B, B-B, D-B, E-B, F-B, G-B, H-B, AND I-B. Specimens shall be representative of each glove body composite construction. Samples and specimens shall be permitted to be materials representative of those used in the construction of the glove. Specimens shall consist of a separable layer outside the barrier layer of the glove composite.

43. Delete section 8.28 in its entirety and replace with the test method below:

**8.28 Moisture Vapor Transmission Rate Test.**

**8.28.1 Application.** This test method shall apply to the single-use protective garment materials or composites.

**8.28.2 Specimens.**
8.28.2.1 Moisture vapor transmission rate testing shall be conducted on at least three specimens.

8.28.2.2 Specimens shall consist of all layers in the protective garment composite arranged in the order and orientation as worn.

8.28.2.3 Specimen composite shall consist only of base composite layers required to meet the specifications of this standard. Specimens shall not include layers added for reinforcement, or externally added materials for visibility or identification.

8.28.3 Sample Preparation.

8.28.3.1 Samples for conditioning shall be at least a 1-m (1-yd) square of each material.

8.28.3.2 Specimens to be tested shall be conditioned as specified in 8.1.2.


8.28.5 Procedure. Testing shall be conducted in accordance with ASTM E96, Standard Test Methods for Water Vapor Transmission of Materials, with the following modifications:
(1) The specimen shall be placed on the test plate with the side normally facing the human body toward the test plate.
(2) For multiple layers, the layers shall be arranged in the order and orientation as worn.
(3) Procedure B, Water Method at 23°C (73.4°F), as specified in X1.1.2 of ASTM E96, Standard Test Methods for Water Vapor Transmission of Materials, shall be used.

8.28.6 Report. The individual and average moisture vapor transmission rate of all specimens shall be recorded and reported.

8.28.7 Interpretation. Pass/fail determination shall be based on the average reported moisture vapor transmission rate of all specimens tested.

Substantiation:

The outbreak of Ebola Virus Disease (EVD) and escalation of civilian deaths in West Africa has heighted the potential for a possible epidemic reaching other parts of the world including the United States. While it is unknown how many cases of EVD will occur domestically until the disease is fully contained, the current situation has demonstrated that the United States is not as fully prepared as it should be for confronting highly deadly liquid-borne pathogens among its population. First response organizations, including EMS personnel, law enforcement officers, and firefighters, as well as medical first receivers will be and have been in contact with potentially infected persons.

Specific recommendations for the selection and use of personal protective equipment (PPE) have been provided by several organizations including the Center for Disease Control (CDC), World Health Organization, and Doctors without Borders. The majority of PPE guidance has focused on healthcare workers with the most recent guidance from CDC requiring (1) repeated training and demonstrated competency for healthcare workers in the wearing and use of PPE, (2) selection of PPE so that no skin is exposed, and (3) supervised donning and doffing of PPE. Further details are provided in this guidance for PPE selection, donning, and doffing procedures. This guidance is found at:

http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html
In addition, CDC and the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) have prepared the “Detailed Emergency Medical Services (EMS) Checklist for Ebola Preparedness,” found at:


This checklist identifies basic types of personal protective equipment that first responder [EMS] organizations should have on hand as part of a preparedness and response program. The CDC recognizes EMS personnel as any first responder including but not limited to law enforcement, fire services and HAZMAT teams. In this checklist, CDC and ASPR acknowledge the Interagency Board for Equipment Standardization and Interoperability (IAB). To meet the specific needs of first response organizations, the IAB provided detailed recommendations for PPE in a document release 24 October 2014:


Consistent with its practice, the IAB attempted to define PPE in terms of meeting national consensus standards. While the IAB recognized that NFPA 1999 is properly positioned in its overall criteria for establish both material/seam biopenetration resistance and overall liquid integrity consistent with the threats presented by the current and potential future epidemics, it was noted that there as a lack of certified products that are currently certified to NFPA 1999.

The appropriateness of PPE against EVD and other similar highly infectious pathogens is also predicated on providing ensembles of PPE items that are properly integrated for full body protection that do not leave exposed skin. Specific design requirements or methods of making this performance assessment are not currently specified in NFPA 1999 for the creation of ensembles as specified by the IAB. The reliance on taping and other means to protect workers leads to highly varied protection levels and can interfere with the doffing of contaminated ensembles.

The majority of proposed changes to NFPA 1999 define specific ensembles that tie individual clothing items together for providing full body protection for first responders and by applying an overall liquid integrity evaluation to demonstrate the level of performance consistent with the provision that there be no unprotected skin as now recommended by CDC. Two specific ensembles have been created on the basis of already specified items of protective clothing and equipment that exist within NFPA 1999. The new single-use emergency medical ensemble is consistent with the “low risk PPE” category established by the IAB, while the new multiple-use emergency medical ensemble reflects the IAB “high risk PPE” category. These ensembles build on current NFPA 1999 test methods and criteria for individual items of protective clothing. Specific references have also been made to define appropriate respiratory protection devices that have been defined by the IAB to complete specific ensembles.

Additional changes have been proposed to correct some portions of NFPA 1999 that create conflicting requirements or test methods and criteria that cannot be adequately implemented for defining appropriate PPE for protection against liquidborne pathogens for certain items. These changes are necessary to allow the certification of the affected item that can then be employed as part of the newly defined ensembles that are needed for first responder protection.

Overall, the philosophy used in creating this proposed amendment has involved the following:

- There is no reduction in the level of protection on the basis of the proposed changes. Rather integrated protection is being defined and included for an entire ensemble by which individual elements are combined.
- The proposed changes enhance current protection requirements since they address the specific newly identified threats presented by Ebola Virus Disease. As such, increased additional liquids presenting hazards, the vulnerability of individuals for infection, and the high mortality rates associated with deadly liquid pathogens are addressed. Original requirements of the NFPA 1999 standard were primarily based on concerns by the Human Immunodeficiency Virus (HIV) and Hepatitis Viruses B and C.
- Where some changes have been made to reduce certain preconditioning or performance requirements, these changes were recommended on the basis of validation or in an effort to correlate with existing practices where
adequate protection has been demonstrated in analogous applications. For example, the laundering cycles applied to multiple-use emergency medical garments and ensemble garments has been reduced from 25 to 10 cycles. This change has been made to correlate with NFPA 1951 for technical rescue protective garments, which have shown in the field to provide more than adequate ruggedness, durability, and service life. There has been no change in the proposed ensemble life cycle as the current requirements primarily demonstrate acceptable levels of material strength and physical hazard resistance.

- It is expected that the majority of the marketplace will be incentivized to respond to this amendment because the proposed changes provide opportunities for new product certifications. Certain element categories identified in the NFPA 1999 standard have not had certified products in the market because of problems or conflicts with the existing criteria. Changes have been made to correct these problems or remove conflicts based on validations through testing on products that are deemed by practitioners and end users as having acceptable product attributes and utility. For example, a change in the test method for breathability for single use garments will facilitate certification of single use garments or single use ensemble products. Similarly, proposed changes to cleaning/utility gloves and work gloves will help promote the certification of acceptable products. Certainly, manufacturers that offer products that are considered deficient or lacking adequate performance might be disadvantaged, but the standard has been based on performance criteria to not limit the design innovation in creating new products.

- The ensemble approach is fundamental in the proposed changes to NFPA 1999, and is paramount for establishing appropriate levels of protection against the Ebola Virus Disease. While some existing PPE and protective clothing may provide acceptable protection, the observation has been made that a range of end user practices have been undertaken by first responders and medical first receivers resulting in end users wearing inadequate protective clothing and equipment which leads to overprotection. Some PPE being worn consists of non-barrier clothing or clothing without liquid integrity which is a hazard and can create risk for exposure. Similarly, heavy clothing that is not breathable creates the potential for heat stress and may invite poor adherence to proper wearing of PPE. The proposed changes for this amendment set a consistent level of protection that addresses the key design and performance attributes of ensembles determined necessary for minimum protection.

- Only one test has been added as part of this proposed amendment. Several minor changes to existing test methods and criteria. The specific rationales for these changes are provided in Table 1 below.

- The Technical Committee has utilized a task group made up of knowledgeable individuals representing a range of interests to develop and propose the specific changes within this amendment. The changes follow the work of the Interagency Board for Equipment Standardization and Interoperability that are described above. Opportunities have also been afforded for the entire committee through teleconferences and a physical meeting to conduct a detailed review of the proposed changes and supporting validation evidence. This group, the task group and technical committee, is uniquely qualified to provide expertise for the establishment of requirements on personal protective equipment against Ebola Virus Disease and other liquidborne or airborne pathogens. They are able to provide specific perspectives and experience that include an understanding of the exposure threats and work environments, actual use of PPE under emergency conditions, test methodology specific to biopenetration, liquid integrity, physical properties and functional clothing use, product certification, and general development of test method and requirements in standards.

Table 1 – Rationales for Specific Proposed Changes

<table>
<thead>
<tr>
<th>Paragraph(s)</th>
<th>Proposed Change</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title, 1.1.2, 1.2.2, 1.3.1 and 1.3.4</td>
<td>Modify scope statement, purpose statement, and application paragraphs to include single and multiple use ensembles</td>
<td>Adds clear language for expansion of standard to address single-use and multi-use ensembles</td>
</tr>
<tr>
<td>2.2 and 2.3.3</td>
<td>Add new references</td>
<td>References new standards or test method cited in proposed changes</td>
</tr>
<tr>
<td>Paragraph(s)</td>
<td>Proposed Change</td>
<td>Rationale</td>
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<tr>
<td>3.3.23 and A.3.3.23</td>
<td>Remove caveat to cleaning/utility glove definition that gloves not designed for patient care</td>
<td>Clarifies application of cleaning/utility gloves in some aspects of emergency patient care</td>
</tr>
<tr>
<td>3.3.28</td>
<td>Provide small modification of definition for emergency medical footwear covers</td>
<td>Clarifies that footwear covers provide only limited physical protection</td>
</tr>
<tr>
<td>3.3.XX</td>
<td>Add definitions and supplemental information for ensembles, ensemble and elements</td>
<td>Provide the definitions of single-use and multiple-use ensembles that defines their application within the standard through the proposed design and performance requirements; significant guidance is provided through annex for explaining each type of ensemble</td>
</tr>
<tr>
<td>3.3.XX</td>
<td>Add definition for storage life</td>
<td>Use definition from related standards (NFPA 1994)</td>
</tr>
<tr>
<td>Table 4.4.1</td>
<td>Modify table to account addressing frequency of annual testing as part of certification</td>
<td>Addresses proposed changes for inclusion of single-use and multiple-use ensembles and incorporation of new test method</td>
</tr>
<tr>
<td>5.1.2, 5.1.2.2, 5.1.2.4, 5.1.3, 5.1.3.2, and 5.1.36</td>
<td>Modify labeling requirements</td>
<td>Addresses labeling of single-use and multiple-use ensembles requiring specific identification of individual elements making up the ensemble</td>
</tr>
<tr>
<td>5.2.2</td>
<td>Modify user instruction requirements</td>
<td>Generalizes information requirements to different types of respirators that are provided in single-use and multiple-use ensembles in addition to current C]BRN ensembles</td>
</tr>
<tr>
<td>5.2.3</td>
<td>Add new specific instructions for single-use and multiple-use ensembles</td>
<td>Establishes additional critical end user information requirements for donning, creating interfaces, decontamination, and contaminated donning with additional guidance provided in annex section</td>
</tr>
<tr>
<td>5.2.4</td>
<td>Add requirement to add storage life for single-use and multiple-use ensemble</td>
<td>Include recommended storage life and basis of recommendation in user information</td>
</tr>
<tr>
<td>6.1.1.8 through 6.1.1.8.6 and related Annex references</td>
<td>Provide detailed design criteria for single-use ensembles</td>
<td>Specifies specific elements of single-use ensembles and different variants, particularly in terms of footwear options, eye/face protection devices, and respirators; specific provision made for permitting taping of interface areas when tape is not used as a principal barrier and secures elements that have a minimum overlap</td>
</tr>
<tr>
<td>6.1.2.9 through 6.1.29.4, A.6.1.2.9</td>
<td>Provide detailed design criteria for multiple-use ensembles</td>
<td>Specifies specific elements of multiple-use ensembles and different variants, particularly in terms of footwear options and respirators</td>
</tr>
<tr>
<td>6.2.3.6</td>
<td>Modify current sizing requirements for work gloves</td>
<td>Provides greater latitude in sizing gloves that must also work with inner examination gloves; related annex item is moved to 6.2.3.7 since reference to tables is no longer made</td>
</tr>
<tr>
<td>Paragraph(s)</td>
<td>Proposed Change</td>
<td>Rationale</td>
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</tr>
<tr>
<td>6.3.3.3, 6.3.3.4, and 6.3.3.5</td>
<td>Modify requirements for eye and face protection device requirements</td>
<td>Provide updated reference that accounts for current, referenced ANSI Z87.1 standard</td>
</tr>
<tr>
<td>7.1.1.1</td>
<td>Add ensembles as part of garment requirements</td>
<td>Applies liquid integrity test to full single-use emergency medical ensembles</td>
</tr>
<tr>
<td>7.1.1.8</td>
<td>Change to different test to address garment breathability</td>
<td>Replaces total heat loss (THL) with MVTR THL underestimates breathability of lightweight fabrics since air flow lists materials off of test plate; new test is established industry practice for assessing fabric breathability and proposed criteria align with THL of 450 W/m²</td>
</tr>
<tr>
<td>7.1.2.1</td>
<td>Add ensembles as part of garment requirements</td>
<td>Applies liquid integrity test to full multiple-use emergency medical ensembles</td>
</tr>
<tr>
<td>7.2.1.6</td>
<td>Relax dexterity criteria for examination gloves</td>
<td>Adjusts criteria to account for test method variation, which has been reported by certification laboratories as being higher than the specified 6% now allowed; current criteria are not always met by existing gloves and bias against slightly thicker gloves that are appropriate for patient care; proposed criteria take into account large degree of test variation</td>
</tr>
<tr>
<td>7.2.2.4</td>
<td>Lower ultimate tensile strength criteria for cleaning/utility gloves</td>
<td>Adjusts criteria to permit range of gloves deemed to have acceptable breaking strength field performance; based on validation testing of selected gloves provided in Technical Committee presentation</td>
</tr>
<tr>
<td>7.2.2.5</td>
<td>Slightly reduce puncture resistance requirement for cleaning/utility gloves</td>
<td>Aligns puncture resistance criteria with requirements of NFPA 1994, Class 3 that has several certified products with no specific glove complaints; also validated on selected as shown in Technical Committee presentation</td>
</tr>
<tr>
<td>7.2.3.3</td>
<td>Reduce puncture resistance for work gloves</td>
<td>See 7.2.2.5</td>
</tr>
<tr>
<td>7.2.3.6</td>
<td>Increase hand function requirement for work gloves</td>
<td>Aligns work glove requirement with same requirement for cleaning/utility gloves; work gloves are perceived as potentially having poorer hand function as cleaning/utility gloves</td>
</tr>
<tr>
<td>7.2.3.8</td>
<td>Remove donning test for work gloves</td>
<td>Accounts for potential use of multi-glove systems that could be used, particularly for multiple-use ensembles, where donning test cannot be applied</td>
</tr>
<tr>
<td>7.4.2.3, 7.4.3.3</td>
<td>Increase allowable footwear abrasion for multiple-use emergency medical footwear and multiple-use medical facility footwear</td>
<td>Makes correction applied to other related standards in the project</td>
</tr>
<tr>
<td>Paragraph(s)</td>
<td>Proposed Change</td>
<td>Rationale</td>
</tr>
<tr>
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</tr>
<tr>
<td>8.1.3.7</td>
<td>Reduce number of launderings used as preconditioning of multiple use launderings</td>
<td>Current laundering is considered excessive and beyond the intended service life of multiple-use garments; the laundering is considered primarily as a means for demonstrating garment ruggedness; garments with special interfaces or attachments are not believed to be able to hold up under the 25 launderings while still providing adequate durability in the field to multiple reuses; the proposed change aligns the laundering preconditioning with NFPA 1951 (for technical rescue garments) that are considered to have greater or at least similar ruggedness protection needs</td>
</tr>
<tr>
<td>8.1.3.12</td>
<td>Exempt outer gloves of multi-glove work glove systems from laundering requirements</td>
<td>Accounts for fact that outer glove of a multi-glove work glove system can be disposed of and the durability of the glove is addressed in other testing (abrasion resistance)</td>
</tr>
<tr>
<td>8.1.4</td>
<td>Remove flex preconditioning for examination and cleaning/utility gloves</td>
<td>Removes problematic procedure that adds little value to assessment of glove durability; the current procedures utilize individuals conducting the procedures of the respective dexterity or hand function tests for gloves; this is both inefficient and does no tax physical integrity of the gloves</td>
</tr>
<tr>
<td>8.2.2.3, 8.2.3.1, 8.2.3.2, 8.2.3.3</td>
<td>Add ensembles as part of liquid tight integrity testing</td>
<td>Establishes changes in method to address testing of both single-use and multiple-use emergency medical ensembles for liquidtight integrity, the key evaluation for assessing the performance of the newly defined ensembles</td>
</tr>
<tr>
<td>8.2.4.2, 8.2.4.3</td>
<td>Differentiate manikin position between garment and ensemble testing</td>
<td>Does not change testing of garments, but requires the left arm of the manikin to be raised as currently specified in NFPA 1992 and NFPA 1994 for ensemble testing to evaluate the sleeve-glove interface; the specific recommended position has been validated by ITS and UL in a recent government study</td>
</tr>
<tr>
<td>8.2.5.4</td>
<td>Provide change to permit taping of single-use ensemble</td>
<td>Addresses industry issue where taping is perceived as a necessary means for creating interfaces; but is limited to areas where there is a minimum overlap of elements</td>
</tr>
<tr>
<td>8.2.5.5 (old 8.2.5.4)</td>
<td>Change exposure time for liquidtight integrity testing of single-use garments and ensembles</td>
<td>Further differentiates between low risk and high risk ensembles for liquid protection; retains the 8-minute duration multiple-use ensembles currently specified in the standard, but for which have been demonstrated in certified NFPA 1999 multiple-use ensembles; a shorter duration test is proposed for single-use ensembles that has been demonstrated through validation test carried out on selected representative ensembles as shown in the attached Technical Committee presentation</td>
</tr>
<tr>
<td>Paragraph(s)</td>
<td>Proposed Change</td>
<td>Rationale</td>
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<tr>
<td>8.13.4.1</td>
<td>Remove current puncture probe calibration procedure</td>
<td>Eliminates the puncture probe calibration procedure that only appears in NFPA 1999 and has not be subject to an interlaboratory validation; no tolerance has been provided for the use of the standard reference material.</td>
</tr>
<tr>
<td>8.18.8.3</td>
<td>Decrease cut resistance for work gloves</td>
<td>Aligns puncture resistance criteria with requirements of NFPA 1994, Class 3 that has several certified products with no specific glove complaints</td>
</tr>
<tr>
<td>8.24</td>
<td>Replace chemical permeation procedures with test method provided in NFPA 1999-2003</td>
<td>Current procedures cannot be used with aqueous-based liquid challenges for effective measurement of permeation, particularly when a liquid collection medium is used.</td>
</tr>
<tr>
<td>8.28</td>
<td>Remove glove donning test method</td>
<td>See 7.2.3.8</td>
</tr>
<tr>
<td>8.28 (new)</td>
<td>Add new standard test for measurement of water vapor transmission rate of single-use garment materials</td>
<td>See 7.1.1.8</td>
</tr>
</tbody>
</table>

**Emergency Nature:**

There is an extreme urgency for modifying and correcting NFPA 1999 to address the current PPE needs of first responders and medical first receivers against EVD and future outbreaks for highly infectious pathogenic diseases. NFPA 1999 was originally created to deal with the threat of HIV and Hepatitis Viruses. While it establishes appropriate levels of material/seam biopenetration resistance and overall liquid integrity, the development and prior revisions of this standard did not anticipate the specific additional protection needs posed by highly virulent transmissible disease, which can be encountered by first responders and medical first receivers, for which the standard is intended. In addition, certain products cannot be certified because of conflicts and unobtainable performance current specified in some requirements. The required approach demands an integrated ensemble of certified items that can be combined to provide full body protection.

Anyone may submit a comment by the closing date indicated above. To submit a comment, please identify the number of the TIA and forward to the Secretary, Standards Council, 1 Batterymarch Park, Quincy, MA 02169-7471.