



INTERNATIONAL ASSOCIATION OF FIRE FIGHTERS

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President

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Thursday, January 27, 2000

Dockets Management Branch (HFA-305)
The Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-0313 Reclassification of Surgeon's and Patient Examination Gloves

Dear Madam/Sir:

The International Association of Fire Fighters (IAFF) represents 230,000 fire fighters and emergency medical services (EMS) personnel who protect more than 80 percent of the lives and property in the United States. The IAFF is pleased to provide comments on reclassifying examination gloves as Class II medical devices.

Like other health care workers, fire fighters and EMS personnel routinely come in contact with patients in situations where there is significant potential for exposure to bloodborne pathogens. As such, our members routinely use latex gloves to protect themselves. In fact, patient examination gloves are frequently the only piece of personal protective equipment preventing exposure to infectious agents such as HIV and Hepatitis B and C.

The IAFF is pleased that the FDA is considering additional regulations to reduce the adverse health effects attributable to latex allergies and foreign body reactions. While the labeling of powdered and powder-free latex gloves is a good start, the IAFF believes that latex-free gloves should be a category the FDA considers. The use of new synthetic materials that are latex-free can more effectively mitigate the problem of latex allergies.

Therefore, rather than the four proposed categories of examination gloves there should be another whole class of gloves – latex-free. The additional class of gloves would result in 6 categories of gloves, e.g., powdered, powder-free, and latex-free gloves (surgeon's and patient examination).

Lastly, we wish to offer comments on the FDA's proposal to improve the quality and barrier integrity of medical gloves. The FDA's proposed rule to require expiration

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date labeling does not result in any significant improvement in integrity of gloves and corresponding improvements in glove quality and both worker and patient safety.

Instead, the IAFF proposes that the FDA fully adopt by reference the segments of the National Fire Protection Association *NFPA 1999 Standard on Protective Clothing for Emergency Medical Operations* that apply to emergency medical glove performance requirements.

The National Fire Protection Association is a national consensus standards organization. The adoption of these performance requirements will provide meaningful and significant measurements of the quality and barrier integrity issues and concerns. Furthermore, adoption of these requirements will provide a meaningful method for testing latex-free gloves to ensure adequate protection from bloodborne pathogens.

Enclosed are the applicable sections of NFPA 1999. Please contact Frederick Nesbitt, Governmental Affairs Director, at 202.737.8484 if you have any questions or need more information.

Thank you for your time and attention to this matter.

Sincerely,

Alfred K. Whitehead
General President

AKW/hhk

5-2 Emergency Medical Glove Performance Requirements.

5-2.1 Specimen gloves shall be tested for liquidtight integrity as specified in Section 6-9, Liquidtight Integrity Test Two, and shall have an Acceptable Quality Limit of 1.5 or better.

5-2.2 Specimen gloves shall be tested for biopenetration resistance as specified in Section 6-10, Biopenetration Test Two, and shall exhibit no penetration of the Phi-X-174 bacteriophage.

5-2.3 Specimens of a glove material shall be tested for strength as specified in Section 6-11, Ultimate Tensile Strength, Elongation, and Modulus Test, and shall have an ultimate tensile strength of not less than 13.8 MPa (2000 psi) and shall have a modulus of not more than 2.07 MPa (300 psi) at 300 percent elongation.

5-2.4 Specimens of a glove material shall be tested for elongation as specified in Section 6-12, Ultimate Elongation Test, and shall have an ultimate elongation of not less than 500 percent.

5-2.5 Specimens of a glove material shall be tested for puncture resistance as specified in Section 6-13, Puncture Resistance Test, and shall have a puncture resistance of not less than 4.45 N (1.0 lbf).

5-2.6 Specimen gloves shall be tested for dexterity as specified in Section 6-14, Dexterity Test, and shall have test times no greater than 106 percent of baseline test measurements.

5-2.7 Specimens of a glove material shall be tested for protein levels as specified in Section 6-15, Protein Content Test, and shall have protein levels no greater than 100 µg/g.

Chapter 6 Test Methods

6-1 Sample Preparation Procedures.

6-1.1 Application.

6-1.1.1 The sample preparation procedures contained in this section shall apply to each test method in this chapter, as specifically referenced in the sample preparation section of each test method.

6-1.1.2 Only the specific sample preparation procedure or procedures referenced in the sample preparation section of each test method shall be applied to that test method.

6-1.2 Room Temperature Conditioning Procedure for Garments, Gloves, and Face Protection Devices.

6-1.2.1 Samples shall be conditioned at a temperature of 21°C, ±3°C (70°F, ±5°F) and a relative humidity of 65 percent, ±5 percent, until equilibrium is reached, as determined in accordance with Section 4 of Federal Test Method

Standard 191A, Textile Test Methods, or for at least 24 hr, whichever time period is shortest.

6-1.2.2 Specimens shall be tested within 5 min after removal from conditioning.

6-1.4 Flexural Fatigue Procedure for Gloves.

6-1.4.1 Sample gloves shall be subjected to one full cycle of testing for dexterity testing as specified in Section 6-14.

6-1.5 Isopropanol Immersion Procedure for Gloves.

6-1.5.1 Sample gloves shall be totally immersed in 100 percent isopropanol at room temperature for a period of 2 hr.

6-1.5.2 Sample gloves shall be removed from the isopropanol, hung in a vertical position for 5 min, laid horizontal with AATCC textile blotting paper both under and over the specimen, under a weight of 0.002 kg/cm², ± 0.0002 kg/cm² (0.5 psi ± 0.05 psi) for a period of 20 min as specified in ANSI/AATCC 70, Test Method for Water Repellency: Tumble Jar Dynamic Absorption Test.

6-1.5.3 Specimens then shall be cut from the sample after conditioning.

6-1.5.4 Specimens shall be tested within 5 min following blotting.

6-1.6 Heat Aging Procedure for Gloves.

6-1.6.1 Glove samples shall be subjected to heat aging in accordance with ASTM D 573, Standard Test Method for Rubber-Deterioration in an Air Oven, at a temperature of 70°C, ± 2 °C (158°F, ± 3.6 °F) for 166 hr, ± 2 hr.

6-1.6.2 The sample gloves shall be allowed to cool for 10 min, ± 1 min prior to testing.

6-9 Liquidtight Integrity Test Two.

6-9.1 Application.

6-9.1.1 This test shall be applied to whole gloves.

6-9.2 Specimens.

6-9.2.1 A minimum of 32 whole-glove specimens shall be tested.

6-9.3 Sample Preparation.

6-9.3.1 Samples for conditioning shall be whole gloves.

6-9.3.2 Specimens shall be conditioned as specified in 6-1.2.

6-9.4 Procedure.

6-9.4.1* Liquidtight integrity shall be conducted in accordance with ASTM D 5151, Standard Test Method for Detection of Holes in Medical Gloves, with the following modifications. Water shall be replaced with water treated with a surfactant to achieve a surface tension of 35 ± 5 dynes/cm.

6-9.5 Report.

6-9.5.1 The pass/fail result for each specimen shall be reported.

6-9.6 Interpretation.

6-9.6.1 Passing performance shall be considered for a set of glove specimens meeting an Acceptable Quality Limit of 1.5 or better.

6-10 Biopenetration Test Two.

6-10.1 Application.

6-10.1.1 This test shall be applied to whole gloves.

6-10.2 Specimens.

6-10.2.1 A minimum of five whole-glove specimens shall be tested.

6-10.3 Sample Preparation.

6-10.3.1 Samples for conditioning shall be whole gloves.

6-10.3.2 Specimens shall be conditioned as specified in 6-1.4.

6-10.4 Procedure.

6-10.4.1 Liquid penetration resistance testing shall be conducted in accordance with ASTM F 1671, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X-174 Bacteriophage Penetration as a Test System, with the following modifications:

(a) The test shall be performed by placing 800 ml, ± 20 ml (27 fl oz, ± 0.7 fl oz) of Phi-X-174 Bacteriophage suspension into a 1000-ml (34-oz) Erlenmeyer flasks. The specimen shall be carefully immersed into the challenge suspension and shall be positioned such that the distance from the top of the flask to the middle finger of the glove is 180 mm (7 in.). The top of the specimen shall be stretched over the mouth of the flask.

(b) The specimen shall be filled with 250 ml, ± 20 ml (8.5 fl oz, ± 0.7 fl oz) of nutrient broth. Five ml (0.2 fl oz) of nutrient broth shall be removed from the interior of the specimen and assayed to determine that the specimen was not contaminated.

(c) The specimen cuff shall be sealed onto the flask using parafilm or tape. A sterile closure shall be placed on the top of the flask.

(d) The flask shall be placed onto the platform of an orbital shaker and adjusted to 100 rpm. The flask shall be shaken for a period of 1 hr, ± 5 min.

(e) At the end of 1 hr, the flask shall be removed from the orbital shaker and the contents from inside the specimen shall be carefully transferred to a sterile bottle and assayed for the presence of Phi-Z-174 Bacteriophage.

6-10.5 Report.

6-10.5.1 The pass/fail result for each specimen shall be reported.

6-10.6 Interpretation.

6-10.6.1 A failure of any specimen constitutes failure of the material.

6-11 Ultimate Tensile Strength, Elongation, and Modulus Test.

6-11.1 Application.

6-11.1.1 This test shall be applied to glove materials.

6-11.2 Specimens.

6-11.2.1 A minimum of 10 specimens shall be tested.

6-11.2.2 Specimens shall be taken from the palm and back of individual gloves.

6-11.3 Sample Preparation.

6-11.3.1 Samples for conditioning shall be whole gloves.

6-11.3.2 Specimens shall be tested for ultimate tensile strength after conditioning as specified in 6-1.2.

6-11.3.3 Specimens shall be tested for ultimate tensile strength after conditioning as specified in 6-1.6.

6-11.3.4 Specimens shall be tested for modulus at 300 percent elongation after conditioning as specified in 6-1.2.

6-11.4 Procedure.

6-11.4.1 Specimens shall be tested in accordance with Method A - Dumbbell Specimens, of ASTM D 412, Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers - Tension.

6-11.5 Report.

6-11.5.1 The ultimate tensile strength before and after heat aging and modulus at 300 percent elongation shall be reported for each specimen to the nearest 138 kPa (20 psi). The average ultimate tensile strength before and after heat aging and modulus at 300 percent elongation shall be reported for all specimens tested.

6-11.6 Interpretation.

6-11.6.1 The average of three test sets for ultimate tensile strength before and after heat aging and the average of three test sets for modulus at 300 percent elongation shall be used to determine pass/fail performance.

6-12 Ultimate Elongation Test.

6-12.1 Application.

6-12.1.1 This test shall be applied to glove materials.

6-12.2 Specimens.

6-12.2.1 A minimum of 10 specimens shall be tested.

6-12.2.2 Specimens shall be taken from the palm and back of individual gloves.

6-12.3 Sample Preparation.

6-12.3.1 Samples for conditioning shall be whole gloves.

6-12.3.2 Specimens shall be tested after conditioning as specified in 6-1.5.

6-12.3.3 Specimens shall be tested after conditioning as specified in 6-1.6.

6-12.4 Procedure.

6-12.4.1 Specimens shall be tested in accordance with Method A - Dumbbell Specimens, of ASTM D 412, Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers - Tension.

6-12.5 Report.

6-12.5.1 The ultimate elongation (percentage) shall be reported for each specimen to the nearest 0.1 percent. The average ultimate elongation (percentage) shall be reported for all specimens tested.

6-12.6 Interpretation.

6-12.6.1 The average ultimate elongation after heat aging and the average ultimate elongation after isopropanol immersion shall be used to determine pass/fail performance.

6-13 Puncture Resistance Test.

6-13.1 Application.

6-13.1.1 This test shall be applied to glove materials.

6-13.2 Specimens.

6-13.2.1 A minimum of three specimens measuring at least 76.2 mm (3 in.) square shall be tested.

6-13.2.2 Specimens shall be taken from the palm and back of individual gloves.

6-13.3 Sample Preparation.

6-13.3.1 Samples for conditioning shall be whole gloves.

6-13.3.2 Specimens shall be tested after conditioning as specified in 6-1.2.

6-13.4 Procedure.

6-13.4.1 Specimens shall be tested in accordance with ASTM F 1342, Standard Test Method for Protective Clothing Material Resistance to Puncture.

6-13.5 Report.

6-13.5.1 The puncture force shall be reported for each specimen to the nearest 0.44 N (0.1 lbf) of force. The average puncture force shall be reported for all specimens tested.

6-13.6 Interpretation.

6-13.6.1 The average puncture force shall be used to determine pass/fail performance.

6-14 Dexterity Test.

6-14.1 Application.

6-14.1.1 This test shall be applied to whole gloves.

6-14.2 Specimens.

6-14.2.1 A minimum of three glove pairs each for size small and for size large shall be used for testing.

6-14.2.2 Each glove pair shall be tested as a complete set of gloves in new, as distributed, condition.

6-14.3 Sample Preparation.

6-14.3.1 Samples for conditioning shall be whole-glove pairs.

6-14.3.2 Glove pair specimens shall be preconditioned as specified in 6-1.2.

6-14.3.3 Glove pair specimens shall not receive special softening treatments prior to tests.

6-14.4 Procedure.

6-14.4.1 Dexterity shall be evaluated using the standardized procedure known as the Crawford Small Parts Dexterity Test, Screws Technique.

6-14.4.2 Test subjects shall be selected such that their hand dimensions are consistent with those specified in Table 4-2.5.

6-14.4.3 Each test subject used to perform the test shall practice until the baseline times of that person's last three repetitions vary no more than 6 percent.

6-14.4.4 Each test subject shall be tested with a minimum of three pairs of gloves. A minimum of six dexterity tests with gloves shall be conducted, with at least three dexterity tests with size small gloves and three dexterity test with size large gloves.

6-14.4.5 Dexterity test times with gloves shall be compared with baseline dexterity test times for specific test subjects. The percentage of dexterity test

times with gloves to baseline dexterity test times shall be calculated as follows:

6-14.5 Report.

6-14.5.1 The percent of barehanded control shall be reported for each glove pair specimen and test subject tested.

6-14.6 Interpretation.

6-14.6.1 One or more glove pair specimens failing this test shall constitute failing performance.

6-15 Protein Content Test.

6-15.1 Application.

6-15.1.1 This test shall be applied to glove materials.

6-15.2 Specimens.

6-15.2.1 Specimens, measuring at least 25 mm (1.0 in.) square, shall be taken from a minimum of three different gloves for each glove type. A minimum of three specimens per glove shall be tested.

6-15.3 Sample Preparation.

6-15.3.1 Samples for conditioning shall be whole gloves and shall be conditioned as specified in 6-1.2.

6-15.3.2 Specimens shall be taken from conditioned samples.

6-15.4 Procedure.

6-15.4.1 Specimens shall be tested in accordance with ASTM D 5712, Standard Test Method for Analysis of Protein in Natural Rubber and Its Products.

6-15.5 Report.

6-15.5.1 The protein level of each specimen shall be reported to the nearest 10 mg per gram of glove material. The average protein level shall be calculated for all specimens.

6-15.6 Interpretation.

6-15.6.1 Pass/fail performance shall be based on the average reported protein level for each glove type.

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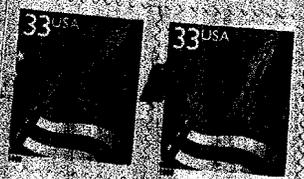


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