

Institute of Environmental Sciences and Technology

IEST-RP-CC005.4

Contamination Control Division
Recommended Practice 005.4

Gloves and Finger Cots Used in Cleanrooms and Other Controlled Environments



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1 SCOPE AND LIMITATIONS

1.1 Scope

This Recommended Practice (RP) describes procedures for testing and evaluating gloves and finger cots used in cleanrooms and other controlled environments. Tests are provided for determining cleanliness, physical and chemical integrity, and other relevant properties. Guidelines are also provided to assist users in the proper selection of gloves or finger cots.

1.2 Limitations

It is impractical to design and manufacture gloves or finger cots to meet all requirements of every application. Therefore, the user should base the selection of gloves and finger cots on the requirements of the process, the analytical data resulting from evaluation testing, and the product data provided by the manufacturer. The application for which a glove is intended should determine which tests are appropriate and relevant.

2 REFERENCES

The cited editions of the following documents are incorporated into this RP to the extent specified herein. Users are encouraged to investigate the possibility of applying the most recent editions of the references.

2.1 Applicable documents

ANSI/AAMI/ISO 11737-1:2006/(R) 2011: Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product

ANSI/AAMI ST72:2011: Bacterial Endotoxins – Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing.

ANSI/ESD STM11.12-2007: Volume Resistance Measurement of Static Dissipative Planar Materials

ANSI/ISEA 105-2011: American National Standard for Hand Protection Selection Criteria. Appendix B, “Test Method for Chemical Degradation Resistance”

ASTM D130-10: Standard Test Method for Corrosiveness to Copper from Petroleum Products by Copper Strip Test

ASTM D297-93(2006): Standard Test Methods for Rubber Products—Chemical Analysis

ASTM D412-06ae2: Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

ASTM D413-98 (2007): *Standard Test Methods for Rubber Property—Adhesion to Flexible Substrate*

ASTM D471-06e1: *Standard Test Method for Rubber Property—Effect of Liquids*

ASTM D573-04(2010): *Standard Test Method for Rubber—Deterioration in an Air Oven*

ASTM D1349-09: *Standard Practice for Rubber—Standard Temperatures for Testing*

ASTM D2420-07: *Standard Test Method for Hydrogen Sulfide in Liquefied Petroleum (LP) Gases (Lead Acetate Method)*

ASTM D3389-10: *Standard Test Method for Coated Fabrics Abrasion Resistance (Rotary Platform Abrader)*

ASTM D3577-09e1: *Standard Specification for Rubber Surgical Gloves*

ASTM D3578-05(2010): *Standard Specification for Rubber Examination Gloves*

ASTM D3767-03(2008): *Standard Practice for Rubber—Measurement of Dimensions*

ASTM D3772-01(2010): *Standard Specification for Natural Rubber Finger Cots*

ASTM D4966-98(2007)e1: *Standard Test Method for Abrasion Resistance of Textile Fabrics (Martindale Abrasion Tester Method)*

ASTM D5151-06(2011): *Standard Test Method for Detection of Holes in Medical Gloves*

ASTM D5250-06e1: *Standard Specification for Poly(vinyl chloride) Gloves for Medical Application*

ASTM D6319-10: *Standard Specification for Nitrile Examination Gloves for Medical Application*

ASTM E595-07: *Standard Test Method for Total Mass Loss and Collected Volatile Condensable Materials from Outgassing in a Vacuum Environment*

ASTM F311-08: *Standard Practice for Processing Aerospace Liquid Samples for Particulate Contamination Analysis Using Membrane Filters*

ASTM F312-08: *Standard Test Methods for Microscopical Sizing and Counting Particles from Aerospace Fluids on Membrane Filters*

ASTM F739-07: *Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact*

ASTM F1060-08: *Standard Test Method for Thermal Protective Performance of Materials for Protective Clothing for Hot Surface Contact*

ASTM F1790-05: *Standard Test Method for Measuring Cut Resistance of Materials Used in Protective Clothing*

California Code of Regulations. Title 8, Section 3407. Hand and Wrist Protection. Subchapter 7. General Industry Safety Orders. Group 2. Safe Practices and Personal Protection. Article 10.1. Personal Protective Clothing and Equipment for Fire Fighters. California Division of Occupational Safety and Health (Cal/OSHA)

Federal Test Method Standard 191A: *Federal Standard for Textile Test Methods*. “Method 5903.2: Textile Test Methods” (Available from GSA)

IEST-RP-CC022.2: *Electrostatic Charge in Cleanrooms and Other Controlled Environments*

IEST-STD-CC1246E: *Product Cleanliness Levels – Applications, Requirements, and Determination*

ISO 14644-1: *Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness*

MIL-STD-168B: *Visual Inspection Guide for All-Rubber Gloves Except Surgical*. (Available from DODSSP)

United States Pharmacopeia (USP) Chapter <85>: “Bacterial Endotoxins Test”

2.2 Sources

AAMI

Association for the Advancement of Medical Instrumentation
(For standards and publications orders)
PO Box 0211
Annapolis Junction, MD 20701-0211
Phone: 877-249-8226
Fax: 240-396-5781
Website: www.aami.org

ANSI

American National Standards Institute
25 West 43rd Street
New York, NY 10036
Phone: 212-642-4900
Fax: 212-398-0023
E-mail: info@ansi.org
Website: www.ansi.org

ASTM International

100 Barr Harbor Drive
West Conshohocken, PA 19428-2959
Phone: 610-832-9585
Fax: 610-832-9555
E-mail: service@astm.org
Website: www.astm.org

CA OSHA

California Occupational Safety and Health Administration
2211 Park Towne Circle, Suite 4
Sacramento, CA 95825
Tel: (916) 574-2528
Fax: (916) 574-2532
E-mail: DOSHEducation@dir.ca.gov
Website: www.dir.ca.gov/dosh/PubOrder.asp

DODSSP

Database for Military Specifications and Military Standards
Building 4, Section D
700 Robbins Avenue
Philadelphia, PA 19111-5098
Phone: 215 697-6396
Website: <http://www.assist.dla.mil>

ESDA

Electrostatic Discharge Association
7900 Turin Road, Building 3
Rome, NY 13440-2069
Phone: 315-339-6937
Fax: 315-339-6793
E-mail: info@esda.org
Website: www.esda.org

GSA

General Services Administration
Specifications Activity
Materials Supply Division, Building 197
Naval Weapons Plant
Washington, D.C. 20407
Website: apps.fas.gsa.gov/pub/fedspecs

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ISEA

The International Safety Equipment Association
1901 North Moore Street
Arlington, VA 22209-1762
Phone: 703-525-1695
Fax: 703-528-2148
Website: www.safetysystem.org

ISO

In US, documents may be ordered from:
Institute of Environmental Sciences and Technology
1827 Walden Office Square, Suite 400 | Schaumburg, IL 60173 USA
Website: www.ient.org
Outside US: Documents available from representative ISO member body organization

United States Pharmacopeia (USP)

12601 Twinbrook Parkway
Rockville, MD 20852-1790, USA
Phone: 800-227-8772
301-881-0666
www.usp.org

3 TERMS AND DEFINITIONS

abrasion resistance

The ability of a surface of a material to resist abrasion while in use.

aliquot

A part that is a definite fraction of a whole.

barrier glove

A glove designed to prevent transmission of materials.

basted

Sewn with long, loose stitches.

bioburden

The measure of the number of microorganisms resident on or within products and inanimate objects; also *microcount*.

chemical compatibility

The ability of a glove to withstand chemical contact with minimal interaction.