Designation: F3267 – 22

Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs[1]

This standard is issued under the fixed designation F3267; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification establishes design, performance, documentation, and labeling requirements and provides test methods for protective clothing used in preventing exposure to liquid chemotherapy and other liquid hazardous drugs.

1.1.1 The principal requirement of this specification is permeation resistance testing of the protective clothing barrier material and seams to a specified battery of seven chemotherapy drugs. Two levels of protective clothing barrier material and seam performance are established for complying with Part A labeling requirements specific to these seven liquid chemotherapy drugs.

1.1.1.1 Broad chemotherapy drug protection is based on the protective clothing barrier material and seams demonstrating breakthrough detection times of 30 min or more for the seven specified chemotherapy drugs.

1.1.1.2 Selective chemotherapy drug protection is based on the protective clothing barrier material and seams demonstrating breakthrough detection times of 30 min or more for at least five of the seven specified chemotherapy drugs.

1.1.2 It is also possible to report permeation resistance test results for additional liquid chemotherapy and other liquid hazardous drugs of interest as determined by the manufacturer or end user organization using the same breakthrough detection criteria for individual drugs for complying with the Part B labeling requirements.

1.1.3 Protective clothing meeting this specification is also required to meet minimum flammability requirements, and if used as a medical device, biocompatibility (if used for breached skin contact), and demonstrate sterility assurance, if sterilized prior to use.

1.1.4 Physical properties that indicate the strength, durability, and breathability of the protective clothing are optionally reported.

1.1.5 Additional requirements are established for the label and user information to be provided for protective clothing meeting this specification.

1.1.6 This specification also requires products intended to be used as medical devices such as surgical gowns and isolation gowns to meet the respective requirements of AAMI PB70, Specification F2407/F2407M, and Specification F3352/F3352M, as applicable.

1.2 This specification does not address all conditions of exposure for individuals who wear protective clothing in the manufacture, transport, compounding, preparation, and administration of liquid chemotherapy and other hazardous drugs in addition to patient care activities and spills where contaminated items with these drugs are encountered.

1.3 This specification does not address chemotherapy drugs or hazardous drugs that may be encountered in the form of a vapor or aerosol and does not provide any criteria for respiratory protection.

1.4 This specification does not address the selection, use, or care of protective clothing used for protection against liquid chemotherapy or other liquid hazardous drugs. While this specification does not specifically determine which barrier material to select, the results of the tests described in this specification are useful for selecting barrier materials by comparing the test results among different materials under consideration. See USP 800, Hazardous Drugs—Handling In Healthcare Settings, for specific guidelines on the selection, use, and care of personal protective equipment for protection of healthcare workers against chemotherapy or other hazardous drugs.

1.5 This specification is intended to provide the basis for manufacturers or suppliers to make specific claims that protective clothing products provide protection against liquid chemotherapy and other liquid hazardous drugs.

1.6 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.7 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

[1] This specification is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.30 on Chemicals.

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1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D751 Test Methods for Coated Fabrics

D1683/D1683M Test Method for Failure in Sewn Seams of Woven Fabrics

D1776/D1776M Practice for Conditioning and Testing Textiles

D3786/D3786M Test Method for Bursting Strength of Textile Fabrics—Diaphragm Bursting Strength Tester Method

D3787 Test Method for Bursting Strength of Textiles—Constant-Rate-of-Traverse (CRT) Ball Burst Test

D5034 Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

D5587 Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

D6701 Test Method for Determining Water Vapor Transmission Rates Through Nonwoven and Plastic Barriers

D6978 Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

E96/E96M Test Methods for Gravimetric Determination of Water Vapor Transmission Rate of Materials

F739 Test Method for Permeation of Liquids and Gases Through Protective Clothing Materials Under Conditions of Continuous Contact

F1494 Terminology Relating to Protective Clothing

F1868 Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate

F2061 Practice for Chemical Protective Clothing: Wearing, Care, and Maintenance Instructions

F2407/F2407M Specification for Surgical Gowns Intended for Use in Healthcare Facilities

F3352/F3352M Specification for Isolation Gowns Intended for Use in Healthcare Facilities

2.2 *AAMI Documents:*[3]

AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities

ISO 10993-5:2021 Biological Evaluation of Medical Devices—Part 5: Tests for in Vitro Cytotoxicity

ISO 10993-10:2021 Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Skin Sensitization

ISO 10993-23:2021 Biological Evaluation of Medical Devices—Part 23: Tests for Irritation

2.3 *ANSI/ASQ Standards:*[4]

ANSI/ASQ Z1.4 Sampling Procedures and Tables for Inspection by Attributes

ANSI/ASQ Z1.9 Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming

2.4 *Federal Standards:*[5]

16 CFR 1610 Standard for the Flammability of Clothing Textiles, Federal Register, Vol 40, No. 59891, Dec. 30, 1975

21 CFR Part 801 Labeling, Federal Register, Vol 41, No. 6896, Feb. 13, 1976

21 CFR Part 801.437 User Labeling for Devices That Contain Natural Rubber, Federal Register, Vol 62, No. 64029, Sept. 30, 1997, as amended in Vol 63, No. 46175, Aug. 31, 1998

2.5 *INDA Standard:*[6]

WSP 70.4 Water Vapor Transmission Rate—Mocon Method

2.6 *ISO Standards:*[4]

ISO 2859-1 Sampling Plans for Inspection by Attributes

ISO 3951 Sampling Procedures and Charts for Inspection by Variables for Percent Nonconforming

ISO 11134 Sterilization of Health Care Products—Requirements for Validation and Routine Control—Industrial Moist Heat Sterilization

ISO 11135 Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization

ISO 11137 Sterilization of Health Care Products—Requirements for Validation and Routine Control—Radiation Sterilization

ISO 13683 Sterilization of Health Care Products—Requirements for Validation and Routine Control of Moist Heat Sterilization in Health Care Facilities

2.7 *NIOSH Document:*[7]

Publication No. 2016-161 List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings

2.8 *NFPA Standard:*[8]

NFPA 1999:2018 Standard on Protective Clothing for Emergency Medical Operations

2.9 *U.S. Pharmacopeia:*[9]

USP 800 Hazardous Drugs—Handling in Healthcare Settings

3. Terminology

3.1 *Definitions:*

3.1.1 *analytical technique, n*—a procedure whereby the concentration of the test chemical in a collection medium is quantitatively measured.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from Association for the Advancement of Medical Instrumentation (AAMI), 901 N. Glebe Road, Suite 300, Arlington, VA 22203-1633, http://www.aami.org.

[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[5] Available from U.S. Government Publishing Office (GPO), 732 N. Capitol St., NW, Washington, DC 20401, http://www.gpo.gov.

[6] Available from Association of the Nonwoven Fabrics Industry (INDA), 1100 Crescent Green, Suite 115, Cary, NC 27518, http://www.inda.org.

[7] Available from National Institute for Occupational Safety and Health (NIOSH), Patriots Plaza 1, 395 E Street, SW, Suite 9200, Washington, DC 20201. https://www.cdc.gov/niosh/docs/2016-161/default.html.

[8] Available from National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-7471, http://www.nfpa.org.

[9] Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, http://www.usp.org.