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.

3.1.1.1 *Discussion*—In this specification, the analytical technique is specified by the manufacturer, supplier, a pharmacy, or a clinical specifier of the chemotherapy drug or hazardous drug, or demonstrated by the testing laboratory when using a scientifically sound, validated analytical technique.

3.1.2 *barrier material, n*—the layer of the protective clothing item that protects against the potential hazard or that serves to isolate the external environment from contamination by the wearer of the clothing.

3.1.2.1 *Discussion*—In some protective clothing designs, a composite of different material layers is used. For the purpose of this specification, if the composite can be separated without damaging or compromising the individual layers, then only the material layer or layers that provides the actual permeation resistance against liquid chemotherapy or other liquid hazardous drugs is tested. If the clothing item being tested involves a seam of barrier materials, then the full seam construction providing the barrier performance is tested.

3.1.3 *breakthrough detection time, n*—the elapsed time measured from the start of the test to the sampling time that immediately precedes the sampling time at which the test chemical (drug) is first detected.

3.1.3.1 *Discussion*—In this specification, the specified breakthrough detection time is when the permeation rate is 0.1 μg/cm^{2}min.

3.1.4 *chemotherapy drug, n*—a drug that controls or kills neoplastic cells, which is typically used in chemotherapy to kill cancer cells.

3.1.4.1 *Discussion*—For this specification, only protection from the liquid form of chemotherapy drugs or other hazardous drugs is assessed.

3.1.5 *collection medium, n*—a liquid, gas, or solid that absorbs, adsorbs, dissolves, suspends, or otherwise captures the test chemical (drug) and does not affect the measured permeation.

3.1.5.1 *Discussion*—In this specification, a liquid collection medium is used. In some cases, the collection medium can be the drug vehicle in which the chemotherapy drug is mixed (one or more solvents) while in other cases, it can be either distilled water or a solvating medium that is the least harmful to the clothing fabric/seam subject to testing.

3.1.6 *hazardous drug, n*—a drug with at least one of the following six characteristics: carcinogenicity, teratogenicity, reproductive toxicity, genotoxicity, organ toxicity at low doses, and drugs that mimic existing drugs in structure or toxicity.

3.1.7 *protective clothing, n*—an item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing.

3.1.7.1 *Discussion*—In this specification, the potential hazard is exposure to liquid chemotherapy drugs or other liquid hazardous drugs by permeation of protective clothing materials and seams used in garments.

3.1.8 *test chemical, n*—solid, liquid, gas, or mixture thereof used to evaluate the performance of a protective clothing material.

3.1.8.1 *Discussion*—In this specification, the test chemical is a liquid chemotherapy or other liquid hazardous drug that is mixed with a solvent, a co-solvent, and additives as provided for clinical use.

3.1.9 *validated statistical rationale, n*—the requirement for an objective cause or reason to be stated why the initial test or results are considered incorrect.

3.2 For definitions of other protective clothing-related terms used in this specification, refer to Terminology F1494.

4. Significance and Use

4.1 The purpose of this specification is to establish the barrier performance properties of materials and seams involved in the construction of protective clothing used for protection against liquid chemotherapy and other liquid hazardous drugs. This specification also sets requirements for other areas of protective clothing performance, the optional documentation of material performance properties related to the intended use of chemotherapy protective clothing, protective clothing design and labeling, and the provision of user information and technical information.

4.1.1 The protective clothing selected for use must be selected based on an assessment of the potential exposure hazards involved in the handling of liquid chemotherapy and other liquid hazardous drugs. USP 800, Hazardous Drugs—Handling In Healthcare Settings, provides specific recommendations for the types of personal protective equipment (PPE) to be used in different types of handling and operations involving liquid chemotherapy and other liquid hazardous drugs for healthcare.

4.1.2 It is recognized that individuals involved in the manufacturing, transport, packaging, compounding, preparation, and administration of liquid chemotherapy and other liquid hazardous drugs are exposed to these drugs in different concentrations, volumes, and exposure conditions. In this specification, protective clothing is evaluated against liquid chemotherapy and other liquid hazardous drugs at the concentration for which the drug is typically prepared for clinical use.

4.2 For uniformity of demonstrating claims against this specification under Part A labeling requirements, seven individual chemotherapy drugs are specified for permeation testing that represent a range of drug formulations, molecular structures, and typical material permeation resistance characteristics associated with protective clothing.

4.2.1 It is also permissible to represent protective clothing permeation against specific liquid chemotherapy and other hazardous drugs for meeting Part B labeling requirements.

4.3 The specific test procedures applied for the measurement of protective clothing material and seam permeation resistance are based on procedures established in Test Method F739 as modified in this specification. These procedures include specific sampling times for determining the permeation

resistance of protective clothing material and seam specimens and reporting of specific test results.

4.3.1 Practice D6978, which specifies procedures for the evaluation of medical glove permeation by chemotherapy drugs, also specifies the use of Test Method F739 but uses a more rigorous criterion for establishing breakthrough detection time at a permeation rate of 0.01 μg/cm^{2}min.

4.3.2 A permeation rate of 0.1 μg/cm^{2}min is used for this specification because in most cases, there is less intimate contact of the clothing with the wearer's skin as there is for examination gloves, which are close fitting to the hands. Moreover, if splashed or contacted with liquid chemotherapy or other dangerous drugs, clothing is more likely to be removed and changed.

4.3.3 Requirements in this standard also require reporting the amount (μg/cm^2) of cumulative permeation at 30, 60, and 240 min, to enable an understanding for the amount of chemical (drug) that permeates a given area of material for comparison purposes. Cumulative permeation is not used for establishing conformity with this specification.

4.4 This specification requires the protective clothing material and seams be tested for permeation resistance against seven common chemotherapy drug formulations, which are listed in Table 1, to meet Part A labeling requirements. An additional list of 17 chemotherapy drugs is provided in Table 2 to which protective clothing materials and seams can also be tested that can be evaluated to meet Part B labeling requirements. These lists are the same as those specified in Practice D6978. In addition to the list of specific chemotherapy drugs in Tables 1 and 2 of this standard, this specification is also intended to address additional liquid chemotherapy or other liquid hazardous drugs that are used in healthcare and related industries. The National Institute for Occupational Safety and Health publishes a list of antineoplastic and other hazardous drugs in healthcare settings in DHHS (NIOSH) Publication No. 2016-161.

4.5 For the purposes of this specification, three different levels of liquid chemotherapy drug protective performance are established.

4.5.1 Broad chemotherapy drug protection pertains to protective clothing that has barrier materials and seams with a normalized breakthrough time of at least 30 min for each of the seven required liquid chemotherapy drugs from Table 1 that are specified for testing.

4.5.2 Selective chemotherapy drug protection pertains to protective clothing that has barrier materials and seams with a normalized breakthrough time of at least 30 min for at least five of the seven required liquid chemotherapy drugs from Table 1 that are specified for testing.

4.5.3 When this specification is applied to other liquid chemotherapy drugs or other liquid hazardous drugs, the barrier materials and seams are required to demonstrate a normalized breakthrough detection time of at least 30 min for each additional drug tested.

4.6 This specification is based on the use of protective clothing for a single use only as recommended by USP 800.

NOTE 1—It is recognized that reusable protective clothing could be specified for certain liquid chemotherapy drugs or other liquid hazardous drugs when the specific risks for reuse have been investigated and accounted for. While specific requirements for reusable protective clothing use against liquid chemotherapy drugs and other liquid hazardous drugs are not addressed in this standard, particularly for use in healthcare, any representation of such products for multiple use would need to consider the effectiveness of decontamination techniques for removing residual drug contamination and the impact of the repeated cleaning and decontamination on the barrier performance and other properties of the product.

4.7 The types of protective clothing covered by this specification include, but are not limited to, full-body clothing such as gowns or coveralls and partial-body clothing such as aprons, sleeved aprons, sleeve protectors, and footwear covers used in any manufacturing, transport, or in healthcare settings such as for patient care. Some design requirements are included to ensure complete barrier protection to the portions of the body covered by the protective clothing item.

4.8 Specific design criteria have been included in this specification to address attributes of the protective clothing to ensure consistent barrier protection to the portions of the body that are covered by the protective clothing item. These criteria are primarily based on design criteria found in USP 800 and NFPA 1999 for protective clothing used in emergency medical operations.

NOTE 2—It is recommended that end users consult the regulatory guidance appropriate for this protective clothing to determine if selected protective clothing meets applicable requirements. Not all protective clothing can be represented against this standard as appropriate for all applications, particularly for those organizations that choose to comply with USP 800. For example, protective clothing configured as coveralls

TABLE 1 List of Required Chemotherapy Drugs and Their Concentrations as Typically Prepared for Clinical Use

Chemotherapy Drug	Concentration (mg/mL)[A]	Collection Medium
Carmustine	3.3	10 % ethanol (aq.)
Cyclophosphamide	20.0	Distilled water
Doxorubicin HCl (Adriamycin)	2.0	Distilled water
Etoposide	20.0	Distilled water
Fluorouracil (Adrucil)	50.0	9.20 pH NaOH sol'n
Paclitaxel (Taxol)	6.0	30 % methanol (aq.)
Thio TEPA	10.0	Distilled water

[A] Initial reconstitution or commercially available concentration.

TABLE 2 Sample List of Additional Chemotherapy Drugs and Their Concentrations as Typically Prepared for Clinical Use

Chemotherapy Drug	Concentration (mg/mL)[A]	Collection Medium
Bleomycin sulfate	15.0	Distilled water
Carboplatin	10.0	Distilled water
Cisplatin	1.0	Distilled water
Cytarabine HCl	100.0	Distilled water
Dacarbazine	10.0	Distilled water
Daunorubicin HCl	5.0	Distilled water
Docetaxel	10.0	Distilled water
Gemcitabine	38.0	Distilled water
Idarubicin	1.0	Distilled water
Ifosfamide	50.0	Distilled water
Irinotecan	20.0	Distilled water
Mechlorethamine HCl	1.0	Distilled water
Melphalan	5.0	Distilled water
Methotrexate	25.0	Distilled water
Mitomycin	0.5	Distilled water
Mitoxantrone	2.0	Distilled water
Vincristine sulfate	1.0	Distilled water

[A] Initial reconstitution or commercially available concentration.

used by non-medical personnel with a front zipper do not meet USP 800 criteria.

4.9 Performance criteria are established for protective clothing material flammability; for biocompatibility for protective clothing where the protective clothing is intended for use as medical devices, such as surgical gowns or isolation gowns; and for sterility assurance, if protective clothing items are provided in a sterile condition.

4.10 The testing of protective clothing materials and seams for a number of performance properties related to strength, durability, or breathability is optional and for documentation purposes only. The purpose of these test results is to aid an end user in the comparison of product performance relative to its intended use and other hazards that may be present.

4.11 Where protective clothing is intended for use as a surgical or isolation gown, requirements are provided that the clothing item also meet AAMI PB70, Specification F2407/F2407M, or Specification F3352/F3352M, as applicable to the clothing item.

5. General Requirements

5.1 All protective clothing items evaluated against this specification are required to meet the applicable design requirements specified in Section 6, performance requirements specified in Section 7, documentation requirements specified in Section 8, if elected by the manufacturer, applicable labeling requirements specified in Section 12, and technical information requirements specified in Section 14.

5.2 If the protective clothing item is also intended for use as a surgical gown or isolation gown, test and classify the barrier performance of the protective clothing materials and seams as specified in AAMI PB70, and the protective clothing shall meet Specification F2407/F2407M for surgical gowns and Specification F3352/F3352M for isolation gowns.

NOTE 3—The classification of protective clothing to AAMI PB70 does not confer any specific performance against liquid chemotherapy and other liquid hazardous drugs.

NOTE 4—AAMI PB70 establishes the barrier performance of surgical gowns and isolation gowns at a specified Acceptable Quality Level (AQL). In contrast, this specification does not rely on permeation resistance using an established AQL, but rather requires testing three specimens for permeation resistance against each chemotherapy or other drug that is evaluated for each barrier material and type of seam in the protective clothing item. AQL-based performance is not established in this specification.

6. Design Requirements

6.1 Protective clothing shall be permitted to be configured as full-body garments such as gowns or coveralls, and non-full-body garments such as aprons, sleeve protectors, and sleeved aprons or smocks.

6.1.1 Where garments are configured as aprons or smocks, garments shall be designed to protect the front torso of the wearer from the neck to below the knees.

6.1.2 Where garments are configured as sleeve protectors, garments shall be designed to protect the arm of the wearer from the wrist crease to a distance of no less than 405 mm [16 in.] from the wrist crease. The wrist crease is shown in Fig. 1.

6.1.3 Where garments are configured as sleeved aprons, garments shall be designed to protect the front torso of the wearer from the neck to below the knees and arms of the wearer and from the wearer's shoulder to the wrist crease.

6.1.4 Where garments are configured as gowns, the gowns shall have no openings in the front, have long sleeves, and have closures positioned in the back. The protective fabric shall wrap around the torso and overlap by at least 100 mm [4 in.] at all points on the wearer's back. The back of the garment shall extend from within 100 mm [4 in.] of the nape of the neck to the hemline.

6.2 Protective clothing items with sleeves shall have close or tight-fitting cuffs.

NOTE 5—Knit cuffs by themselves do not offer any protection from exposure to liquids, including liquid chemotherapy and other liquid hazardous drugs. It is advised that protective clothing having sleeves with knit cuffs include instructions as part of the required user information (Section 13) that require that the knit cuff be covered with a chemotherapy glove that has been evaluated in accordance with Practice D6978, or other

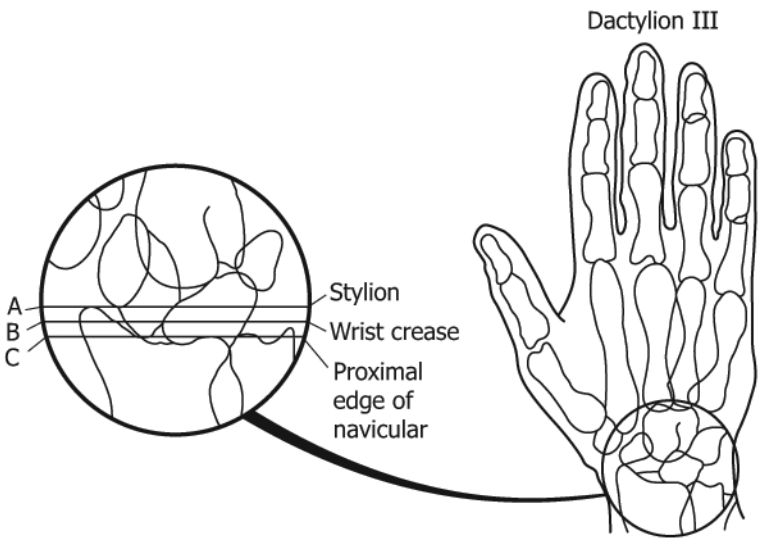

FIG. 1 Location of Wrist Crease

means to prevent direct exposure of the knit material to liquid chemotherapy or other liquid hazardous drugs.

6.3 Where garments are configured as coveralls, the coveralls shall include a protective flap over the front positioned zipper or other closure that can be temporarily secured to protect any liquid exposure to the garment closure.

6.4 Protective clothing items shall be permitted to include integrated socks to protect the wearer's feet in conjunction with outer footwear.

6.4.1 Where protective clothing items incorporate socks, the socks shall be designed as an extension of the garment leg and shall cover the entire foot and ankle.

6.4.2 Separate protective clothing items are also permitted in the form of footwear covers that shall provide protection of the wearer's footwear and that extend at least above the wearer's ankle.

6.5 Protective clothing items shall be permitted to include integrated hoods to protect portions of the wearer's head, neck, and face in conjunction with eye and face protection devices and appropriate respirators.

6.5.1 Protective clothing items shall also be permitted to be a separate hood with a clear visor to protect the wearer's head, neck, and face in conjunction with appropriate respirators.

6.5.2 Where protective clothing items incorporate hoods, the hood shall cover at least the back and sides of the head and neck.

6.6 The manufacturer shall specify all portions of the body covered by the protective clothing item that is provided with chemotherapy or hazardous drug barrier protection. Any portion of the protective clothing item that can potentially come into contact with liquid chemotherapy or other liquid hazardous drugs shall include barrier material.

7. Performance Requirements

7.1 *Permeation Resistance:*

7.1.1 To be labeled as meeting this standard for broad chemotherapy drug protection, each barrier material specimen and each seam specimen tested shall be tested against each of the seven Table 1 drugs and exhibit a breakthrough detection time of 30 min or more for each chemotherapy drug.

7.1.2 To be labeled as meeting this standard for selective chemotherapy drug protection, each barrier material specimen and each seam specimen tested shall exhibit a breakthrough detection time of 30 min or more for at least five of the chemotherapy drugs specified in Table 1.

NOTE 6—A set of specimens, in permeation testing, is the full number of test replicates separately for material and seam. For interpreting the above requirement, the lowest breakthrough detection time in each set must be 30 min or greater. For example, if a protective clothing item has one type of material that has measured breakthrough detection times of 45, 30, and 30 min, and a single seam type that yields breakthrough detection times of 45, 60, and 60 min, the lowest breakthrough detection time for both sets of permeation resistance data is 30 min.

7.1.3 When specific permeation data is provided by the manufacturer for other liquid chemotherapy and hazardous drugs, the breakthrough detection time reported for each additional drug shall be the lowest result obtained on each barrier material and seam.

NOTE 7—Additional chemotherapy drugs for consideration are provided in Table 2.

7.2 *Flame Spread:*

7.2.1 Materials used in the construction of protective clothing shall meet the requirements for Class 1 "normal flammability" in accordance with 16 CFR Part 1610.

7.3 *Biocompatibility:*

7.3.1 If represented by the manufacturer as being suitable for use for patient contact in a medical device setting, materials used in the construction of protective clothing items shall meet the biocompatibility requirements as external devices that contact breached or compromised surfaces for limited exposures when passing the appropriate evaluations in accordance with ANSI/AAMI/ISO 10993.

7.4 *Sterility Assurance Level:*

7.4.1 If sterilization of the protective clothing item is specified as part of the pre-use or use procedures, the clothing item shall achieve a sterility assurance level of at least 10^{-6} for the selected sterilization process.

NOTE 8—Appropriate sterilization processes include those specified in ISO 11134 for moist heat, ISO 11135 for EtO, and ISO 11137 for gamma. ISO 13683 is a permitted alternative also for moist heat sterilization.

8. Documentation Requirements

8.1 If the manufacturer elects to provide physical property information with its products, test and report the physical properties of the protective clothing materials and seams as specified in Table 3.

8.2 If the protective clothing materials are to be represented as breathable, then material breathability is permitted to be tested using either the evaporative resistance or water vapor transmission rate as specified in Table 3.

9. Sampling

9.1 Select representative specimens of barrier materials and seams from the protective clothing item for testing.

9.1.1 If the protective clothing includes more than one barrier material, then separately test each unique barrier material.

9.1.2 If the protective clothing item uses more than one type of seam construction, then separately test each different type of clothing barrier material seam.

NOTE 9—Seam construction in a protective clothing item can vary based on the stitch type and number of stitches per inch (for sewn seams) and by the seam type (configuration) and technique by which seams may be sealed (for example, ultrasonic, RF, and taping). For the purpose of this specification, barrier materials do not include knit cuffs if used in the construction of the clothing item or the seam by which the knit cuff is attached to the clothing item sleeve.

9.1.3 If the seam specimens include at least 10 mm of barrier material unaffected by the seam on either side of the seam as the exposed area in the permeation test cell, then testing of the barrier material alone is not required.

9.2 Where specified by the purchaser or organization reviewing the product, test multiple lots of protective clothing items to demonstrate consistent performance for the respective protective clothing product.

TABLE 3 Physical Property Documentation Requirements (Documentation Only)[A]

Performance Property	Test Method	Subsection	Reported Data
Tensile strength[B]	ASTM D5034	11.5	Average tensile strength for each material direction[C]
Tear resistance[B]	ASTM D5587	11.6	Average tearing force for each material direction[C]
Burst strength	ASTM D3786/D3786M (woven); ASTM D3787 (nonwoven or knit)	11.7	Average burst strength
Seam strength	ASTM D751 (stretch woven or knit) or ASTM D1683/D1683M (woven or nonwoven)	11.8	Average seam strength for each seam type used in the protective clothing item
Evaporative resistance[D] or	ASTM F1868, Part B	11.9	Average evaporative resistance for all material layers used in the construction of the protective clothing
Water vapor transmission rate[D]	ASTM D6701, ASTM E96/E96M, or WSP 70.4 (nonwoven and plastic barrier materials)	11.10	Average water vapor transmission rate for all material layers used in construction of the protective clothing

[A] Appendix X1 provides a description of each method, its intended application, and limitations.
[B] Measurement of tensile and tear strength properties may not be indicative of snag or puncture resistance. There are no generally accepted test methods for snag or puncture resistance available at this time.
[C] This standard follows industry practice for reporting strength properties in both material directions (warp and fill, machine and cross-machine, or wales and course as specified by the manufacturer) to provide the end user with a comparison of material performance because a material may have different strengths associated with each direction of its manufacture.
[D] This standard permits reporting either evaporative resistance or water vapor transmission rate if the user of this standard elects to report the protective clothing material as breathable. Appendix X1 provides a comparison of the two methods with their respective procedures, application, and limitations. Garment comfort is a function of several factors, including but not limited to, fabric "breathability," garment design, weight, fabric stiffness, the degree of garment fit on the individual wearer, and other possible individual wearer preferences (for example, noise, odor). Due to the complexity of these factors, the best assessment of overall protective clothing comfort can be made through actual wear testing. Measuring the breathability of the fabrics used to construct protective clothing is one method of predicting thermal comfort. Those protective clothing items that are designed and constructed of materials which more freely allow evaporation of perspiration and body heat transfer provide better thermal comfort. When protective clothing is constructed or reinforced with different materials in different areas of the garment, then testing the breathability of all the materials is important to help gain an understanding of the impact of overall garment design on thermal comfort. Comparisons of breathability between different protective clothing materials should only be made using the same test method. Also included in Appendix X1 are other potential factors that can affect comfort.

NOTE 10—While this specification can be used to make claims of performance against liquid chemotherapy and other liquid hazardous drugs, it is not a quality control standard. Examples of acceptable sampling plans for the other physical properties are found in references such as ANSI/ASQ Z1.4 and Z1.9, ISO 2859-1, and ISO 3951.

10. Conditioning

10.1 *Ambient Conditioning*—Condition all specimens at a temperature of 27 ± 3 °C [81 ± 5 °F] and relative humidity of 65 ± 10 % for at least 24 h according to Practice D1776/D1776M, unless otherwise specified by the selected test method.

10.2 *Sterilization*—If specified by the manufacturer for use of the protective clothing, sterilize specimens from protective clothing items using the manufacturer's recommended sterilization process and specific sterilization cycle parameters (for example, time, temperature, sterilant concentration, humidity, etc.) prior to ambient conditioning of specimens prior to testing.

11. Test Methods

11.1 *Permeation Resistance*—Use Test Method F739 with the conditions and procedures stated hereafter to measure the permeation resistance of each type of barrier material and seam against all seven chemotherapy drugs listed in Table 1 and any other liquid chemotherapy or liquid hazardous drugs, such as those listed in Table 2, depending on the type of product labeling claims to be made.

11.1.1 For each chemotherapy or hazardous drug to be tested, prepare the chemotherapy or hazardous drug using the manufacturer's or clinician's recommended solvent, co-solvent, and other additives and at the highest concentration of the drug to which a worker might be exposed during handling as referenced in the most recent edition of the Physicians' Desk Reference, or the package insert of the test drug. Document the concentration and preparation procedures for each chemotherapy and hazardous drug that is tested.

11.1.2 Conduct permeation testing at 27 ± 3 °C [81 ± 5 °F] and record the actual test temperature.

11.1.3 Choose a collection medium appropriate for the specific drug being tested which does not influence the permeation of the drug through the protective clothing material or seam. Ensure that the collection medium is continuously mixed.

NOTE 11—If other than distilled water is used, an assessment is needed to determine that the collection medium does not influence the permeation behavior of the drug through the respective protective clothing material or seam.

11.1.4 Select and apply a detection method that is capable of analyzing the concentration of the drug to achieve a minimum detectable permeation rate of 0.01 $\mu g/cm^2 min$.

NOTE 12—The selected minimum detectable permeation rate is one order of magnitude below the permeation rate that is used to establish the standardized breakthrough time and is specified in Test Method F739.

NOTE 13—If available, it is recommended to use the drug manufacturer's specified detection method for analysis of the drug concentration in the collection medium.

11.1.5 Configure the permeation test cell in a closed-loop configuration.

11.1.6 Measure the concentration of the drug in the collection medium at the start time, and at 30, 60, 120, and 240 min after the start time.

11.1.7 Terminate the test after 4 h unless a longer test period is specified.