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Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities[1]

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INTRODUCTION

Healthcare personal protective equipment, including isolation gowns, is worn by healthcare workers to protect the patient, the healthcare worker, and visitors from the transfer of microorganisms, blood and other body fluids, and other contaminants.

Healthcare workers and patients can be exposed to body fluids and other potentially infectious materials capable of transmitting diseases. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne pathogens, such as Hepatitis (Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)) and Human Immunodeficiency Virus (HIV), as well as other healthcare-associated infections. Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential for direct skin contact with microorganisms, blood or other body fluids, and other potentially infectious materials through the use of protective clothing.

The ASTM F23.40 Biological Subcommittee work group surveyed infection preventionists to determine use/wear issues, familiarity with isolation gown performance standards, and to identify compliance perceptions and problems.[2] Results of this survey clearly indicated issues with the physical performance of the isolation gowns used in healthcare settings. Development of this standard, which includes performance and design criteria for isolation gowns, is intended to assist end users in correct gown selection. The minimum criteria in this specification were established based on the findings of a study in collaboration with National Institute for Occupational Safety and Health[3] and committee discussions.

This specification addresses the performance of isolation gowns designed to protect the healthcare worker, the patient, and visitors from exposure to blood, body fluids, and other potentially infectious materials during patient care or patient procedures.

This specification establishes uniform testing and reporting requirements for isolation gown manufacturers in order to provide information to end users that can be used in making informed decisions in the evaluation, selection, and purchase of isolation gowns according to the anticipated exposures.

1. Scope

1.1 This specification establishes minimum requirements for the performance and labeling of isolation gowns intended for use by healthcare workers to provide protection for standard and transmission-based precautions. The intended use of this specification is to ensure the performance properties of isolation gowns for the protection of the wearer. Four levels of barrier properties for isolation gowns are specified in ANSI/AAMI PB 70, and are included in this specification for reference purposes.

1.2 There are other types of gowns that are used in healthcare settings, including: cover gowns, procedure gowns, comfort gowns, precaution gowns, and open-back gowns. All gowns not meeting the definition of isolation gown in 3.1.7 as defined by ANSI/AAMI PB70 are excluded from this standard.

1.3 This specification does not address protective clothing used for surgical applications, such as surgical gowns or

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[2] Cloud, R., Favret, U. B., Cunningham, T., Daley, J., Harris, L. G., Kilinc-Balci, F. S., and Lewis, J. A., "Isolation Gown Use, Performance and Potential Compliance Issues Identified by Infection Control Professionals," *American Journal of Infection Control*, Vol 40, No. 5, 2012, pp. e74–e75.

[3] Kilinc-Balci, F. S., Nwoko, J., and Hillam, T., "Evaluation of the Performance of Isolation Gowns," *American Journal of Infection Control*, Vol 43, No. 6, 2015, p. S44.

decontamination gowns; protective clothing for the hands, such as surgical gloves, patient examination gloves, or other medical gloves; protective clothing for the head, such as goggles or face shields, surgical caps or hoods, surgical masks, or respirators; protective clothing for the feet, such as operating room shoes, shoe covers, or surgical boots; or other types of protective clothing and equipment worn by healthcare providers.

1.4 *Units*—The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard.

1.5 *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.*

1.6 *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:*[4]

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

D4966 Test Method for Abrasion Resistance of Textile Fabrics (Martindale Abrasion Tester Method)

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

F392/F392M Practice for Conditioning Flexible Barrier Materials for Flex Durability

F1154 Practices for Evaluating the Comfort, Fit, Function, and Durability of Protective Ensembles, Ensemble Elements, and Other Components

F1494 Terminology Relating to Protective Clothing

F1671/F1671M Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

F1868 Test Method for Thermal Resistance, Evaporative Resistance, and Total Heat Loss Measurements of Clothing Materials Using a Sweating Hot Plate

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

F3050 Guide for Conformity Assessment of Personal Protective Clothing and Equipment

2.2 *AAMI Documents:*[5]

ANSI/AAMI PB70 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Healthcare Facilities

AAMI TIR11 Selection and Use of Protective Apparel and Surgical Drapes in Healthcare Facilities

2.3 *AATCC Standards:*[6]

AATCC 42 Water Resistance: Impact Penetration Test

AATCC 127 Water Resistance: Hydrostatic Pressure Test

2.4 *ANSI/ASQ Standards:*[7]

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

2.5 *ISO Standards:*[8]

ISO 2859-1 Sampling Plans for Inspection by Attributes

ISO 3951 Sampling Procedures for Inspection by Variables

ISO 9001 Quality Management Systems—Requirements

ISO 9073-10 Textiles—Test Methods for Nonwovens—Part 10: Lint and Other Particles Generation in the Dry State

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

ISO 10993-7 Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals

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

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

ANSI/AAMI/ISO 13485 Medical Devices—Quality Management Systems—Requirements for Regulatory Purposes

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories

ISO/IEC 17026 Conformity Assessment—Example of a Certification Scheme for Tangible Products

2.6 *Federal Standards:*

16 CFR 1610 Standard for the Flammability of Clothing Textiles, Federal Register, Vol 40, No. 59891, Dec. 30, 1975[9]

[4] 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.

[5] Available from Association for the Advancement of Medical Instrumentation (AAMI), 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633, http://www.aami.org.

[6] Available from American Association of Textile Chemists and Colorists (AATCC), P.O. Box 12215, Research Triangle Park, NC 27709-2215, http://www.aatcc.org.

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

[8] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

[9] Available at https://www.ecfr.gov/current/title-16/chapter-II/subchapter-D/part-1610.

16 CFR 1611 Standard for the Flammability of Vinyl Plastic Film, Federal Register, Vol 40, No. 59891, Dec. 30, 1975[10]

29 CFR 1910.1030 Occupational Exposure to Blood-Borne Pathogens: Final Rule, Federal Register, Vol 66, No. 12, Jan. 18, 2001[11]

FDA Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings—Guidance for Industry and Food and Drug Administration Staff[12]

2.7 *INDA Standard:*[13]

WSP 70.4 Water Vapor Transmission Rate—Mocon Method

3. Terminology

3.1 *Definitions:*

3.1.1 *blood-borne pathogen, n*—an infectious bacterium or virus, or other disease-inducing microbe carried in blood or other potentially infectious body fluids.

3.1.2 *body fluid, n*—any liquid produced, secreted, or excreted by the human body.

3.1.2.1 *Discussion*—In this specification, body fluids include liquids potentially infected with blood-borne pathogens, including, but not limited to: blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, urine, feces, bile, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids (see 29 CFR 1910.1030).

3.1.3 *critical zone(s), n*—area of a gown where direct contact with blood, body fluids, and other potentially infectious materials is most likely to occur.

3.1.3.1 *Discussion*—Annex B of ANSI/AAMI PB70 provides examples of barrier classification for isolation gowns stating that the entire isolation gown, including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1.

3.1.4 *critical zone component, n*—any element, constituent, or item incorporated into the critical zone, including the materials, seams, attachments, and closures.

3.1.4.1 *Discussion*—Seams, ties, attachments, closures, or other components of the gown are considered to be a critical zone component.

3.1.5 *flammability, n*—those characteristics of a material that pertain to its ignition and support of combustion.

3.1.6 *healthcare protective clothing, n*—protective clothing/apparel used in a healthcare setting.

3.1.7 *isolation gown, n*—item of protective clothing/apparel used to protect healthcare personnel, visitors, and patients from the transfer of microorganisms and body fluids in patient isolation situations.

3.1.7.1 *Discussion*—This definition is consistent with the definition provided by AAMI TIR11. Isolation gowns might also be used to protect visitors in the healthcare setting. According to the Centers for Disease Control and Prevention's Guideline for Isolation Precautions,[14] isolation gowns are worn to protect the healthcare workers' arms and exposed body areas during procedures and patient care activities when anticipating contact with clothing, blood, body fluids, secretions, and excretions.

3.1.8 *multiple-use, adj*—refers to an item of protective clothing that is intended to be used several times with appropriate care of the protective clothing item between uses.

3.1.8.1 *Discussion*—In this specification, multiple-use protective clothing is subject to processing (laundering and sterilization, if used sterile) between each use.

3.1.9 *other potentially infectious materials, n*—any materials, other than blood or body fluids, containing blood-borne pathogens or materials that have been linked with the potential transmission of infectious disease.

3.1.10 *protective clothing, n*—an item of clothing/apparel 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.

3.1.10.1 *Discussion*—For the purpose of this standard, protective clothing refers to isolation gowns. The primary purpose of the protective clothing is to act as a barrier between the wearer and a hazard. However, the wearer may be the source of the hazard (contamination), so the product might also offer protection to the patient or others from the wearer.

3.1.11 *single-use, adj*—refers to an item of protective clothing that is intended to be used once and then disposed.

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

4. Significance and Use

4.1 This specification provides minimum requirements for isolation gowns used for protection of healthcare workers where the potential for exposure to blood, body fluids, and other potentially infectious materials exists. This specification requires barrier testing based on the system of classifying gowns established in ANSI/AAMI PB70 and sets general safety requirements for isolation gowns based on biocompatibility. Performance requirements are established for important physical properties including tensile strength, tear strength, and seam strength. Methods to be used for optional reporting of performance of linting resistance, evaporative resistance, water vapor transmission rate, abrasion resistance, and flex durability are provided.

[10] Available at https://www.ecfr.gov/current/title-16/chapter-II/subchapter-D/part-1611.

[11] Available at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030.

[12] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings.

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

[14] Siegel, J. D., Rhinehart, E., Jackson, M., and Chiarello, L., "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings," *American Journal of Infection Control*, Vol 35, No. 10, 2007, pp. S65–S164.

4.2 Isolation gowns are either multiple-use or single-use products, as designated by the manufacturer. This specification is intended to provide the basis for manufacturer claims for isolation gown performance and efficacy. For multiple-use gowns, this specification takes into account the anticipated care and maintenance of these products by examining test requirements for isolation gown materials both before and after the maximum expected number of cycles for laundering and sterilization, if used sterile.

4.3 While isolation gowns are classified for barrier performance as specified in ANSI/AAMI PB70, this specification establishes other design criteria, physical performance criteria, labeling, and documentation requirements for isolation gowns and their materials.

4.3.1 By design, isolation gowns are required to provide 360° protection to the healthcare worker in a manner that, at a minimum, ensures that both arms and the front, sides, and back of the body from the knees up to but not including the neck, are fully covered during movement and use when the correct gown size is worn. Multiple-use isolation gowns are required to either have a means for recording or marking the number of processing cycles or to have an area (or multiple areas) on the gown that a processor could use to employ their own means for recording or marking the number of processing cycles.

4.3.2 Isolation gown materials are required to be non-sensitizing, non-irritating, and non-cytotoxic to meet biocompatibility criteria.

4.3.3 In addition to the barrier performance of the isolation gown material and seams, isolation gown material and seams are also required to meet minimum strength requirements for tensile strength, tear strength, and seam strength that have been established on the basis of an analysis of workplace requirements. Isolation gowns with different barrier level claims shall meet the same minimum strength requirements regardless of their barrier level.

4.3.4 Additional properties for isolation gown material, such as lint generation, evaporative resistance or water vapor transmission rate, abrasion resistance, and durability are optional for testing for the purpose of documenting performance. No minimum criteria are established for these properties, but purchasers may use this information to compare products.

4.4 Isolation gowns differ from surgical gowns based on their intended use and the expectation that the isolation gown provides 360° protection to the healthcare worker. Specific requirements for surgical gowns beyond the barrier performance of surgical gown materials and seams are provided in Specification F2407/F2407M.

4.5 Additional information for the testing, selection, and use of isolation gowns is provided in AAMI TIR11.

5. Design Requirements

5.1 Isolation gowns shall be designed to comply with the barrier performance requirements of ANSI/AAMI PB70.

5.2 For isolation gowns and other gowns intended for use in isolation applications, the critical zone shall comprise the entire gown, including the seams but excluding the cuffs, hems, and bindings, and shall have a barrier performance of at least Level 1. The manufacturer shall provide detailed information about the barrier performance of each critical zone component.

5.3 To ensure 360° coverage, isolation gowns shall be designed in a manner that, at a minimum, ensures that both arms and the front, sides, and back of the body from the knees up to but not including the neck, are fully covered during movement and use when the correct gown size is worn.

NOTE 1—Isolation gowns are able to achieve 360° coverage with the closure in the back, due to the overlap of the back portions of the gown.

5.4 Isolation gowns which are intended for reuse shall have either a means for recording or marking the number of processing cycles, or have an area (or multiple areas) on the gown that a processor could use to employ their own means for recording or marking the number of processing cycles. The recording area shall be visible/readable by the wearer.

6. General Safety Requirements

6.1 *Biocompatibility*—Assessment shall be conducted to ensure the safety of the device. Materials used in the construction of isolation gowns are classified as external devices that contact breached or compromised surfaces for limited exposures and shall pass the appropriate evaluations in accordance with ANSI/AAMI BE78. Alternatively, ISO 10993-5, ISO 10993-10, and ISO 10993-23 are permitted to be used. Assessment shall be conducted to ensure the safety of the device. Materials used in the construction of isolation gowns shall be non-sensitizing, non-irritating, and non-cytotoxic.

NOTE 2—The entire gown is considered body contacting. For the purposes of evaluating gown biocompatibility, all materials and colors used in the construction of isolation gowns should be part of the test samples. These materials should include all different materials and components used in the gown, including thread and elastic, seam binding, or knit cuffs, if used in the gown's construction.

NOTE 3—FDA categorizes the final, finished isolation gown as surface-contacting devices that contact breached or compromised surfaces for short-term exposure and therefore the isolation gown shall pass the appropriate evaluations in accordance with ISO 10993, if supplied in the USA. Common test methods used for the assessment of the biocompatibility, including cytotoxicity, skin sensitization, and irritation, are ISO 10993-5, ISO 10993-10, and ISO 10993-23.

NOTE 4—If an isolation gown includes drugs, biologics, nanomaterials, or antimicrobial/antiviral agents, additional testing or information (for example, chemical characterization) associated with a toxicological risk assessment may be warranted.

NOTE 5—The common test methods for biocompatibility of finished isolation gowns are *in vitro* cytotoxicity (for example, MEM elution), irritation, and skin sensitization.

NOTE 6—If the isolation gown is sterilized by the ethylene oxide sterilization method, then the residual ethylene oxide and ethylene chlorohydrin shall be within the maximum allowable limits specified in ISO 10993-7, or the isolation gown shall exhibit negligible irritation as specified in ISO 10993-23.

6.2 *Flame Spread*—Materials used in the construction of isolation gowns shall meet the requirements for Class 1 "normal flammability" in accordance with 16 CFR Part 1610 (or 16 CFR 1611 if the material is vinyl) before and after the conditioning specified in Section 9.

6.3 *Natural Rubber Latex*—Gowns that contain natural rubber latex shall include the latex caution statement CFR

801.437, "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTION." (See 11.3 for labeling requirements.)

7. Barrier and Physical Property Requirements

7.1 The barrier performance and physical property performance requirements of single and multiple-use isolation gowns shall be tested and reported as specified in Table 1. Multiple-use isolation gowns shall meet these minimum requirements after one washing/drying and sterilization cycle, if used sterile, and after the maximum number of cycles of washing/drying and sterilization processing, if used sterile, specified by the manufacturer.

NOTE 7—Tensile and tear strength requirements apply to both machine (MD) and cross-machine (CD) direction of material. The seam strength is tested perpendicular to the seam and shall be tested in locations where the material orientations are different.

7.2 Additional performance properties that can be reported are listed in Table 2.

NOTE 8—Refer to Section 10 and Appendix X1 for more information about Table 1 and Table 2 test methods.

8. Sampling

8.1 Sample size for the physical property requirements shall be determined as following for each lot. For tensile strength, take five samples from the machine direction and eight samples from the cross-machine direction for each test condition described in 9.1 – 9.3, as applicable to a material specification. For tear strength, take five samples from the machine direction and five samples from the cross-machine direction, for each test condition described in 9.1 – 9.3, as applicable to a material specification. For seam strength, take five test samples for each specified seam assembly used in the isolation gown for each test condition described in 9.1 – 9.3, as applicable to a material specification. In these test methods, each sample shall be taken from a different garment and minimum three non-consecutive lots.

8.2 Sample size for the barrier requirements shall be sufficient to establish an acceptable statistical confidence interval for the property being measured. Test specimens shall be selected randomly according to a statistical sampling plan that is appropriate for the type of data being generated. For examples of suitable sampling plans specific to barrier performance properties, see ANSI/AAMI PB70 Annex C. In this document, the maximum AQL is set at 4.0 % at a 95 % acceptance level (Alpha = 0.05), with the maximum RQL set at 20 % at a 10 % acceptance level (Beta = 0.10). For an original classification of a product, the sampling plan shall be applied independently to each material or component, or both, and the finished product across multiple non-consecutive lots (three or more with a minimum sample size of 32 per lot).

8.2.1 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.

8.3 Material, seam, and point-of-attachment specimens shall be removed from manufactured isolation gowns and conditioned in accordance with Section 9, and shall be representative of the actual finished gowns.

8.3.1 If different types of seams are used in the construction of a gown, each type of seam shall be separately tested.

8.3.2 If the seam/point of attachment is located close to the edge (less than 2 in. to the edge), barrier resistance testing is not required on those areas.

9. Conditioning

9.1 *General Requirements*—Testing used for demonstrating performance of isolation gowns shall be conducted after ambient conditioning on both single and multiple-use products as specified in 9.2. For isolation gowns where laundering and sterilization (if used sterile) are required before use, the manufacturer must conduct testing outlined in this specification after all required laundering and sterilization processing (if used sterile) have been completed. If the manufacturer is claiming continued barrier performance after multiple uses, then the manufacturer must conduct testing outlined in this specification after one washing/drying and sterilization cycle, if used sterile, and the maximum number of cycles of washing/drying and sterilization processing, if used sterile (9.3), specified by the manufacturer using samples taken from the same lots.

9.2 *Ambient Conditioning*—All specimens shall be conditioned at a temperature of 21 ± 3 °C [70 ± 5 °F] and relative humidity of 65 ± 5 % for at least 24 h in accordance with Practice D1776/D1776M, unless otherwise specified by the selected test method.

9.3 *Processing Conditioning*—Specimens from multiple-use isolation gowns shall be processed (laundered, sterilized, or both) using the manufacturer's recommended processing procedures. The total number of processing cycles specified in the manufacturer's claims shall be used.

TABLE 1 Barrier Performance and Physical Property Performance Requirements of Single and Multiple-Use Isolation Gowns

Property	Material Type	Test Method	AAMI PB70 Level			
			1	2	3	4
Barrier Performance[A]	All	AATCC 42	≤4.5 g	≤1.0 g	≤1.0 g	N/A
	All	AATCC 127	N/A	≥20 cm	≥50 cm	N/A
	All	ASTM F1671/F1671M	N/A	N/A	N/A	Pass
Tensile Strength	All	ASTM D5034	≥30 N [≥7 lbf]	≥30 N [≥7 lbf]	≥30 N [≥7 lbf]	≥30 N [≥7 lbf]
Tear Strength	All	ASTM D5587	≥10 N [≥2.3 lbf]	≥10 N [≥2.3 lbf]	≥10 N [≥2.3 lbf]	≥10 N [≥2.3 lbf]
Seam Strength	All	ASTM D1683/D1683M	≥30 N [≥7 lbf]	≥30 N [≥7 lbf]	≥30 N [≥7 lbf]	≥30 N [≥7 lbf]

[A] According to ANSI/AAMI PB70 with 4 % acceptable quality level (AQL), 20 % rejectable quality level (RQL).

TABLE 2 Optional Tests Documentation Requirements (Documentation Only)[A]

Performance Property	Test Method	Subsection	Reported Data
Lint Generation[B]	ISO 9073-10	10.3.1	Particle count for each side, unless material is the same on each side
Evaporative Resistance *or*	ASTM F1868	10.3.2	Average evaporative resistance
Water Vapor Transmission Rate *or*	ASTM D6701	10.3.3	Average water vapor transmission rate
Water Vapor Transmission Rate[C] (Mocon Method)	WSP 70.4	10.3.3	Average WVTR or g/m^2/24 h
Abrasion Resistance (Martindale)	ASTM D4966	10.3.4	Average abrasion resistance
Flex Durability	ASTM F392/F392M	10.3.4	Average flex durability

[A] Appendix X1 provides a description of each method, its intended application, and limitations.
[B] Results from lint testing are highly operator and equipment dependent. It is recommended that data be collected using a single piece of equipment, using a single operator, and on the same day to minimize variability.
[C] This specification permits reporting either evaporative resistance or water vapor transmission rate using Test Method F1868, Test Method D6701, or WSP 70.4. Appendix X1 provides a comparison of the three methods with their respective procedures, applications, specified conditions, 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 gown comfort can be made through actual wear tests. Measuring the breathability of the fabrics used to construct isolation gowns is one method of predicting thermal comfort. Those gowns that are designed and constructed of materials which more freely allow evaporation of perspiration and body heat transfer provide better thermal comfort. When gowns are constructed or reinforced with different materials in different zones, 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 isolation gowns (or gown materials) should only be made using the same test method. Also included in Appendix X1 are other potential factors that can affect comfort.

10. Test Methods (Refer to Tables 1 and 2)

10.1 *Barrier Performance*—Determine the barrier performance in accordance with ANSI/AAMI PB70.

10.2 *Physical Performance*—Determine the physical performance in accordance with test methods provided in 10.2.1 – 10.2.3.

10.2.1 *Tensile Strength*—Determine the tensile strength of each material except for fastening elements (for example, hook-and-loop closure tape, snaps, belts, ties, and cuffs) used in the construction of the isolation gown as specified in Test Method D5034, following the conditioning specified in Section 9. Where multiple separable layers of materials are used in the construction of isolation gowns, each layer shall be tested individually. Average tensile strength for each material direction shall be reported. The tensile strength of each specimen shall be recorded and reported to the nearest 0.5 N [0.1 lbf] of force. An average tensile strength shall be calculated and reported for both machine and cross-machine direction. Pass/fail performance shall be based on the average tensile strength in both the machine and cross-machine direction. A failure in any one direction shall constitute failure for the material.

10.2.2 *Tear Strength*—Determine the tear strength of each material except for fastening elements (for example, hook-and loop-closure tape, snaps, belts, ties, and cuffs) used in the construction of the isolation gown as specified in Test Method D5587 using Option 1 to calculate the tearing force, following the conditioning specified in Section 9. Option 2 could be used for only those fabrics that exhibit less than five peaks. Average tear strength for each material direction shall be reported. The tear strength of each specimen shall be recorded and reported to the nearest 0.5 N [0.1 lbf] of force. An average tear strength shall be calculated and reported for both machine and cross-machine direction. Pass/fail performance shall be based on the average tear strength in both the machine and cross-machine direction. A failure in any one direction shall constitute failure for the material.

10.2.3 *Seam Strength*—Determine the seam strength of isolation gown woven or nonwoven materials and materials that incorporate woven or nonwoven fabric layers, as specified in Test Method D1683/D1683M, following the conditioning specified in Section 9. Determine the seam strength of isolation gown knit or stretch woven materials as specified in Test Methods D751, using the tension testing machine with ring clamp, following the conditioning specified in Section 9. The seam strength of each specimen shall be recorded and reported to the nearest 0.5 N [0.1 lbf] of force. An average seam strength shall be calculated and reported for each type of seam used in the isolation gown. Pass/fail performance shall be based on the average seam strength in each type of seam used in the isolation gown. A failure in any one type of seam shall constitute failure for the seam.

10.3 *Optional Testing:*

10.3.1 *Lint Generation*—Determine the lint generation of each side of each material used in the construction of the isolation gowns as specified in ISO 9073-10, using a 5-min test time, following the conditioning specified in Section 9. If the surface for each side of the material is the same, it shall be permitted to test only one side. Cuffs and attachments are excluded from the lint generation testing.

10.3.2 *Evaporative Resistance*—Determine evaporative resistance of the materials or composites in the isolation gown, exclusive of cuffs and attachments, as specified in Test Method F1868, Part B. Where multiple separable layers of materials are used in the construction of isolation gowns, the combination of all material layers shall be tested. Separately report the average evaporative resistance for materials or composites.

10.3.3 *Water Vapor Transmission Rate*—Determine the water vapor transmission rate of materials or composites, exclusive of cuffs and attachments, as specified in Test Method D6701 or WSP 70.4. Separately report the average water vapor transmission rate for materials or composites. All measurements conducted must disclose the temperature and relative humidity used to obtain the water vapor transmission rate.

10.3.4 *Durability*—Determine the durability of materials or composites, exclusive of cuffs and attachments, as specified in Test Method D4966. Separately report the average durability for materials or composites. Resistance of ties to the typical stresses applied during wear is also another important property

to evaluate. Resistance of ties to pulling actions can be determined by using a modified tensile strength test (Test Method D5034) with the use of tied areas and ties. Some ties used in the construction of isolation gowns are made to break during doffing of the gown; however, they shall withstand typical stresses applied during use. Flex durability of the materials or composites and seams in the isolation gown, exclusive of cuffs and attachments, can be determined as specified in Practice F392/F392M, subsection 4.3.4 or 4.3.5. Where multiple materials or seam types are used in the construction of isolation gowns, the combination of all material seams shall be tested. Separately report the flex durability for materials or seam types.

NOTE 9—Procedures D and E are suggested for barrier materials in Practice F392/F392M.

11. Labeling Requirements

11.1 *Product Labeling*—The gown shall be folded and packaged in such a way that the size and level of barrier performance is visible. Each isolation gown item shall be labeled with the following information, at a minimum:

11.1.1 Manufacturer name.

11.1.2 Product or style name.

11.1.3 The barrier performance level for the isolation gown as classified by ANSI/AAMI PB70.

11.1.4 Product lot or serial number.

11.1.5 Size.

11.1.6 For multiple-use products, use-by date, integral tracking mechanism (for example, marking grid, bar code system, radio frequency chip, or other suitable method) for recording the number of processing.

NOTE 10—The product lot or serial number applies to either individually manufactured isolation gowns or to groups or lots of manufactured isolation gowns, and serves as a means for tracing the manufacture of products.

11.2 *Package Labeling*—Each package containing isolation gowns shall be prominently labeled with the following information:

11.2.1 Manufacturer name.

11.2.2 Product or style name.

11.2.3 The barrier performance level for the isolation gown as classified by ANSI/AAMI PB70.

11.2.4 Meets requirements of Specification F3352/F3352M.

11.2.5 Product lot or serial number.

11.2.6 Manufacturing date.

11.2.7 Use-by date.

11.2.8 Size.

11.2.9 Manufacturer address and phone number.

11.2.10 For multiple-use products, processing instructions, including a statement of the number of times that the product can be processed and continue to maintain its safety and performance characteristics.

NOTE 11—The product lot or serial number applies to either individually manufactured isolation gowns or to groups or lots of manufactured isolation gowns, and serves as a means for tracing the manufacture of products.

11.2.11 Recommended storage conditions.

11.2.12 Label as “sterile” if sold sterilized.

11.3 If the gown contains natural rubber latex, it must be labeled with a caution statement (see 6.3). If the gown and its components are composed of materials that are free from natural rubber latex, it is optional for this information to be on a label.

12. Technical Information

12.1 When requested by the purchaser, the following technical information shall be provided:

12.1.1 Detailed information on the performance of all areas of the isolation gowns.

12.1.2 The results of each test used for the performance properties of materials and seams for the isolation gown, based on this specification.

12.1.3 For multiple-use products, instructions on inspections and testing that can be performed by processors to verify the continued safety and effectiveness of the product.

12.1.4 A statement indicating compliance of the isolation gown with this specification, including the number, year of issue, and revision letter.

13. Sizing

13.1 A description of the manufacturer’s sizing system indicating the range of wearer dimensions for which the specific size is intended shall be provided upon request.

NOTE 12—An example of a sizing system is the lists of specific isolation gown sizes provided by the manufacturer and the respective range in wearer height and girth that is accommodated by each size.

14. Conformity Assessment

14.1 Isolation gowns that are declared to be compliant with this standard specification shall meet or exceed all Model B requirements for conformity assessment specified in Annex A3 of Guide F3050, with the following additions:

14.1.1 For the purposes of claiming that a isolation gown meets this specification, testing specified in Section 7 shall be performed by a laboratory or laboratories accredited to ISO/IEC 17025, with scope of accreditation that includes the specific test or tests. Laboratories shall be accredited by an accreditation body signatory to the International Laboratory Accreditation Cooperation, Mutual Recognition Arrangement (ILAC MRA).

NOTE 13—It is not the intent of this requirement that all testing be performed at the same laboratory, and manufacturers can perform their own testing if they hold the appropriate accreditation.

14.1.2 As part of the Model B conformity assessment requirements in Guide F3050, manufacturers of conforming isolation gowns shall issue a declaration of conformity (Supplier Declaration of Conformity, SDOC) that the specific product meets the applicable requirements of this specification.

14.1.3 Manufacturers shall be permitted to have a quality management system that is certified to ANSI/AAMI/ISO 13485 in lieu of ISO 9001.

14.2 Manufacturers shall be permitted to meet the more rigorous conformity assessment requirements of Model C or D of Guide F3050 that include additional requirements in independent oversight, quality management system, and other conformity requirements.