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

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INTRODUCTION

Healthcare workers can be exposed to biological fluids 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). Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin contact with microorganisms, body fluids, and other potentially infectious materials through the use of protective apparel.

Healthcare protective clothing, including surgical gowns, is worn by healthcare workers to protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and other contaminants from one person to another.

This specification addresses the performance of surgical gowns designed to preserve the sterile field and/or protect against exposure of healthcare workers to blood, body fluids, and other potentially infectious materials during surgery and other healthcare procedures.

This specification establishes uniform testing and reporting requirements for surgical gown manufacturers in order to provide information to end users that can be used in making informed decisions in the selection and purchase of surgical gowns according to the anticipated exposures. This information is also useful for helping end users comply with the Occupational Safety and Health Administration's blood-borne pathogen standard (29 CFR 1910.1030).

1. Scope

1.1 This specification establishes requirements for the performance, documentation, and labeling of surgical gowns used in healthcare facilities. Four levels of barrier properties for surgical gowns are specified in ANSI/AAMI PB70 and are included in this specification for reference purposes.

NOTE 1—Some properties require minimum performance and others are for documentation only.

NOTE 2—ANSI/AAMI PB70 evaluates the barrier properties of surgical gown fabrics using water only in Levels 1, 2, and 3. Since surgical gowns are exposed to blood and other fluids with different surface tensions, the performance of additional testing to identify the barrier levels to simulated biological fluids is required for a Level 4 gown.

1.2 This specification does not cover all the requirements that a healthcare facility deems necessary to select a product, nor does it address criteria for evaluating experimental products.

1.3 This specification is not intended to serve as a detailed manufacturing or purchase specification, but can be referenced in purchase specifications as the basis for selecting test requirements.

1.4 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.

1.5 *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] This specification is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

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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:*[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

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

D5733 Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure (Withdrawn 2008)[3]

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

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

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

F1494 Terminology Relating to Protective Clothing

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

F3050 Guide for Conformity Assessment of Personal Protective Clothing and Equipment

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

2.2 *AAMI Documents:*[4]

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

ANSI/AAMI ST65 Processing of Multiple-Use Surgical Textiles for Use in Healthcare Facilities

AAMI TIR11 Selection of Surgical Gowns and Drapes in Healthcare Facilities

ANSI/AAMI BE78 Biological Evaluation of Medical Devices, Part 10: Test for Irritation and Sensitization

2.3 *AATCC Standards:*[5]

AATCC 42 Water Penetration Resistance: Impact Penetration Test

AATCC 127 Water Resistance: Hydrostatic Pressure Test

2.4 *ANSI/ASQ Standards:*[6]

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:*[7]

ISO 2859-1 Sampling Plans for Inspection by Attributes

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

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 10993-7 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

ISO 11134 Sterilization of Healthcare 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 Healthcare Products—Requirements for Validation and Routine Control—Radiation Sterilization

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

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

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[8]

16 CFR 1611 Standard for the Flammability of Vinyl Plastic Film, Federal Register, Vol 40, No. 59891, Dec. 30, 1975[9]

21 CFR 801.437 User Labeling for Devices That Contain Natural Rubber[10]

21 CFR 820 Subpart K Labeling and Packaging Control, Federal Register, Vol 8, April 1, 2019[11]

[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] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from the Association for the Advancement of Medical Instrumentation, 110 North Glebe Road, Suite 220, Arlington, VA 22201.

[5] Available from American Association of Textile Chemists and Colorists (AATCC), One Davis Dr., P.O. Box 12215, Research Triangle Park, NC 27709-2215.

[6] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[7] 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.

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

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

[10] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.437.

[11] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820&showFR=1&subpartNode=21:8.0.1.1.12.11.

21 CFR 878.4040 Surgical Apparel, Federal Register, Vol 63, No. 318, Nov. 12, 1998, No. 63247[12]

29 CFR 1910.1030 Occupational Exposure to Blood-Borne Pathogens: Final Rule, Federal Register, Vol 66, No. 12, Jan. 18, 2001[13]

Food and Drug Administration UDI FDA Final Rule from Federal Register[14]

2.7 *INDA Standard:*[15]

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.

3.1.1.1 *Discussion*—For the purpose of this test method, the primary blood-borne pathogens include Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Other microorganisms must be considered on a case-by-case basis.

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, 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 Part 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 surgical gowns based on the critical zone(s). The critical zone can encompass multiple parts of the garment.

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

3.1.4.1 *Discussion*—Seams at the boundary between the critical and noncritical zones are not considered parts of the critical zone(s).

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 used in a healthcare setting.

3.1.7 *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 use.

3.1.7.1 *Discussion*—In this specification, multiple-use protective clothing is subject to cleaning (laundering) and sterilization between each use.

3.1.8 *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.

3.1.9 *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.

3.1.9.1 *Discussion*—Examples of protective clothing include surgical gowns, isolation gowns, decontamination garments, aprons, sleeve protectors, and certain types of laboratory coats. The primary purpose of the protective clothing is to act as a barrier between the wearer and a hazard. However, the product may also offer protection as a barrier, which prevents the body from being a source of contamination.

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

3.1.10.1 *Discussion*—In this specification, single-use protective clothing is subject to sterilization prior to use per the manufacturer's instructions.

3.1.11 *surgical gown, n*—protective clothing that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate matter.

3.1.11.1 *Discussion*—This definition is consistent with the definition provided by the U.S. Food and Drug Administration (21 CFR 878.4040) except that the word "device" is used instead of protective clothing. However, while historically surgery happens in the operating room, currently, invasive procedures are also performed in procedure rooms and in certain situations (for example, patient cannot be moved) at the bedside. Therefore, surgical gowns are worn by personnel during these procedures to protect both the patient and personnel from the transfer of microorganisms, body fluids, and particulate matter.

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 surgical gowns used for protection of healthcare workers where the potential for exposure to blood, body fluids, and other potentially infectious materials exists. The specification requires barrier testing based on the system of classifying gowns established in ANSI/AAMI PB70 and sets general safety requirements for surgical gowns based on biocompatibility, sterility assurance, and flame spread. Performance requirements are established for important physical properties, including tensile strength, tear strength, and seam strength. Methods

[12] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=878.4040.

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

[14] Available at https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system.

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

to be used for optional reporting of performance of linting resistance, evaporative resistance, water vapor transmission rate, and abrasion resistance are provided.

4.2 This specification does not address protective clothing used for nonsurgical applications, such as isolation gowns or 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.

4.3 Surgical 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 surgical 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 surgical gown materials both before and after the maximum expected number of cycles for laundering and sterilization.

4.4 Additional information on the processing of multiple-use surgical gowns is provided in ANSI/AAMI ST65.

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

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

4.5.2 Additional properties for surgical gown material such as lint generation, evaporative resistance or water vapor transmission rate, 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.

4.5.3 Surgical gowns differ from isolation gowns based on their intended use and anticipated location of liquid contact. Specific requirements for isolation gowns beyond the barrier performance of isolation gown materials and seams are provided in Specification F3352/F3352M.

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

5. Design Requirements

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

5.2 Surgical 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 laundering and sterilization cycles. The recording area shall be visible/readable by the wearer.

5.3 The sizes of the critical zone(s) of a surgical gown shall be defined by anatomical reference in accordance with ANSI/AAMI PB70.

6. General Safety and Performance Requirements

6.1 *Biocompatibility:*

6.1.1 Materials used in the construction of surgical gowns shall be 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 10993-10 is permitted to be used.

6.2 *Sterility Assurance Level:*

6.2.1 The selected sterilization process for surgical gowns shall have a sterility assurance level of at least 10-6.

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

NOTE 3—Appropriate sterilization processes include those specified in ISO 11134 for moist heat, ISO 11135 for EtO, ISO 11137 for Gamma, or ISO 13683 also for moist heat.

6.3 *Flame Spread:*

6.3.1 Materials used in the construction of surgical 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.

6.4 *Natural Rubber Latex:*

6.4.1 Gowns that contain natural rubber latex should be clearly labeled and include the latex caution statement per CFR 801.437, "THIS PRODUCT CONTAINS NATURAL RUBBER LATEX WHICH MAY CAUSE ALLERGIC REACTION." (See 11.2.13 for labeling requirements.)

7. Barrier and Physical Property Requirements

7.1 The barrier performance of single and multiple-use surgical gowns shall be tested and reported as specified in ANSI/AAMI PB70-2012.

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

NOTE 4—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.

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

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

Property	Material Type	Test Method	ANSI/AAMI PB70 Level All Barrier Levels (1, 2, 3, and 4)
Tensile strength	All	ASTM D5034	≥30 N [≥7 lbf]
Tear strength	All	ASTM D5587 or D5733	≥10 N [≥2.3 lbf]
Seam strength	All	ASTM D1683/D1683M	≥30 N [≥7 lbf]

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

Performance Property	Test Method	Subsection	Reported Data
Lint generation[B]	ISO 9073, Part 10	10.3.1	Particle count for each side, unless material is the same on each side
Evaporative resistance[C] or	ASTM F1868	10.3.2	Average evaporative resistance
Water vapor transmission rate[C] 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 water vapor transmission rate
Water vapor transmission rate[C]	ASTM E96/E96M	10.3.3	Average permeance
Abrasion resistance (Martindale)	ASTM D4966	10.3.4	Average abrasion resistance

[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 or D6701, WSP 70.4, or Test Methods E96/E96M. Appendix X1 provides a comparison of the four methods with their respective procedures, application, 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 surgical 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 surgical 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.

NOTE 5—Refer to Section 10 and Appendix X1 for more information and conditions about Table 1 and Table 2 test methods.

8. Sampling

8.1 Sample size for the physical property requirements shall be determined as follows 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 – 9.4, 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 – 9.4, as applicable to a material specification. For seam strength, take five test samples for each specified seam assembly used in the surgical gown for each test condition described in 9.1 – 9.4, as applicable to a material specification. In these test methods, each sample shall be taken from a different garment and minimum three nonconsecutive 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 lots (minimum three nonconsecutive lots 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 surgical 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), the barrier resistance testing is not required on those areas.

9. Conditioning

9.1 *General Requirements*—Testing used for demonstrating performance of surgical gowns shall be conducted after ambient conditioning on both single and multiple-use products as specified in 9.2. For surgical gowns where the manufacturer is claiming continued barrier performance after multiple uses, or if laundering/sterilization is required before use, then testing shall also be conducted after the maximum number of cycles of washing/drying (9.3) and sterilization (9.4) 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 *Laundering Conditioning*—Specimens from multiple-use surgical gowns shall be laundered using the manufacturer's

recommended washing and drying procedures. These procedures shall conform to ANSI/AAMI ST65. The total number of washing and drying cycles specified in the manufacturer's claims shall be used.

9.4 *Sterilization*—If specimens are not removed from sterile surgical gowns, specimens from surgical gowns shall be sterilized using the manufacturer's recommended sterilization process and specific sterilization cycle parameters (for example, time, temperature, sterilant concentration, humidity, etc.). Sterilization of specimen surgical gowns shall be performed following each laundering cycle as specified in 9.3 for multiple-use surgical gowns. The total number of sterilization cycles specified in the manufacturer's claims shall be followed.

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 surgical 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 surgical gowns, the combination of all material layers shall be tested. Report the average tensile strength for each material direction. 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 machine and cross-machine directions. 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 surgical gown as specified in Test Method D5587 (woven) using Option 1 to calculate the tearing force, or Test Method D5733 (nonwovens), following the conditioning specified in Section 9. Where multiple separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. Report the average tear resistance for each material direction. 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 the both 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 surgical 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 surgical 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. Where multiple separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. 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 surgical gown. Pass/fail performance shall be based on the average seam strength in each type of seam used in the surgical 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 surgical gowns as specified in ISO 9073 Part 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.

10.3.2 *Evaporative Resistance*—Determine evaporative resistance of the materials or composites in the critical zone and noncritical zone, 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 surgical gowns, the combination of all material layers shall be tested. Separately report the average evaporative resistance for critical zone and noncritical zone materials or composites.

10.3.3 *Water Vapor Transmission Rate*—Determine the water vapor transmission rate of materials or composites in the critical zone and noncritical zone, exclusive of cuffs and attachments, as specified in Test Method D6701, WSP 70.4, or Test Methods E96/E96M. Where multiple separable layers of materials are used in the construction of surgical gowns, the combination of all material layers shall be tested. Separately report the average water vapor transmission rate for the critical zone and noncritical zone materials or composites. All measurements conducted must disclose the temperature and relative humidity used to obtain the water vapor transmission rate.

NOTE 6—Either evaporative resistance (10.3.2) or water vapor transmission rate (10.3.3) is tested.

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 surgical gowns are made to break during doffing of the gown; however, they shall withstand typical stresses applied during use.

11. Labeling Requirements

11.1 *Product Labeling*—Each surgical gown item shall be prominently 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 surgical gown as classified by ANSI/AAMI PB70.

11.1.4 Product lot or serial number.

NOTE 7—The product lot or serial number applies to either individually manufactured surgical gowns or to groups or lots of manufactured surgical gowns, and serves as a means for tracing the manufacture of products.

11.1.5 Size.

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

11.2 *Package Labeling*—Each package containing surgical 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 surgical gown as classified by ANSI/AAMI PB70.

11.2.4 Meets requirements of ASTM Specification F2407/F2407M.

11.2.5 Product lot or serial number.

11.2.6 Manufacturing date.

11.2.7 Use-by date.

NOTE 8—Information and data used by the manufacturer for determining the use-by date are to be available upon request by the purchaser. Such information should be validated in some fashion and, while it is currently beyond the scope for the revision of the standard, the manufacturer making a "use-by date" claim should be able provide information or data to substantiate the provided shelf life.

11.2.8 Size.

11.2.9 Manufacturer address and phone number.

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

11.2.11 Label as "sterile" if sold sterilized.

11.2.12 Recommended storage conditions.

11.2.13 If the gown contains natural rubber latex, it must be labeled with a caution statement (see 6.4). 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.

NOTE 9—FDA administers the Global Unique Device Identification Database (GUDID) to serve as a reference catalog for every device with a unique device identifier (UDI). The FDA established the unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use.

12. Technical Information

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

12.1.1 Manufacturer address and phone number.

12.1.2 Detailed information on the performance of all areas of the critical zone(s).

12.1.2.1 A detailed description of the gown areas representing the critical zone(s).

NOTE 10—Suggested forms of this information are a graphical presentation of the product showing the level of barrier performance of each component, a narrative description of the level of barrier performance of each component, or both.

12.1.3 A description of the manufacturer's sizing system indicating the range of wearer dimensions for which the specific size is intended.

12.1.4 The results of each test used for the performance properties of materials and seams for the surgical gown based on this specification.

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

12.2 Information that shall always be included in packages containing multiple-use products are listed in 12.2.1 and 12.2.2.

12.2.1 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.

12.2.2 Instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product.

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 11—An example of a sizing system is the lists of specific surgical 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 Surgical 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 surgical 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 12—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 surgical 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 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.