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.

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

This standard is issued under the fixed designation F2407/F2407M; 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.

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

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 Resistance, Evaporative Resistance, and Total Heat Loss Measurements 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:*[3]

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:*[4]

AATCC 42 Water Penetration Resistance: Impact Penetration Test

AATCC 127 Water Resistance: Hydrostatic Pressure Test

2.4 *ANSI/ASQ Standards:*[5]

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:*[6]

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 10993-5 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

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[7]

16 CFR 1611 Standard for the Flammability of Vinyl Plastic Film, Federal Register, Vol 40, No. 59891, Dec. 30, 1975[8]

21 CFR 801.437 User Labeling for Devices That Contain Natural Rubber[9]

21 CFR 820 Subpart K Labeling and Packaging Control,

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

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

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

[6] 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.

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

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

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

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Full document details: ASTM F2407/F2407M-23a

Federal Register, Vol 8, April 1, 2019[10]
21 CFR 878.4040 Surgical Apparel, Federal Register, Vol 63, No. 318, Nov. 12, 1998, No. 63247[11]
29 CFR 1910.1030 Occupational Exposure to Blood-Borne Pathogens: Final Rule, Federal Register, Vol 66, No. 12, Jan. 18, 2001[12]
Food and Drug Administration UDI FDA Final Rule from Federal Register[13]
2.7 *INDA Standard:*[14]
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

[10] 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.
[11] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=878.4040.
[12] Available at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030.
[13] Available at https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system.
[14] Available from Association of the Nonwoven Fabrics Industry (INDA), 1100 Crescent Green, Suite 115, Cary, NC 27518, http://www.inda.org.

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Full document details: ASTM F2407/F2407M-23a

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 10993-5, 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 surgical gowns shall be non-sensitizing, non-irritating, and non-cytotoxic.

NOTE 3—The entire gown is considered body contacting. For the purposes of evaluating gown biocompatibility, all materials and colors used in the construction of surgical gowns should be part of the test samples. These materials should include all different materials and components used in the gown, including the thread and elastic, seam binding, or knit cuffs, if used in the gown's construction.

NOTE 4—FDA categorizes the final, finished surgical gown as surface-contacting devices that contact breached or compromised surfaces for short-term exposure and therefore the surgical 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 5—If a surgical 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 6—The common test methods for biocompatibility of finished surgical gowns are *in vitro* cytotoxicity (for example, MEM elution), irritation, and skin sensitization.

NOTE 7—If the surgical gown is sterilized by 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 surgical gown shall exhibit negligible irritation as specified in ISO 10993-23.

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 8—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.

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