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StandardSpecification for Surgical Gowns Intended for Use in Healthcare Facilities[1]

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INTRODUCTION

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.

Healthcare workers can be exposed to biological fluids capable of transmitting disease. 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.

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 the healthcare facilities. Four levels of barrier properties for surgical gowns are specified in AAMI PB70:2003 and are included in this specification for reference purposes.

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

NOTE 2—AAMI PB70:2003 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

D751 Test Methods for Coated Fabrics

[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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[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.

D1683 Test Method for Failure in Sewn Seams of Woven Apparel Fabrics
D1776 Practice for Conditioning and Testing Textiles
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 (Withdrawn 2008)[3]
F1494 Terminology Relating to Protective Clothing
F1671 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 and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate

2.2 *AAMI Documents:*[4]

AAMI PB70:2003 Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities
AAMI ST65:2000 Processing of multiple-use surgical textiles for use in health care facilities
AAMI TIR11:1994 Selection of Surgical Gowns and Drapes in Healthcare Facilities
AAMI/ANSI BE78:2002 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/ASQC Standard:*[6]

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

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 non-conforming
ISO 9073 Part 10 Textiles—Test methods for nonwovens—Part 10: Lint and other particles generation in the dry state
ISO 10993-10 Biological evaluation of medical devices—Part 10: Tests for irritation and delayed-type hypersensitivity
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
ISO 13683 Sterilization of healthcare products—Requirements for validation and routine control of moist heat sterilization in healthcare facilities

2.6 *Federal Standards:*[7]

16 CFR 1610 Standard for the Flammability of Clothing Textiles, Federal Register, Vol. 40, No. 59891, Dec. 30, 1975
21 CFR Parts 801.437 and 878.4040 Surgical Apparel, Federal Register, Vol. 63, No. 318, Nov. 12, 1998, pp. 63247.
29 CFR Part 1910.1030 Occupational Exposure to Bloodborne Pathogens: Final Rule, Federal Register, Vol. 66, No. 12 / Thursday, January 18, 2001.

3. Terminology

3.1 *Definitions:*

3.1.1 *bloodborne 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, and 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 AAMI PB70:2003 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 non-critical 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] 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 U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401.