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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

D5733 Test Method for Tearing Strength of Nonwoven Fabrics by the Trapezoid Procedure (Withdrawn 2008)[5]

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 and Evaporative Resistance 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:*[6]

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:*[7]

AATCC 42 Water Resistance: Impact Penetration Test

AATCC 127 Water Resistance: Hydrostatic Pressure Test

2.4 *ANSI/ASQ Standards:*[8]

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:*[9]

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[10]

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

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

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

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

[9] 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.

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