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Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities¹

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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 Health³ 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

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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.

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

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

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.

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, 1975⁹

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, 1975¹⁰

29 CFR 1910.1030 Occupational Exposure to Blood-Borne Pathogens: Final Rule, Federal Register, Vol 66, No. 12, Jan. 18, 2001¹¹

FDA Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings—Guidance for Industry and Food and Drug Administration Staff¹²

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 content information.