

**American
National
Standard**

ANSI/AAMI PB70:2003

**Liquid barrier performance
and classification of
protective apparel and drapes
intended for use in
health care facilities**

AAMI

Association for the
Advancement of Medical
Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

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Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

Developed by
Association for the Advancement of Medical Instrumentation

Approved 23 October 2003 by
American National Standards Institute, Inc.

Abstract: This standard establishes a system of classification for protective apparel and drapes used in health care facilities based on their liquid barrier performance and specifies related labeling requirements and standardized test methods for determining compliance. By specifying a consistent basis for testing and labeling protective apparel and drapes and providing a common understanding of barrier properties (e.g., efficacy against liquid or liquidborne microorganism penetration) based on this new classification system, the standard is intended to ultimately assist end-users in determining the types of protective product most appropriate for a particular task or situation.

Keywords: surgical gowns, surgical drapes, protective apparel, decontamination gowns, other potentially infectious materials (OPIM)

AAMI Standard

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Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by international designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical

International designation	U.S. designation	Equivalency
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2002	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Protective Barriers Committee

This standard was developed by the AAMI Protective Barriers Committee. Committee approval of this standard does not necessarily mean that all committee members voted for its approval.

At the time this document was published, the **AAMI Protective Barriers Committee** had the following members:

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NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Acknowledgments

The committee gratefully acknowledges Peter L. Brown (W.L. Gore & Associates Inc.), who served as co-chairman of the committee from 1998 to 2002 and whose enormous contributions of time, effort, and technical expertise to this standards-development project were essential to its ultimate success. His dedication and commitment are very much appreciated.

The committee also gratefully acknowledges Michael H. Scholla (DuPont Nonwovens), who served as an AAMI committee representative and whose contributions to this standards-development project were invaluable.

Finally, the AAMI Protective Barriers Committee dedicates this standard to the late Dr. William Beck, the original chair of the AAMI Aseptic Barrier Committee, for his decades-long commitment to defining and providing aseptic barriers for patients and the health care team, his vital research, and his tireless and important communications on aseptic barrier issues through publications and public speaking.

Foreword

This standard was developed by the AAMI Protective Barriers Committee and establishes a classification system and the associated minimum requirements for the liquid barrier performance of protective apparel and drapes based on industry-accepted test methods. It is intended to assist manufacturers in testing and labeling their devices so that health care personnel can make more informed decisions when selecting the appropriate product for the anticipated task at hand.

Protective apparel is intended to be worn by health care workers to help preserve the integrity of the sterile field and inhibit the transfer of blood, body fluids, other potentially infectious materials (OPIM), and associated microorganisms. Drapes and drape accessories are also intended to inhibit the transfer of microorganisms, body fluids, and OPIM. Drapes and drape accessories are used as protective patient coverings to isolate a site of surgical incision from microbial and other cross-contamination.

In the United States, surgical apparel, surgical drapes, and drape accessories are medical devices and, under the Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of May 28, 1976, are subject to regulation by the U.S. Food and Drug Administration (FDA), including but not limited to FDA requirements for premarket notification (section 510(k) of the Act) and medical device reporting. Barrier efficacy has long been recognized as important in helping to prevent infections and is now mandated by Occupational Safety and Health Administration (OSHA) regulations limiting occupational exposure to bloodborne pathogens (29 CFR 1910.1030). See also the Centers for Disease Control and Prevention's (CDC's) *Guideline for the prevention of surgical site infection* (CDC, 1999; Mangram, et al., 1999).

Surgical gowns, other protective apparel, surgical drapes, and drape accessories are devices intended to promote infection control practices and help protect patients and health care workers. This standard is based on key barrier performance tests that are used to classify the subject products into levels of performance. Knowledge of these defined levels of performance will allow informed and consistent choices about the type of protective product necessary for the situation at hand.

As used within the context of this document, “shall” indicates requirements strictly to be followed in order to conform to the recommended practice; “should” indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited; “may” is used to indicate that a course of action is permissible within the limits of the recommended practice; and “can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated in this standard should be considered flexible and dynamic. The recommendations set forth in this document are reviewed and updated periodically to assimilate progressive technological developments. AAMI policies and procedures require that AAMI standards and recommended practices be reviewed and, if necessary, revised at least once every 5 years.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the American National Standard, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities* (ANSI/AAMI PB70:2003), but it does provide important information about the development and intended use of the document.

Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

1 Scope

1.1 General

This standard establishes minimum barrier performance requirements, a classification system, and associated labeling requirements for protective apparel, surgical drapes, and drape accessories intended for use in health care facilities.

1.2 Inclusions

This standard covers surgical drapes, drape accessories, and all types of protective apparel that are labeled with liquid barrier claims or liquidborne microbial barrier claims (e.g., single-use and multiple-use surgical gowns, decontamination garments, isolation gowns, aprons, sleeve protectors, laboratory attire, and other garments) and that are regulated by the U.S. Food and Drug Administration (FDA) as medical devices under 21 CFR 878.

NOTE 1—Surgical apparel is classified by the FDA under 21 CFR 878.4040, and surgical drapes and drape accessories are classified under 21 CFR 878.4370.

NOTE 2—For additional important information regarding the scope of this standard, see Annex A, A.1.1 and A.1.2. Other informative annexes are also included in this standard.

1.3 Exclusions

This standard does not cover

- a) protective apparel for the hands, such as surgical gloves, patient examination gloves, and other medical gloves;
- b) protective apparel for the head, face, and eyes, such as goggles, face shields, surgical caps or hoods, surgical masks, and respirators;
- c) protective apparel for the feet, such as operating room shoes, shoe covers, and surgical boots;
- d) other types of protective clothing worn by health care personnel, such as (1) apparel that is not intended or labeled as a barrier to liquid or microorganisms (e.g., surgical scrubs, cover coats) and (2) apparel or equipment that is used when handling hazardous chemicals, chemotherapeutic agents, or hazardous wastes;
- e) absorbent operating room (OR) towels;
- f) all of the requirements necessary to ensure the safety and effectiveness of the products within the scope of this standard;
- g) the interfaces between products, such as the gown/glove interface;
- h) all of the labeling or other information that a health care facility might deem necessary or desirable in product selection;
- i) protection from dry particulate and dry microbial penetration;
- j) manufacturing, quality assurance, or purchasing specifications;
- k) criteria for evaluating experimental products; or

- l) guidance for properly handling, processing, or preparing products for reuse in health care facilities.

NOTE—For guidelines on the processing of multiple-use surgical textile products, refer to ANSI/AAMI ST65, *Processing of reusable surgical textiles for use in health care facilities*.

2 Normative references

The following documents contain provisions that, through reference in this standard, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and users of this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

2.1 AMERICAN ASSOCIATION OF TEXTILE CHEMISTS AND COLORISTS. *Water resistance: Impact penetration test*. AATCC 42. Research Triangle Park (NC): AATCC, 2000.

2.2 AMERICAN ASSOCIATION OF TEXTILE CHEMISTS AND COLORISTS. *Water resistance: Hydrostatic pressure test*. AATCC 127. Research Triangle Park (NC): AATCC, 1998.

2.3 ASTM INTERNATIONAL. *Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood*. ASTM F1670. West Conshohocken (PA): ASTM International, 2003.

2.4 ASTM INTERNATIONAL. *Standard 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*. ASTM F1671. West Conshohocken (PA): ASTM International, 2003.

3 Definitions

3.1 acceptable quality level (AQL): For a continued series of lots, the quality level that for the purpose of sampling inspection is the limit of a satisfactory process average.

3.2 bacteriophage: Type of virus that infects only bacteria.

NOTE—A bacteriophage causes lysis of host bacteria by multiplying within the bacterial cell, using the bacterial cell metabolism for growth and development. Rapid growth causes the bacterial cell to burst, which releases many more bacteriophage viruses capable of destroying similar bacteria. (See also O'Toole, 1997.)

3.3 barrier properties: Ability of a protective product to resist the penetration of liquids and liquidborne microorganisms. For purposes of this standard, levels of barrier performance are defined and classified according to the barrier properties of the critical zone. (See Table 1.)

3.4 binding: Material used to cover a raw edge (e.g., at the neck area) in lieu of hemming.

3.5 bloodborne pathogen: Infectious bacterium, virus, or other disease-inducing microbe carried in blood or other body fluids.

NOTE—Examples of bloodborne pathogens include the hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

3.6 body fluid: Any liquid produced (secreted or excreted) by the body.

NOTE—For purposes of this standard, body fluids include those liquids potentially infected with bloodborne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, 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 1910.1030.)

3.7 body fluid simulant: Liquid used to act as a model for human body fluids.

3.8 critical zone: Area of protective apparel or surgical drape where direct contact with blood, body fluids, and OPIM is most likely to occur.

3.9 critical zone component: Element, constituent, or item incorporated into the critical zone, including the materials, seams, and points of attachment.

3.10 decontamination garment: Protective apparel used to protect health care personnel from the transfer of microorganisms and body fluids during the sorting and decontamination of medical devices potentially contaminated with blood, body fluids, and/or OPIM (e.g., surgical instruments, surgical garments, and patient-care utensils and equipment).

NOTE—This standard does not address the properties of decontamination garments that protect against hazardous chemical agents that may be used in the cleaning, disinfection, decontamination, or sterilization of medical devices.

3.11 fenestration: Opening provided in surgical drapes to allow access to the surgical site.¹

3.12 hem: Raw edge of material that is turned over and stitched.

3.13 isolation gown: Item of protective apparel used to protect health care personnel and patients from the transfer of microorganisms and body fluids in patient isolation situations.

3.14 laminate: Material of two or more layers bonded to one another.

3.15 laundry processes: Activities that encompass the handling, washing, and drying of multiple-use textiles.

3.16 manufacturer: According to the FDA, “any person who designs, manufactures, fabricates, assembles, or processes a finished product. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.” (21 CFR 820.3(o))

3.17 other potentially infectious materials (OPIM): Any materials, other than blood or body fluids, containing bloodborne pathogens or materials that have been linked with the potential transmission of infectious disease.

3.18 penetration: Movement of matter, on a nonmolecular level, through porous materials, closures, seams, or imperfections (e.g., pinholes) in a protective product.

3.19 ply: Separable sheet or layer of material.

3.20 protective apparel: Item of clothing that is specifically designed and constructed for the 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.

NOTE—Examples of protective apparel include surgical gowns, isolation gowns, decontamination garments, aprons, sleeve protectors, and certain types of laboratory attire.

3.21 reinforced area: Region of some surgical drapes or protective apparel in which the base material has been supplemented with one or more plies of the same or a different material for the purpose of enhancing or modifying the performance of the area (e.g., increasing strength, increasing resistance to liquid penetration, and/or providing absorptive qualities).

3.22 seam: Area at which two or more pieces of material are joined together.

NOTE—Many types of seams can be formed, including conventional needle-and-thread, adhesive, welded, and “false” seams.

3.23 simulated product: Test sample specifically designed and constructed for the purpose of modeling the performance of the finished product.

3.24 sterile: State of being free from all viable microorganisms.

NOTE—In practice, no such absolute statement regarding the absence of microorganisms can be proven. (See **sterilization**.)

3.25 sterile field: Area created with sterile draping materials where sterile technique is required (e.g., around a surgical site, on a back table, or on a gowning table).

NOTE—For persons around a sterile field in the OR, appropriate attire includes, but might not be limited to, gowns, gloves, face masks, and hair coverings. The need for additional attire is determined by the anticipated exposure to blood, body fluids, and OPIM.

3.26 sterilization: Process used to render a product free of all forms of viable microorganisms.

NOTE—In a sterilization process, the nature of microbiological death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

3.27 strike-through: Passage of a liquid that could contain microorganisms through a barrier product, including its seams and/or points of attachment.²

¹ Adapted, with the permission of the publisher, from: ECRI. Evaluation: Surgical drapes. *Health Devices*, 1986, vol. 15, no. 5, pp. 111–140.

² The term “strike-through” was first introduced to the clinical community by Laufman. In: LAUFMAN H, EUDY WW, VANDERNOOT AM, et al. Strike-through of moist contamination by woven and nonwoven surgical materials. *Ann Surg*, 1975, vol. 189, no. 1, pp. 68–74.

3.28 surface tension: Intermolecular forces acting on the molecules at the free surface of a liquid. Surface tension affects the degree to which a liquid can wet a material (i.e., the lower the surface tension, the more easily the liquid wets a material surface).

3.29 surgical drape (and drape accessories): As described by FDA, “. . . a device made of natural or synthetic materials intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination . . .” (21 CFR 878.4370)

NOTE—Surgical drape accessories include auxiliary protective coverings used in addition to the surgical patient drape to help maintain the sterile field, such as table covers and extra draping layers placed over the patient.

3.30 surgical gown: Type of surgical apparel, which is described by FDA as “. . . devices that are 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 . . .” (21 CFR 878.4040)

NOTE—Protection from the transfer of particulate matter is not addressed by this standard.

3.31 surrogate microbe: As defined in ASTM F1671:2003, “a microorganism which is used to act as a simulant for other microorganisms which are pathogenic to humans.”

NOTE—In ASTM F1671, the surrogate microbe is the Phi-X174 bacteriophage, which is used in viral penetration resistance testing and is intended as a model for HCV and to simulate both HBV and HIV.

3.32 synthetic blood: As defined in ASTM F1670:2003, “a mixture of red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids and the color of blood.”

NOTE—The synthetic blood specified in ASTM F1670 does not simulate all of the characteristics of real blood or body fluids (e.g., polarity (a wetting characteristic), coagulation, and content of cell matter).

3.33 viral penetration: As defined in ASTM F1671:2003, “the penetration of a material by a virus.”

3.34 viscosity: Resistance of a fluid to flow.

4 Requirements

4.1 Labeling requirements

NOTE—Additional labeling requirements exist beyond those specified in this standard (e.g., FDA labeling requirements applicable to all medical devices).

4.1.1 Device labeling

Each surgical gown, other item of protective apparel, surgical drape, and drape accessory shall be prominently labeled with its class of barrier performance, as determined in accordance with 4.2.1.

Each surgical gown having back panels that do not meet at least the requirements for Level 1 barrier performance (see 4.2.1) shall be prominently labeled with a warning stating “Back is Non-Protective” (see 4.2.3.1).

Each isolation gown shall be labeled as an isolation gown.

4.1.2 Package labeling

Each package containing surgical gowns, other items of protective apparel, surgical drapes, or drape accessories shall be prominently labeled with the class of barrier performance of each item that is contained in the package and has a barrier claim, as determined in accordance with 4.2.1.

4.1.3 Technical information

Technical literature shall be provided by the manufacturer upon request. This literature shall contain

- a) detailed information on the barrier performance of each critical zone component;

NOTE—This information may take the form of a graphical representation of the product showing the class of barrier performance of each component (as determined in accordance with 4.2.1), a narrative description of the class of barrier performance of each component, or both.

- b) detailed information on the barrier performance of each area outside the critical zone;

NOTE—This information may take the form of a graphical representation of the product showing the class of barrier performance of each area outside the critical zone (as determined in accordance with 4.2.1), a narrative description of the class of barrier performance of each area outside the critical zone, or both.

- c) for multiple-use products, 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;
- d) for multiple-use products, instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product; and
- e) for multiple-use products, an instruction to processors that if the labeled barrier performance of the product cannot be verified or the product has reached the end of its labeled use life, the product should be downgraded to a nonprotective category of use rather than a lower level of barrier performance.

4.1.4 Education

The manufacturer shall provide technical information and/or training explaining the barrier performance classification system and its implications for the end-user. Thereafter, the end-user is responsible for making judicious selections of products according to (a) the barrier performance class of the product and (b) the anticipated degree of exposure of health care personnel to blood, body fluids, and OPIM during a given procedure or activity.

4.2 Performance requirements

4.2.1 Barrier performance

4.2.1.1 General

The barrier performance classification of all protective and nonprotective areas of surgical gowns, other protective apparel, surgical drapes, and drape accessories shall be determined according to 5.2.1.

Surgical gowns, other protective apparel, surgical drapes, and drape accessories shall be classified and labeled according to the barrier performance properties of their critical zones. The barrier performance of all critical zone components, including seams and points of attachments, shall be determined. The classification of the product shall be a number denoting the performance of the critical zone component having the lowest barrier performance. The performance of seams between critical zones and other protective areas or between critical zones and nonprotective areas shall not determine the barrier classification. (See also 4.2.3.) The classification of multiple-use products shall be based on their performance at the end of the labeled use-life (i.e., after being processed in the manner recommended by the manufacturer for the number of processings claimed).

4.2.1.2 Classification levels of barrier performance

The critical zones of surgical gowns, other protective apparel, surgical drapes, and drape accessories shall be sampled and tested according to 5.2.1 and classified as defined below and as summarized in Table 1.

Level 1: When tested for water resistance in accordance with AATCC 42 (impact penetration) and under the conditions specified in 5.2.1, all critical zone components shall have a blotter weight gain of no more than 4.5 grams (g), with an AQL of 4 %. The test results shall be reported in the manufacturer's product technical information, as specified in 4.1.3.

Level 2: When tested for water resistance in accordance with AATCC 42 (impact penetration) and AATCC 127 (hydrostatic pressure) and under the conditions specified in 5.2.1, all critical zone components shall have a blotter weight gain of no more than 1.0 g and a hydrostatic resistance of at least 20 cm, with an AQL of 4 %. The test results shall be reported in the manufacturer's product technical information, as specified in 4.1.3.

Level 3: When tested for water resistance in accordance with AATCC 42 (impact penetration) and AATCC 127 (hydrostatic pressure) and under the conditions specified in 5.2.1, all critical zone components shall have a blotter weight gain of no more than 1.0 g and a hydrostatic resistance of at least 50 cm, with an AQL of 4 %. The test results shall be reported in the manufacturer's product technical information, as specified in 4.1.3.

Level 4:

Surgical gowns and other protective apparel: When a surgical gown or other item of protective apparel is tested for resistance to bacteriophage Phi-X174 in accordance with ASTM F1671 and under the conditions specified in 5.2.1, all critical zone components shall demonstrate passing results with an AQL of 4 %. The test results, including a statement regarding whether Procedure A or Procedure B was used in the testing, shall be reported in the manufacturer's product technical information, as specified in 4.1.3.

Surgical drapes and drape accessories: When a surgical drape or drape accessory is tested for synthetic blood resistance in accordance with ASTM F1670 and under the conditions specified in 5.2.1, all critical zone components shall demonstrate passing results with an AQL of 4 %. The test results, including a statement regarding whether Procedure A or Procedure B was used in the testing, shall be reported in the manufacturer's product technical information, as specified in 4.1.3.

Table 1—Classification of barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories

Level	Test	Result	AQL requirement
1	AATCC 42:2000	≤ 4.5 g	4 %
2	AATCC 42:2000	≤ 1.0 g	4 %
	AATCC 127:1998	≥ 20 cm	4 %
3	AATCC 42:2000	≤ 1.0 g	4 %
	AATCC 127:1998	≥ 50 cm	4 %
4	ASTM F1671:2003 (surgical gowns and other protective apparel)	Pass	4 %
	ASTM F1670:2003 (surgical drapes and drape accessories)	Pass	4 %

4.2.1.3 Nonprotective products

Products with no classification on the label shall be considered nonprotective.

4.2.1.4 Changes affecting barrier performance

If any changes are made in the design, fabrication, or materials of construction of a product after its original classification, its barrier properties shall be retested in accordance with 5.2.1 and, if necessary, reclassified.

4.2.2 Tracking mechanism for multiple-use products

Each surgical gown, other item of protective apparel, surgical drape, and drape accessory that is intended for multiple use shall have an integral tracking mechanism (e.g., marking grid, bar code system, radiofrequency chip, or other suitable method) for recording the number of processes to which the specific item has been subjected. The tracking mechanism shall remain functional throughout the claimed life of the product.

4.2.3 Construction

4.2.3.1 Surgical gowns and other protective apparel

The critical zone of a surgical gown or other protective apparel (excluding isolation gowns) shall, at a minimum, comprise the front area of the gown from chest to knees and the sleeves from the cuff to above the elbow. The manufacturer shall define the exact dimensions of the critical zone and shall, as specified in 4.1.3(a), provide detailed information on the barrier performance of each critical zone component. As specified in 4.1.3(b), the manufacturer also shall provide detailed information on the barrier performance of areas outside the critical zone.

For gowns intended for use in surgery, the entire front of the gown and the areas of the sleeves outside of the critical zone shall have a barrier performance of at least Level 1; the back panel of the gown may be nonprotective, but in that case, the gown shall be labeled as specified in 4.1.1. Seams between protective areas shall have at least the barrier performance of the lower-performing area. Seams between protective and nonprotective areas have no barrier requirements.

For 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 on the barrier performance of each critical zone component.

See Annex B for illustrations of these requirements.

4.2.3.2 Surgical drapes and drape accessories

The entire surgical drape shall have a barrier performance of at least Level 1. Seams between protective areas shall have at least the barrier performance of the lower-performing area.

See Annex B for illustrations of these requirements.

5 Tests

NOTE—This section contains test methods for determining compliance with the requirements of section 4. The numbering of the tests corresponds with the numbering of the requirements, except for the first digit. For example, compliance with the requirement of 4.2.2 can be determined by the test method of 5.2.2.

5.1 Tests for the labeling requirements

Compliance with the labeling requirements of 4.1 can be determined by examining the product and labeling for the required information.

5.2 Tests for the performance requirements

NOTE—The test methods chosen to classify the level of barrier performance address only the modes of potential exposure associated with liquid penetration. With the exception of ASTM F1671, the required tests use only liquids to provide a relative indication of the ability of a product to resist strike-through.

5.2.1 Barrier performance

5.2.1.1 Sampling

- a) **Sample size.** The manufacturer, when determining the barrier performance classification of a critical zone component or other area of the product for compliance with the requirements of 4.1 and 4.2.1, shall use acceptable statistical design and analytical techniques to select a sample size for testing that will ensure an AQL of no more than 4 %.
- b) **Test specimens.** If, in the design of the product, different materials are specified at separate locations, either inside or outside of the critical zones, specimens shall be selected from each location.

Test specimens shall be taken from different products from the same lot. If multiple tests must be performed (e.g., the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same product. Each material and component tested shall meet the established specifications for the design and construction of the final finished product. In all barrier performance tests, the outermost surface of the test specimen shall be oriented toward the challenge. If the area to be tested is reinforced or is constructed from multiple plies, the reinforcement layers or plies shall be tested together in the proper order. When materials and components are tested according to AATCC 42 and AATCC 127, it is important to position the test specimens the same way every time. For AATCC 42, seams must be centered and extend down the 13 inch length of the specimen; any points of attachment should be positioned in the center of the 7 inch by 13 inch specimen. For AATCC 127, seams must be centered across the width of the 8 inch by 8 inch specimen; any points of attachment should be positioned in the center of the 8 inch by 8 inch specimen.

NOTE 1—Simulating the critical design and construction features of the product is acceptable if it can be demonstrated that the simulated products are representative of actual production.

NOTE 2—For surgical drapes, it may not be technically possible to test the area (finished edge) between the fenestration and the critical zone barrier material, since the fenestration is an open area.

- c) **Sampling plan.** Test specimens shall be selected randomly according to a statistical sampling plan that is appropriate for the type of data being generated. See Annex C for examples of suitable sampling plans.

5.2.1.2 Barrier test methods for surgical gowns, other protective apparel, surgical drapes, and drape accessories

To be classified as Level 1, all critical zone components of a surgical gown or other protective apparel and all components of a surgical drape or drape accessory shall be tested according to AATCC 42 and meet the criteria specified in 4.2.1.2. To be classified as Level 2 or Level 3, all critical zone components of a surgical gown, other protective apparel, surgical drape, or drape accessory shall be tested according to AATCC 42 and AATCC 127 and meet the criteria specified in 4.2.1.2. To be classified as Level 4, all critical zone components of a surgical gown or other protective apparel shall pass ASTM F1671 and meet the criteria specified in 4.2.1.2. All critical zone components of a surgical drape or drape accessory shall pass ASTM F1670 and meet the criteria specified in 4.2.1.2.

For the AATCC 42 test, blotter paper that meets the following specifications should be used:

- The blotter paper should exhibit no distortions when wet.
- It should have an absorbent rate of < 5 seconds.
- It should have an absorbent capacity of 480 % \pm 30 %.
- It should have a sheet density of 0.24 g/cc \pm 0.06 g/cc.
- It should exhibit uniform sheet formation.
- It should be traceable to the production lot.

5.2.1.3 Nonprotective products

Compliance with the requirement of 4.2.1.3 can be determined by examining the labeling to verify that, if there is no barrier performance classification, barrier claims are not made for the product.

5.2.1.4 Changes affecting barrier performance

Products that have been changed in design, fabrication, or materials of construction shall be tested in the same manner as the original product.

NOTE—See also the FDA's design control requirements (21 CFR 820.30).

5.2.2 Tracking mechanism for multiple-use products

Compliance with the requirement of 4.2.2 can be verified by inspection.

5.2.3 Construction

5.2.3.1 Compliance with the requirements of 4.2.3.1 can be verified by inspection and by testing the specified protective areas in accordance with 5.2.1.

5.2.3.2 Compliance with the requirements of 4.2.3.2 can be verified by inspection and by testing the specified protective areas in accordance with 5.2.1.

Annex A

(informative)

Rationale for the development and provisions of this standard

A.1 Need for the standard, history of development, and scope

A.1.1 Need for the standard and history of development

Health care personnel can be exposed to biological fluids capable of transmitting disease. Those diseases, which are caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of bloodborne organisms such as the hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). Patients can also be exposed to microorganisms and other contamination during surgical and other health care procedures. Because engineering controls cannot eliminate all possible exposures, attention is placed on the use of protective apparel, drapes, and drape accessories to reduce the potential for contact with blood, body fluids, OPIM, and microorganisms associated with these materials.

Health care workers wear protective apparel to help protect both the patient and themselves from the transfer of microorganisms by blood, body fluids, or OPIM. Drapes and drape accessories are also intended to inhibit the transfer of microorganisms and are used to isolate the surgical incision from microorganisms and other contamination.

This standard addresses the barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories designed to help preserve the sterile field and/or protect health care workers during surgery and other health care procedures in which exposure to blood, body fluids, and OPIM might be anticipated.

Active work on this standard began in 1998, but there had long been a perceived need for a performance standard for surgical gowns, other protective apparel, surgical drapes, and drape accessories, especially regarding barrier performance. In 1978, the FDA promulgated regulations classifying both surgical apparel (21 CFR 878.4040) and surgical drapes and drape accessories (21 CFR 878.4370) as Class II (performance standards). An AAMI standards-development effort began in the early 1980s but ultimately failed, largely because of the lack of consensus regarding test methods for assessing barrier performance. In the early 1990s, AAMI published a Technical Information Report (TIR), *Selection of surgical gowns and drapes in health care facilities* (AAMI TIR11:1994), which described important safety and performance attributes of surgical gowns and drapes but did not establish specific performance limits. When that document was reviewed for possible updating and revision in early 1998, there was increased concern about how strike-through events in health care facilities could be reduced.

With the convergence of these review activities and the recent availability of standard test methods for the assessment of barrier performance, AAMI judged the timing to be desirable and feasible to resume work on a standard for surgical gowns, other protective apparel, surgical drapes, and drape accessories. Consequently, the AAMI Protective Barriers Committee was formed to undertake the standards-development effort. Work on the review and revision of the associated TIR was placed in abeyance because it was considered likely that a performance standard would affect the need for and/or provisions of the TIR.

A.1.2 Scope of the standard

This standard primarily addresses the barrier performance of the devices within its scope. Many other attributes are related to the safety and efficacy of surgical gowns, other protective apparel, surgical drapes, and drape accessories. However, a consensus has not yet been reached on specific minimum performance requirements for these attributes. The important safety and performance characteristics of surgical gowns and drapes, as well as associated test methods, are discussed in general terms in AAMI TIR11.

This standard does not address the surgical gown/glove interface because many factors not related to the performance of the gown itself can have an impact on the effectiveness of the gown/glove interface in preventing leakage. Those factors include variations in glove size, elasticity, and surface friction characteristics, as well as the placement of the gown cuff during gowning and gloving procedures (e.g., open versus closed gloving and single versus double gloving). It is important that the lower sleeve of the gown and the gown cuff are conformable, and that the gown cuff is short enough to allow the glove cuff to extend to and mate properly with the critical zone of the lower sleeve. The gown must also be sized properly so that when the arm is extended the cuff does not pull out of the glove.

This standard does not address the barrier properties of protective apparel or drapes in relation to dry microbial penetration. However, it is generally accepted that, as the interstices between fibers in repellent materials (or pores in

hydrophobic films) become smaller, the resistance to liquid penetration increases. Those products providing a higher level of liquid penetration resistance should also offer a higher level of dry microbial penetration resistance. Therefore, by determining the liquid penetration resistance of protective apparel and drapes, an indirect assessment of the dry microbial penetration resistance can be made, especially for those products in Level 4 that contain film reinforcements.

This standard is intended to be used mainly by device manufacturers in qualifying, classifying, and labeling the barrier performance of their products so that health care personnel can make more informed decisions when selecting the appropriate class of product for the anticipated task at hand. It is not intended to be used for quality assurance purposes by processors of multiple-use products. (AAMI's American National Standard ANSI/AAMI ST65, *Processing of reusable surgical textiles intended for use in health care facilities*, addresses the handling, laundering, and quality control of multiple-use products.) However, this standard does require that the manufacturer of a multiple-use product supply adequate processing instructions and specify the number of times that the product can be processed and maintain its barrier performance classification.

A.2 Normative references

No further guidance is needed for this section.

A.3 Definitions

No further guidance is needed for this section.

A.4 Requirements

A.4.1 Rationale for the labeling requirements

NOTE—In the United States, manufacturers of medical devices must comply with FDA labeling regulations (21 CFR 801), and those regulatory requirements are not repeated here.

A.4.1.1 Device labeling

It is necessary to label each surgical gown, other item of protective apparel, surgical drape, and drape accessory with its class of barrier performance so that end-users can determine whether a product is suitable for the intended application. Labeling of the device itself is particularly important because the original outer packaging is generally not immediately available to the end-user. Products labeled according to this standard must meet a minimum level of barrier performance in all areas, with only one exception: the back panel of a surgical gown may be nonprotective. For surgical gowns that do not have a protective back, a prominent warning label must be provided to alert users. End-users concerned about the potential for contact with blood, body fluids, and OPIM from the rear should not choose a gown with a nonprotective back.

A.4.1.2 Package labeling

Packages should be labeled with the class of barrier performance to allow end-users to easily identify the level of barrier protection.

A.4.1.3 Technical information

Detailed technical information on the barrier performance of all product components is important to end-users for both product evaluation and determination of whether a product is suitable for a particular procedure or activity. For multiple-use products, processing instructions are necessary to help ensure that a product is handled, laundered, inspected or tested, and sterilized in such a way that its barrier properties and other safety and performance characteristics can be maintained for the number of uses specified by the manufacturer. Processors should not independently reclassify a product in terms of barrier performance because the product's performance has been qualified by the manufacturer according to specific test methods that are not practical for routine use by processors.

A.4.1.4 Education

Since this standard establishes a new classification system of barrier performance, with new terminology, it is important that the manufacturer provide technical information or training to end-users to ensure that they understand the relationship between the labeled barrier performance of products, the standardized test methods used to determine those labels, and what the tests do and do not signify (e.g., that the tests are laboratory tests, not actual in-use tests).

A.4.2 Rationale for the performance requirements

A.4.2.1 Barrier performance

Because of the variety of health care settings and patient-care activities, the barrier requirements for surgical gowns, other protective apparel, surgical drapes, and drape accessories might vary with the application. The level of barrier protection needed depends primarily on the potential for exposure to blood, body fluids, and OPIM. This standard establishes classifications of barrier performance according to the hierarchy of risks associated with the anticipated blood, body fluid, OPIM, or other liquid volume involved in the type and duration of procedure or activity being performed. These classifications are as follows:

Level 1—Gowns and drapes: This classification describes surgical gowns, other protective apparel, surgical drapes, and drape accessories that demonstrate the ability to resist liquid penetration in a laboratory test, AATCC 42 (*Water resistance: Impact penetration test*).

Level 2—Gowns and drapes: This classification describes surgical gowns, other protective apparel, surgical drapes, and drape accessories that demonstrate the ability to resist liquid penetration in two laboratory tests, AATCC 42 (*Water resistance: Impact penetration test*) and AATCC 127 (*Water resistance: Hydrostatic pressure test*).

Level 3—Gowns and drapes: This classification describes surgical gowns, other protective apparel, surgical drapes, and drape accessories that demonstrate the ability to resist liquid penetration in two laboratory tests, AATCC 42 (*Water resistance: Impact penetration test*) and AATCC 127 (*Water resistance: Hydrostatic pressure test*). For Level 3, the test criterion for AATCC 127 performance has been set at a higher value than for Level 2.

Level 4—Gowns: This classification describes surgical gowns and protective apparel that demonstrate the ability to resist liquid and viral penetration in a laboratory test, ASTM F1671 (*Standard 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*).

Level 4—Drapes: This classification describes surgical drapes and drape accessories that demonstrate the ability to resist liquid penetration in a laboratory test, ASTM F1670 (*Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood*).

The classification system established by this standard is intended to set a common foundation for the different levels of barrier protection available but does not take into account potential variations in specific procedures and techniques used in health care facilities. The end-user is the ultimate judge of the appropriateness of the barrier level required, based on his or her experience and the potential or known exposure risks.

The test methods used for classifying the barrier properties of the products covered by this standard were chosen by consensus. The more stringent tests, ASTM F1670 and ASTM F1671, involve the use of body fluid and bloodborne pathogen simulants according to time and pressure protocols that have been found to discriminate a higher level of barrier performance in the laboratory setting. The less stringent tests, AATCC 42 and AATCC 127, involve the use of indirect (splash or spray) and direct contact with water according to time and pressure protocols.

A.4.2.2 Tracking mechanism for multiple-use products

Because the barrier performance of multiple-use products has been qualified for only a specified number of uses and processings, it is necessary for the processor to be able to determine how many times a product has been used and, thus, to retire or downgrade a product at the appropriate time. An integral tracking mechanism is the only practical means by which the processor can make this determination.

A.4.2.3 Construction

A.4.2.3.1 Surgical gowns and other protective apparel

The requirements for the design and construction of surgical gowns and protective apparel are based on the anticipated location and degree of liquid contact, given the expected conditions of use. The critical zones include those areas where direct contact with blood, body fluids, and OPIM is most likely to occur, although areas outside of the critical zones can be inadvertently splashed or sprayed as well. Therefore, the entire front of a gown intended for use in surgical applications, including the seams and other components, is required to provide at least the minimum level of barrier performance (Level 1) defined by this standard. Since the back of a gown intended for surgical applications is expected to stay dry, there is no liquid barrier performance requirement for that area; to optimize the comfort of the gown, the materials used in the back are often made from lighter weight and more breathable materials. (See Beck, 1991; Beck, et al., 1995.) Gowns used for isolation applications, on the other hand, need to be protective in the front and back because of the more unpredictable types of potential contact with blood, body fluids, and OPIM associated with general patient care. Also, in many cases, isolation gowns are expected to protect the

patient from microbial contamination from the wearer, which can be present on all sides of the wearer's body and work clothing.

A.4.2.3.2 Surgical drapes and drape accessories

The requirements for design and construction of surgical drapes are based on the anticipated location and degree of liquid contact, given the expected conditions of use. The critical zones include those areas where direct contact with blood, body fluids, and OPIM is most likely to occur, although areas outside of the critical zones can be inadvertently splashed or sprayed as well. Because of the variation in patient size, patient positioning, and draping technique, as well as the possible expansion of the surgical site or field during the procedure, the entire drape is expected to meet at least the minimum level of barrier performance (Level 1) defined by this standard.

Annex B (informative)

Examples of barrier performance classification of surgical gowns, other protective apparel, and surgical drapes

This annex provides examples to elucidate the barrier performance requirements of this standard. The illustrations are not intended to reflect specific products or designs.

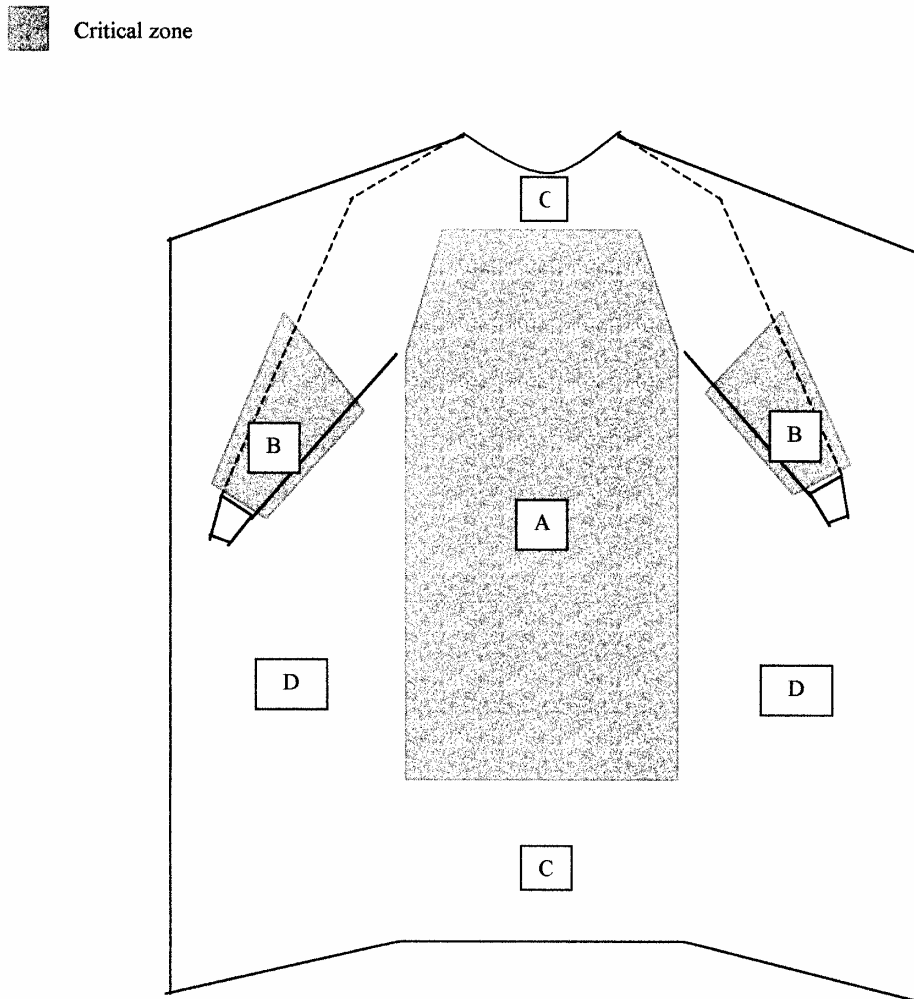


Figure B.1—Example of a gown intended for surgical applications

NOTE 1—The entire front of the gown (areas A, B, and C) is required to have a barrier performance of at least Level 1 (as per 4.2.3.1).

NOTE 2—The critical zone comprises at least areas A and B. The classification of the surgical gown is based on the lower-performing component of the two (as per 4.2.1.1).

NOTE 3—The back of the surgical gown (area D) may be nonprotective (as per 4.2.3.1).

NOTE 4—Seams between protective and nonprotective areas have no barrier requirements (as per 4.2.3.1).

NOTE 5—Seams between two protective areas are required to have at least the barrier performance of the lower-performing area (as per 4.2.3.1).

NOTE 6—Table B.1 illustrates the requirements of 4.2.1.1 and 4.2.3.1 and shows how the barrier performance classification of the surgical gown would be determined.

Table B.1—Barrier performance classification of surgical gowns

Area A (Critical zone—front)	Area B (Critical zone—sleeve)	Area C (Front)	Area D (Back)		Final classification
Level 1, 2, 3, or 4	Level 1	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 1
Level 1	Level 1, 2, 3, or 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 1
Level 2, 3, or 4	Level 2	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 2
Level 2	Level 2, 3, or 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 2
Level 3 or 4	Level 3	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 3
Level 3	Level 3 or 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 3
Level 4	Level 4	Level 1, 2, 3, or 4	Nonprotective, Level 1, 2, 3, or 4		Level 4

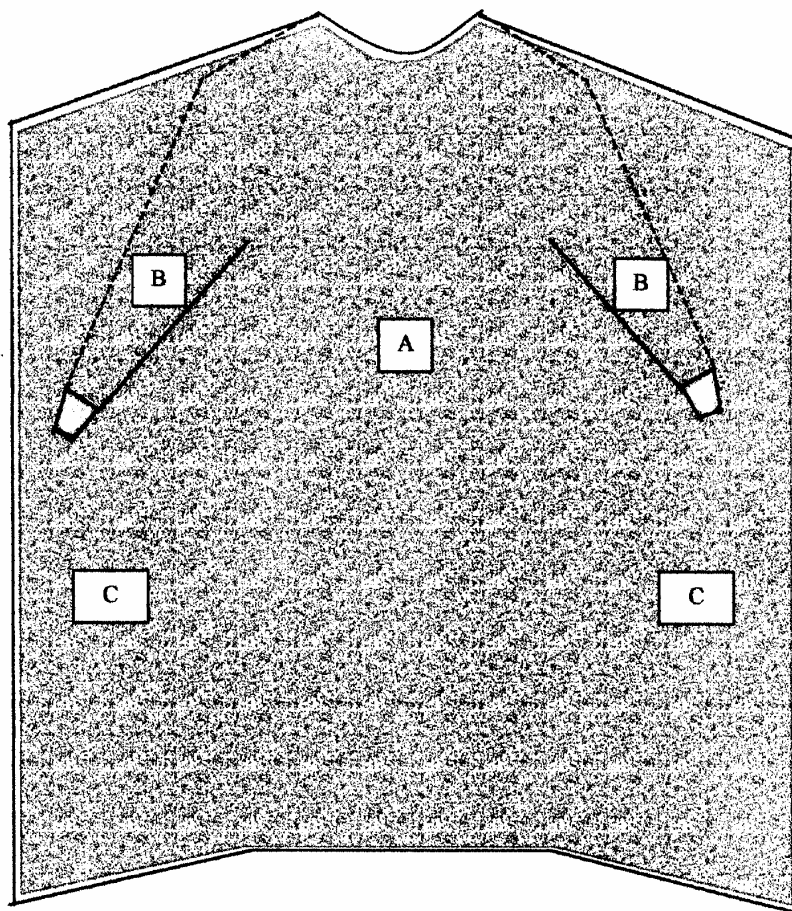


Figure B.2—Example of a gown intended for isolation applications

NOTE 1—The entire isolation gown (areas A, B, and C), including seams but excluding cuffs, hems, and bindings, is required to have a barrier performance of at least Level 1 (as per 4.2.3.1).

NOTE 2—Table B.2 illustrates the requirements of 4.2.1.1 and 4.2.3.1 and shows how the barrier performance classification of the isolation gown would be determined.

Table B.2—Barrier performance classification of isolation gowns

Area A (Front)	Area B (Sleeve)	Area C (Back)		Final barrier performance classification
Level 1, 2, 3, or 4	Level 1, 2, 3, or 4	Level 1		Level 1
Level 1, 2, 3, or 4	Level 1	Level 1, 2, 3, or 4		Level 1
Level 1	Level 1, 2, 3, or 4	Level 1, 2, 3, or 4		Level 1
Level 2, 3, or 4	Level 2, 3, or 4	Level 2		Level 2
Level 2, 3, or 4	Level 2	Level 2, 3, or 4		Level 2
Level 2	Level 2, 3, or 4	Level 2, 3, or 4		Level 2
Level 3 or 4	Level 3 or 4	Level 3		Level 3
Level 3 or 4	Level 3	Level 3 or 4		Level 3
Level 3	Level 3 or 4	Level 3 or 4		Level 3
Level 4	Level 4	Level 4		Level 4

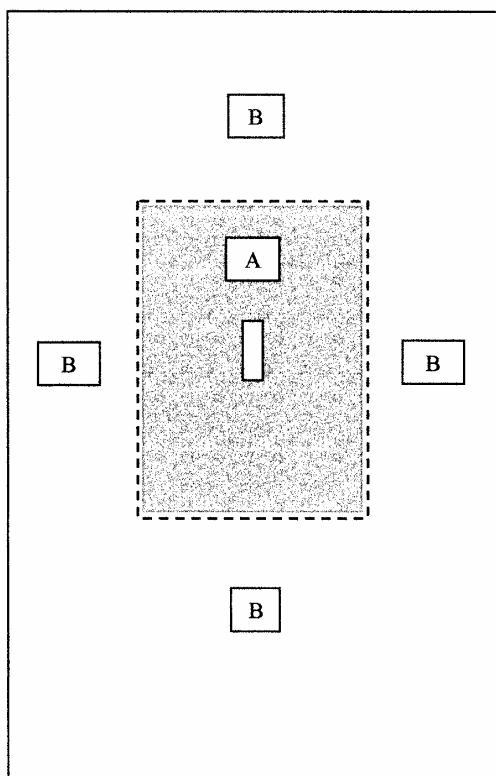


Figure B.3—Example of a surgical drape

NOTE 1—The entire surgical drape (areas A and B) is required to have a barrier performance of at least Level 1 (as per 4.2.3.2).

NOTE 2—Seams between two protective areas must have at least the barrier performance of the lower-performing area (as per 4.2.3.2).

NOTE 3—Table B.3 illustrates the requirements of 4.2.3.2 and shows how the barrier performance classification of the drape would be determined.

Table B.3—Barrier performance classification of surgical drapes

Area A (Critical zone)	Area B		Final barrier performance classification
Level 1	Level 1, 2, 3, or 4		Level 1
Level 2	Level 1, 2, 3, or 4		Level 2
Level 3	Level 1, 2, 3, or 4		Level 3
Level 4	Level 1, 2, 3, or 4		Level 4

Annex C

(informative)

Examples of sampling plans

When pass/fail (attribute) data is to be generated, samples should be selected as described in ANSI/ASQC Z1.4:1993, or, as shown below, ISO 2859-1, Table X-G-2:

**Table C.1—Sampling plans for sample size code letter G,
acceptable quality level (normal inspection) 4.0**

Type of sampling plan	Cumulative sample size	Accept	Reject
Single	32	3	4
Double	20	1	4
	40	4	5
Multiple	8	*	3
	16	0	3
	24	1	4
	32	2	5
	40	3	6
	48	4	6
	56	6	7

* Acceptance not permitted at this sample size.

When normally distributed measurements for percent nonconforming data are to be generated, samples should be selected as described in ANSI/ASQC Z1.4:1993 or ISO 3951, Table B.1 (Master table for normal and tightened inspection plans based on variability unknown (single inspection limit—form 1) for sample size code letter G, acceptable quality level (normal inspection) 4.0), as follows:

- Obtain 15 normally distributed measurements, and
- Use an acceptability criteria of $(U - \bar{X}) / s = k$, where

U = upper specification limit,

\bar{X} = sample mean of the 15 measurements,

s = sample standard deviation of the 15 measurements, and

k = 1.30, as obtained from Table B.1 for sample size code letter G and nominal AQL = 4.0 %.

Alternatively, replace the above sampling plan ($n = 15$, $k = 1.30$, estimated AQL = 3.1 %) with the optimal variable sampling plan ($n = 19$, $k = 1.25$, estimated AQL = 4.0 %), as described in Taylor (1992).

Annex D (informative)

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³ Subpart E of Title 21, Part 878, of the *Code of Federal Regulations* contains classification regulations for surgical devices. Surgical apparel is classified in 21 CFR 878.4040. Surgical drapes and drape accessories are classified in 21 CFR 878.4370.

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