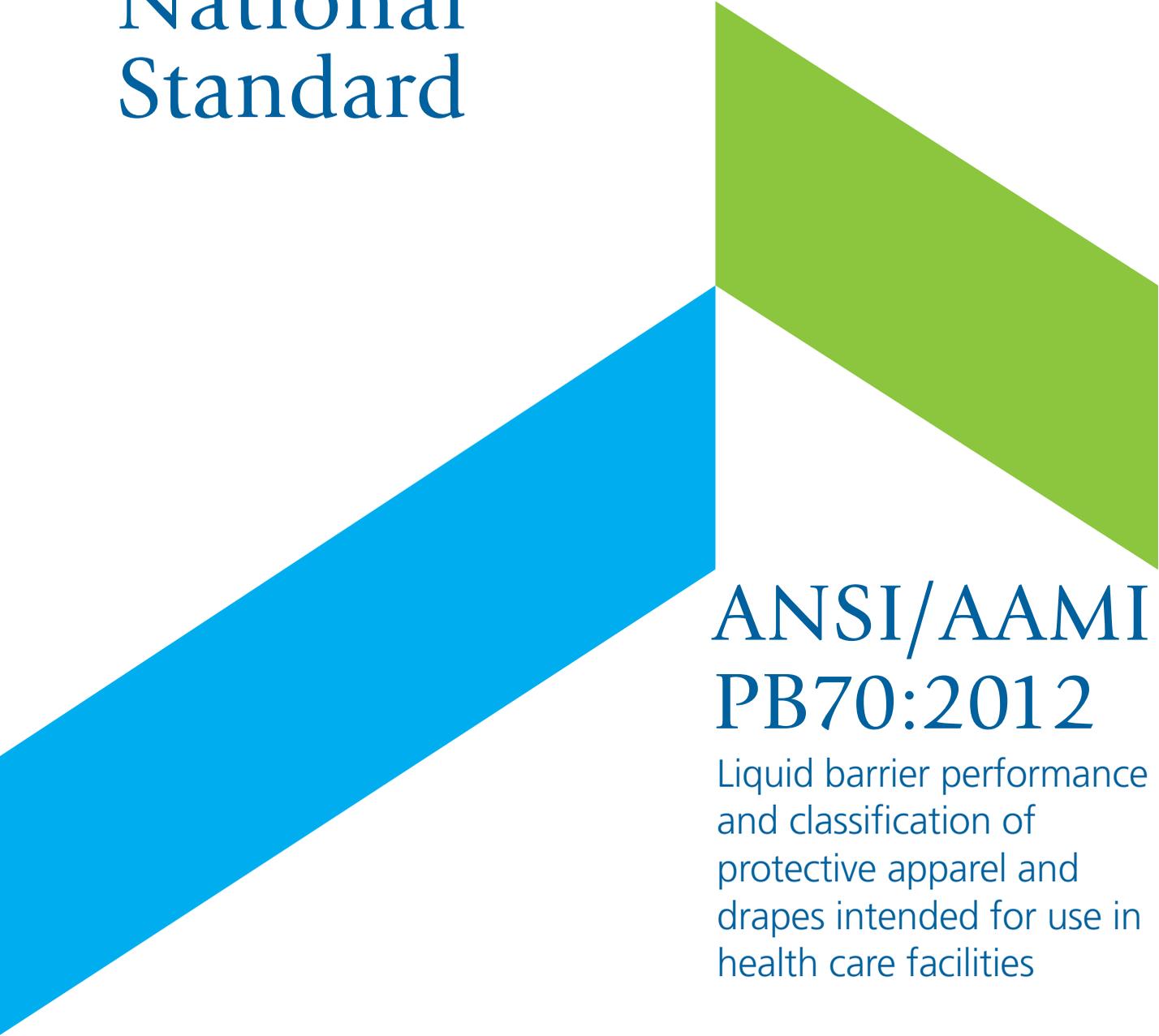


# American National Standard



## ANSI/AAMI PB70:2012

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



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# 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 frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare 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 decision-making.

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.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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

Developed 3 May 2012 by  
**Association for the Advancement of Medical Instrumentation**

Approved 21 June 2012 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 liquid-borne microorganism penetration) based on this new classification system, the standard is intended to ultimately assist end-users in determining the type(s) 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)

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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. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

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 60601-1:2005<br>Technical Corrigendum 1 and 2  | ANSI/AAMI ES60601-1:2005/(R)2012 and<br>ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012<br>ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012<br>(amdt) | Major technical variations<br><br>C1 Identical to Corrigendum<br>1 & 2 |
| IEC 60601-1-11:2010                                | ANSI/AAMI HA60601-1-11:2011  | Major technical variations   |
| IEC 60601-1-2:2007                                 | ANSI/AAMI/IEC 60601-1-2:2007/(R)2012   | Identical  |
| IEC 60601-2-2:2009                                 | ANSI/AAMI/IEC 60601-2-2:2009   | Identical  |
| IEC 60601-2-4:2010                                 | ANSI/AAMI/IEC 60601-2-4:2010   | Identical  |
| IEC 60601-2-16:2008                                | ANSI/AAMI/IEC 60601-2-16:2008  | Identical  |
| IEC 60601-2-19:2009                                | ANSI/AAMI/IEC 60601-2-19:2009  | Identical  |
| IEC 60601-2-20:2009                                | ANSI/AAMI/IEC 60601-2-20:2009  | Identical  |
| IEC 60601-2-21:2009                                | ANSI/AAMI/IEC 60601-2-21:2009  | Identical  |
| IEC 60601-2-24:1998                                | ANSI/AAMI ID26:2004/(R)2009  | Major technical variations   |
| IEC 60601-2-25:2011                                | ANSI/AAMI/IEC 60601-2-25:2011  | Identical  |
| IEC 60601-2-27:2011                                | ANSI/AAMI/IEC 60601-2-27:2011  | Identical  |
| IEC 60601-2-47:2012                                | ANSI/AAMI/IEC 60601-2-47:2012  | Identical  |
| IEC 60601-2-50:2009                                | ANSI/AAMI/IEC 60601-2-50:2009  | Identical  |
| IEC 80001-1:2010                                   | ANSI/AAMI/IEC 80001-1:2010   | Identical  |
| IEC 80601-2-30:2009 and Technical<br>Corrigendum 1 | ANSI/AAMI/IEC 80601-2-30:2009 and<br>ANSI/AAMI/IEC 80601-2-30:2009/C1:2009<br>(amdt) – consolidated text                               | Identical (with inclusion)<br>C1 Identical to Corrigendum<br>1         |
| IEC 80601-2-58:2008                                | ANSI/AAMI/IEC 80601-2-58:2008  | Identical  |
| IEC/TR 60878:2009                                  | ANSI/AAMI/IEC TIR60878:2003  | Identical  |
| IEC/TR 61289:2011                                  | ANSI/AAMI/IEC TIR61289:2011  | Identical  |
| IEC/TR 62296:2009                                  | ANSI/AAMI/IEC TIR62296:2009  | Identical  |
| IEC 62304:2006                                     | ANSI/AAMI/IEC 62304:2006   | Identical  |
| IEC/TR 62348:2006                                  | ANSI/AAMI/IEC TIR62348:2006  | Identical  |
| IEC/TR 62354:2009                                  | ANSI/AAMI/IEC TIR62354:2009  | Identical  |
| IEC 62366:2007                                     | ANSI/AAMI/IEC 62366:2007   | Identical  |
| IEC/TR 80002-1:2009                                | ANSI/IEC/TR 80002-1:2009   | Identical  |
| ISO 5840:2005                                      | ANSI/AAMI/ISO 5840:2005/(R)2010  | Identical  |
| ISO 7198:1998                                      | ANSI/AAMI/ISO 7198:1998/2001/(R)2010   | Identical  |
| ISO 7199:2009 and<br>Amendment 1:2012              | ANSI/AAMI/ISO 7199:2009 and<br>Amendment 1:2012  | Identical  |
| ISO 8637:2010                                      | ANSI/AAMI/ISO 8637:2010  | Identical  |
| ISO 8638:2010                                      | ANSI/AAMI/ISO 8638:2010  | Identical  |
| ISO 10993-1:2009                                   | ANSI/AAMI/ISO 10993-1:2009   | Identical  |
| ISO 10993-2:2006                                   | ANSI/AAMI/ISO 10993-2:2006/(R)2010   | Identical  |
| ISO 10993-3:2003                                   | ANSI/AAMI/ISO 10993-3:2003/(R)2009   | Identical  |
| ISO 10993-4:2002 and<br>Amendment 1:2006           | ANSI/AAMI/ISO 10993-4:2002/(R)2009 and<br>Amendment 1:2006/(R)2009   | Identical  |
| ISO 10993-5:2009                                   | ANSI/AAMI/ISO 10993-5:2009   | Identical  |
| ISO 10993-6:2007                                   | ANSI/AAMI/ISO 10993-6:2007/(R)2010   | Identical  |
| ISO 10993-7:2008                                   | ANSI/AAMI/ISO 10993-7:2008/(R)2012   | Identical  |
| ISO 10993-9:2009                                   | ANSI/AAMI/ISO 10993-9:2009   | Identical  |
| ISO 10993-10:2010                                  | ANSI/AAMI/ISO 10993-10:2010  | Identical  |
| ISO 10993-11:2006                                  | ANSI/AAMI/ISO 10993-11:2006/(R)2010  | Identical  |
| ISO 10993-12:2012                                  | ANSI/AAMI/ISO 10993-12:2012  | Identical  |
| ISO 10993-13:2010                                  | ANSI/AAMI/ISO 10993-13:2010  | Identical  |
| ISO 10993-14:2001                                  | ANSI/AAMI/ISO 10993-14:2001/(R)2006  | Identical  |
| ISO 10993-15:2000                                  | ANSI/AAMI/ISO 10993-15:2000/(R)2006  | Identical  |
| ISO 10993-16:2010                                  | ANSI/AAMI/ISO 10993-16:2010  | Identical  |
| ISO 10993-17:2002                                  | ANSI/AAMI/ISO 10993-17:2002/(R)2008  | Identical  |
| ISO 10993-18:2005                                  | ANSI/AAMI BE83:2006/(R)2011  | Major technical variations   |
| ISO/TS 10993-19:2006                               | ANSI/AAMI/ISO TIR10993-19:2006   | Identical  |
| ISO/TS 10993-20:2006                               | ANSI/AAMI/ISO TIR10993-20:2006   | Identical  |
| ISO 11135-1:2007                                   | ANSI/AAMI/ISO 11135-1:2007   | Identical  |

| <b>International designation</b> | <b>U.S. designation</b>                                | <b>Equivalency</b>          |
|----------------------------------|--|-----------------------------|
| ISO/TS 11135-2:2008              | ANSI/AAMI/ISO TIR11135-2:2008                          | Identical                   |
| ISO 11137-1:2006                 | ANSI/AAMI/ISO 11137-1:2006/(R)2010                     | Identical                   |
| ISO 11137-2:2012                 | ANSI/AAMI/ISO 11137-2:2012                             | Identical                   |
| ISO 11137-3:2006                 | ANSI/AAMI/ISO 11137-3:2006/(R)2010                     | Identical                   |
| ISO 11138-1:2006                 | ANSI/AAMI/ISO 11138-1:2006/(R)2010                     | Identical                   |
| ISO 11138-2:2006                 | ANSI/AAMI/ISO 11138-2:2006/(R)2010                     | Identical                   |
| ISO 11138-3:2006                 | ANSI/AAMI/ISO 11138-3:2006/(R)2010                     | Identical                   |
| ISO 11138-4:2006                 | ANSI/AAMI/ISO 11138-4:2006/(R)2010                     | Identical                   |
| ISO 11138-5:2006                 | ANSI/AAMI/ISO 11138-5:2006/(R)2010                     | Identical                   |
| ISO/TS 11139:2006                | ANSI/AAMI/ISO 11139:2006                               | Identical                   |
| ISO 11140-1:2005                 | ANSI/AAMI/ISO 11140-1:2005/(R)2010                     | Identical                   |
| ISO 11140-3:2007                 | ANSI/AAMI/ISO 11140-3:2007/(R)2012                     | Identical                   |
| ISO 11140-4:2007                 | ANSI/AAMI/ISO 11140-4:2007/(R)2012                     | Identical                   |
| ISO 11140-5:2007                 | ANSI/AAMI/ISO 11140-5:2007/(R)2012                     | Identical                   |
| ISO 11607-1:2006                 | ANSI/AAMI/ISO 11607-1:2006/(R)2010                     | Identical                   |
| ISO 11607-2:2006                 | ANSI/AAMI/ISO 11607-2:2006/(R)2010                     | Identical                   |
| ISO 11663:2009                   | ANSI/AAMI/ISO 11663:2009                               | Identical                   |
| ISO 11737-1:2006                 | ANSI/AAMI/ISO 11737-1:2006                             | Identical                   |
| ISO 11737-2:2009                 | ANSI/AAMI/ISO 11737-2:2009                             | Identical                   |
| ISO/TS 12417:2011                | ANSI/AAMI/ISO TIR12417:2011                            | Identical                   |
| ISO 13022:2012                   | ANSI/AAMI/ISO 13022:2012                               | Identical                   |
| ISO 13408-1:2008                 | ANSI/AAMI/ISO 13408-1:2008/(R)2011                     | Identical                   |
| ISO 13408-2:2003                 | ANSI/AAMI/ISO 13408-2:2003                             | Identical                   |
| ISO 13408-3:2006                 | ANSI/AAMI/ISO 13408-3:2006                             | Identical                   |
| ISO 13408-4:2005                 | ANSI/AAMI/ISO 13408-4:2005                             | Identical                   |
| ISO 13408-5:2006                 | ANSI/AAMI/ISO 13408-5:2006                             | Identical                   |
| ISO 13408-6:2006                 | ANSI/AAMI/ISO 13408-6:2006                             | Identical                   |
| ISO 13408-7:2012                 | ANSI/AAMI/ISO 13408-7:2012                             | Identical                   |
| ISO 13485:2003                   | ANSI/AAMI/ISO 13485:2003/(R)2009                       | Identical                   |
| ISO 13958:2009                   | ANSI/AAMI/ISO 13958:2009                               | Identical                   |
| ISO 13959:2009                   | ANSI/AAMI/ISO 13959:2009                               | Identical                   |
| ISO 14155:2011                   | ANSI/AAMI/ISO 14155:2011                               | Identical                   |
| ISO 14160:2011                   | ANSI/AAMI/ISO 14160:2011                               | Identical                   |
| ISO 14161:2009                   | ANSI/AAMI/ISO 14161:2009                               | Identical                   |
| ISO 14708-3:2008                 | ANSI/AAMI/ISO 14708-3:2008                             | Identical                   |
| ISO 14708-4:2008                 | ANSI/AAMI/ISO 14708-4:2008                             | Identical                   |
| ISO 14708-5:2010                 | ANSI/AAMI/ISO 14708-5:2010                             | Identical                   |
| ISO 14937:2009                   | ANSI/AAMI/ISO 14937:2009                               | Identical                   |
| ISO/TR 14969:2004                | ANSI/AAMI/ISO TIR14969:2004                            | Identical                   |
| ISO 14971:2007                   | ANSI/AAMI/ISO 14971:2007/(R)2010                       | Identical                   |
| ISO 15223-1:2007 and A1:2008     | ANSI/AAMI/ISO 15223-1:2007/(R)2012 and A1:2008/(R)2012 | Identical                   |
| ISO 15223-2:2010                 | ANSI/AAMI/ISO 15223-2:2010                             | Identical                   |
| ISO 15225:2010                   | ANSI/AAMI/ISO 15225:2010                               | Identical                   |
| ISO 15674:2009                   | ANSI/AAMI/ISO 15674:2009                               | Identical                   |
| ISO 15675:2009                   | ANSI/AAMI/ISO 15675:2009                               | Identical                   |
| ISO 15882:2008                   | ANSI/AAMI/ISO 15882:2008                               | Identical                   |
| ISO 15883-1:2006                 | ANSI/AAMI ST15883-1:2009                               | Major technical variations  |
| ISO/TR 16142:2006                | ANSI/AAMI/ISO TIR16142:2005                            | Identical                   |
| ISO 17664:2004                   | ANSI/AAMI ST81:2004                                    | Major technical variations  |
| ISO 17665-1:2006                 | ANSI/AAMI/ISO 17665-1:2006                             | Identical (with inclusions) |
| ISO/TS 17665-2:2009              | ANSI/AAMI/ISO TIR17665-2:2009                          | Identical                   |
| ISO 18472:2006                   | ANSI/AAMI/ISO 18472:2006/(R)2010                       | Identical                   |
| ISO/TS 19218-1:2011              | ANSI/AAMI/ISO TIR19218:2011                            | Identical                   |
| ISO 20857:2010                   | ANSI/AAMI/ISO 20857:2010                               | Identical                   |
| ISO 22442-1:2007                 | ANSI/AAMI/ISO 22442-1:2007                             | Identical                   |
| ISO 22442-2:2007                 | ANSI/AAMI/ISO 22442-2:2007                             | Identical                   |
| ISO 22442-3:2007                 | ANSI/AAMI/ISO 22442-3:2007                             | Identical                   |
| ISO/TR 22442-4:2010              | ANSI/AAMI/ISO TIR22442-4:2010                          | Identical                   |
| ISO 23500:2011                   | ANSI/AAMI/ISO 23500:2011                               | Identical                   |
| ISO/TS 23810:2012                | ANSI/AAMI/ISO TIR23810:2012                            | Identical                   |
| ISO 25539-1:2003 and A1:2005     | ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009 | Identical                   |
| ISO 25539-2:2008                 | ANSI/AAMI/ISO 25539-2:2008                             | Identical                   |
| ISO 25539-3:2011                 | ANSI/AAMI/ISO 25539-3:2011                             | Identical                   |
| ISO 26722:2009                   | ANSI/AAMI/ISO 26722:2009                               | Identical                   |
| ISO 27185:2012                   | ANSI/AAMI/ISO 27185:2012                               | Identical                   |
| ISO 27186:2010                   | ANSI/AAMI/ISO 27186:2010                               | Identical                   |
| ISO 80369-1:2010                 | ANSI/AAMI/ISO 80369-1:2010                             | Identical                   |
| ISO 81060-1:2007                 | ANSI/AAMI/ISO 81060-1:2007                             | Identical                   |
| ISO 81060-2:2009                 | ANSI/AAMI/ISO 81060-2:2009                             | Identical                   |

## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Protective Barriers Committee

This American National Standard was developed by the AAMI Protective Barriers Committee. Committee approval of the standard does not necessarily imply 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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|-------------------|---|
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NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

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NOTE: This acknowledgement is from the original version of PB70:2003.

## 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 health care personnel can make more informed decisions when selecting the appropriate product for the anticipated task at hand.

Protective apparel is 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.

This is the second edition of *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*, which was first published as an American National Standard in 2003. In comparison to the first edition, the most significant revisions are allowing the use of the newer WSP 80.3 water-impact resistance test, in addition to the AATCC 42 test; and the addition of "rejectable quality level" (RQL) criteria in testing of product to determine if the test results are acceptable and product can be released. See also Annex E.

As used within the context of this document, "shall" indicates requirements strictly to be followed to conform to the standard. "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 standard. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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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 PB70:2012), but it does provide important information about the development and intended use of the document.

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# 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 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 the following:

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

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*.

- m) assessment of antimicrobial properties

## 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.

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

**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.

**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.

## 3 Definitions

For the purposes of this standard, the following definitions apply.

**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.

NOTE—AQL defines a producer's protection level in the sense that a lot at the stated AQL has a high probability of acceptance and therefore a low probability of rejection.

**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 blood-borne 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.

NOTE—Definition is from ASTM F1670.

**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.<sup>1</sup>

**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 rejectable quality level (RQL):** The RQL, also known as Lot Tolerance Percent Defective, defines the relationship between the probability of acceptance by a consumer of a product compared to the possible percent of defectives within that lot.

NOTE—RQL defines a consumer's protection level in the sense that a lot at the stated RQL has a low probability of acceptance and therefore a high probability of rejection.

**3.23 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.

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

**3.25 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**.)

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

**3.26 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.

**3.27 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.

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

**3.29 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).

**3.30 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.

**3.31 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.

**3.32 surrogate microbe:** As defined in ASTM F1671, “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.

**3.33 synthetic blood:** As defined in ASTM F1670, “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).

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

**3.35 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.

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<sup>2</sup> 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.

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, isolation 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 the following:

- 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, isolation gowns, other protective apparel, surgical drapes, and drape accessories shall be determined according to 5.2.1.

Surgical gowns, isolation gowns, other protective apparel, surgical drapes, and drape accessories shall be classified and labeled according to the barrier performance properties of their critical zones (See A4.2.3.3). 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, isolation 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 %/RQL of 20 %. 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 or WSP 80.3 (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 %/RQL of 20 %. 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 or WSP 80.3 (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 %/RQL of 20 %. The test results shall be reported in the manufacturer's product technical information, as specified in 4.1.3.

#### Level 4:

**Surgical gowns, isolations gowns and other protective apparel:** When a surgical gown, isolation 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 %/RQL of 20 %. 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.

NOTE: If an antimicrobial element is inactivated to meet the requirements of ASTM 1671, this must be noted.

**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, isolation gowns, other protective apparel, surgical drapes, and drape accessories**

| Level | Test  | Result             | AQL requirement<br>(Alpha=.05) | RQL requirement<br>(Beta = 0.10) |
|-------|---|--------------------|--------------------------------|----------------------------------|
| 1     | AATCC 42  | ≤ 4.5 g            | 4 %                            | 20 %                             |
| 2     | AATCC 42: AATCC 127   | ≤ 1.0 g<br>≥ 20 cm | 4 %<br>4 %                     | 20 %                             |
| 3     | AATCC 42<br>AATCC 127   | ≤ 1.0 g<br>≥ 50 cm | 4 %<br>4 %                     | 20 %                             |
| 4     | ASTM F1671 (surgical gowns, isolation gowns and other protective apparel) | Pass               | 4 %                            | 20 %                             |
|       | ASTM F1670 (surgical drapes and drape accessories)                        | Pass               | 4 %                            | 20 %                             |

**1. Blotter paper used with the AATCC method must meet the specifications provided in section 5.2.1.2 of this standard.**

**2. Test results should state both the AQL and RQL levels for the sampling plans employed.**

**3. WSP 80.3 is equivalent to and may be substituted for AATCC 42 when the blotter paper specified in 5.2.1.2 is used.**

#### **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 a design, fabrication, or material change is made that has a potential of affecting barrier level or variability, then retesting of the impacting material is required per this revision.

#### **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, isolation 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 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 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 %/RQL of 20 %.
- 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 because 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. In this document, the maximum AQL is set at 4.0 % at a 95 % acceptance level (Alpha = 0.05) with the maximum RQL set at 20 % at a 10 % acceptance level (Beta = 0.10). For an original classification of a product, the sampling plan shall be applied independently to each critical zone component. For an original classification of a product, the sampling plan shall be applied to multiple lots.

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

To be classified as Level 1, all critical zone components of a surgical gown, isolation 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, isolation gown or 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, isolation 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 or **WSP 80.3** test, blotter paper that meets the following specifications should be used.

- It should exhibit no distortions when wet.
- It should have an absorbent rate of < 5 seconds.
- It should have an absorbent capacity of 480 % ± 30 %.
- It should have a sheet density of 0.24 g/cc ± 0.06 g/cc.
- It should exhibit uniform sheet formation.
- It should be traceable to the production lot.
- It should be weighed to the nearest 0.01 grams.

The test nozzle should be calibrated prior to testing to insure that it delivers 500 ml of test fluid in 22 +/- 2 seconds.

### **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 blood-borne pathogens 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, isolation 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, isolation 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, isolation 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, isolation 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 primarily by device manufacturers in qualifying, classifying, and labeling the barrier performance of their products so 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 ST65:2008, *Processing of reusable surgical textiles 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; 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**

Because this standard establishes a classification system of barrier performance, with 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, isolation 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, isolation 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, isolation 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, isolation 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, isolation 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, isolation gowns and other protective apparel**

The requirements for the design and construction of surgical gowns, isolation 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. Because 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.

#### **A.4.2.3.3 The sterile field and the critical zone**

##### Principles of the sterile field

The primary method through which surgical patients are protected and microbes are prevented from causing a surgical site infection (SSI) is through the creation of a sterile field for each surgical procedure. The sterile field can be described as a separate, sterile area that consists of the draped portions of the patient, O.R. table, Mayo stand, back table and gowns and gloves of the sterile surgical team members. Within the sterile field are the sterile instruments, equipment, supplies, and sutures that will be needed during the procedure.

The following are specific principles as related to the sterile field:

- **The top of a sterile, draped table is the only portion that is considered sterile.** Any part of the drape extending below the top of the table is considered non-sterile.
- **Any item extending or falling below the table edge is considered non-sterile.** Examples include suction tubing, electrosurgery cord or a cord to a power instrument that hangs below the table edge; they are considered non-sterile and should not be brought back up onto the sterile surface.
- **Once sterile drapes have been placed they should not be repositioned.** The portion of the drape that falls below the table edge is considered non-sterile and repositioning the drape brings up to the sterile field the contaminated portion of the drape.

The following are specific principles as related to the sterile surgical gown:

- **The surgical gown is considered sterile from the waist to the mid-chest line in front and up to 2-inches above the elbows on the sleeves.** The upper chest area on the front of the gown is considered non-sterile because it cannot be directly viewed by the wearer and because of the possibility of the chin coming into contact with the gown.
- **The back of the sterile gown is considered non-sterile.** When wearing a sterile gown, the non-sterile back should never be turned towards the sterile field. The back cannot be viewed directly by the wearer.
- **The stockinette cuffs of the surgical gown are considered non-sterile and should be covered by the cuff of the sterile gloves at all times.** When the team member is self-gowning and self-gloving, the hands should not extend beyond the cuffs and should remain covered by the sleeve of the gown.
- **When a sterile team member is standing at a sterilely draped table, the gown should be considered sterile to the top of the operating table or the back table's top surface.** Areas below this level may contact non-sterile surfaces and are considered non-sterile.
- **The arms should not be folded with the hands in the axillary region.** This region is considered non-sterile because it cannot be viewed by the wearer and because of strike-through contamination from perspiration that can occur in this area.

The following are specific principles as related to draping a non-sterile table:

- **When a non-sterile person is draping a non-sterile table to create a sterile field, the non-sterile individual should cuff the hands in the underside folds of the drape or table cover to avoid contaminating the top surface.** The drape should be opened away from the body toward the far side of the table first and then toward the body to avoid contamination.
- **The inside of paper wrappers containing sterile items are considered sterile except for a one-inch perimeter around the outside edge of the wrapper.** For example a sterile patient skin prep kit is opened on the prep table, and the paper wrapper is used to create a sterile field. The wrapper is sterile up to one-inch around the perimeter of the wrapper.

#### Principles of the critical zone

The critical zone can be described as an area approximately 12 inches around the fenestration of a drape where it is thought that reinforcement is needed to resist the penetration and strike-through of fluids. Additionally, the critical zone on surgical gowns encompasses the front area from mid-chest to waist and the sleeves to 2 inches above the elbows.

However, there are two important factors as related to the critical zone:

1. **Fluid is often not always contained in the proximity of the critical zone.** For example, during an arthroscopic procedure a large amount of fluid can be used during the procedure and is not contained within the critical zone of the arthroscopic drape.
2. **Specialty drapes, such as extremity drapes, may have a reinforced critical zone; however, due to the amount of fluids that may be encountered and/or manipulation of the body part the surgical team should consider draping reinforcement of the areas outside of the critical zone.** For example, during a hip arthroplasty the leg is placed through several maneuvers to initially dislocate the joint, facilitate bone excision and placement of the prostheses, put the joint back into place, and further maneuvers to test the prostheses prior to closing the surgical wound. This calls for draping reinforcement of the entire leg and foot in order to prevent an SSI.

In this situation, it might be considered that the critical zone should be further expanded outside of the manufacturers region of reinforcement around the fenestration, thus further suggesting that the critical zone is a fluctuating zone that is dependent on the procedure to be performed.

#### Conclusion

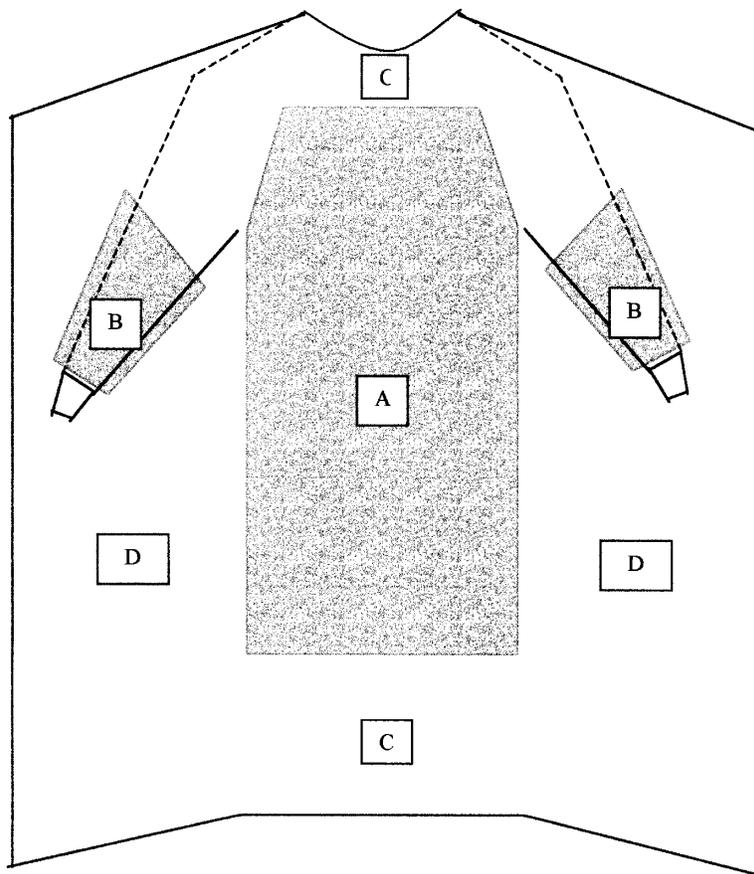
As indicated by the information above, there are black-and-white principles related to the sterile field and surgical gowns that all surgical personnel should follow strictly in order to prevent the patient from acquiring a SSI. However, when discussing the critical zone of sterile drapes and gowns, the surgical team should consider the procedure to be performed and the amount of fluids anticipated and make the appropriate decisions regarding placement of additional drapes for the purpose of reinforcement.

**Annex B**  
(informative)

**Examples of barrier performance classification of surgical gowns, isolation 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.

 Critical zone



**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).

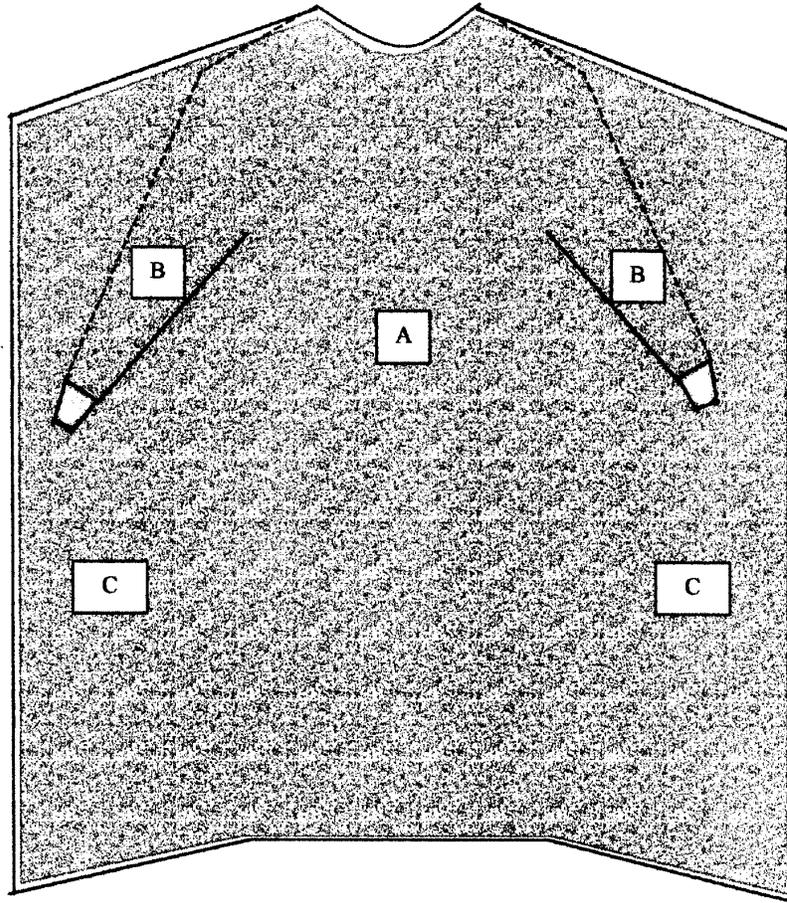
NOTE 5—Seams between two protective areas are required to have at least the barrier performance of the lower-performing area (as per 4.2.3.1).

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**

| <b>Area A (Critical zone—front)</b> | <b>Area B (Critical zone—sleeve)</b> | <b>Area C (Front)</b> | <b>Area D (Back)</b>               |  | <b>Final classification</b> |
|-------------------------------------|--------------------------------------|-----------------------|------------------------------------|--|-----------------------------|
| 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                     |

 Critical zone



**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).

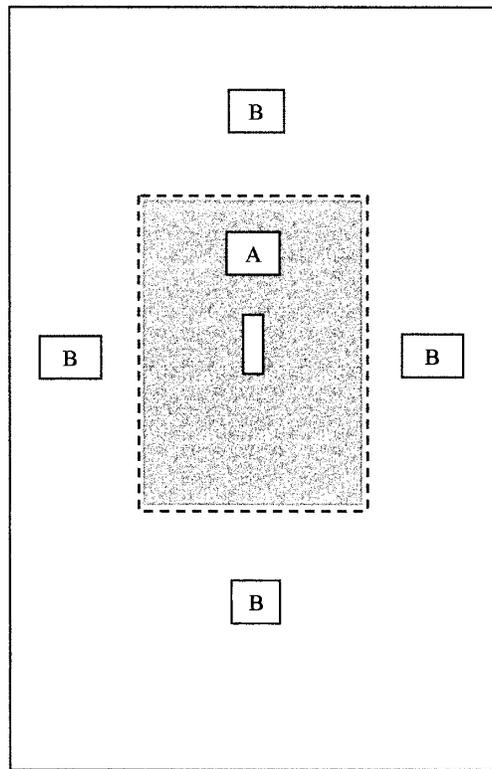
NOTE 2—Table B.2 illustrates the requirements of 4.2.1.1 and 4.2.3.1 and shows how the barrier performance classification of the isolation gown would be determined.

**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                                  |



Critical zone



**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                                  |

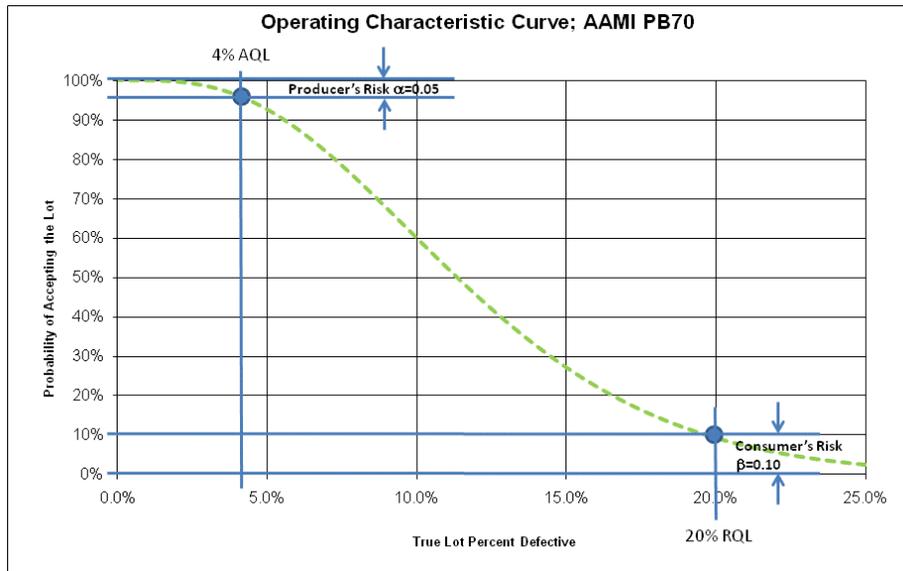
## Annex C (informative)

### Examples of sampling plans

The sensitivity of any product inspection system is related to the quality control plan as well as the statistical sampling scheme appropriate to that product. The sampling plan should weigh both the producer and consumer risks. The Acceptable Quality Level (AQL) and Alpha define the “producer’s risk” of the operating characteristic curve. This point is referred to as the “producer’s risk,” because it satisfies the producer’s intentions of having a high probability of accepting lots if those lots are truly AQL fraction defective or lower. The value, (1-Alpha) is the probability of accepting a lot if it contains AQL fraction defective. Alpha represents the probability that the lot would be rejected. On the other hand, the Rejection Quality Level (RQL) and Beta define that fraction defective of a lot that the plan that will have a small probability (Beta) of accepting. The RQL and Beta define the “consumer’s risk”. This point is referred to as the “consumer’s risk,” because it satisfies the consumer’s desire of having a low probability of not receiving product if those lots are truly RQL fraction defective or worse. The value, (1-Beta) is the probability of rejecting a lot if it contains RQL fraction defective.

An OC (Operational Characteristic) Curve is often used to highlight the strength of a sampling system. The curve shows the changing probability of a product being accepted as the true lot defective level changes. High quality levels have a high probability of being accepted, and as the product quality deteriorates the probability of the product being accepted lessens.

For attribute data, these curves are often calculated using the binomial distribution. To the right, the OC curve shows the n=32, c=3 sampling plan and the protection it provides across a range of possible defect levels.



In this document, the maximum AQL is set at 4.0 % at a 95 % acceptance level (Alpha = 0.05) with the maximum RQL set at 20 % at a 10 % acceptance level (Beta = 0.10). The table below provides these details as well as the acceptance criteria. Additional sample sizes may be appropriate and should be documented in a similar fashion, where both consumer and producer risks for the sampling plan are documented.

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

| Total Sample Size | AQL | RQL  | Accept | Reject |
|-------------------|-----|------|--------|--------|
| 32                | 4.0 | 20.0 | 3      | 4      |

The above discussion treats the test results as an attribute. The upside of analyzing the data in this manner is that the underlying distribution does not need to be defined; the data is strictly assessed by meeting the requirement or not meeting it. When normally distributed measurements are to be generated, then a variable sampling plan can be utilized. Statistical tolerance limit approach could also be used, because it puts the emphasis on the RQL level. For example, the 99/90 requirement would meet the minimum requirement because it requires 99 % confidence that at least 90 % of the product meets the requirement.

A list of commonly used sample size standards is provided below. The first two are focused more on the RQL protection and the last two are more AQL focused.

**1) Military Standard 1916 (U.S. Department of Defense, 1996)**

These are C=0 attribute plans and alternative variables plans (*SD Unknown, SD= Standard Deviation*).

**2) ANSI/ASQC Standard Q3 (1988)**

This attribute-only standard assigns sampling plans based on user assigned RQL level and the lot size (N).

**3) ANSI/ASQC Z1.4 (2008), or ISO 2859-1 (1999)**

*Sampling Procedures and Tables for Inspection by Attributes* is an acceptance sampling system to be used with switching rules on a continuing stream of lots for Acceptance Quality Limit (AQL) specified.

**4) ANSI/ASQC Z1.9, or ISO 3951-1 (2005)**

Sampling plans and procedures for inspection by variables indexed by an AQL level.

## Annex D (informative)

### Bibliography

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<sup>3</sup> 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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## **Annex E**

(informative)

### **Rationale for changes to the 2003 edition of PB70**

The most significant revision to PB70 involves two water-impact resistance tests: AATCC 42 and the newer WSP 80.3, which has more stringent specifications for blotter paper and equipment calibration. WSP 80.3 has been added in Table 1 of the document as an acceptable test, with a note referencing section 5.2.1.2 for more information about blotter paper requirements.

The committee considered allowing the optional use of a retaining screen in AATCC 127 as a means to reduce the test variability by supporting lighter weight or more elastic Level 2 and Level 3 critical zone components. However, the results from an interlaboratory study (round robin testing) did not demonstrate a reduction in variability with the use of a retaining screen. Therefore it was decided to continue to conduct AATCC 127 as written.

AQL and RQL were updated and are described in Annex C.

References in the document have been updated where applicable.