American National Standard

ANSI/AAMI PB70:2012

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

AAMI
Advancing Safety in Medical Technology

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.

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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:

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

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

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American National Standard **ANSI/AAMI PB70:2012**
(Revision of ANSI/AAMI PB70:2003/(R)2009)

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)

AAMI Standard

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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 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005/(R)2012 and ANSI/AAMI ES60601-1:2005/A2:2010/(R)2012 ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
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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
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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
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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 Amendment 1:2012	ANSI/AAMI/ISO 7199:2009 and 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
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ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical

International designation	U.S. designation	Equivalency
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
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ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
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ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
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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
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ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
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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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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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Finally, the AAMI Protective Barriers Committee dedicates this standard to the late Dr. William Beck, the original chair of the AAMI Aseptic Barrier Committee, for his decades-long commitment to defining and providing aseptic barriers for patients and the health care team, his vital research, and his tireless and important communications on aseptic barrier issues through publications and public speaking.

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.

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.

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