

American National Standard



ANSI/AAMI PB70:2022

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

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

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Abstract: 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.

Keywords: acceptable quality level (AQL), Bacteriophage, barrier properties, Binding, blood-borne pathogen, body fluid, body fluid simulant, critical zone, critical zone component, decontamination garment, decontamination gown, Fenestration, full coverage gown, Gown, Hem, Hood, isolation gown, Laminate, laundry processes, Manufacturer, non-protective back gown, open back gown, other potentially infectious materials (OPIM), Ply, point of attachment, procedure gown, protective apparel, reinforced area, rejectable quality level (RQL), Seam, service life, simulated product, Sterile, sterile field, Sterilization, strike-through, surgical drape, surgical gown, surgical gown–E, surrogate microbe, synthetic blood, Toga, viral penetration, viscosity

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Protective Barriers Committee

The publication of ANSI/AAMI PB70 as an American National Standard was initiated by the AAMI Protective Barriers Committee.

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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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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
- “should” and “should not” are used to express recommendations;
- “may” and “may not” are used to express permission;
- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall.”

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.



Introduction

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) [10]. See also the Centers for Disease Control and Prevention's (CDC's) Guideline for the prevention of surgical site infection (CDC, 1999 [11]).

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 third 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 second edition, the most significant revisions are expansion of the scope to include additional types of personal protective equipment.

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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE This foreword does not contain provisions of the American National Standard ANSI/AAMI PB70:2022, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*, 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 liquid borne microbial barrier claims that are not specifically excluded in 1.3 (e.g., single-use and multiple-use surgical gowns, isolation gowns, other gowns, other types of open back gowns including over the head gowns, decontamination attire, aprons, toga, protective headwear such as hats and caps, hoods, footwear covers, sleeves, and laboratory attire). Some of these devices 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 Isolation gowns are classified by the FDA under 21 CFR 878.4040.

NOTE 3 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 face, and eyes, such as goggles, non-integrated face shields, surgical masks, and non-integrated respirators;
- c) other types of protective apparel worn by health care personnel that is not intended or labeled as a barrier to liquid or microorganisms;
- d) absorbent operating room (OR) towels;
- e) all of the requirements necessary to ensure the safety and effectiveness of the products within the scope of this standard;
- f) the interfaces between products, such as the gown/glove interface;
- g) all of the labeling or other information that a health care facility might deem necessary or desirable in product selection;

- h) protection from dry particulate and dry microbial penetration;
- i) protection from gas permeation;
- 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.

AATCC 42, *Water resistance: Impact penetration test*

AATCC 127, *Water resistance: Hydrostatic pressure test*

ASTM F1670, *Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood*

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*

3 Definitions

For the purposes of this document, the following terms and 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 to entry: 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 to entry: 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 liquid borne microorganisms under test conditions.

Note to entry: 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 to entry: 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 to entry: 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

[SOURCE: ASTM F1670]

3.8

critical zone

area of protective apparel or surgical drape identified by this standard for testing 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 to entry: 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

decontamination gown

gown that is used as protective apparel during decontamination procedures

3.12

fenestration

opening provided in surgical drapes to allow access to the surgical site

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

3.13

full coverage gown

item of protective apparel designed to protect health care personnel and patients from the transfer of microorganisms and body fluids from exposure to the front and back of the wearer

Note to entry: A full coverage gown has overlap in the back so that when an appropriately sized gown is worn there are no gaps in the back, with no slits, perforations, or holes in any part of the gown.



3.14

gown

an open-bottom garment with sleeves that, when worn properly over the clothing, provides coverage and acts as a protective barrier between the wearer and the environment

3.15

hem

raw edge of material that is turned over and stitched or bonded

3.16

hood

type of protective apparel comprised of head and neck covering that contains designated areas of liquid barrier protection and with or without an integrated face shield

3.17

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

3.18

laminate

material of two or more layers bonded to one another

3.19

laundry processes

activities that encompass the handling, washing, and drying of multiple-use textiles

3.20

manufacturer

an entity meeting the definition provided in FDA regulation 21 CFR 820.3(o), "...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."

[SOURCE: U.S. Food and Drug Administration (FDA). Code of Federal Regulations, Title 21, Volume 8, Subchapter H, Medical devices, Part 820. *Quality system regulation*. Washington, DC.]

3.21

non-protective back gown

item of protective apparel other than an open back gown that is used to protect health care personnel and patients from the transfer of microorganisms and body fluids and does not claim barrier protection from exposures to the back

Note to entry: A gown is a nonprotective back gown when the back of the gown contains slits, perforations, or holes, or if the back panels do not meet at least the requirements for Level 1 barrier performance. Nonprotective back gowns are only used when exposure to the back is not anticipated.

3.22

open back gown

item of protective apparel used to protect health care personnel and patients from the transfer of microorganisms and body fluids when exposure to the back is not anticipated

Note to entry: An open back gown is defined as open back when the gown leaves portions of the back uncovered.

3.23

other potentially infectious materials

OPIM

a term defined by OSHA regulation 29 CFR 1910.1030(b) to refer to any of the following:

- the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, anybody fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

- any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

3.24

penetration

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

3.25

ply

separable sheet or layer of material

3.26

point of attachment

area at which an attachment occurs providing a physical connection between one thing that is attached to another (e.g., areas where belts, ties, pockets, snaps, etc., are attached)

3.27

procedure gown

non-sterile item designed to protect health care personnel and patients from the transfer of microorganisms and body fluids during procedures that do not require a surgical gown.

3.28

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 to entry: Examples of protective apparel include surgical gowns, isolation gowns, other gowns, decontamination attire, aprons, togas, hoods, sleeve protectors, and certain types of laboratory attire.

3.29

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

Note to entry: Regions may be reinforced to increase strength or resistance to liquid penetration, providing absorptive qualities, or improving other qualities.

3.30

rejectable quality level

RQL

specified fraction of a tested lot that, if all the fractions would fail and all of the others would pass a performance test, would theoretically lead to a probability of lot acceptance less than a specified “beta” percentage, used to select a sampling plan

Note to entry: 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.

3.31

seam

area at which two or more pieces of material are joined together

Note to entry: Many types of seams can be formed, including conventional needle-and-thread, adhesive, welded, or other seaming methods.

3.32

service life

number of processing cycles and/or lifetime that a medical device can be subjected to and remain suitable and safe for its intended use

3.33

simulated product

test sample specifically designed and constructed for the purpose of modeling the performance of the finished product

3.34

sterile

free from viable microorganisms

3.35

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 to entry: 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.

3.36

sterilization

validated process used to render a product free of all forms of viable microorganisms

3.37

strike-through

passage of a liquid that could contain microorganisms through a barrier product, including its seams and/or points of attachment

Note to entry: The term “strike-through” was first introduced to the clinical community by Laufman. In: Laufman, Eudy, and Vandernoot, et al. Strike-through of moist contamination by woven and nonwoven surgical materials. *Ann Surg*, 1975, vol. 189, no. 1, pp. 68–74.

3.38

surgical drape (and drape accessories)

item meeting the definition provided in FDA regulation 21 CFR 878.4370, “...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 to entry: 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, equipment drapes (e.g., robotic, C-arm), and additional draping layers placed over the patient.

3.39

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 to entry: Protection from the transfer of particulate matter is not addressed by this standard.

3.40

surgical gown–E

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 1 to entry: A surgical gown–E will have extended critical zones beyond that of a surgical gown as described in Clause 4.2.3.2 and as shown in Figure B.2.

Note 2 to entry: Protection from the transfer of particulate matter is not addressed by this standard.

3.41

surrogate microbe

microorganism which is used to act as a simulant for other microorganisms which are pathogenic to humans

Note to entry: 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.

[SOURCE: ASTM F1671, modified – Note to entry has been added.]

3.42

synthetic blood

challenge agent used in ASTM F1670 that is intended to simulate the liquid properties of blood

Note to entry: Synthetic blood used in ASTM F1670 is, “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.” The synthetic blood specified in ASTM F1670 does not simulate all the characteristics of real blood or body fluids (e.g., polarity (a wetting characteristic), coagulation, and content of cell matter).

3.43

toga

type of personal protection system used to protect healthcare personnel and patient from the transfer of microorganisms and body fluids, combining the use of a protective gown integrated with a loose-fitting hood with or without an integrated face shield and may incorporate filters or helmet system.

3.44

viral penetration

the penetration of a material by a virus

[SOURCE: ASTM F1671]

3.45

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

Each toga integrated hood and integrated gown shall be labeled separately and prominently with its class of barrier performance, as determined in accordance with Clause 4.2.1.

4.1.2 Package labeling

Each package containing surgical gowns, isolation gowns, other gowns, decontamination gowns, togas, hoods, 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 Clause 4.2.1.

Each package containing surgical gowns, isolation gowns, other gowns, other items of protective apparel, surgical drapes, or drape accessories shall be labeled with an expiration date to the lowest unit of packaging (e.g., box, bag, etc.).

Each package containing surgical gowns shall be labeled as a surgical gown.

Each package containing isolation gowns shall be labeled as an isolation gown.

Each package containing gowns other than surgical or isolation gowns (e.g., procedure gown, decontamination gown) shall be labeled with one of the following that meets the appropriate description of the gown:

- a) full coverage gown;
- b) non-protective back gown; or
- c) open back gown.

Each package containing togas shall be labeled according to type of gown that is integrated into the toga according to Clause 4.2.3.1, Clause 4.2.3.2, and Clause 4.2.3.5.

NOTE More information on labeling multiple-use products, may be found in ASTM F2047-20 and ASTM F3352-19.

4.1.3 Technical information

4.1.3.1 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, and test results if requested as specified in Clause 4.2.1.2;

NOTE 1 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 Clause 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 2 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 Clause 4.2.1), a narrative description of the class of barrier performance of each area outside the critical zone, or both.

4.1.3.2 In addition, technical literature to be included with multiple-use products shall contain the following:

- a) 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; and
- b) instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product.

NOTE See Clause 4.2.2 for Tracking mechanism for multiple-use products.

- c) instructions on inspections that can be performed by processors to verify the continued safety and effectiveness of the product.

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.