American National Standard

ANSI/AAMI PB70:2022

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

AAMI
Advancing Safety in Health Technology

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

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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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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;

