

# Technical Information Report

## AAMI TIR11:2005/ (R)2015

Selection and use of  
protective apparel and  
surgical drapes in health  
care facilities



# Selection and use of protective apparel and surgical drapes in health care facilities

Approved 17 October 2005 and reaffirmed 21 October 2015 by  
**Association for the Advancement of Medical Instrumentation**

**Abstract:** This technical information report (TIR) covers the selection and use of protective apparel and surgical drapes. It includes information on types of protective materials, safety and performance characteristics of protective materials, product evaluation and selection, levels of barrier performance, and care of protective apparel and drapes. Definitions of terms and informative annexes are also provided.

**Keywords:** barrier properties, drapes, isolation gowns, protective apparel, surgical attire

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## Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard.

NOTE—Documents are sorted by international designation.

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

International designation	U.S. designation	Equivalency
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-04:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI I136:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI I151:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical
ISO TS 10993-19:200x <sup>1</sup>	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO TS 10993-20:200x <sup>1</sup>	ANSI/AAMI/ISO TIR10993-20:2006	Identical

<b>International designation</b>	<b>U.S. designation</b>	<b>Equivalency</b>
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:200x <sup>1</sup>	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:200x <sup>1</sup>	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:200x <sup>1</sup>	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO TS 11139:200x <sup>1</sup>	ANSI/AAMI/ISO 11139:200x	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:200x <sup>1</sup>	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:200x <sup>1</sup>	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 200x <sup>1</sup>	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161:2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000 and A1:2004	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO TR 16142:200x <sup>1</sup>	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:200x <sup>1</sup>	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:200x <sup>1</sup>	ANSI/AAMI/ISO 18472:2006	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

<sup>1</sup>In production

## Committee representation

### Association for the Advancement of Medical Instrumentation

#### AAMI Protective Barriers Committee

This technical information report was developed by the AAMI Protective Barriers Committee. Approval of the TIR does not necessarily mean that all committee members voted for its approval.

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

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	Nanlin Deng, DuPont Nonwovens
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	David W. Johnson, Kimberly-Clark Corporation
	Frances Ann Koch, RN, Presbyterian Hospital of Dallas
	Barbara Lawless, Precision Fabrics Group
	Philip C. Mann, Kappler Safety Group
	Marian G. McCord, PhD, North Carolina State University College of Textiles
	Martha T. O'Lone, U.S. Food and Drug Administration
	Joseph A. Palomo, Cardinal Health
	Carolyn Pritchyk, Kaiser Permanente
	Carl Richard, ASQ, CQE, Ahlstrom Windsor Locks LLC
	Barbara Rusynko, RN, MEd, CNOR, Inova Fairfax Hospital, Falls Church, VA
	Laura N. Simmons, Simcon International
	Linda Slone, RN, CNOR, Sibley Memorial Hospital, Washington, DC
	Donna Swenson, CSPDM, Sterile Recovery Division, Hospital Laundry Services
	Lisette Swenson, Molnlycke Health Care
	Nathaniel Terry, Burlington Industries Inc.
	William N. Thompson, TYCO Healthcare/Kendall
<i>Alternates:</i>	Andrew Giles, DuPont Nonwovens
	Michael Groesbeck, Cardinal Health
	Laura Kappler-Roberts, Kappler Safety Group
	Michael Mathis, Kimberly-Clark Corporation
	Scott S. Sardeson, 3M Health Care
	Michael Smith, RM, Nelson Laboratories Inc.

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

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The AAMI Protective Barriers Committee wishes to gratefully acknowledge the extensive contributions of Jay R. Sommers, PhD, who served on the committee for many years as the representative of Kimberly-Clark Corporation.

## Foreword

This technical information report (TIR) was developed by the AAMI Protective Barriers Committee. The TIR is intended to provide technical information that will assist health care personnel in the selection and use of surgical gowns, other protective apparel, and surgical drapes. It covers subjects such as types of materials used in the construction of protective apparel and drapes, safety and performance characteristics of protective materials, selection and evaluation of protective apparel and drape products, guidelines for choosing the level of barrier performance needed for anticipated exposure risks, care of protective apparel and drapes, proper disposition of used protective apparel and drapes, and pertinent references.

The first edition of this TIR was published in 1994 and was titled *Selection of surgical gowns and drapes in health care facilities*. This second edition incorporates changes to take into account the publication of ANSI/AAMI PB70, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*, and ANSI/AAMI ST65, *Processing of reusable surgical textiles for use in health care facilities*. Also, the scope of this edition has been expanded to include other types of protective apparel in addition to surgical gowns, such as isolation gowns and decontamination garments, and to cover use considerations, such as the relationship between barrier performance levels and particular health care applications. In addition, an attempt has been made to reflect new trends in health care, changes in practices, and the state of the art in materials used for both single-use and multiple-use protective apparel and drapes.

The safety and performance of a surgical gown, other item of protective apparel, or surgical drape depend not only on the materials from which it is fabricated but also on product design. There is considerable variation in design among commercially available protective apparel and drapes. The particular gown or drape design chosen should be commensurate with the product's level of barrier performance, the intended application, and the manner in which the product will be integrated with other protective products (e.g., surgical masks and face shields) into a complete protective system. This TIR addresses the characteristics of protective materials in some detail, touches on the importance of design, and discusses various performance issues applicable to protective apparel and drapes, including test methods for barrier properties and other important attributes. It is recommended that health care personnel screen products on the basis of material and product test data (see Section 4) and then evaluate the performance of selected products through a formal process (see Section 5). Health care personnel should also use the information in Section 6, "Guidelines for choosing levels of barrier performance needed for particular health care applications," in the decision-making process.

A new table, "General relationships between barrier performance and anticipated exposure risks" (Table 3), can assist clinicians in choosing drapes and protective apparel that are labeled in accordance with ANSI/AAMI PB70 and that are appropriate for the health care procedure and for the level of protection required for both patient and staff. The examples cited in the table are only general suggestions and should not be interpreted as absolutes or policy statements. Clinical end-users of surgical gowns, other protective apparel, and drapes must always comply with federal, state, and local regulations. They also should take into account the relevant health care literature, as well as current recommended practices, guidelines, and statements promulgated by professional associations and other relevant organizations, such as the Centers for Disease Control and Prevention. The bibliography of this TIR provides many of these pertinent documents.

During the development of the TIR, the committee's goal was to produce a reference that would enhance excellence in patient care practices involving protective apparel and drapes. This TIR is thus intended for clinical professionals as well as for managers and purchasing agents who influence the selection and proper use of protective apparel and drapes.

Like any other AAMI technical information report, this TIR is not a performance standard. It is not intended to establish minimum safety and performance criteria, and none of its provisions should be so interpreted.

This TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving technology and because it does not treat all issues associated with protective apparel and drapes in depth, readers are encouraged to consider information from other sources and, in particular, to keep abreast of the relevant health care literature.

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



# Selection and use of protective apparel and surgical drapes in health care facilities

## 1 Introduction and scope

Traditionally, surgical gowns, other protective apparel, and surgical drapes have been intended to help prevent wound infections by providing a barrier between nonsterile and sterile areas. However, given the increasing concerns related to bloodborne pathogens such as the human immunodeficiency virus (HIV) and the increasing number of hepatitis B virus (HBV) and hepatitis C virus (HCV) infections among health care personnel, the protection of the surgical team and other health care personnel has become an important issue.

Protective apparel and surgical drapes are fabricated from either multiple-use materials or single-use materials. Each of these two basic types of products has advantages and disadvantages. Within the material types available, design and performance characteristics vary considerably. This variation stems from trade-offs in economy, comfort, and the degree of protection required for particular surgical and other health care procedures. Consequently, health care personnel are faced with a complex decision-making process when choosing the types or performance levels of products that will best serve their needs.

This technical information report (TIR) is intended to assist health care personnel in the selection of protective apparel and drapes that are listed by and have received marketing clearance from the Food and Drug Administration (FDA). These products are classified as medical devices and are subject to FDA's labeling, premarket notification (510[k]),<sup>1</sup> and medical device reporting (MDR) regulations. In addition, under FDA's quality system regulation (QSR), good manufacturing practices (GMPs) must be used in the manufacture and commercial reprocessing of these devices.

This TIR is also meant to serve as a resource that health care professionals can use when directing questions to manufacturers about the performance characteristics of specific products and when choosing products for use in particular surgical and other invasive or patient care procedures.

The scope of this TIR includes

- a) types of protective materials,
- b) safety and performance characteristics,
- c) product evaluation and selection,
- d) guidelines for choosing the level of barrier performance, and
- e) care of protective apparel and surgical drapes.

Definitions of terms and informative annexes are also provided.

This TIR might not cover all the requirements that a health care facility could deem necessary to select a product, nor does it address criteria for evaluating experimental products.

## 2 Definitions of terms

**2.1 barrier properties:** Ability of a protective product to resist the penetration of liquids and liquidborne microorganisms.

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

**2.3 blood:** Human blood, human blood components, and products made from human blood.

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<sup>1</sup> For new or changed products introduced to the market after May 28, 1976, manufacturers are required to submit a premarket notification to FDA. Products found to be substantially equivalent to existing products are "cleared" by FDA for marketing. This clearance for marketing does not constitute FDA approval of the product's safety and effectiveness.

**2.4 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 in which it is difficult or impossible to differentiate between body fluids. See 29 CFR 1910.1030.

**2.5 calender:** Machine used to impart a variety of surface effects to fabrics. It usually consists of two or more heavy rollers, sometimes heated, through which the fabric passes under pressure.

**2.6 contaminated:** State of having been actually or potentially in contact with microorganisms.

NOTE—*Contaminated* may be construed to mean in contact with blood or other potentially infectious materials whether or not they are known to contain microorganisms.

**2.7 critical zone:** Area of protective apparel or surgical drapes where direct contact with blood, body fluids, and other potentially infectious materials is most likely to occur.

**2.8 fenestration:** Opening provided in surgical drapes to allow access to the surgical site.<sup>2</sup>

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

**2.10 hydrostatic pressure:** Force exerted by a static liquid (e.g., pressure applied to a surgical drape by a puddle of fluid).

**2.11 incise drape:** Adherent plastic film affixed to the patient's skin or over the primary drape during the draping procedure. This film usually extends beyond the fenestrated area of the drape, including the incision site; the incision is made by cutting through the film adhering to the patient's skin.<sup>3</sup>

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

**2.13 knitted fabric:** Structure produced by interlooping one or more ends of yarn or comparable material.<sup>4</sup>

**2.14 linting:** Release of fiber fragments and other particles from a fabric during handling and use.

**2.15 mechanical pressure:** Force exerted by one solid object on another (e.g., pressure applied to a surgical gown when the wearer leans against a table).

**2.16 microbial model:** Microorganism that simulates a specific human pathogenic microorganism in size, shape, and concentration and that can be used in testing the microbial barrier properties of protective materials.

**2.17 nonwoven fabrics:** Fabrics broadly defined as sheet or web structures bonded together by entangling fiber or filaments mechanically, thermally, or chemically. They are flat, porous sheets that are made directly from separate fibers or from molten plastic or plastic film. They are not made by weaving or knitting and do not require converting the fiber to yarns.

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

NOTE—In 29 CFR 1910.1030, the Occupational Safety and Health Administration (OSHA) describes the following materials as OPIM:

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial 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;

(2) Any unfixated tissue or organ (other than intact skin) from a human (living or dead); and

(3) 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.

**2.19 particulates:** Very small solids that are suspended in air or liquid and that can vary in size, shape, density, and electrical charge.

<sup>2</sup> Adapted, with the publisher's permission, from ECRI, Evaluation: Surgical drapes, *Health Devices*, 15 (5):111–40, 1986.

<sup>3</sup> Adapted, with the publisher's permission, from ECRI, Evaluation: Surgical drapes, *Health Devices*, 15 (5):111–40, 1986.

<sup>4</sup> Adapted from *Hoechst Celanese Dictionary of Fiber and Textile Technology*. Charlotte (NC): Hoechst Celanese Corporation, 1990.

**2.20 penetration:** Movement of matter, on a nonmolecular level, through porous materials, closures, seams, or imperfections (such as pinholes) in a protective product.

**2.21 ply:** Separable sheet or layer of a material.

**2.22 protective apparel:** Item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard or for 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.

**2.23 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, rendering it more resistant to liquid penetration, providing absorptive qualities).

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

NOTE—For persons around a sterile field in the operating room (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 and OPIM.

**2.25 strike-through:**<sup>5</sup> Passage of a liquid that could contain microorganisms through a barrier product (including its seams or points of attachment).

**2.26 surface tension:** The 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).

**2.27 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.

**2.28 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)

**2.29 woven fabric:** Structure produced by interlacing two yarns or similar materials so that they cross at right angles to produce a fabric.<sup>6</sup>

### 3 Types of surgical protective materials

#### 3.1 Introduction

A great many materials and manufacturing technologies have evolved in the attempt to meet the conflicting criteria for a safe, effective, and comfortable protective barrier. Each type of material offers advantages and disadvantages in safety, performance, and economics, and each could be more suitable for some uses than others. This section provides a general description of the major types of protective materials available at the time this TIR was published.

#### 3.2 Multiple-use materials

##### 3.2.1 General considerations

The term *multiple-use materials* is a general classification encompassing a wide range of fabrics and technologies used in the manufacture of protective apparel and surgical drapes. The element common to all is the material's ability to be reprocessed and reused.

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<sup>5</sup> The term *strike-through* was first introduced to the clinical community in Laufman, et al. (1975).

<sup>6</sup> Adapted from *Hoechst Celanese Dictionary of Fiber and Textile Technology*. Charlotte (NC): Hoechst Celanese Corporation, 1990.

### 3.2.2 Historical materials

The use of surgical fabrics began with what was readily available. Thus, hospital sheeting (cotton muslin) was the primary fabric used beginning in the late 19<sup>th</sup> century. Little changed in the use of these fabrics until the early 1970s, when tightly woven fabrics with water-repellent chemical finishes were adopted for surgical use. The following three fabrics were the most commonly used during this era:

- *All-cotton muslin* (140-thread-count muslin). A loosely woven fabric that is soft, absorbent, drapeable, and extremely porous. Because it is readily permeable, this material does not possess any liquid barrier capability. In addition, it tends to abrade easily and to generate lint.
- *Blended sheeting* (180-thread-count percale). A polyester-and-cotton blended sheeting that has permanent-press characteristics but otherwise exhibits the same performance characteristics as muslin.
- *“T280 barrier”* (280-thread-count, 270-thread-count, 272-thread-count, 175-thread-count fabric). A tightly woven cotton or polyester-and-cotton blended fabric. This material was the first reusable fabric with a water-repellent chemical finish. The fabric provided a barrier to liquids when new, but resistance to liquid penetration diminished with repeated washing, drying, sterilization, and use cycles.

### 3.2.3 Current materials

In the 1980s, a new generation of engineered surgical textiles with consistent, multiple-use protective qualities was developed. In general, these reusable fabrics provided more consistent barrier properties, reduced flammability, low lint generation, and extended durability as compared with their traditional reusable fabric predecessors. The reusable materials most commonly used for manufacturing surgical gowns and drapes today are as follows:

- *Polyester fabric*. A tightly woven fabric that is made of continuous-filament synthetic yarn, is chemically finished, and may be calendered (compacted to minimize pore size) to enhance liquid barrier properties. The yarns in these fabrics may also be made from very fine filaments, sometimes called *microfibers*.
- *Composite materials*. Combinations of woven or knitted fabrics that are engineered to obtain enhanced performance characteristics (e.g., increased protection against strike-through) by laminating them with various types of films or by coating them (see 3.4).

### 3.3 Single-use materials

Single-use protective apparel and surgical drapes are commonly constructed of nonwoven materials (although other types of materials may be used), alone or in combination with materials that offer increased protection from liquid penetration, such as plastic films.

Nonwoven materials are engineered fabrics that rely on fiber-bonding technologies (thermal, chemical, or mechanical) to provide integrity and strength rather than on the interlocking geometries associated with woven and knitted materials. The basic raw materials used for nonwovens are various forms of natural fibers (e.g., wood pulp, cotton) and synthetic fibers (e.g., polyester, polyolefin). Fabrics can be engineered to achieve desired properties by using particular fiber types, bonding processes, and fabric finishes. The most commonly used nonwoven fabrics for protective apparel and surgical drapes are as follows:

- *Spunlace*. A material often consisting of a blend of wood pulp and polyester fibers. High-velocity water jets are used to entangle the fibers to achieve mechanical bonding. For protective apparel and surgical drapes, a chemical treatment may also be used to improve liquid penetration resistance.
- *Spunbond/meltblown/spunbond*. A fabric consisting of three thermally or adhesively bonded layers. Typically, for medical applications, this material is made of polypropylene. Treatments are often applied to improve liquid penetration resistance. Spunbonded materials are made up of continuous filaments formed by in-line melt spinning. Meltblown materials are similar in that they are formed from a polymer by means of in-line melt spinning, but the fibers are finer and might not be continuous.
- *Wet-laid*. A nonwoven fabric consisting of wood pulp or a blend of polyester and wood pulp fibers. The fibers are suspended in water to obtain a uniform dispersion and are then separated from the slurry by draining the water through a fine mesh screen. For medical-grade fabrics, a chemical binder is often used to bond the fibers together. A chemical treatment can be used to improve liquid penetration resistance.
- *Composite*. A combination of nonwoven fabrics, films, or both created through lamination or coating processes. The resulting material has enhanced performance because it has attributes of each component.

### 3.4 Reinforcement of multiple-use and single-use products

Both multiple-use and single-use products are often modified to enhance or improve their performance characteristics. For example, single-ply gowns or drapes might not provide an adequate level of barrier protection for some applications. In those cases, the manufacturer may opt to modify the basic product by using additional layers, coatings, reinforcements, or laminates (overall or zoned) in order to offer a product with a higher level of barrier protection. In addition, manufacturers can enhance or add other product attributes, depending on the anticipated end-use application, to impart absorbency, slip resistance, additional strength, or other desirable characteristics. Some of the most common enhancements include the following:

- a) *Multiple layers.* Two or more layers of the material can be used to improve the barrier properties or the strength of the product.
- b) *Films.* A variety of films can be combined with other materials, usually by means of a lamination process, to provide a fabric for use in protective apparel and drapes. Microporous, monolithic, and bicomponent films are currently available:
  - *Microporous films* have pores that allow moisture vapor to pass through and, depending on the technology used, can provide various degrees of barrier protection against liquid and microbial penetration.
  - *Monolithic films* are nonporous and, depending on the technology used, may or may not be permeable to moisture vapor. These products typically provide a barrier to liquid and microbial penetration.
  - *Bicomponent films* usually consist of a microporous film and a breathable polymer. These products typically provide a barrier to liquid and microbial penetration.
- c) *Coatings.* A coating is a semiliquid material, such as urethane or silicone, that is usually applied to one side of a fabric. Depending on the coating characteristics (e.g., type, thickness), various degrees of protection against liquid and microbial penetration can be provided.
- d) *Liquid control.* For surgical drape applications, absorbent or adsorbent materials can be added to the surface of the drape, usually in the area around the fenestration, to impart some ability to control liquids. However, it is generally accepted that these materials do not eliminate the need for suction or other liquid-control measures during irrigation or when high volumes of liquid are expected.
- e) *Non-skid surfaces.* For surgical drape applications, surfaces can be modified (e.g., coated, brushed) or additional materials can be added, usually in the area around the fenestration, to provide for a non-skid surface for placement of instruments or other devices.

## 4 Safety and performance characteristics

### 4.1 Introduction

The primary performance characteristic of a surgical gown, other items of protective apparel, or surgical drape is its effectiveness in providing the appropriate level of protection against the penetration of liquids and microorganisms. Other important safety and performance properties may include abrasion resistance, strength, softness, drapeability, breathability, stain resistance, flammability, propensity for linting, toxicity, sterility (the majority of isolation gowns are sold nonsterile), sizing, and color. Producing a product that is superior in all these performance attributes is a significant challenge for manufacturers. Users often accept certain trade-offs, and they recognize that no one product is likely to possess all the properties that they need or desire. The test methods outlined in this section are intended to provide a basis for comparing products and some indication of how they will ultimately perform during actual use. However, given the limitations of all test methods, test results might not necessarily correlate directly with performance seen during actual use. This is why it is highly recommended that a formal evaluation process be undertaken before final product selection (see Section 5). Because barrier effectiveness is a primary focus of ANSI/AAMI PB70 and of this TIR, the limitations associated with extrapolating barrier performance test results to actual use will be discussed in some detail in 4.2.1.

This section discusses the safety and performance characteristics of protective materials, along with some of the test methodologies that may be used to evaluate them. The tests are discussed here in general terms; references to specific standard test methods are provided in Annex B.

### 4.2 Barrier effectiveness

#### 4.2.1 Resistance to liquid and microbial penetration

Surgical gowns, other protective apparel, and surgical drapes must provide an effective barrier against the transmission of microorganisms, both to protect the patient against contamination that could result in postoperative

wound infection and to protect the surgical team and other health care professionals against the transmission of bloodborne pathogens or other microorganisms. Health care providers have typically worn isolation gowns to protect their clothing from contamination when caring for a patient for whom isolation precautions apply. Until recently, the level of protection provided by isolation gowns, surgical gowns, other protective apparel, and surgical drapes was uncertain, because there were no requirements to classify or disclose their barrier properties. Eliminating this ambiguity was the reason ANSI/AAMI PB70, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*, was developed.

There are two general categories of protective materials, those that rely on repellent finishes and/or construction and those that rely on reinforcement by films. Even within the same product, one area or "zone" might be more resistant to liquid penetration than another; for example, the area around the fenestration of surgical drapes is typically reinforced in some way to provide more resistance to liquid penetration than other portions of the drape.

It has been clearly documented in the literature that when liquid containing microorganisms penetrates a material, microorganisms are carried with it and that microorganisms can penetrate a reinforced material without liquid being visible (Brown, 1992; Kotilainen, et al., 1992; Shaddock, et al., 1990). Traditionally, the user community has associated lack of visible strike-through with lack of microbial transfer; it has been demonstrated that this is not necessarily the case.

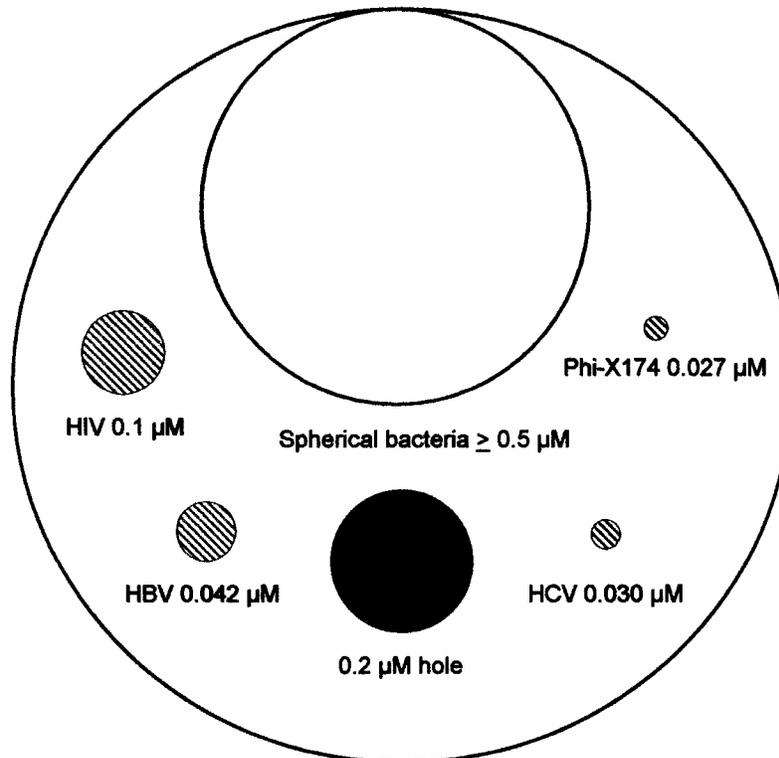
Liquids are generally accepted as the most important vector of microbiological transport in surgery. Other possible vectors of microbiological transport in surgery include air, aerosols, plume, lint, and skin cells. Dry penetration of microorganisms that is promoted by mechanical action might also be possible through porous materials. An effective microbial barrier must resist both "wet" and "dry" penetration of microorganisms.

Two fundamentally different types of liquid exposures occur in surgery: spraying and splashing, or soaking with pressing and leaning. More than one of either type of exposure can occur in the course of a surgical procedure, as well as various combinations of both types. Understanding these differences will help in determining the most appropriate type of challenge test to use to predict product performance more accurately and to help select the appropriate product for the application.

Some of the most commonly used industry test methods are as follows:

- *Water resistance (hydrostatic pressure)*. This type of test determines the ability of a material to resist water penetration under constant contact with increasing pressure. Typically, the test sample is clamped in place horizontally, and the hydrostatic pressure is increased at a specified rate from zero to the level at which visible penetration of water droplets is observed. The test is terminated at this point, and the pressure at which penetration occurred is recorded. The higher the hydrostatic pressure, the more resistant the material is to penetration by water. The test failure pressure may be reported in centimeters (cm) of water, inches of water, pounds per square inch (psi), or kilopascals (kPa). For example, in the case of AATCC 127 (the "hydrohead" test), a value of 70 cm of water is approximately equal to 28 inches water, 1.0 psi, or 7.0 kPa.
- *Water resistance (impact penetration)*. This type of test determines the ability of a material to resist water penetration under spray impact. The test sample is oriented at a 45° angle and clamped in place over a piece of preweighed blotter paper. A measured amount of water is released from a funnel with a spray head located a specified distance above the test sample. The test is terminated when the funnel is empty. After the water spray is concluded, the test sample is removed and the blotter is weighed again. The lower the weight gain in the blotter, the more resistant the material is to penetration by water.
- *Alcohol repellency*. This type of test determines the ability of a material to resist the spontaneous wetting and penetration of droplets of various alcohol-and-water solutions. Alcohol has low surface tension. In one such test method, 11 different test solutions, ranging from 0% to 100% isopropyl alcohol, are used. The sample is placed on a glass plate and, starting with the 0% alcohol solution, one small drop is put on the surface of the sample in three different locations. The test is terminated when visible penetration of one of the test solutions occurs within 5 minutes (min). The higher the alcohol concentration when penetration occurs, the more resistant the material is to penetration by alcohol.
- *Synthetic blood resistance*. ASTM F1670-03, *Standard test method for resistance of materials used in protective clothing to penetration by synthetic blood*, determines the ability of a material to resist the penetration of synthetic blood under constant contact. The test sample is mounted on a cell separating the synthetic blood challenge liquid and a viewing port. The time and pressure protocol specifies atmospheric pressure for 5 min, 2.0 psi for 1 min, and atmospheric pressure for 54 min. The test is terminated if visible liquid penetration occurs before or at 60 min. This is a pass/fail screening test. Materials that pass this test may also be tested using ASTM F1671-03.
- *Resistance to viral penetration*. ASTM F1671-03, *Standard test method for resistance of materials used in protective clothing to penetration by blood-borne pathogens using Phi-X174 bacteriophage penetration as a*

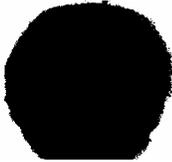
*test system*, determines the ability of a material to resist the penetration of a microorganism under constant contact. This test method has been specifically designed for modeling penetration of HBV, HCV, and HIV. Because these organisms are difficult to use, the test uses a bacteriophage, Phi-X174. Phi-X174 is one of the smallest known viruses, at 0.027 microns ( $\mu$ ) in diameter, and it is similar in size and shape to HCV, the smallest bloodborne viral pathogen (Figure 1). The test sample is mounted on a cell separating the microbial challenge and a viewing port. The time and pressure protocol specifies atmospheric pressure for 5 min, 2.0 psi for 1 min, and atmospheric pressure for 54 min. The test is terminated if visible liquid penetration occurs before or at 60 min. If visible penetration is not seen, a very sensitive microbial assay is performed to determine the passing or failing result. Materials that pass this test are considered to be highly protective against liquid and microbial penetration.



**Figure 1—Bloodborne pathogen size comparison (1.0  $\mu$ M reference sphere)**

Liquid challenge testing has been used over the years to characterize the barrier properties of protective materials. However, the industry liquid challenge test methods that have been developed as a means of predicting liquidborne microbial barrier properties have limitations. Some of the more significant limitations are as follows:

- a) Detecting liquid penetration by means of the naked eye or by weight gain in a paper blotter is significantly less sensitive than a microbial assay. Although microbial assays might provide a higher level of assurance, none of these test methods should be used to infer absolute liquidborne microbial barrier properties. A significant number of microorganisms can be carried in a very minute volume of liquid, which might not be visible to the naked eye or measurable by weight gain in a blotter (Figure 2). For example, the number of infectious units of HBV in a 0.1-microliter ( $\mu$ L) droplet is  $10^4$ , which is one reason HBV is so highly infectious and easily transmitted. Figure 1 shows that a very small amount of infectious body liquid is capable of carrying a significant number of bloodborne pathogens. The number of a particular type of microorganism necessary to cause infection might not be known and might vary widely among microorganisms. For example, that number is estimated to be  $10^7$  for staphylococci (Krizek and Robson, 1975), whereas a single HBV could be infectious (Shikata, et al., 1977). Although the dosage required for infection might be unknown, gross and obvious transmission of infectious liquid cannot be the criterion for barrier quality.

Volume of strike-through <sup>(1)</sup>	100 µL	10 µL	1 µL	0.1 µL
<i>Actual size</i>				
<b>Number of bloodborne pathogens<sup>(2)</sup></b>				
<b>HBV</b>	10,000,000	1,000,000	100,000	10,000
<b>HCV</b>	100–100,000	10–10,000	1–1,000	0.1–100
<b>HIV</b>	6–700	0.6–70	0.06–7	0.006–0.7

(1) Volume of red 40 dyne/cm synthetic blood delivered to white blotter paper.

(2) Based on documented whole blood concentrations of infected patients.

**Figure 2—Bloodborne pathogen strike-through conversion chart.** This chart converts the amount of strike-through to the amount of potential bloodborne pathogen contamination. The four spots at the top were formed from premeasured droplets of synthetic blood and are marked in microliters (µL) ranging from 100 µL to 0.1 µL. Listed on the left are the three primary bloodborne pathogens: HBV, HCV, and HIV. The approximate number of infectious units that could be present in each spot, on the basis of documented whole blood concentrations in infected patients, is shown for each type of virus. These data were derived from Bradley (1984), Ho et al. (1989), and Shikata et al. (1977). A study of transmission of bloodborne pathogens to health care workers found serum concentrations of HBV, HCV, and HIV to be as high as  $10^8$ ,  $10^6$ , and  $10^3$  viral particles per milliliter, respectively (Lanphear, 1994). [Figure courtesy of W.L. Gore & Associates, Inc.]

- b) Liquids commonly used in liquid challenge tests, such as water and saline, have different physical properties than blood and body fluids and do not wet or penetrate through protective materials as easily as blood and body fluids. Even using the whole blood of humans or animals or synthetic blood might not be predictive of the wetting and penetration characteristics of the entire range of potentially infectious human body liquids. Part of the problem with using natural blood sources is the inherent risk of handling them as well as the fact that there can be significant variations in these natural sources as a result of the person's or animal's age, diet, and medication use. In general, the surface tension range of human blood and body liquids, excluding saliva, is 42 to 60 dyne/cm, the surface tension of water is 72 dyne/cm, and the surface tension of saline is 74 dyne/cm.
- c) Most test devices have limitations on the amount of hydrostatic pressure that can be applied to the liquid during the challenge procedure. For methods that operate at the lower end of the pressure scale, test pressures might not be indicative of the pressures that can be exerted on liquids during surgical use. (The pressures exerted on surgical gowns and drapes during pressing and leaning activities in surgery can range from less than 1.0 psi to more than 60 psi [Altman, et al., 1991]. Smith and Nichols [1991] estimated representative abdominal pressures during surgical procedures to be between 0.25 and 2.0 psi.) There might well be a difference between the pressure applied to protective materials and the pressure actually applied to liquids during pressing and leaning, because unless the liquids are completely trapped, they take the path of least resistance and move out of the way. The pressures exerted on liquids have not yet been accurately quantified in surgical use.
- d) Most liquid challenge test methods have specific time–pressure protocols and are conducted for shorter periods of time than the anticipated time of liquid challenge in surgery. The time of the liquid challenge test should be meaningful and representative of the end-use application for the protective apparel or surgical drape. It is generally agreed that shorter times might be necessary with higher liquid challenge pressures to achieve definitive test results.
- e) The condition of the protective apparel or surgical drape at the time of the liquid challenge test is very important. Liquid challenge testing before degradation by physical, chemical, and thermal stresses that could negatively affect the protective qualities of the material might lead to a false prediction of actual in-use performance. The ultimate purpose of protective products is to form an effective barrier to liquids and

microorganisms throughout their entire use in surgery. The effects of other physical, chemical, and thermal stresses imposed during use in surgery and during reprocessing of multiple-use products should be assessed. Physical stresses could include stretching and relaxation, mechanical flexing, and abrasion (both wet and dry). Chemical stresses could include exposure to other clinical liquids, skin disinfectants and lubricants, irrigation fluids, perspiration, and body oils. Thermal stresses could include direct contact with hot instruments and contact with the output of high-energy devices.

- f) Development of ASTM F1671 focused on a “model” organism that was relatively small and readily detectable by analytical means: the Phi-X174 bacteriophage (approximately 0.027  $\mu$  in diameter). However, because the mode of transmission of many viruses is not well understood, it is likely that the ASTM F1671 model is not universally applicable to all exposure incidents. Consequently, FDA has taken the position that no manufacturer can make a blanket viral resistance claim about a product even if it passes ASTM F1671. The FDA has recommended the following labeling for those materials that pass this test: “The [device name] has been tested and meets the following standard: 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.’ “

#### 4.2.2 Resistance to penetration by airborne, aerosol-borne, or dry particles

Test methods have been developed to evaluate the resistance of air-permeable or porous materials to airborne, aerosol-borne, or dry-particle microbial penetration. These methods typically involve pressure and are applied to materials intended for use in face masks and sterile packaging wraps. Therefore, they might not be representative of the types of challenges that confront protective apparel and drape products. Such methods include the following:

- *Bacterial penetration (aerosol filtration)*. For this test, liquid containing the bacterial challenge is aerosolized and then sprayed onto or drawn through the test material. The reverse side of the material is then cultured and the number of colony-forming units (cfus) counted. The most commonly used microorganisms for this test are *Staphylococcus aureus* and *Pseudomonas aeruginosa*.
- *Bacterial penetration (dry-particle method)*. This test method is used to determine the resistance of materials to airborne microorganisms that could be carried by skin cells or lint. Talc particles are inoculated with *Bacillus subtilis* spores and then pumped through or sprayed against the test material. The reverse side of the material is then cultured and the number of cfus counted.

#### 4.3 Abrasion resistance

Protective materials should not abrade significantly during normal use, under wet or dry conditions. Abrasion could weaken the material, adversely affecting barrier properties and causing the material to tear or generate more lint. Of primary concern is the abrasion of one material against itself or against another material, as would occur if the arm rubs against the chest area of a surgical gown or if the stomach area of a gown rubs against a drape on the surgical table. Among the commonly used test methods are the following:

- *Rotary platform*. Under controlled conditions of pressure and abrasive action, a specimen is abraded through rotary rubbing action, using a rotary-platform, double-head tester. The test specimen, mounted on a platform, turns on a vertical axis against the sliding rotation of two abrading wheels. One abrading wheel rubs the specimen outward toward the periphery, and the other rubs it inward toward the center. The resulting abrasion marks form a pattern of crossed arcs over an area of approximately 30 cm<sup>2</sup>. Various means can be used to evaluate resistance.
- *Martindale abrasion*. Abrasion resistance is assessed by means of a Martindale abrasion tester. This test requires that the test sample be subjected to rubbing motion in the form of a geometric figure; that is, a straight line becomes a gradually widening ellipse until it forms another straight line in the opposite direction and traces the same figure again under known conditions of pressure and abrasive action.
- *Inflated bladder*. In this test, an inflated bladder is used to determine the resistance to abrasion of woven textiles, both conditioned and wet.

#### 4.4 Strength

##### 4.4.1 General considerations

Barrier materials should be strong enough to withstand the stresses encountered during typical use, under both wet and dry conditions. Tears or perforations compromise the sterile field and can allow penetration of liquid. A material can be tested for breaking strength, tear strength, and puncture resistance. Several test methods are used to determine each of these properties (see 4.4.2, 4.4.3, and 4.4.4).

NOTE—The end-user should be aware that test results can vary significantly, depending on the direction in which the material is tested.

#### 4.4.2 Breaking strength

*Breaking strength* is defined as the force required to rupture or break a material under specified conditions. Among the test methods commonly used to determine breaking strength are the following:

- *Grab tensile strength.* This test measures a material's resistance to breaking under an increasing pulling force, without an initial tear in the material. A 4-inch-wide by 6-inch-long sample is typically used. The greater the force required to cause breaking, the greater the strength of the material is.
- *Strip tensile strength.* This test also measures a material's resistance to breaking under an increasing pulling force, without an initial tear in the material. A 1-inch-wide by 6-inch-long sample is typically used. The greater the force required to cause breaking, the greater the strength of the material is.
- *Burst strength.* This test measures a material's resistance to rupture under increasing pressure. The higher the pressure needed to cause a rupture, the greater the strength of the material is.

#### 4.4.3 Tear strength

*Tear strength* is defined as the force required to propagate a tear in a material under specified conditions. An initial tear is intentionally made in the test sample. Tests of tear strength determine the force needed to continue this initial tear. The three test methods most commonly used to measure tear strength are as follows:

- *Elmendorf tear strength.* This test measures a material's resistance to tearing under a controlled force when there is an initial tear in the material. The greater the force required, the greater the strength of the material is.
- *Trapezoidal tear strength.* This test measures a material's resistance to tearing under an increasing force, with the force being applied perpendicularly to the direction of the tear. The greater the force required, the greater the strength of the material is.
- *Tongue tear strength.* This test measures a material's resistance to tearing under an increasing force, with the force being applied in the same direction as, or parallel to, the initial tear. The greater the force required, the greater the strength of the material is.

#### 4.4.4 Puncture and tear resistance

Protective apparel and surgical drapes should be resistant to puncture, snagging, and subsequent tearing under conditions of expected use. Of primary concern are the stresses imposed on surgical table covers and patient drapes by contact with various types of sharp or pointed instruments.

- *Puncture propagation tear method.* This test is used to evaluate the dynamic puncture and subsequent tear resistance of materials to end-use, snagging-type punctures. The greater the force required, the greater the strength of the material is.
- *Puncture penetration method.* This test is used to evaluate the puncture resistance of protective clothing materials by measuring the force required to cause a sharp-edge puncture probe to penetrate the material. The puncture probe is applied perpendicular to the material's surface, and there is no supporting structure under the material sample. The greater the force required, the greater the strength of the material is.

#### 4.5 Drapeability

*Drapeability* refers to the tendency of a material to conform to a given shape or object. Surgical drapes and related draping products should be flexible so that they will cover the patient closely and smoothly, allow placement and manipulation of instruments, and appropriately drape out other related equipment, such as ringstands, back tables, and Mayo stands. Drapeability can be evaluated by tests that measure the softness of a material:

- *Handle-o-meter.* This test measures the force required to push a specimen of defined size through a slot of specified width, which is recorded as the softness. The testing is conducted in both principal directions of the sample. The lower the reading, the more drapeable the test sample is.
- *Cantilever stiffness.* This test measures the stiffness of a material by sliding test samples over the edge of a horizontal surface. Test samples 1-inch wide by 6-inch long are typically used. The length of the material that has been pushed over the edge when the specimen bends to a certain point is determined. The shorter the length, the more drapeable (less stiff) the material is.
- *Cusick drape.* This test measures the drapeability of a material by measuring the amount of material that drapes over the edge of a rigid circular disk. A circular sample of the material is cut and placed concentrically over a circular disk of smaller size. A beam of light projects a shadow over a preweighed paper disk cut to the same size as the sample. The excess, non-shadow area is cut from the paper disk, which is then

reweighed and the percentage of paper remaining is calculated. The lower this percentage, the more drapeable the material is.

NOTE—This test cannot assess any directional stiffness characteristics of a material.

These tests do not necessarily correlate with the actual perception of a material's softness and drapeability; however, no consensus method is currently available.

#### 4.6 Comfort

The overall comfort of protective apparel can be influenced by a number of factors, such as design, fit, breathability, weight, “hand” or feel (softness), surface slickness, electrostatic properties, color, light reflectance (glare), odor, and skin sensitivity. Other important variables that can influence the comfort of the wearer include additional clothing layers, health and physical condition, workload, and mental stress, as well as environmental conditions (e.g., temperature, relative humidity, air changes) in the OR or other use area. Comfort is very subjective and can be influenced by one or a combination of the aforementioned factors, which are very difficult to predict through experimental testing. The best assessment of overall comfort can be made by wear testing the product during use in surgery (after determining that the product's protective properties are appropriate for the application).

Thermal comfort exists when there is a balance between the heat the human body loses and the heat the body generates. Traditionally, the term *breathability* has been used to describe the ability of porous protective materials to allow both air and moisture vapor penetration. Breathability is used as a predictive assessment of the potential comfort of protective apparel constructed from the materials. However, because some of the film reinforcements used in protective apparel are not permeable to air, moisture vapor transmission is recognized as a measurement that allows a direct comparison of all materials, air-permeable and air-impermeable, with respect to the potential for surgical gown materials to prevent discomfort attributable to heat stress. As noted above, many factors affect comfort; air permeability and moisture vapor transmission rate lend themselves to objective measurement in materials although not in entire items of protective apparel.

Surgical gowns are typically constructed from several materials, which vary in air permeability and moisture vapor transmission characteristics. Gowns or portions of gowns that permit evaporation and transfer of perspiration vapor from the surface of the skin through to the environment are more likely to allow the human body to maintain a thermoregulatory balance. Typically, a broader comfort range—or tolerance for higher temperatures, relative humidities, and workloads—is exhibited by those gowns that are constructed entirely or partially from materials that have higher air permeability or moisture vapor transmission rates. Gowns that do not permit sufficient evaporation or transport of perspiration vapor are more likely to interrupt the equilibrium and to result in discomfort.

Health care workers have the option of selecting various levels of protection according to the intended use. Historically, less protective materials have had higher moisture vapor transmission rates than more protective materials. Today, however, with the advent of breathable laminates and composites, choosing a high level of protection can be a comfortable option. Comfort can also be achieved by means of special design characteristics.

Among the tests used to assess air permeability, moisture vapor transmission, and thermal resistance properties are the following:

- *Air permeability.* One method used to assess air permeability determines the ability of a material to allow air penetration under specific conditions with a differential pressure. The results are expressed in volume of air/area/time. The higher the number, the more air-permeable the material is. Materials demonstrating air flows of less than 1 ft<sup>3</sup>/ft<sup>2</sup>/min require testing by other methods.
- *Moisture vapor transmission.* Moisture vapor transmission is the ability of water vapor to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable. Several test methods are available for measuring moisture vapor transmission, some of which are listed in Annex B. Caution should be exercised when comparing test results from different test methods, because they may not be comparable.
- *Thermal and evaporative heat loss.* The thermal (dry heat loss) and water vapor (evaporative heat loss) resistance of a material can be determined under steady-state conditions using a sweating guarded hot plate (also known as the “skin model” because it represents a thermoregulatory model of the human skin). This device simulates the heat and mass transfer processes that occur next to both dry and sweating human skin. Measurements involving the thermal and water vapor resistance can be carried out either separately or simultaneously on protective apparel and drape materials using a variety of environmental conditions simulating different wear and environmental situations. The main component of the skin model is a porous metal plate. The plate is electrically heated to 35°C (human skin temperature) and then covered by the material being tested. Sweating is simulated by feeding water to the plate; the water then flows through and evaporates from the pores. Lower thermal resistance numbers denote higher thermal conductivity of the

protective apparel or drape material; lower water vapor resistance numbers denote less resistance to the permeation of moisture vapor.

#### 4.7 Staining, discoloration, and residues

The issue of aesthetic acceptability is important in the selection of products. Items (whether multiple-use or single-use) presented for use in a surgical or other health care procedure should be free from discolorations and residues that could warrant rejection from both an aesthetic and a septic standpoint. (Certain types of residues can protect microorganisms and prevent adequate sterilization.) For multiple-use products, the launderability of a material and its resistance to staining should be evaluated. Because the processing of multiple-use products may vary from institution to institution, part of the evaluation should involve the ability of the process to prevent problems with discoloration and residues. The reprocessing of multiple-use products is covered in detail in ANSI/AAMI ST65.

#### 4.8 Electrostatic properties

In the context of protective apparel and drapes, the primary electrical safety consideration is the ability of the material to accept or dissipate electrical charge. It should be noted, though, that many other factors affect electrostatic discharge, such as the relative humidity in the environment, time of wear, motion during wear, and combination of products used.

Protective apparel and drapes, just like any other fabric, can generate electrostatic sparks. Alcohol-based products could be in the environment; therefore, it is important for users to follow the guidelines of the manufacturers of patient prep and hand antiseptics and ensure that such products are allowed to dry (i.e., alcohol vapors have dissipated) before donning protective apparel or working with surgical drapes.

Testing the electrostatic properties of protective apparel and drapes in anesthetizing locations is not required in the United States because flammable anesthesia is no longer used. In NFPA 99, *Standard for health care facilities*, information on electrostatic properties is placed in Annex 2 for informational purposes only. A warning label against the use of these products if flammable gases might be encountered should be affixed to the product or its package. If, however, a product is susceptible to acquiring an electrical charge, it may be evaluated for “electrostatic cling”:

- *Electrostatic clinging of fabrics: Fabric-to-metal test.* This test method evaluates the relative clinging tendency of certain fabrics resulting from electrical charge generation. In this test, specific rubbing fabrics are used to induce an electrostatic charge on the test specimen. After the specimen is placed on a metal plate, the time is measured for the charge to decay to a level at which the electrical attractive forces between the specimen and the metal plate are overbalanced by gravitational forces and the specimen pulls away from the plate.

If flammable anesthetics could be encountered (outside the United States), the products may be tested by either of the following test methods:

- *Electrostatic decay.* In this test method, a sample of material is equilibrated to specific temperature and humidity conditions. The sample is then suspended between two electrodes and charged with 5,000 volts (V) of static electricity. The discharge to 500 V (10% charge) is timed. The acceptance criteria described in NFPA 99 is a decay time of 0.5 seconds.
- *Surface resistivity.* In this test method, a sample of material is equilibrated to specific temperature and humidity conditions and then tested for electrical resistance using an electrical resistance meter. The acceptance criteria described in NFPA 99 is a resistivity of less than or equal to  $1 \times 10^{11}$  ohms per square.

#### 4.9 Flammability

By law (16 CFR 1610), all materials used in clothing must meet the Consumer Product Safety Commission’s *Standard for the flammability of clothing textiles* (CPSC, 1954). In the past, an NFPA test method (NFPA 702-1980) was used to assess flame spread rate in textiles. That document was removed from NFPA’s list of active standards in 1987 and is no longer used in the textile industry. In both methods, the time it takes for a flame to travel the length of the sample is measured; however, the flame impingement location and the time vary between methods.

The modern OR contains many potential ignition sources, including surgical lasers, electrosurgical units, endoscopic fiberoptics, and other high-energy electromedical devices. All materials will burn if a high-intensity heat source (e.g., the output of a laser or electrosurgical instrument) is applied to them, especially in the presence of elevated oxygen levels, but the resistance to burning differs among materials under various conditions. Appropriate training and work practices in the handling and use of high-energy sources are key factors in reducing the incidence of fires in the surgical setting.

#### 4.10 Generation of particulates and visible lint

Most materials (woven, nonwoven, and knitted) will generate and release lint particles to some degree when abraded. In addition, it is well documented that some materials have a tendency to generate more lint particles than others. It is also generally accepted that the more lint that is generated in the OR, the greater the possibility of a postoperative wound infection caused by either microorganism transfer or a foreign body reaction. Nonviable particles (lint) as small as 2 to 4  $\mu$  in size have been reported to be the pathway for the introduction of viable organisms into the wound site (Scheinberg, et al., 1983). It has also been demonstrated that lint particles generated from the surgical gowns and drapes themselves can cause foreign body reactions (Tinker, et al., 1974; Tinker, et al., 1977; Dragan, 1979; Janoff, et al., 1984). Finally, the generation of lint can cause a buildup of particles in the ductwork of air-handling systems and on the tops of cabinets and shelves, potentially impairing the operating efficiency of the air circulation system and increasing the maintenance and housekeeping required in ORs. Therefore, to minimize the possibility of postoperative complications caused by lint, surgical gowns and drapes should be as lint-free as possible (AORN 2005a).

Several test methods can be used to assess the propensity of a material to generate particulates or visible lint:

- *Flexing in air.* A sample of material is flexed inside a clean test chamber; air is withdrawn from the chamber, and particulates are counted by means of an optical particle counter.
- *Shaking in water.* This test involves placing a sample of material in a container of ultrapure water. The container is shaken to release the particles, the water is withdrawn, and the particles are counted in a liquidborne optical particle counter.
- *Helmke drum.* Test materials are placed in a rotating drum and tumbled to release particulate matter; an automatic particle counter samples the air within the drum to determine the particle density. Depending on the results, the material is classified as Category I (lowest particle density), Category II, or Category III.
- *Twisting in air.* This test measures the relative levels of particles released from a material when it is subjected to a continuous twisting movement.

In addition, Buras and Harris (1983) published a method that measures a material's propensity to generate lint by subjecting it to an abrasion test and then determining the weight of the loose particles.

#### 4.11 Shrinkage

One available test procedure monitors the dimensional change of a material when it is subjected to laundering procedures commonly used in institutional and commercial washing situations. The original dimensions of the sample are recorded and then remeasured after the client's prescribed washing, drying, and sterilization procedures are performed. The final test result is provided as a percentage indicating the amount of change in each direction. A gain in measurement is expressed by a plus (+) sign. Change in all locations is reported to the nearest 0.1%.

#### 4.12 Biocompatibility

The materials from which protective apparel and drapes are fabricated should be free of ingredients that could irritate tissue or could otherwise adversely affect the patient or user. Permanently bonded chemicals or other additives are sometimes used to enhance barrier properties or stain resistance; some of these substances might leach out, others might be nonleaching. Generally speaking, there has been little evidence of adverse reactions to protective apparel or drapes currently on the market, although infrequent incidents of dermatitis have been observed, as well as a very small number of allergic reactions.

The current standard for biocompatibility testing is the ANSI/AAMI/ISO 10993 series, *Biological evaluation of medical devices*. Test methods are listed according to the type of contact that a device has with a patient and the duration of the contact. Protective apparel and drapes would be classified as surface devices that contact breached or compromised surfaces for short-term exposures (defined as less than 24 hours). It should be noted that even exhaustive biocompatibility testing might not preclude the possibility of individual allergic reactions to materials.

#### 4.13 Sterility assurance

Typical methods of sterilization include radiation, chemical gas (ethylene oxide [EO]), and steam. Assurance of the sterility of protective apparel and drape products is a critical issue and should not be assumed or taken for granted. Other possible patient and worker safety issues, such as residual sterilants and other chemical by-products of sterilization processes, should be evaluated. Residuals and other by-products of sterilization might not be immediately obvious; however, any evidence of unusual odors or dermal reactions should be investigated.

Prepackaged, sterilized multiple-use and single-use products are considered sterile unless the integrity of the package is compromised. Those products that are to be sterilized by the health care facility should be accompanied

by the appropriate documentation and guidelines provided by the manufacturer to ensure that the on-site sterilization process will be effective. Protective apparel and drape products that are to be sterilized must allow for the effective permeation and removal of sterilants. Other important variables include recommended folding techniques and pack configurations, limitations on pack components and densities, and limitations on sterilizer chamber load configurations. Guidelines for in-hospital sterility assurance are provided in AORN (2005b), ANSI/AAMI ST41, and ANSI/AAMI ST79. Guidelines for processing multiple-use protective apparel and drapes before sterilization are provided in ANSI/AAMI ST65.

#### **4.14 Performance in use**

With each surgical or other health care procedure, under normal conditions of use and for the duration of use, protective apparel and drape products should prevent the penetration of blood and OPIM. Conditions of use and time in use for various tasks and procedures can vary significantly and might dictate the use of products that provide different levels of protection (see Section 6). Careful consideration should be given to attributes that can affect functionality during use, such as strength (break, puncture, and tear resistance); abrasion resistance (to the loss in barrier properties); flex durability; contamination resistance; and flammability. For protective apparel and drape products intended to be used sterile, the effect of sterilization and storage time on product degradation should be assessed for both single-use and multiple-use products, and the effect of proper cleaning and disinfection procedures should be assessed for multiple-use products.

For multiple-use products, a system should be in place to ensure that products are removed from the system at the end of their useful life. Manufacturers of protective apparel and surgical drapes should be consulted to determine not only the anticipated, qualified life expectancy but also the means by which use life can be tracked (see 7.5.2). If these services are outsourced, the health care facility should also ensure that external processors, such as central laundries, repackaging operations, and sterile pack lease or rental operations, are meeting these requirements. See also ANSI/AAMI ST65.

Health care facilities are also required to implement a system of repair or replacement of all personal protective equipment (PPE) to maintain barrier effectiveness (29 CFR 1910.1030). Systems for inspecting, testing, and repairing or replacing to ensure the proper maintenance and continued integrity of protective products are critical and must be thoroughly addressed by the manufacturer or supplier. Standards for acceptable end-product quality (the type, location, and amount of patching, repairs, and stains) should be developed and implemented with the input of the end-users (see 7.5.4). It is the responsibility of the health care facility to implement the appropriate systems for the products that it processes.

#### **4.15 Strike-through investigation**

The effectiveness of barrier products in maintaining the sterile field is normally determined during their use in surgery by their ability to prevent strike-through. Strike-through in surgical apparel, surgical drapes, or accessories should be considered a breach of the barrier, and appropriate steps should be taken to prevent the situation from recurring.

The end-user should properly document strike-through events and report them to the processor and product manufacturer or distributor for investigation. Products that allow strike-through to occur during use in surgery should be isolated and returned for evaluation to the processor (and, if appropriate, to the manufacturer or distributor) to determine the cause of failure. The evaluation should be performed very carefully and, ideally, cooperatively between the health care facility, the processor, and the manufacturer or distributor.

Strike-through can occur as a result of device failure or malfunction; improper or inadequate design, manufacture, or labeling; or user error. In addition, incorrect care and handling procedures should be considered in order to appropriately determine the cause of the strike-through. Depending on the circumstances, a qualified individual (user, processor, or manufacturer) should ask the following questions:

- a) Was the product used in accordance with the health care facility's exposure control plan?
- b) Was the strike-through an isolated incident, or does it reflect a pattern of occurrences? If the latter, does the exposure control plan need to be reevaluated?
- c) Was the correct level of protection chosen for the level of anticipated risk (e.g., the right gown for the right procedure)?
- d) Was the appropriate size of item selected?
- e) Where did the strike-through occur?
- f) Did strike-through occur in a noncritical zone?
- g) Did strike-through occur through a seam?

- h) Did strike-through occur at an interface (e.g., gown cuff to glove)?
- i) Did strike-through occur when blood or liquid traveled down the crease of the gown sleeve and under the glove cuff, to be absorbed by the gown cuff?
- j) Was the product damaged in any way during use?
- k) If the product is reusable, how many times had it been used?
- l) If the product is reusable, was laundering, inspection, testing, maintenance, and sterilization carried out in accordance or consistent with the manufacturer's instructions?
- m) If applicable, what was the expiration date for the product?

If the product is to be returned to the manufacturer, proper infection control practices must be used to isolate it.

Thorough investigation of strike-through events and appropriate follow-up actions will help prevent recurrences and thus promote personnel and patient safety.

## **5 Product evaluation and selection of protective apparel and surgical drapes**

### **5.1 Introduction**

Selecting the protective apparel and drapes that will best meet the needs of a particular health care facility involves a complex decision-making process. Many factors must be considered, such as protective properties, comfort, strength, and quality of materials. In today's health care environment, there is also the need for cost containment. This section provides guidelines on facility evaluation and selection of barrier products, including a framework and scale of value by which a hospital evaluator can objectively and quantitatively measure the performance of a product most appropriate for a particular use.

### **5.2 Information from manufacturers and suppliers**

Health care personnel performing the evaluation might wish to request from manufacturers test data and other information pertaining to the performance characteristics described in previous sections. In addition, for multiple-use products, the health care facility should request information on reprocessing and care (see Section 6, ANSI/AAMI ST65, and AAMI PB70). Health care personnel might wish to pose the following questions to manufacturers when selecting protective apparel or drape products:

- a) What are the regulatory requirements for the product (e.g., listing, quality systems, 510[k] submission)? If applicable, has a 510(k) premarket notification for the product been submitted to FDA, and has the product been cleared for marketing?<sup>7</sup>
- b) Are there clinical reports, scientific papers, or research data available to substantiate the efficacy of the product? Are the data provided representative of the current product? Are the laboratory tests used consistent with those referenced in this TIR?
- c) Are there references who can be contacted concerning their experience with the product?
- d) Are there any precautions that should be taken to ensure that the product performs as intended?
- e) What are the recommended disposal guidelines for the product? If it is to be incinerated, what are the potential by-products?
- f) If the product is intended for multiple uses, what are the recommended processing guidelines? What could be the result of not following the recommended guidelines?
- g) If the product is intended for multiple uses, what are the manufacturer's recommendations for assessing its performance (e.g., barrier properties) after reprocessing in order to help prevent failure under usual conditions of use?
- h) If the product is intended to be sterilized by the health care facility, are data available to validate that the product can be effectively sterilized? Will the sterilization process used in the health care facility effectively

<sup>7</sup> For new or changed products introduced to the market after May 28, 1976, manufacturers intending to market a surgical gown or drape are required to submit a premarket notification to FDA [21 CFR 807]. Products found to be substantially equivalent to existing products are "cleared" by FDA for marketing. This clearance for marketing does not constitute FDA approval of the product's safety and effectiveness.

sterilize the product? How can the effectiveness of the sterilization process be demonstrated? Is the product permeable to steam or EO? Does it allow elution of EO to take place within the time frames and aeration cycles available in hospital equipment? What are the recommended sterilization guidelines? Are there any limitations on folding configurations, pack size or density, load mix, or chamber-loading capacity?

- i) If the product is intended for multiple uses, is there a limit on the number of reuses? What is the expected use life of the product, and how should it be monitored?

### **5.3 Product evaluation**

The comparison and review of clinical or laboratory data will provide, at best, an indication of how a product will perform in actual use. Therefore, part of any selection process should include a formal evaluation under actual conditions of use. Factors that this evaluation should take into consideration include

- a) the design and construction of the protective apparel or surgical drape for the specific tasks being performed (Quebbeman, et al., 1992; AORN, 2005a; ANSI/AAMI PB70);
- b) aesthetic and comfort considerations for which no or few test standards are available;
- c) for both single-use and multiple-use products, the effect of sterilization and storage time on product degradation;
- d) for multiple-use products, the effect of processing conditions and maintenance and repair procedures on product performance; and
- e) the effects of stresses seen when products are exposed to worst-case use conditions that could involve such factors as flexing, abrasion, laser or cautery contact, contamination issues, and strength (break, puncture, and tear resistance).

Caution should be exercised in the use of non-objective field tests that do not duplicate clinical applications. Also, to avoid risks to themselves and patients, health care personnel should understand the performance characteristics of the product in relation to the product use before embarking on in-use testing.

### **5.4 Cost comparisons**

Costs are generally comparable only for functional equivalencies; that is, cost assessments are valid only if all the costs of all products necessary to accomplish a particular objective are compared. Evaluations should be made among products that are functionally equivalent, not different. It is also important to include nonclinical costs in comparing products used in the OR (e.g., staff time and acquisition, storage, inventory, reprocessing, and disposal costs).

### **5.5 Staff input**

Rarely can department managers make product choices for successful large-scale conversions without staff involvement and input, which should include actual in-use trials. This observation is true not only because of the variety of clinical input needed but also because of the psychological effect of active participation. General guidelines for staff participation and other aspects of product evaluation are provided in AORN (2005d).

### **5.6 Performance priorities in relation to product function**

The selection of the protective apparel and drapes to be used by a health care facility is a complex and cumbersome task. Product selection should be guided by the product's anticipated use, the performance attributes of the product in relation to the anticipated use, the cost of the product, and the quality systems built into the manufacture and supply of the product. Typically, the most important consideration is barrier performance.

More than one type of product may be needed in the surgical or other health care setting, and it could be appropriate to evaluate each need separately (e.g., ophthalmic surgery has different needs than orthopedic surgery). Table 1 is an example of one method of assessing performance priorities in relation to product function. The table lists minimum considerations; health care facilities may wish to add others, depending on their individual needs. The following procedure is used to complete the table:

- 1) Select the test methods to be used in evaluating the various properties from the methods described in this TIR (see Annex B) or from methods with which evaluators have had previous experience, and list them in the appropriate section of the table.
- 2) Assign a priority to each performance attribute as it relates to the needs of the health care facility. Use the following scale to assign priorities:

1—Not important, expected, applicable

2—Desired

3—Important

4—Extremely important

Once a priority has been assigned to a particular performance attribute, it should be used for all products being evaluated for that level of performance.

- 3) Assign a performance rating to each of the products when they are tested using the methods chosen. The performance rating should be based on testing performed by the health care facility or on documentation provided by the manufacturer. The following scale should be used to assign performance ratings:

1—Poor (falls well below requirements)

2—Below average

3—Average (meets requirements)

4—Above average

5—Exceptional (exceeds requirements)

It could be appropriate to use the above rating scale when comparing the actual test results for all of the products being evaluated. However, if the rating system is used in this fashion, all products must be evaluated by the same test methods.

- 4) Multiply the priority by the performance rating; enter this value in the results column.
- 5) Add up the values in the results column to calculate the total score for each product being evaluated. It is important that all products have a score for each of the properties being evaluated.

The resultant total scores can then be used to rank the overall physical performance of the various products evaluated in relation to the needs of the particular health care facility. This score, when used in conjunction with the costing and quality assurance attributes of the individual products, can help simplify the task of selecting the protective products to be used by the health care facility.

### **5.7 Periodic reassessment**

In light of the continuing evolution of available products and changing practices in surgery and other health care procedures, it is advisable to reassess products at least every 2 years.

**Table 1—Example of a product evaluation table**

<b>Institution:</b> _____		<b>Date:</b> _____					
<b>Classification, anticipated use:</b> _____							
<b>Desired ANSI/AAMI PB70 performance level:</b> _____							
Performance attribute	Priority	Product 1		Product 2		Product 3	
		Name:		Name:		Name:	
		Description:		Description:		Description:	
		Rating	Results	Rating	Results	Rating	Results
Barrier performance							
Abrasion resistance							
Strength							
Drapeability							
Comfort							
Staining, discoloration, residues							
Electrostatic properties							
Flammability							
Linting propensity							
Shrinkage							
Biocompatibility							
Other							
		<b>Total score:</b>		<b>Total score:</b>		<b>Total score:</b>	

## **6 Guidelines for choosing levels of barrier performance needed for particular health care applications**

### **6.1 Introduction**

Historically, various terms—such as *liquid-resistant*, *liquid barrier*, *microbial barrier*, *liquid-proof*, and *impervious*—have been used to describe the barrier properties of protective apparel and surgical drapes. The qualitative nature of these terms has led to ambiguity in the health care community with respect to performance claims and user expectations. In part, this ambiguity stemmed from the lack of standardized test methods used to support claims associated with these terms. The major impetus for the development of ANSI/AAMI PB70, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*, was the need to better quantify barrier performance claims through a classification system of levels of barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories. This classification system is based on standardized test methods and is intended to enable users to better choose the appropriate level of protection for a given clinical use.

This section of the TIR covers general considerations in choosing the appropriate level of barrier performance—based on the classification system established in ANSI/AAMI PB70—that is needed for particular health care applications. It should be noted that although it is the personnel involved in surgical and other invasive procedures who most often require barrier protection against bloodborne pathogens, personnel who perform other activities within the health care facility (e.g., certain emergency room procedures) may also require such protection.

### **6.2 Exposure control plan**

Each facility must have in place an exposure control plan that identifies areas of occupational risk (potential exposure) and must take appropriate measures to prevent occupational exposure (29 CFR 1910.1030). As part of those measures, selected protective apparel, including surgical gowns and isolation gowns, should prevent the penetration of blood and OPIM. Garments should be removed immediately—or as soon as is feasible—if visible penetration of blood or OPIM is noted. See also AORN (2005c).

Some of the factors that are important to consider when assessing the risk of exposure are

- a) the presence of liquid (expected blood loss, volume of irrigation liquid);
- b) the pressure and type of contact (splash, spray, pooling, soaking, pressing or leaning);
- c) the duration of procedure (longer duration increases the likelihood of liquid and/or pressure being present);
- d) the type of procedure (open versus minimally invasive surgical technique, deep body cavity versus superficial incision); and
- e) the role of each surgical team member.

### **6.3 Classification and labeling of barrier performance by manufacturers**

Table 2 summarizes the requirements of ANSI/AAMI PB70 regarding the classification and labeling of the barrier performance of surgical gowns, other protective apparel products, surgical drapes, and drape accessories.

### **6.4 Examples of possible barrier performance levels for particular applications**

Table 3 provides examples of expected use conditions and health care applications for which each level of barrier performance might be appropriate. The table may be used as an aid in the development of the health care facility's exposure control plan. The examples in the table are not intended to be all-inclusive, nor are they intended to substitute for professional judgment and experience. Table 3 might not cover every situation encountered in the facility. Numerous factors can affect the selection of the appropriate barrier product. For example, variations in surgical technique and the duration of the procedure could increase the likelihood of liquid contact and the incidence of pressure applied and thus could influence the risk of exposure. In cases in which the risk of exposure increases after the procedure is underway, a change to a higher level of protection should be made, if appropriate. In addition, clinical experience over time could well dictate the choice of levels of barrier performance for particular applications different from those suggested in Table 3. Because exposure risks are not equal and procedures could have multiple parts, users should select the highest level of protection required by the scheduled procedure. Therefore, Table 3 should be considered to provide general guidelines as a starting point for decision-making.

**Table 2—Classification of barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories**

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

**Table 3—General relationships between barrier performance and anticipated exposure risks**

ANSI/AAMI PB70 barrier performance	Anticipated risk of exposure			Examples of procedures with anticipated exposure risks
	Fluid amount	Fluid spray or splash	Pressure on gown or drape	
Level 1	Minimal	Minimal	Minimal	Simple excisional biopsies Excision of “lumps and bumps” Ophthalmological procedures Simple ear, nose, and throat (ENT) procedures
Level 2	Low	Low	Low	Tonsillectomies and adenoidectomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery Interventional radiology or catheter lab procedures
Level 3	Moderate	Moderate	Moderate	Mastectomies Arthroscopic orthopedic procedures Endoscopic urological procedures (e.g., transurethral prostate resections) Open gastrointestinal and genito-urinary procedures
Level 4	High	High	High	Any procedure in which the surgeon’s hands and arms are in a body cavity Orthopedic procedures without a tourniquet Open cardiovascular or thoracic procedures Trauma procedures Caesarean sections

NOTE 1—This table provides examples of expected use conditions and health care applications for which each level of barrier performance might be appropriate. The table may be used as an aid in the development of the health care facility’s exposure control plan. The examples in the table are not intended to be all-inclusive, nor are they intended to substitute for professional judgment and experience. This table might not cover every situation encountered in the health care facility. Numerous factors can affect the selection of the appropriate barrier product. For example, variations in surgical technique and the duration of the procedure could increase the likelihood of liquid contact and the incidence of pressure applied and thus could influence the risk of exposure. In cases in which the risk of exposure increases after the procedure is underway, a change to a higher level of protection should be made, if appropriate. In addition, clinical experience over time could well dictate the choice of levels of barrier performance for particular applications different from those suggested above. Because exposure risks are not equal and procedures could have multiple parts, the users should select the highest level of protection required by the scheduled procedure. Therefore, this table should be considered to provide general guidelines as a starting point for decision-making.

NOTE 2—Risk is a function of fluid, quantity, time, and pressure.

## 6.5 Special considerations for isolation gowns

Standard precautions require personnel to wear an isolation gown when caring for any patient, regardless of the diagnosis, if it is likely that clothing will be soiled with patient secretions, patient excretions, or items contaminated with patient secretions or excretions. The use of an isolation gown when personnel are caring for patients suspected or known to have a specific infectious disease entity is based on the mode of transmission. Whether isolation gowns are used to carry out standard precautions or other types of isolation precautions, the choice of the type of isolation gown should be determined by the type and nature of the anticipated exposure and the protection afforded by the particular gown.

The choice of isolation gown should be based on several important considerations. The first consideration is the nature of the disease (or suspected disease). Most important is whether the etiology and mode of transmission are understood. When the mode of transmission is well defined, it is much easier to select an appropriate isolation gown and other PPE. The selection of an appropriate isolation gown and other PPE becomes more difficult when a previously undefined infectious disease emerges, as was demonstrated in 2003 with severe acute respiratory syndrome (SARS). Initially, the etiological agent and primary mode of transmission were not known, and the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommended the use of maximum PPE because of the alarming numbers of health care workers contracting the disease. By 2004, it was known that the coronavirus causes SARS and that the primary mode of transmission is not respiratory. Consequently, the CDC issued new guidance.

The second consideration is the potential exposure to body fluids. When this potential is high, as when a patient has projectile vomiting or severe diarrhea, higher barrier protection is warranted. The type of procedure being conducted is also important, especially when body fluids can be produced, as when an intubation tube is inserted.

Third, isolation gowns serve two purposes: protection of the health care worker from the patient, and protection of the patient from the health care worker. When high-barrier PPE is used during the initial phases of an epidemic such as SARS, it is difficult to change PPE between patients. In these situations, wearing a traditional isolation gown over a more protective garment and changing the gown between patients can protect both the worker and the patient.

Fourth, additional PPE beyond just an isolation gown might be required. Additional PPE might include shoe coverings, leg coverings, coveralls, an apron, and/or a respirator. Isolation gowns are only part of an overall strategy for health care worker protection and patient safety in the face of an infectious disease.

Table 4 provides general guidance on the barrier performance level that might be needed when the mode of disease transmission is defined or undefined and when the anticipated risk of exposure is high, medium, or low.

**Table 4—General relationships between the barrier performance of isolation gowns, mode of disease transmission, and anticipated exposure risks**

Mode of transmission	Anticipated risk of exposure to etiological agent or body fluids	Appropriate barrier performance level
Defined	Low	Level 1 or 2
	Medium	Level 2 or 3
	High	Level 2, 3, or 4
Undefined	Not applicable	Level 2, 3, or 4

## 7 Care and handling of protective apparel and surgical drapes

### 7.1 Introduction

The safety and performance characteristics of all protective apparel and drape products, both multiple-use and single-use, are of the utmost importance, because the quality and performance of these products can directly affect both patient care and employee safety. Health care facilities should take appropriate precautions, with respect both to suppliers and to in-hospital care and handling procedures, to ensure the continued safety and effectiveness of barrier products. This section provides guidelines on the care and handling of single-use and multiple-use protective apparel and surgical drapes.

## 7.2 General considerations

Protective apparel and surgical drapes are used as a barrier to liquids and, therefore, to microorganisms. In consideration of their fabric nature, the frequency of challenge to their integrity should be minimized. Any surgical gown, other item of protective apparel, or surgical drape on the market today can be punctured, cut, or torn, thereby compromising the intended barrier quality; for this reason, the use of instruments such as perforating towel clamps is no longer considered aseptically acceptable and should be discontinued. Surgical drapes, other than those that are intended to be cut, should not be cut. Cutting drapes generates lint, is contrary to the principles of aseptic technique, and could necessitate the repair or retirement of multiple-use products. Proper handling of all products is critical to their cost-effectiveness and protective properties.

## 7.3 Handling of contaminated protective apparel and surgical drapes at the point of use

Protective apparel and surgical drapes that have been contaminated with potentially infectious material should be handled with caution. PPE should be used when handling regulated medical waste and when collecting and transporting contaminated products from the point of use to the reprocessing area or to the holding area for external pickup. In accordance with the OSHA standard on occupational exposure to bloodborne pathogens (29 CFR 1910.1030), the user should also review the exposure control plan for personnel protection before handling any potentially infectious materials. State Department of Transportation (DOT) regulations should be consulted for requirements applicable to the transport of contaminated protective apparel and drapes.

## 7.4 Disposal of single-use products

Users of single-use protective apparel and surgical drapes should review the policies and procedures that govern the removal of soiled or waste items generated during a surgical or other health care procedure. The health care institution should have a facility-wide waste management program that defines when protective apparel and drapes should be considered regulated medical waste and describes the transport and disposal procedures to be followed.

NOTE—OSHA defines *regulated waste* as “liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.” (29 CFR 1910.1030)

Single-use protective apparel and drapes that have been used during a surgical or other health care procedure and that have been determined to be regulated medical waste under the facility’s waste disposal policies should be placed in the proper regulated waste container for disposal. Those items that are not regulated medical waste should be placed in the general waste container. See also AORN (2005e).

Single-use protective apparel and surgical drapes should be treated and disposed of in the same manner as other items considered to be regulated medical waste by the health care facility. Recommended treatment methods include, but are not limited to, incineration, steam sterilization, and chemical disinfection. The user should check local, state, and federal regulations for the approved methods of treatment and disposal of regulated medical waste in that area. Some users might have the option to contract with an approved commercial regulated-waste disposal firm for the treatment and disposal of this waste.

## 7.5 Processing of multiple-use products

### 7.5.1 Quality assurance program

Many multiple-use product options are available to health care facilities. These options range from purchasing and reprocessing products on-site to leasing or renting sterile products. Health care facilities should take appropriate steps to ensure that adequate quality assurance programs are in place to maintain the safety and performance of the protective apparel and surgical drapes that they use.

The manufacturer should provide 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 to a lower level of barrier performance.

### 7.5.2 Tracking the number of uses

Manufacturers of multiple-use protective apparel and surgical drapes should specify the number of times that their products can be reprocessed by the health care facility and reused while still maintaining acceptable safety and performance characteristics, and they should provide the appropriate data to substantiate their claims (ANSI/AAMI PB70, ANSI/AAMI ST65). The health care facility should establish a method of tracking the number of times that each drape or item of protective apparel can be used before it is no longer appropriate for continued use as a barrier product. ANSI/AAMI PB70 requires that manufacturers of multiple-use products provide an integral tracking mechanism (e.g., marking grid, bar code system, radiofrequency chip, or other suitable method) that can be used to record the number of times that a specific item has been processed.

### **7.5.3 Laundering**

Many types of multiple-use protective materials are available today. Consequently, laundry techniques are specifically designed for the particular type of material or combination of materials. The manufacturer should be consulted for validated processing procedures. The health care facility should verify that the processor (in-house laundry or institutional laundry) is capable of following the manufacturer's recommended laundering process and should request that the manufacturer work with the processor to ensure correct implementation. ANSI/AAMI ST65 provides detailed recommendations for processing procedures.

Laundry workers should be advised of the risk of exposure to bloodborne pathogens and OPIM from contaminated protective apparel, towels, and drapes. An exposure control plan should be established (see 6.2), and personnel should wear the appropriate PPE when transporting and sorting contaminated items and when loading them into the washing machines in the laundry. Infection control procedures and work practice controls should be developed to minimize the risk of contaminating clean laundry products.

Multiple-use laundry bags used for collecting and transporting contaminated, multiple-use protective apparel and surgical drapes should also be considered contaminated and should be processed appropriately. In accordance with OSHA regulations, all bags used for containing and transporting contaminated textiles should be appropriately labeled to alert workers to the potential hazards associated with the full and empty contaminated bags. Single-use laundry bags should be handled and disposed of in accordance with the facility's guidelines and, where appropriate, with federal, state, and local laws regarding regulated medical waste.

### **7.5.4 Inspection, testing, folding, and assembly**

Before selecting any product as a surgical barrier, the user should establish quality standards for its performance. In addition to the important performance characteristics of barrier properties and comfort, the user's standards should address product integrity—prior to reuse—through visual inspection, performance testing, and criteria for incidence and severity of staining, incidence and quality of patching, and frequency and type of other repair or replacement (see 4.14 and ANSI/AAMI ST65). Cost-effectiveness should be evaluated using these criteria.

The method of folding should represent the reverse sequence of the easiest method of aseptic presentation and use, and it should be documented for consistency. Similarly, the assembly sequence for the positioning of products within a pack should be the reverse of the actual use of the products. The assembly sequence should also be documented for consistency.

## Annex A (Informative)

### Historical background

This Annex is intended only as a brief historical review of significant studies pertaining to the protective properties of surgical gowns and drapes. Some of the papers cited have generated controversy, and the data have been interpreted in various ways. Readers are encouraged to review the original articles and reach their own conclusions. It is recognized that this historical review is not all-inclusive. At the time the TIR was drafted, additional articles had been published that were not cited.

The age of aseptic surgery emanated from the works of Semmelweis, Pasteur, Lister, and Koch. In the late 1800s, it was determined that “the surgeon’s hands must be scrubbed, his instruments must be boiled, and the wound drapes must be rendered germ-free. . . . The disease-stained old frock coat must give way to the freshly laundered, sterile gown” (Nuland, 1988). One or more layers of sterile cotton sheeting were typically used to drape the surgical wound and gown the surgical team.

In February 1952, Beck and Collette published their classic paper challenging the barrier effectiveness of cotton cloth when it becomes wet. They demonstrated that various agents—water, plasma, and salt solutions—transported bacteria from the nonsterile to the sterile surface. The paper recommended that cotton cloth be replaced with an impermeable, waterproof material for draping instrument tables, that gowns be changed when they become wet, and that a method be pursued to render cotton cloth either waterproof or bacteria-proof. Karlson et al. (1959) confirmed the studies of Beck and Collette.

In 1963, Beck experimented with plastic drapes, but he abandoned this option because plastic prevents the normal homeostatic mechanisms of sweat evaporation. Then he tested a new fabric that was described as scrim-reinforced tissue with a water-repellent treatment. This fabric was characterized as impervious to bacterial passage, wet or dry, and was disposable.

In August 1963, Beck and Carlson defined an *aseptic barrier* as a “material placed between an aseptic area, such as an operative incision, and areas which harbor microorganisms with the purpose of preventing the spread of bacteria into the sterile zone.” This definition established the principle of wicking action, which diffuses liquid media over a wide area. Beck and Carlson (1963) also suggested that a surgical organization set up a special committee to formulate specifications and standardized tests for barrier materials.

Sweeney (1964) conducted a comparative study in obstetrical patients. Clinical patients with an anticipated higher infection rate attributable to less favorable living conditions, nutrition, and hygiene factors were draped with the new fabric; private patients were draped with conventional cloth drapes. The anticipated higher infection rate in clinic patients did not occur, thereby demonstrating a “superior aseptic barrier to bacterial migration in obstetrical patients.”

In 1967, it was demonstrated that direct bacterial transfer across the surgical gown and scrub attire could be reduced by wearing surgical attire constructed of tightly woven cotton cloth (Bernard, et al., 1967). Charnley and Eftekhar (1969) demonstrated bacterial penetration of gowns made of finely woven material (balloon cloth) even in the presence of sterile air in the OR. Beck and Mandeville (1969) described a modification to the “hydrostatic head test” developed for testing waterproofing of barrier materials.

Dineen (1969) compared permeability, shedding, and clinical observations with readily permeable muslin and liquid-resistant disposable materials. His results demonstrated that the disposable materials prevented both wet and dry bacterial penetration. Dineen also identified the impact of weakened host defenses on the ability of a variable-size inoculum to cause postoperative infection.

The 1970s brought a proliferation of interest in and publications on protective materials. Dineen’s efforts continued, and his comparative study of airborne bacteria in ORs using disposable surgical drapes and gowns versus ORs using cotton or traditional, loosely woven muslin cloth drapes and gowns revealed a 90% reduction in airborne organisms in ORs using disposable drapes (Dineen, 1973).

Laufman et al. (1975) “described a test that correlated the stress of stretching surgical gown and drape material with moist bacterial strike-through.” In this “unopposed weight-support test,” a 2-kilogram (4.4-pound) weight was suspended in a hammock of test material to evaluate unopposed pressure or friction points on surgical gowns. The authors concluded that “not all woven and nonwoven surgical gown and drape materials are impermeable to moist contamination for equal periods of time. Under the conditions of our tests, Quarpel-treated Pima tight-woven cotton was impermeable to moist bacterial strike-through equally well after up to 75 washing and sterilizing cycles. Ordinary linen and untreated Pima cloth, on the other hand, permitted bacterial penetration almost immediately. Among the

nonwoven gown and drape materials, spread tow plastic film composite remained impermeable to moist bacterial penetration throughout all tests . . . . Four other nonwoven gown and drape materials were considered satisfactory, but not as consistently impermeable as the spread tow plastic film composite. These were scrim-reinforced tissue, scrim-reinforced embossed tissue, spunbonded polyethylene nonwoven fabric, and spunlace nonwoven fabric. Two gown and drape materials were found to be poor bacterial barriers, allowing wet bacterial penetration within 5 minutes in most test runs. These were wet-laid nonwoven fabric and fiber-reinforced tissue.”

In 1975, “the Board of Regents of the American College of Surgeons endorsed a suggestion made by the Subcommittee on Aseptic Barriers of the Committee on Operating Room Environment, indicating that the Fellowship of the College accepted the principle that materials used as barriers in operating rooms for gowns, drapes, pack[s], instrument covers, etc. should be impervious to the penetration of bacteria under the usual conditions of use” (Bernard and Beck, 1975). In the same year, the Association of Operating Room Nurses (later the Association of periOperative Registered Nurses) became the first organization to publish standards of practice requiring an effective barrier between sterile and nonsterile areas (AORN, 1975). (The latest edition of these recommended practices was published in AORN [2005a].) In 1978, the Association for the Advancement of Medical Instrumentation (AAMI) established a committee to develop guidelines for selecting and processing aseptic barrier materials. However, that effort was abandoned several years later when it proved impossible for the committee to reach consensus on standard test methods.

Belkin (1978) acknowledged that “all cotton, loosely woven, type 140 muslin is quite readily permeable to both liquids and bacteria.” He identified the barrier qualities of 272-threads-per-square-inch, Quarpel-treated Pima cotton.

In 1979, Laufman et al. used a modified water-resistance, hydrostatic-pressure test to evaluate protective materials and reported findings similar to those of their 1975 study. Using scanning electron microscopy, Laufman et al. (1980) reconfirmed the barrier effectiveness of tightly woven, water-proofed linen and “demonstrated that nonwovens were dependably impermeable to moist, bacterial strike-through only if reinforced with plastic material.”

Seaman (1980) reviewed the available tests that measured liquid barrier or repellency properties and selected two for consideration: the hydrostatic head test (AATCC Test Method 127-1974) and the vented mason jar test (INDA IST 80.9-70T). Using these tests on six materials—four nonwoven types and two woven types—Seaman concluded that only the 140-thread-count muslin exhibited extensive strike-through and bacterial growth.

Schwartz and Saunders (1980) conducted tests similar to Moylan’s 1975 protocol (Moylan, et al., 1975) and demonstrated that spunbonded olefin, spunlace wood pulp polyester, and treated 270-plus Pima cotton were effective barriers under both laboratory and in-use conditions. Penetration depended on the surface tension of the liquid as defined in their surface penetration test.

Moylan and Kennedy (1980) reported on the first prospective clinical study to determine the effect of surgical gown and draping material on the incidence of surgical wound infections. During alternating 6-week periods of the 18-month study, two draping materials—spunbonded olefin and traditional, loosely woven cotton—were used in two hospitals by the same surgeons and residents. Moylan and Kennedy reported a significant reduction in postoperative wound infection rate when a disposable, spunbonded olefin gown and drape system was used.

In 1981, Ha’eri and Wiley used human albumin microspheres labeled with <sup>99m</sup>Tc to trace wound contamination postoperatively in orthopedic procedures. They concluded that “conventional woven fabrics” were totally ineffective barriers and that nonwoven fabrics were effective barriers. In the same year, Baldwin et al. (1981) reported the results of a clinical study demonstrating a significant reduction in postoperative wound infections when a wood pulp polyester disposable was used, compared with 140-thread-count muslin.

Laufman (1982) recommended that all 140-thread-count cotton and unreinforced nonwoven materials sold for surgical use be imprinted: “WARNING: This material is not impermeable to bacterial strike-through, especially when wet.” He also recommended the use of a grid to annotate the number of use cycles for Quarpel-treated materials. Olderman (1984) recommended the use of two tests, the fixed liquid pressure test and the dynamic impact test, to assess liquid penetration and surface wettability of a barrier material.

Moylan et al. (1987) assessed the wound infection rates in 2,181 clean and clean-contaminated general surgical procedures, comparing a spunlace disposable with 280-thread-count cotton. He concluded that using the disposable barrier system resulted in a significant reduction in surgical wound infections. Although this study and the earlier reports cited indicated a strong correlation between type of barrier material and incidence of surgical wound infections, other studies during the same period did not demonstrate such a relationship (e.g., Garibaldi, et al., 1986; Bernard, 1982; Olson and Lee, 1980; Cruse and Foord, 1980).

With the end of the decade and the rise in the prevalence of HIV and acquired immunodeficiency disease syndrome (AIDS), the focus began to shift from “aseptic barriers” for the protection of patients to “protective barriers” for the protection of surgical staff as well as patients.

In October 1990, Shadduck et al. reported the use of hydrostatic-pressure generators to test the ability of 17 commercially available surgical gowns to resist strike-through of HIV. Four gowns demonstrated penetration of HIV-1 in the absence of visible liquid soak-through, 9 gowns allowed visible penetration, and 4 were impermeable to HIV-1 at all exposures tested.

Reeves (1990) referenced a test that was designed to measure the level of resistance to blood strike-through in protective clothing, specifically the blood repellency under conditions of uniformly applied pressure.

Smith and Nichols (1991), using an apparatus designed to simulate the pressures experienced at the OR table, demonstrated that all gowns tested, both reusable and disposable, allowed strike-through in varying amounts. The greatest pressure seen during any maneuver was 1.84 psi while reaching. Gowns reinforced with impervious plastic offered the highest level of protection.

Altman et al. (1991) determined that the peak contact pressures exerted on the abdominal and forearm regions in surgical gowns during use in surgery during pressing and leaning exceeded 60 psi. These findings led the authors to question the validity of existing industry standard test methods.

Quebbeman et al. (1991) reported on a study designed to identify the risk of blood contamination and injury to individuals participating in surgical procedures. Blood contamination occurred in 50% of the procedures observed, and injuries occurred in 15% of the procedures. Surgical specialty, individual role, length of procedure, blood loss, number of needles, and amount of irrigating solution affected the level of risk. In early 1992, other findings from the study were reported in the *AORN Journal* (Hubbard, et al., 1992).

In September 1989, in testimony during an OSHA public hearing regarding OSHA's proposed regulation on occupational exposure to bloodborne pathogens (OSHA, 1989), Brown proposed a simple simulated in-use liquid challenge test, known as the "elbow lean." This test, used in combination with a simulated body liquid, was described as being useful for quickly demonstrating which products might be capable of preventing strike-through during pressing and leaning. This elbow-lean method served as the rationale for the modification of the American Society for Testing and Materials (ASTM) test procedure F903, *Standard test method for the resistance of protective clothing materials to penetration by liquids*, which resulted in a new test method being proposed to ASTM by Brown (1992). Brown also strongly recommended the use of a microbial challenge as the definitive measurement of barrier performance. The elbow-lean method was more fully described in Brown (1995).

From 1990 to 1992, Schoenberger, Song, and McCullough at Kansas State University conducted two studies that analyzed and compared the protection and comfort properties of several types of surgical gowns, both single-use and processed multiple-use (Schoenberger and McCullough, 1990; Song and McCullough, 1992). Based on these studies, recommendations were made concerning the protective qualities and comfort of gowns. A comprehensive comparison of test methods for assessing liquid barrier and thermal comfort properties was also made, resulting in recommendations for the use of the new ASTM ES21-92 synthetic blood penetration test (ASTM, 1992a).

In December 1991, OSHA promulgated a final regulation on occupational exposure to bloodborne pathogens (29 CFR 1910.1030). This regulation requires that health care workers be provided with "appropriate personal protective equipment" that "does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used."

Quebbeman et al. (1992) reported on a study conducted "to evaluate the barrier function of several surgical types of gowns during use in surgical procedures and identify the frequency of failure of the gowns and some causes for this failure." They found "significant differences between gowns based on the material used and the design of the gowns," and concluded that "gowns of different designs and degrees of protection should be chosen based on the body area likely to be exposed to blood and the amount of predicted blood contamination."

Also in 1992, ASTM published two "emergency standards": *Emergency standard test method for resistance of protective clothing materials to synthetic blood* (ASTM ES21-92); and *Emergency standard test method for resistance of protective clothing materials to penetration by bloodborne pathogens using viral penetration as a test system* (ASTM ES22-92). ASTM developed these standards in response to questions regarding the performance of personal protective clothing posed during OSHA rulemaking on occupational exposure to bloodborne pathogens (OSHA, 1989). The objective was to develop a laboratory test method that could take into consideration some of the important variables relevant to bloodborne pathogen exposure (surface tension of challenging liquids, pressure, time, microbial model) and that would provide a higher level of assurance for the barrier qualities of protective clothing for health care workers. These tests were intended to assess the liquid and viral resistance of protective materials for those body liquid exposures involving soaking with pressing and leaning. These tests might not be necessary or appropriate for applications involving only modest degrees of body liquid exposure.

ASTM's two Emergency Standard Test Methods were effective through August 1994. They differed from full consensus standards in that they were only balloted through the subcommittee level under the *Regulations Governing*

*ASTM Technical Committees.* Subsequent to their publication, ASTM began developing full consensus Standard Test Methods for evaluating the resistance of protective clothing material to synthetic blood and to bloodborne pathogens.

Using various test methods for barrier properties, McCullough (1993) evaluated 13 different types of reusable and disposable surgical gown materials. In regard to the application of the ASTM emergency standards, she noted the following: “[The ASTM] methods identify the most protective materials that are available for use in the operating room. However, gowns that fail these ASTM tests may still be used in a large number of surgical situations. Hospital personnel should assess the risk (degree of anticipated exposure to blood) to each person and for each type of procedure in the operating room. A decision can be made on the basis of this risk assessment concerning the level of protection needed; that is, whether a liquid-proof gown should be worn (high-risk situation) or a liquid-resistant gown is appropriate. Hospitals should have both types of gowns available for their employees.”

McCullough also described some of the limitations of the ASTM tests and noted that work is underway to develop additional standard test methods “that would apply direct mechanical pressure at different levels on synthetic blood and the materials; distinguish different levels of protection among barrier materials; be small, inexpensive, and portable for use in the field (e.g., by laundry and hospital personnel); and be nondestructive to the barrier product.”

Smith et al. (1995) studied the amount of pressure exerted on the front of a surgical gown during various surgical procedures. Pressure data were obtained for 20 procedures performed by 15 surgeons. The results indicated that in 16 procedures, 87.8% of the observed pressures were 2 Newtons (N)/cm<sup>2</sup> (2.9 psi) or less, with the peak pressure observed being 7.5 N/cm<sup>2</sup>. More than 80% of contacts were 15 seconds or less during 13 of the procedures. The authors concluded that gowns should be chosen on the basis of anticipated pressure and blood loss.

In 1995, ASTM published full consensus Standard Test Methods for evaluating the resistance of protective clothing material to synthetic blood and to bloodborne pathogens. These methods, ASTM F1670 and F1671, were based on ASTM ES21 and ES22, respectively, and are discussed in Section 4 of the main text. ASTM F1671 was subsequently revised in 1997, ASTM F1670 was revised in 1998, and new editions of both methods were published in 2003. These two test methods were recognized by FDA and can be used to expedite the regulatory review process under the provisions of the FDA Modernization Act of 1997.

In 1998, ASTM published Standard Test Method F1819, *Resistance of materials used in protective clothing to penetration by synthetic blood using a mechanical pressure technique* (later revised and published as ASTM F1819-04). This test method was modeled after the elbow-lean test and was intended to address some of the concerns with ASTM F1670 and F1671 by better simulating the pressure applied during actual use and providing a quantitative outcome instead of a pass/fail result. However, the reproducibility of test results throughout the entire pressure range was unproven in practice.

Sommers (1998) reviewed the standards for flammability, both historically and at that time. He described the importance of fire safety training to the surgical team, as well as the information found on product labels of gowns and drapes that should be reviewed by OR management and staff.

In 1999, AAMI established a Protective Barriers Committee to develop a standard for the barrier performance of surgical gowns, other protective apparel, surgical drapes, and drape accessories. This standard, promulgated in 2003 as ANSI/AAMI PB70, established a classification system for barrier performance along with associated labeling requirements (see Section 6.3 of the main text). In October 2004, this standard was recognized by FDA as a consensus standard for use in premarket reviews (U.S. FDA, 2004).

Edmiston et al. (1999) conducted a study sampling airborne particles, viable and nonviable, during vascular surgery. The predominant nonviable particles were wood pulp fibers; nosocomial pathogens were recovered adjacent to the surgical field. The study identified a concern regarding the effect of airborne microbial populations on surgical site infection (SSI) rates, described the vectors that transport microorganisms, and emphasized the effect of traffic in the operating room.

Also in 1999, the Centers for Disease Control and Prevention (CDC) published recommendations for prevention of SSIs (Mangram and HICPAC, 1999). This guideline, developed by the Hospital Infection Control Practices Advisory Committee (HICPAC), provided an overview of SSIs and recommendations for prevention.

Rutala and Weber (2001) reviewed the uses and characteristics of gowns and drapes used in health care. They presented studies comparing infection rates using single-use and reusable products; other comparisons, such as cost and environmental impact, were also discussed.

Belkin (2002) discussed the test methodologies that have been developed in an attempt to determine barrier effectiveness. Gruendemann (2002) reviewed the need for protective apparel and the criteria for selection, considering advantages and disadvantages of both reusable and single-use products.

## Annex B (Informative)

### Test methods

This Annex lists test methods that are available for use in assessing various safety and performance characteristics of barrier materials.

**Table B.1—Summary table of standard test methods that may be used to evaluate safety and performance characteristics\***

	ASTM	AATCC	IST	Other
Liquid penetration				
Water resistance (hydrostatic pressure)		127-1998	80.4-01 80.6-01	EN 20811:92 ERT 120.2-02
Water resistance (impact penetration)		42-2000	80.3-01	
Alcohol repellency			80.8-01	
Synthetic blood resistance	F1670-03 F1819-04			
Microbial penetration				
Viral penetration (direct liquid contact)	F1671-03			
Bacterial penetration (aerosol filtration)	F2101-01			
Bacterial penetration (dry particles)	ISO 22612:2005			
Abrasion resistance				
Rotary platform, double-head	D3884-01e1		20.4-01	
Inflated diaphragm	D3886-99		20.1-01	
Martindale	D4966-98		20.5-01	EN 12947-3:98

NOTE—Caution should be exercised when comparing test results from different test methods, because the results may not be comparable.

\*Key to acronyms:

ASTM:	ASTM International (formerly the American Society for Testing and Materials)
AATCC:	American Association of Textile Chemists and Colorists
BS:	British Standard
CPSC:	Consumer Product Safety Commission
EN:	European Standard (approved by the European Committee for Standardization)
ERT:	European Disposables and Nonwovens Association (EDANA) Recommended Test
ISO:	International Organization for Standardization
IST:	Industry Standard Test (Association of the Nonwoven Fabrics Industry)
IEC:	International Electrotechnical Commission
NFPA:	National Fire Protection Association
TAPPI:	formerly the Technical Association for the Pulp, Paper, and Converting Industry

**Table B.1—Summary table of standard test methods that may be used to evaluate safety and performance characteristics (continued)**

	ASTM	AATCC	IST	Other
Strength				
Breaking				
Grab tensile	D5034-01		110.1-01	ISO 13934-2:1999
Strip tensile	D5035-03		110.4-02	ISO 13934-1:1999
Burst strength (Mullen diaphragm)	D3786-01		30.1-01	ISO 13938-1:1999
Tearing				
Elmendorf	D5734-01		100.1-01	
Trapezoidal	D5733-99		100.2-01	ISO 9073-4:1997
Tongue	D5735-01		100.3-01	
Puncture resistance				
Puncture propagation tear	D2582-00			
Puncture penetration	F1342-91 (1996)e2			
Drapeability				
Handle-o-meter			90.3-01	
Cantilever stiffness			90.1-01	ISO 9073-7
Cusick drape			90.4-01	ISO 9073-9 ERT 90.4:99
Comfort				
Air permeability				
Frazier	D737-04		70.1-01	TAPPI T547 om-02
Moisture vapor transmission				
Upright cup (water)	E96-00 e1		70.2-01	
Upright cup (dessicant)	E96-00 e1		70.2-01	
Inverted cup	E96-00 e1			
Thermal and evaporative heat loss				
Sweating hot plate	F1868-02			ISO 11092:1993
Electrostatic properties				
Electrostatic clinging of fabrics		115-2000		
Electrostatic decay			40.2-01	
Surface resistivity		76-2000	40.1-01	
Flammability				
45°				16 CFR 1610
45°				NFPA 702-1980**
Lint generation				
Flexing in air			160.1-01	ERT 220.1-02 ISO 9073-10:2003
Shaking in water			160.2-01	IES-RP-CC-003-87
Tumbling in air (Helmke drum)				BS 6909:1988
Twisting in air				ISO 9073-10:2003
Abrasion				Buras and Harris (1983)
Shrinkage attributable to commercial laundering		96-2001		
Biocompatibility				ISO 10993-1:2003

\*\*This test method was removed from NFPA's list of active standards in 1987.

## Annex C (Informative)

### Bibliography

#### C.1 Cited references

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