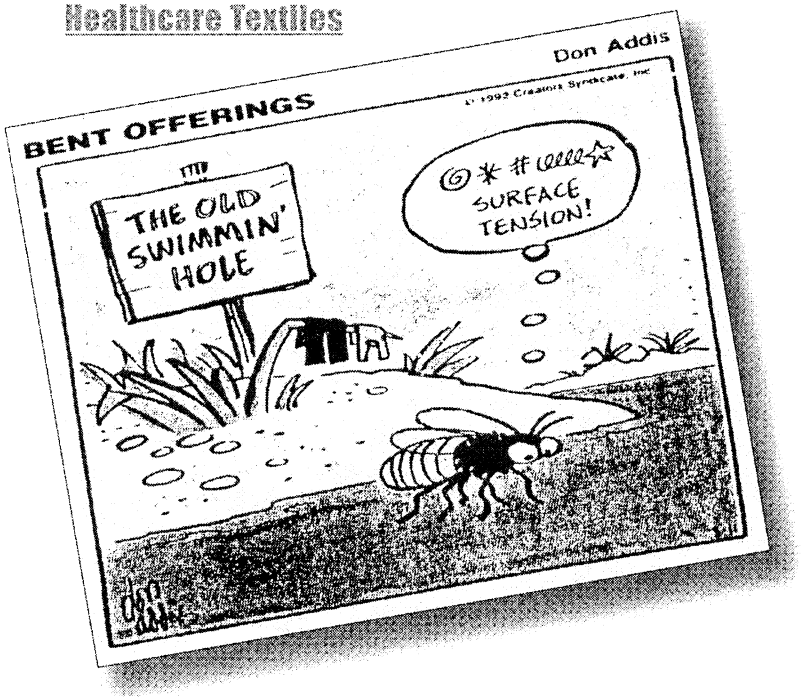
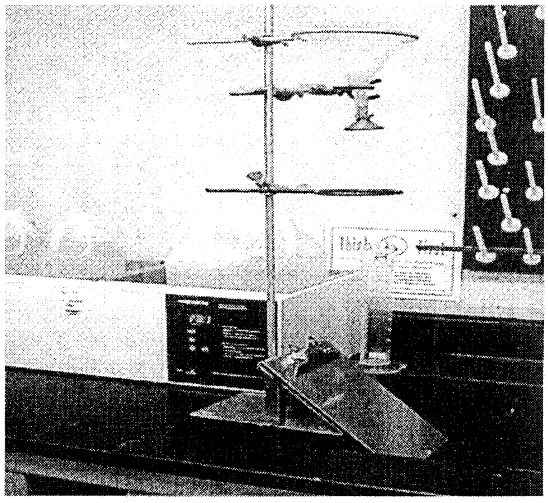




Spray Impact Penetration Test (AATCC 42)

Barrier Materials New Standard— What It Means to the Healthcare TR Industry

Customer-savvy textile rental operators need to understand their professional requirements

By Nathan L. Belkin, Ph.D.

The emergence of HIV

As the hazards associated with the transmission of bloodborne pathogens became more acute, the primary purpose of the surgical gown suddenly changed from third person to first person—to protect the surgeon from the patient. Whatever degree of "strike-through" that may have been tolerated in the past was no longer acceptable.

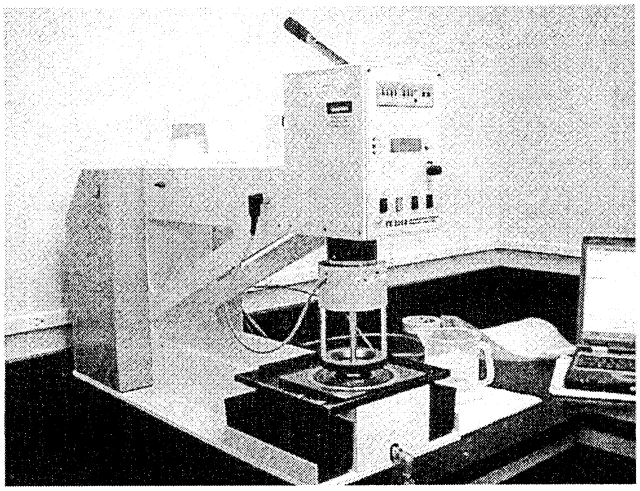
It was reasonable to believe that whatever test method was developed to assess a material's barrier effectiveness would report its ability to resist liquid penetration at various levels. This would facilitate the selection process mandated by OSHA's final rule that the garments be appropriate for the "task and degree of exposure anticipated."[1]

The development of new tests

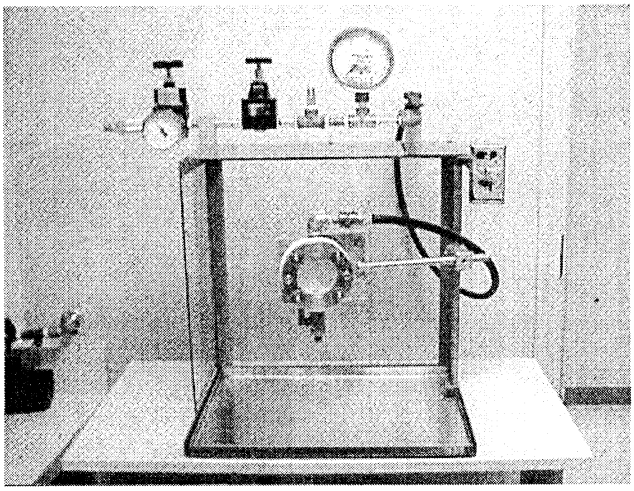
With the pressing need for a test method, an industry-driven committee of the American Society for Testing and Materials (ASTM) released a modification of a complex mechanical device that originally had been developed to determine the effectiveness of protective clothing worn by chemical workers. The group incorporated the methodology in two tests—one for liquid penetration and one for viral penetration. Both methods were first adopted as "Emergency Standards" and subsequently adopted as standards in 1995.[2,3]

However, rather than reporting the results of either test on a comparative basis, results were identified as pass/fail with a "pass" predicated on the material's ability to resist penetration at a level of pressure of 2 lbs. per square inch (psi).

In the meantime, several researchers published the results of their studies. These studies confirmed that actual in-use conditions varied greatly by type of procedure, and that there was no need for all gowns to be made of a material the ASTM had established as the maximum level of resistance.



Hydrostatic Preassure Test (AATCC 127)



Synthetic Blood & Bacteriophage Test (ASTM 1670 & ASTM 1671)

The new standard

Under the joint auspices of the American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI), a "Standard" for determining the barrier effectiveness of materials used in surgical gowns and drapes was published recently. Said to provide a solution to this half-century need, the document is titled "Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities."[4] It has been adopted by the Food and Drug Administration (FDA), which finds it satisfies their performance requirements for Class II medical devices.

In order to accommodate the need to determine a material's "barrier performance" for the "duration and level of anticipated exposure," the standard establishes four levels of barrier effectiveness and uses four different tests and three different liquids. (See Table 1.)

For Level 1, the lowest of the four, the American Association of Textile Colorists and Chemists' (AATCC's) #42 water-impact penetration test is used. The material's ability to resist penetration is determined by spraying a fixed amount of water on it while it is held over a pre-weighed absorbent blotter at a 45° angle. Once the material is challenged in this way, the blotter is again weighed to ascertain its weight gain. According to the standard, the blotter should not have gained more than 4.5 grams for the material to be considered a Level 1 fabric.

For Level 2 fabrics, two tests can be used. One is the same test used for Level 1 except that the weight gain of the blotter can be no more than 1 gram. An alternate test is the AATCC #127 hydrostatic head test.

A sample of the fabric is clamped horizontally on the bottom of a metered glass cylinder. The hydrostatic pressure is steadily increased as the height of the water in the cylinder is raised. To be acceptable for a Level 2 barrier, the fabric must resist penetration of water when it reaches a height of 20 centimeters.

For Level 3 fabrics, both the AATCC tests may be used. For the impact penetration test, the weight gain of the blotter is again 1.0 gram. For the hydrostatic head test, the water level in the cylinder must be at least 50 centimeters.

For Level 4 fabrics, the ASTM's mechanical device is used for both liquid and viral penetration and requires expensive supplies and specially trained personnel. (See Figure 1.) The process for each test takes an entire hour. For surgical gowns, the material must pass the ASTM F1671 test for viral penetration; for surgical drapes, it need only pass the F1670 test for resistance to penetration of synthetic blood.

(It should be noted that the standard makes no mention of the level of protection that a "pass" provides, i.e., 2 psi.)

TABLE 1

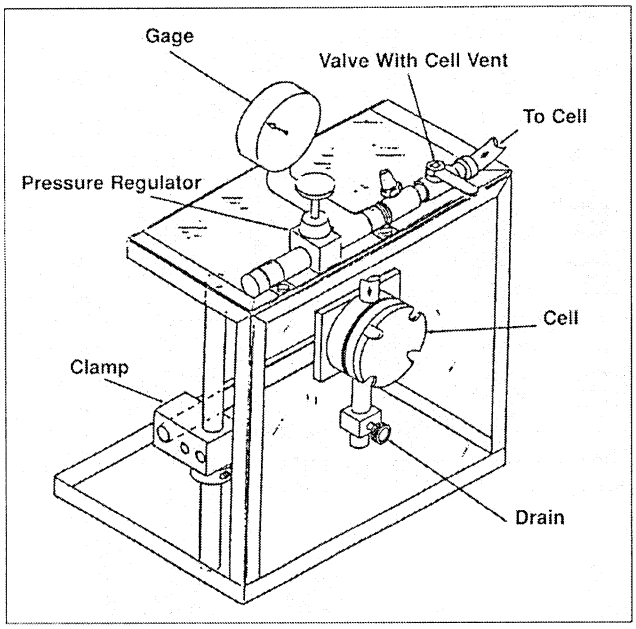
Classification of Barrier Performance of Surgical Gowns, other Protective Apparel, Surgical Drapes and Drape Accessories

Level	Test	Liquid Challenge	*Results
1	AATCC 42-2000	WATER	<= 4.5g
2	AATCC 42-2000 AATCC 127-1998	WATER WATER	<=1.0g >= 20cm
3	AATCC 42-200 AATCC 127-1998	WATER WATER	<=1.0g >=50cm
4	ASTM F1671:2003 For surgical gowns and other protective apparel	BACTERIOPHAGE Phi-X174	PASS
	ASTM F1670:2003 For surgical drapes and other drape accessories	SURROGATE BLOOD	PASS

*All have an Acceptance Quality Level (AQL) of 4%

Adapted from the American National Standards/Association for the Advancement of Medical Instrumentation, American National Standard: Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities. (Arlington, VA, Association for the Advancement of Medical Instrumentation, 2003.)

FIGURE 1



Three-dimensional side view of apparatus used for the ASTM's Standard Methods F-1670 and F-1671

Interpreting the results

For Levels 1, 2 and 3, the results of the water-impact penetration tests must stand on their own merit since there is no known way of correlating the weight of the blotter to a level of pressure.

For the hydrostatic pressure test used for Levels 2 and 3, the correlation between the height (in centimeters) of water and the level of pressure is known. For Level 2, the equivalent of psi at 20 centimeters is 0.20; when the level of water is raised to 50 centimeters the psi is 0.73.

The question that logically arises is how the barrier effectiveness of a material that is awarded a "pass" (at 2 psi) when tested with the ASTM's device can be compared to the psi of the Levels 2 and 3? Unfortunately, it cannot. The reason? Surface tension.

The role of surface tension

As defined in the document, surface tension is 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's surface)." This means that liquids, such as blood, that have a low surface tension, can penetrate fabrics more readily than those with a higher surface tension, such as water.

The results of the tests for Levels 1, 2 and 3, do *not* necessarily mean that under actual conditions of use they would not permit the penetration of blood.

Leakage in the critical zone

The standard defines the critical zone as an "area of protective apparel or surgical drape where direct contact with blood, body fluids and otherwise potentially infectious material (OPIM) is most likely to occur."

One of those areas of the surgical gown where "leakage" has been reported by Drs. Meyer and Beck is the gown/glove interface.[5] Nevertheless, it now appears in the list of exclusions as one of the items that the standard does *not* cover.

This means that the barrier effectiveness of the surgeon's gown, regardless of the material with which it is made, can be compromised in use.

Another omission

It should be noted that the standard classifies the patient drape as an item of protective clothing. As such, the authors failed to consider the widespread use of plastic incise drapes and the advent of minimally invasive surgical procedures. Under those circumstances, there would be no need for the primary drape to have an expensive barrier material included in its design.

The isolation gown

The standard has categorized the isolation gown as an item of protective apparel that requires that the entire gown, including seams, have a barrier performance of at least Level 1. Depending on its application, i.e., in decontamination areas, an area of the gown may include a Level 4 fabric in the critical area. It is the responsibility of the manufacturer to provide detailed information on each component.

What the vendor must do for you

The document delineates the type of technical information the vendor must provide to assure that you have the ability to serve your customer with a product commensurate with the level of protection they selected. This should include:

1. processing instructions, including a statement as to the number of times the item can be processed (this also means that the garment must include a mechanism for tracking those uses, such as a microchip);

2. instructions on inspections and repair that can be performed to assure the product's continued effectiveness;

3. instructions on how the product can be downgraded to a non-protective category once it has reached its labeled use life.

There also is an ANSI/AAMI document on processing these items. The rental company may want to have his supplier provide him with a copy, as well as a copy of the standard.

The bottom line

As stated in the Foreword, the document "is intended to assist manufacturers in testing and labeling their devices. ..." This is the type of information the FDA requires the manufacturer include on his 510k application for marketing approval.

The availability of the standard does not mean that hospitals will be either upgrading (or downgrading) the type of protective apparel they use. The only item they might upgrade is the isolation gown.

Although the standard is not accompanied by a mandate that

requires hospitals to make any change whatsoever, this does not preclude the need for the provider of textile rental services to be familiar with its provisions.

References

1. Occupational exposure to bloodborne pathogens: Final rule, *Federal Register* 56 (Dec 6, 1991), 64040-64182.

2. American Society for Testing and Materials: Standard test method for resistance of materials used in protective clothing to penetration to synthetic blood, F1670-95. West Conshohocken, PA: ASTM, 1995.

3. American Society for Testing and Materials: Standard test method for resistance of materials used in protective clothing to penetration by bloodborne pathogens using Phi-X174 bacteriophage penetration as a test system. F1671-97b. West Conshohocken, PA: ASTM, 1997.

4. ANSI/AAMI PB 70:2003, Liquid barrier performance and classification of protective apparel and drapes intended for use in healthcare facilities, Association for the Advancement of Medical Instrumentation, Arlington, VA. AAMI 2003.

5. Meyer, K K and Beck, W C, *Gown-glove interface: A possible solution to the danger zone*, Infection Control and Hospital Epidemiology 16, August 1995, pp. 488-490. **TR**

Nathan L. Belkin retired in 1991 following a 40-year career in textiles used in healthcare and industrial applications. Since 1966, he has published 108 articles in clinical journals listed by the Library of Congress. Belkin recently served as a consultant to the American College of Surgeons' Committee on the Operating Room Environment. He contributed a chapter on healthcare laundering for a textbook slated for release this spring by the Association for Practitioners of Infection Control and Hospital Epidemiology. Based in Clearwater, FL, Belkin is an occasional contributor to Textile Rental.