New standard aids in selecting barriers

A new standard helps take the guesswork out of choosing the right barrier protection for the amount of blood and body fluid exposure expected during surgery.

The standard from the Association for the Advancement of Medical Instrumentation (AAMI) requires manufacturers to classify and label their surgical gowns, drapes, and certain other products for the level of barrier protection they provide.

Once the labeling is in place, OR staff should be able to go to the shelf and select a gown labeled Level 4, for example, and know it has been tested for conditions found in a procedure with exposure to high levels of blood and body fluids, such as a trauma or open-heart case.

In an interview, Fran Koch, RN, MSN, co-chair of the committee that developed the standard, explained what to expect from the new standard.

What is the purpose of the standard?

Koch: The standard has two basic purposes:

• to assist manufacturers in establishing levels of protection for their products
• to help users be able to understand what level of protection they can anticipate when they select a product from the shelf.

Our goal was to have terminology people could relate to and understand.

What is covered by the standard?

Koch: The standard covers surgical gowns, both disposable and reusable. It also covers decontamination garments, isolation gowns, sleeve protectors, and laboratory attire and other protective apparel, as well as drapes and drape accessories. It does not cover the glove-gown interface.

What will manufacturers be expected to do?

Koch: The standard, though voluntary, says each device (or product) with a barrier claim will be labeled with that barrier claim for its critical zones. Also, each package that contains a barrier product will have every barrier product in the package identified with the level.

We had a great group of users on the committee, and they highly recommended that each device be labeled. For example, if someone comes in after a case has begun, and the package has already been opened, they need to know what level of protection they will have for that case.

Manufacturers are required upon request to provide technical information about the level of barrier performance for each critical zone. The critical zone is the area where you expect to have bloodborne exposure. For gowns, the entire front must be at least Level 1. The back is a nonbarrier and must be labeled as a nonbarrier.

Manufacturers must provide technical information and/or training for the staff on the classification system and its implications for users so they can make good judgments.

It’s also important to note that once the manufacturers have done that, it becomes the institution’s responsibility to make sure their people understand and can make judgments about barrier protection. Obviously, that is a legal issue.
Please describe briefly how the surgical fabrics are going to be classified.

Koch: The standard establishes four levels for classifying protective apparel and drapes based on industry-accepted test methods.

The tests for Level 1 and 2 are water tests that people may be familiar with if they have visited manufacturing plants. In the first test, AATCC 42, the fabric is placed at a slant with a blotter below it. Water is released above, and the blotter is weighed to see how much water came through the fabric. The second test, AATCC 127, measures fluid penetration under hydrostatic pressure.

Level 3 uses AATCC 42 and 127 with more stringent test results for AATCC 127.

Level 4 uses the new ASTM standardized tests 1670 and 1671 that measure artificial blood and virus penetration. (See table.)

Does the standard apply both to disposables and reusables?

Koch: Yes. For reusables, there are some specific requirements. Manufac-
Manufacturers will have to indicate the number of times a product can be reprocessed, give instructions for reprocessing, and supply a means for tracking the number of reuses, such as a marking grid or bar code system.

Also extremely important to know—once a reusable product has reached the end of its life, it cannot be downgraded. That means a Level 4 could not be downgraded to a Level 1, for example. It must be considered a nonbarrier.

[Another standard, ANSI/AAMI ST65, addresses handling, laundering, and quality control for reusable textiles.]

**Q** How will this standard help OR managers and staff?

**Koch:** They now will have consistent definitions for measuring the barrier performance of products. They can make judicious judgments on what level of protection they want.

Within each facility, you will have to look at your own situation and make a determination of how much fluid you expect for specific procedures and surgeons. Then you can decide the level of protection that is necessary.

For example, you might decide that Level 1 barriers will be for lumps and bumps; Level 2 will be for simple orthopedic procedures with a tourniquet, or for hernias; Level 3 will be for procedures with more substantial fluid or blood loss, such as mastectomy; and Level 4 will be for trauma, open-heart, and AAA [abdominal aortic aneurysm].

**Q** How soon can people expect to see labeling?

**Koch:** I think people will be seeing it come out this year.

**Q** What is the role of the Food and Drug Administration in this?

**Koch:** I have been working on this issue for 23 years. The first committee was in 1980 but was unable to develop a consensus document. We then developed a Technical Information Report in 1994 that included criteria for judging products. We are in the process of rewriting that report because we still feel people need to know about criteria for issues such as linting and strength.

The FDA has been supportive of the effort and actively participated in development of this AAMI standard. ❖

Protective barrier classification

Level 1: Gowns and drapes
AATCC 42: Water resistance: Impact penetration test

Level 2: Gowns and drapes
AATCC 42: Water resistance: Impact penetration test
AATCC 127: Water resistance: Hydrostatic pressure test

Level 3: Gowns and drapes
AATCC 42: Water resistance: Impact penetration test
AATCC 127: Water resistance: Hydrostatic pressure test ((higher level than for Level 2))

Level 4:
Gowns: ASTM F1671: Resistance to penetration by bloodborne pathogens
Drapes: ASTM F1670: Resistance to penetration by synthetic blood

Note: More information on the tests is available from the American Association of Textile Chemists and Colorists (AATCC) at www.aatcc.org and from the American Society for Testing and Materials (ASTM) at www.astm.org.