Definition of an Isolation Gown

An isolation gown is a cover-up garment worn by personnel as they enter the room of a patient diagnosed with an infectious disease, such as C-Diff, MRSA, VRE or other contagious conditions. Everyone—physicians, nurses, medical technologists, food service and housekeeping staff, and visitors—must don an isolation gown before entering the room of a contagious patient. Upon leaving the infected patient's hospital room, each person must then remove the isolation gown and deposit in a soiled linen bin for reusable isolation gowns, or a red bag waste container if a disposable gown was worn. The practice of wearing isolation gowns is a major component preventing the spread of disease.

UPDATE: ASTM STANDARDS FOR ISOLATION GOWNS

The industry needs your input in the development of product standards

By Howard M. Zins

The isolation gown is a critical item for healthcare clients in the 21st century. However, until six years ago the American Society for Testing and Materials (ASTM) hadn't developed any specification standards or test methods for the product—reusable and disposable.

ASTM standards are important because they help designers and manufacturers test products to ensure acceptable product quality for the end-user.

ASTM TASK GROUP ON ISOLATION GOWNS

The ASTM Committee on Personal Protective Clothing and Equipment was formed in 2012, and it's the specific responsibility of the Subcommittee F23.40 Biological Hazards to produce a standard for isolation gowns used in a healthcare setting.

The F23 Subcommittee is composed of about 60% disposable manufacturers, 10% reusable producers, and 30% others, including healthcare personnel and representatives of government agencies such as the FDA and the National Institute for Occupational Safety and Health (NIOSH).

"The reusable textile industry is underserved on the subcommittee," said Kevin Schwalb TRSA vice president of government relations. "Anytime a standard is being developed that will have an impact on the linen, uniform and facility services industry, the industry must step up and represent itself."

NIOSH has been a dominant player in the development of an isolation gown standard. When the effort began, NIOSH urged that all materials be tested for performance characteristics. The alternate protocol is to submit testing results from all reusable and disposables manufacturers. I urged that the latter approach, using industry data, be employed. But a majority of the subcommittee voted for the NIOSH recommendation. As a result, the effort has taken some six-plus years and it still isn't complete.

Had industry data been used, the standard might have been issued by now. The testing of materials by NIOSH has been a delaying factor and, in my opinion, industry data would have yielded the same results.

ASTM STANDARD PERFORMANCE CHARACTERISTICS

The proposed product standards for isolation gowns include tensile, tear and seam strength, abrasion resistance, and water-vapor transmission rates. Test results aren't listed in this report, as they are tentative at this point.

With regard to tear strength, the trapezoid method was used for reusable products; however, it was recommended to the ASTM Subcommittee that the Tongue-Tear method (ASTM 2261) should be used.

PHOTO CREDIT: Medline

What is ASTM?

The American Society for Testing and Materials (ASTM) develops textile standards that provide the specifications and test methods for the physical, mechanical and chemical properties of textiles, fabrics, and cloths, as well as the natural and artificial fibers that constitute them. The textiles covered by these standards are commonly formed by weaving, knitting, or spinning together fibers such as glass fiber strands, wool and other animal fibers, cotton and other plant-derived fibers, yarn, sewing threads and mohair, etc. These textile standards help designers and manufacturers test products to ensure acceptable product quality for the end user.

For fluid resistance ANSI/AAMI PB70: 2012 Levels 1, 2, 3 and 4 performance standards are planned for this program. Federal regulations also require that AAMI Level 3 and 4 Isolation gowns be registered with the FDA prior to commercial distribution.

As for FDA labeling methods, a number of items are being debated. However, it's been stated that the new FDA Unique Device Identification (UDI) Rule, should be considered in these ongoing deliberations. Implementation for Class I medical devices, including isolation gowns has been delayed from its anticipated 2018 launch. Class II surgical gowns, drapes, and wrappers already must comply with the UDI requirements.

SUMMARY AND NEXT STEPS

Isolation gowns present the reusable textile industry with an ongoing opportunity to help the healthcare sector reduce the spread of disease, while promoting the health of patients and healthcare workers worldwide. The establishment of professional standards for isolation gowns supports these goals.

During the late 20th century, the reusable textile industry supported the introduction of many product standards that also provided important support for the health of patients and healthcare employees. During that era, there were many textile and fiber producers supporting these efforts in the U.S. However, post NAFTA, many organizations have globalized and now operate overseas.

The challenge is this: Will the reusable textile sector provide support for the development of standards, such as those for ASTM isolation gowns?

We hope that this report will encourage you and your organization to choose to take part in this isolation gown standard-setting program and future efforts as well. Speaking on TRSA's behalf, Schwalb adds that "When standards and policies have an impact on the industry the industry must get involved,"

Please contact me at *hmzins@yahoo.com* if you have questions or would like to participate. TS

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