ON DECEMBER 9, 2015, THE FDA released recommendations contained in the Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.

This guidance is being issued, according to the report, “in light of the public health importance of personal protective equipment in healthcare settings and the recognition that terminology used to describe gowns has evolved, including by FDA, industry, the standards community and health care professionals.”

As to the effect these non-binding recommendations will have on the textile care services industry and suppliers, fresh sought expertise from industry experts.

**Dan Sanchez, Vice-President, Medline Industries, Inc.**

Prior to December 2015, when the FDA enacted new updated guidance relating to gowns used in healthcare settings, there were times, says Sanchez, in which healthcare laundries and healthcare providers became confused as to the level of protection truly provided by the products they purchased.

This guidance was issued to help give clarity to those in the field – both end users and manufacturers – and to find a more simplified explanation of products and labeling. “The updated guidance is directed at protective gowns used in healthcare settings making liquid barrier claims – such as surgeon’s gowns and isolation gowns – as a means to add clarification,” he says.

“When this new guidance, there are no huge changes to the labeling of surgeon’s gowns,” says Sanchez. “Surgeon’s gowns have and will continue to require a 510K to be filed with the FDA before marketing the product.”

As for isolation gowns, “the biggest change is in regards to Level 3 and Level 4 isolation gowns. Per the new guidance, Level 3 and Level 4 reusable and disposable isolation gowns now require a 510K with the FDA. For products currently on the market, a grace period to get all needed paperwork in order has been extended until June 2016,” he says.

Going forward, what impact does the proposed FDA regulation mean for laundries and service providers? Sanchez says:

- In the future, labeling of gowns will be much clearer. Ambiguous claims, such as impervious and resistant, will evolve into more specific test data supported identifiers or AAMI levels. This will be used to allow end users to make more educated decisions as to which gowns will be necessary in specific situations and procedures. This will be important to laundries as they service healthcare providers with rental items.

- End users will be able to easily compare disposable items to reusable items to evaluate protection levels of surgical gowns and isolation gowns.

- Laundries will need to review the current items in their portfolios to confirm they are meeting the needs of their healthcare customers. Such as, what level of protection is the customer expecting? And does the product within their current portfolio meet those expectations? Are the surgical gowns they currently provide labeled in accordance with AAMI guidelines? If they provide Level 3 or Level 4 isolation gowns, are their suppliers meeting the FDA documents requirements once the grace period has expired?

**Brad Bushman, Vice-President, Technical Affairs, Standard Textile**

As background to putting the FDA report into perspective, Bushman points to the dramatic growth in the sales and use of products commonly referred to as isolation or precaution gowns.
These infection protection initiatives were developed in response to hospital acquired infections (HAIs) and consequently, have been the main driving force for growth. "In many cases, healthcare facilities policies and procedures dictate their use. It is not uncommon to find patients, staff, visitors and support services using [gowns]... and lots of them," he says.

Historically, says Bushman, the FDA has regulated both isolation and surgical gowns as defined by the Code of Federal Regulations (CFR) – 21 CFR 878.4040 Surgical Apparel. The regulations list surgical gowns as a Class II medical device, which requires registration with the FDA (known as the 510K process). The FDA will review and permit or deny commercialization of the product based on data being submitted to show that it is safe and effective for its intended use.

"The regulations lists isolation gowns as a Class I medical devices, which are not required to go through the 510K review and registration process," he says. "However, both Class I and Class II medical device claims must be substantiated through testing, and the manufacturing process must follow the medical device quality systems regulation outlined in 21 CFR 820."

In terms of the proposed FDA regulations, Bushman says there will be no change to surgical gowns. In fact, surgical gowns must continue to register with the FDA (510K clearance) prior to commercialization and labeling needs to be in accordance with AAMI PB70 classification standard for substantiating barrier claims. Similarly, he adds, there will be no change to isolation/precaution gowns with AAMI Level 1 or Level 2 barrier claims. The vast majority of gowns used today fall into this category.

The change, he says, "is that isolation, precaution or other protective apparel that make an AAMI Level 3 or Level 4 claim, must complete the FDA 510K registration process prior to product commercialization."

Going forward, what impact does the proposed FDA regulation mean for laundries and service providers? Bushman says:

- Laundry suppliers have a responsibility to include IFU (instructions for use), including label claims as per the PB70 standard for all protective apparel purchased to processors and users of their product – laundering, sterilization, tracking use life and mending (if recommended) procedures. This will not result in any difference at the laundry site for handling the different levels, except for those that are called out in the manufacturers IFUs – laundry formula, patching/mending instructions, sterilization, means to track use life, etc.
- Manufacturers of surgical gowns and AAMI Level 3 and AAMI Level 4 protective apparel products must complete the FDA 510K registration process prior to commercialization. The manufacturer's 510K number should be available upon request.
- The manufacturers are required to provide a means to track use life. This can be grids to mark, bar codes or microchips; any of these tracking methods will work.

- It is recommended – but not required – that a periodic hydrostatic testing program be in place to monitor gown performance over time.
- The same testing and inspection programs should be in place regardless of the level being provided and the area of use. If it is for sterile applications, which is not normal for isolation/precaution gowns, QC should also include sterility assurance activities of their product – laundering, sterilization, tracking use life and mending (if recommended) procedures.

Looking ahead, Bushman says there are opportunities for laundries to provide reusable protective apparel products including isolation/precaution gowns. This is due to the fact that many of the isolation gowns being used are single use products.

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