Additional Guidance to Laundries Considering Implementation of ALM
Interim Guidance for Processing Single-Use Gowns during COVID-19

Why interim guidance?
• The laundry may have been approached by a customer in search of a solution to a shortage of gowns or the laundry may take this to a customer to discuss the possibility of providing them with clean single-use gowns previously used by the hospital.
• The guidance provides laundries with an approach to assist their customers/staff in need of cover apparel for use when faced with a supply shortage of gowns.

What the interim guidance provides:
• A proposed stop-gap measure designed to supplement the provision of gowns to provide an alternative to the absence of any cover apparel during the COVID-19 pandemic.
• The wash formula and process is basic guidance for laundries to provide their customers with a clean product of previously worn, single-use gowns manufactured initially as ANSI/AAMI Level 1, 2, 3, and/or 4 gowns.

What the interim guidance is NOT:
• THE GUIDANCE DOES NOT PRODUCE A GOWN THAT MEETS THE REQUIRED BARRIER STANDARDS FOR WHICH IT WAS INITIALLY MANUFACTURED AND MAY BE LABELED.
• NO GOWN PROVIDED UNDER THE GUIDANCE SHOULD BE USED IN A SURGICAL PROCEDURE PER RECOMMENDATION FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

First steps for the laundries:
• The laundry should be clear with customers when discussing what this process will provide to users and the limitations of the products.
• It is very important to discuss in detail with customers the labeling and communication to users that the single-use gown has been processed and that it bears no claim to barrier protection.

Key points to remember:
• The ANSI/AAMI PB:70-2012 standards make no recommendations for the appropriate use of gowns. As in that standard, the interim guidance reserves selection of a gown to the discretion of the healthcare worker, given the situation at hand and their experience/best judgement/training.
• The interim guidance works best when thorough communication occurs between hospital administration, healthcare workers, and the laundry.
Highpoints from the FDA policy regarding gowns during COVID-19

Gowns, other apparel, and gloves are regulated by the FDA when they meet the definition of a device under section 201(h) of the FD&C Act.

Minimal or Low Barrier protection refers to:
- ANSI/AAMI PB70 Level 1 protection or equivalent
- ANSI/AAMI PB70 Level 2 protection or equivalent

Moderate or High Barrier protection refers to:
- ANSI/AAMI PB70 Level 3 protection or equivalent
- ANSI/AAMI PB70 Level 4 protection or equivalent

As noted above, gowns not intended for use as “surgical gowns” and other minimal-to-low barrier protection surgical apparel are not subject to premarket notification requirements; however, they are subject to general controls. Non-surgical gowns are intended to protect the wearer from the transfer of microorganisms and bodily fluids in low- or minimal-risk patient isolation situations and that are not intended for use during surgical procedures, invasive procedures, or when there is a medium- or high-risk of contamination.

To help foster the availability of these types of gowns and apparel during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of gowns not intended for use as “surgical gowns” and other low-to-minimal barrier protection surgical apparel that does not comply with the following regulatory requirements where the gowns and apparel do not create an undue risk in light of the public health emergency... The FDA currently believes such devices would not create such an undue risk where:
- The product includes labeling that accurately describes the product as a “gown,” or “toga,” or other apparel (as opposed to a “surgical gown,” or “surgical toga”) and includes a list of the body contacting materials (which does not include any drugs or biologics);
- The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, recommendations against: use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected, use in a clinical setting where Level 3 or 4 protection is warranted, and use in the presence of high intensity heat source or flammable gas; and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses.

Non-surgical gowns are intended to protect the wearer from the transfer of microorganisms and bodily fluids in low- or minimal-risk patient isolation situations and are not intended for use during surgical procedures, invasive procedures, or when there is a medium or high risk of contamination. In the circumstances described above, the labeling or descriptions of the device, along with any minimal-or low-barrier protection (or no barrier protection) claims, may be considered by FDA as evidence that its intended use is as a non-surgical gown.

The device is considered to be a class I exempt device because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and the device is not intended for a
use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury, under sections 513(a)(1)(A) and 510(l)(1) of the FD&C Act.

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