



1275 K Street, NW, Suite 1000  
Washington, DC 20005-4006  
Phone: 202/789-1890  
Fax: 202/789-1899  
[apicinfo@apic.org](mailto:apicinfo@apic.org)  
[www.apic.org](http://www.apic.org)

August 28, 2015

Ms. Leslie Kux  
Associate Commissioner for Policy  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

***Re: Docket # FDA-2015-D-2261: Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings; Draft Guidance for Industry and FDA Staff.***

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide comment to the Food and Drug Administration (FDA) on the *Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings, Draft Guidance for Industry and Food and Drug Administration Staff*. We recognize this guidance is for the purpose of defining the required premarket submissions and review process. We applaud the intent for assuring that gowns worn as personal protective equipment (PPE) to prevent healthcare workers from exposure to blood and other potentially infectious materials (OPIM) are safe and effective. Our comments focus on concern about use of the term “surgical isolation gowns”.

FDA’s August 1993 *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes*<sup>1</sup> defines surgical gown, but not isolation gown or surgical isolation gown. There are a few brief references to isolation gowns, but all in the context of the surgical setting. Even the title of the guidance document would suggest that the submission requirements only apply to the surgical environment. The current draft supplement to the 1993 document adds to the confusion.

The term surgical isolation gown is not used or defined in the Centers for Disease Control and Prevention’s (CDC) *2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings*<sup>2</sup> or the Occupational Safety and Health Administration (OSHA) *Bloodborne Pathogen Standard*.<sup>3</sup> Both of these documents are used to guide institutional policy development and practice for preventing exposure to blood and OPIM. We feel that identifying a garment as a surgical isolation gown is confusing. All PPE should ensure the prevention of transmission of microorganisms whether from the healthcare worker to the patient or the patient to healthcare worker. Because the surgical environment is very specific with staff dedicated to that environment, many healthcare



providers would perceive the use of the term “surgical isolation gown” as referring to something that is just worn for surgical procedures. We believe the term is not generic enough for use outside of the surgical environment. The Association for the Advancement of Medical Instrumentation (AAMI) issued a Technical Information Report (TIR) titled *Selection and Use of Protective Apparel and Surgical Drapes in Health Care Facilities* in 2005.<sup>4</sup> The TIR defines four terms that APIC recommends should be incorporated into the draft guidance document. They are as follows: barrier properties, isolation gown, protective apparel and surgical gown. The TIR definition of these terms provides clarity and uses language easily recognizable by all healthcare providers.

Under the current draft guidance, isolation gowns would be considered exempt because they are used in environments outside of surgery, and therefore would not require the same rigorous 510(k) premarket approval process that is required of gowns worn in the surgical environment. The risk for exposure to blood and OPIM following unprotected contact still exists in nonsurgical settings. Standard precautions require personnel to wear an isolation gown when caring for any patient, regardless of the diagnosis, if it is likely that clothing will be soiled with patient secretions, patient excretions, or items contaminated with patient secretions or excretions. The use of an isolation gown when personnel are caring for patients suspected or known to have a specific infectious disease entity is based on the mode of transmission. Whether isolation gowns are used to carry out standard precautions or other types of isolation precautions, the choice of the type of isolation gown should be determined by the type and nature of the anticipated exposure and the protection afforded by the particular gown. End users must have a clear understanding of what level of liquid barrier protection a garment classified as an “isolation gown” provides. As such, the labeling on the gowns must be clear as to how the AAMI/ANSI PB70 barrier classification correlates to the anticipated risk of exposure. For example, a level one gown in this standard is only expected to have minimal fluid amounts, minimal splash or spray and minimal pressure on the gown and would correlate with low risk of exposure.

We agree with the FDA’s stance that disease specific claims are not needed in the basic requirements for 510(k) submission. Consistent with CDC Standard Precautions<sup>2</sup> and the Bloodborne Pathogen Standard<sup>3</sup> the gowns should protect against all potential blood and OPIM hazards and not be organism specific.

As an observation, this document open for public comment repeatedly referred to the ANSI/AAMI PB70:20 standard *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*. This standard is not freely available to the public, but rather must be purchased from ANSI. In the future, APIC would hope that when the FDA refers to documents within its proposals, those documents be made available to the public, in order to provide the optimal input.

In summary, our members provide guidance to healthcare workers and facilities on PPE and prevention of exposure to blood and OPIM on a daily basis. We are instrumental in educating healthcare providers on safe work practices including the type of and use for PPE including isolation gowns. APIC recommends that FDA include the use of the more clearly defined and familiar terms found in the AAMI



TIR in the premarket notification document. Thank you for the opportunity to provide input on this draft guidance. APIC looks forward to continuing to work with FDA in order to assure the safety and well-being of all healthcare providers in all practice settings.

Sincerely,

A handwritten signature in black ink that reads "Mary Lou Manning".

Mary Lou Manning, PhD, CRNP, CIC, FAAN, FNAP  
2015 APIC President

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<sup>1</sup> U.S. Food and Drug Administration. Guidance on Premarket Notification [501(k)] Submissions for Surgical Gowns and Surgical Drapes. Available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081305.pdf>

<sup>2</sup> Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Available at: <http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html>

<sup>3</sup> Department of Labor: Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens: Final rule. 29 CFR Part 1910:1030 Federal Register 1991;56:64003-64182. Revised 2001 CFR 66 2001:5317-25.

<sup>4</sup> Association for the Advancement of Medical Instrumentation. Technical Information Report. Selection and Use of Protective Apparel and Surgical Drapes in Health Care Facilities, 2005.