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Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices, 301-796-5580, and Elizabeth Claverie, 301-796-6298, Elizabeth.claverie@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices

Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for implementing this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA) is issuing this guidance to describe the Agency's premarket regulatory requirements and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings. This guidance is being issued in light of the public health importance of personal protective equipment in health care settings and the recognition that terminology used to describe gowns has evolved, including by FDA, industry, the standards community, and health care professionals.

FDA believes this guidance is important to promote and protect public health by describing premarket regulatory requirements pertaining to gowns regulated under 21 CFR 878.4040. Specifically, it will describe for industry the premarket regulatory requirements and data requirements for marketing of gowns with claims that they meet certain liquid barrier performance standards established by the American National Standards Institute, Inc., and the Association for the Advancement of Medical Instrumentation (ANSI/AAMI) and other similar terminology associated with these claims.

FDA recognizes that differences in terminology used to describe the functional performance of various kinds of gowns intended to provide liquid barrier protection in health care settings have developed among FDA, industry, the standards community, and health care professionals. While this guidance document will not resolve existing differences in

terminology, it is intended to clarify FDA's premarket notification requirements for gowns making liquid barrier protection claims intended for use in health care settings.

This document is intended to supplement the 1993 guidance document, *Guidance on Premarket Notification [510(K)] Submissions for Surgical Gowns and Surgical Drapes* (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081305.pdf).

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

FDA issued a final rule[1] on June 24, 1988, defining "surgical apparel" under 21 CFR 878.4040 as:

> devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

Under this 1988 final rule, surgical gowns and surgical masks were classified as Class II subject to premarket review under section 510(k) of the Federal Food, Drug, and Cosmetic Act, and surgical apparel other than surgical gowns and surgical masks, were classified as Class I also subject to 510(k) premarket review requirements. A manufacturer of any gown that met the intended use of surgical apparel under 21 CFR 878.4040 was required to submit a 510(k) notification before the device could be introduced into interstate commerce.

On January 14, 2000, FDA issued a final rule[2] to designate as exempt from premarket notification (510(k)) requirements surgical apparel other than surgical gowns and surgical masks, subject to the limitations of exemptions under 21 CFR 878.9, which includes requiring a premarket notification for devices intended for a use different from the intended use of a legally marketed device in that generic type of device. Specifically, the classification regulation was modified to read:

[1] 53 FR 23874 (June 24, 1988).
[2] 65 FR 2318(January 14, 2000).

> 21 CFR 878.4040 Surgical apparel.
>
> (a) *Identification.* Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.
>
> (b) *Classification.* (1) Class II (special controls) for surgical gowns and surgical masks.
>
> (2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

At the time of the 2000 final rule, the Agency viewed "surgical gowns" as gowns intended for use during surgical procedures and/or for use to provide moderate to high level barrier protection and "isolation gowns" as gowns intended to provide minimal or low levels of barrier protection. For the purposes of this guidance, isolation gowns that are intended for use to provide moderate to high level barrier protection are referred to as "surgical isolation gowns."

Since the original 1988 final rule, a number of terms have been used to refer to gowns intended for use in health care settings including, but not limited to, surgical gowns, isolation gowns, surgical isolation gowns, nonsurgical gowns, cover gowns, comfort gowns, procedural gowns, and operating room gowns. Although the Agency has not defined the other terms by regulation or guidance, in its 1993 guidance, the Agency referred to the regulation definition of the term "surgical gowns" which was "surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material."[3] In addition, the Agency has reviewed certain gowns based on the intended use of those gowns as surgical gowns and was able to determine substantial equivalence to the other surgical gowns classified under 21 CFR 878.4040(b)(1), based on assessments of liquid chemical permeation, fluid penetration, viral penetration and other appropriate scientific analysis.

In 2004, FDA recognized the consensus standard ANSI/AAMI PB70:2003, *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.*[4] ANSI/AAMI PB70 utilized new terminology for barrier performance of gowns. This terminology described and assessed the barrier protection levels of gowns and

[3] *Guidance on Premarket Notification [510(k)] Submission for Surgical Gowns and Surgical Drapes*, August 1993.(http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081305.pdf)

[4] Approved on October 23, 2003 by American National Standards Institute, Inc.

other protective apparel intended for use in health care facilities, by specifying test methods and performance results necessary to verify and validate the newly defined levels of barrier protection. Although FDA has recognized ANSI/AAMI PB70's barrier performance levels (i.e., Levels 1-4) and the associated test methods, the definitions and terminology used in this standard are inconsistent with FDA's historical definitions of these terms. Thus, the differences in regulatory and standards terminology have added confusion in the market-place as it relates to regulatory requirements for gowns with liquid barrier protection claims. Specifically, ANSI/AAMI PB70 defines an "isolation gown" as an "[i]tem of protective apparel used to protect health care personnel and patients from the transfer of microorganisms and body fluids in patient isolation situations," and "surgical gowns" as "devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids, and particulate matter [material].'"[5] Under 21 CFR 878.4040 and the Agency's regulatory approach, however, both surgical gowns and isolation gowns are "surgical apparel," and surgical isolation gowns are considered to be class II "surgical gowns" because they are intended for use as such based on their moderate to high barrier protection claims.

The Agency has considered gowns that claim moderate to high barrier protection, such as ANSI/AAMI PB70 Level 3 or 4, to be a higher risk device than those that claim minimal or low levels of barrier protection, such as ANSI/AAMI PB70 Level 1 or 2. Thus, FDA considers both level-of-protection claims and the terminology used (e.g., isolation, nonsurgical, procedural, operating room) because of such devices' substantial importance in preventing impairment of human health. The level of protection claimed is particularly relevant in light of the inconsistent terminology used, and that, at the time of the 2000 final rule, surgical apparel other than surgical gowns and surgical masks were associated with low levels of barrier protection. The purpose of this guidance, therefore, is to clarify and describe the premarket regulatory requirements pertaining to gowns regulated under 21 CFR 878.4040 and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings.

III. Scope

The scope of this document is limited to gowns making liquid barrier protection claims and intended for use in health care settings. For the purposes of this guidance document:

Minimal or Low Barrier protection[6] refers to:

- ANSI/AAMI PB70 Level 1 protection or equivalent; or
- ANSI/AAMI PB70 Level 2 protection or equivalent.

[5] See, respectively, sections 3.13 and 3.31 of the ANSI/AAMI PB 70:2012 (citing 21 CFR 878.4040).

[6] Prior to the existence of ANSI/AAMI PB70, minimal or low barrier protection claims included, but were not limited to, "Protective Apparel," "Effective Barrier," "Fluid-Resistant," "Water Resistant," and "Splash Resistant." The Agency discourages the use of these claims because they lack specificity with respect to performance characteristics and test methods. ANSI/AAMI PB70 was developed to address these issues and provide clarity to the user community regarding the levels of liquid barrier protection provided by a gown.

Moderate or High Barrier protection[7] refers to:

- ANSI/AAMI PB70 Level 3 protection or equivalent; or
- ANSI/AAMI PB70 Level 4 protection or equivalent

This guidance document does not address the data needed to support gowns making claims of providing protection against specific organisms, chemical agents, chemotherapy drugs or those making specific disease prevention claims (such as "protects against Ebola"). In addition, this guidance does not address the data needed to support the addition of antimicrobial agents in gowns. Manufacturers desiring to market gowns with these types of claims and/or design features are encouraged to utilize the pre-submission process[8] to obtain further guidance from the Agency prior to the submission of a premarket submission.

IV. Policy

The Agency is describing its approach to determining which gowns are Class I and which are Class II. Specifically, consistent with 21 CFR 878.4040(b), a gown that is not intended for use as a surgical gown is a Class I exempt device that is not subject to premarket notification requirements, and a gown that is intended for use as a "surgical gown" is a class II device subject to premarket notification. The determination of the intended use of a device is factually driven and generally made on a case-by-case basis. In determining whether a gown is intended for use as a "surgical gown" under 21 CFR 878.4040(b)(1) that is class II subject to premarket notification, the Agency considers a number of factors, including, but not limited to, the terminology used, level of barrier protection claimed, and the device's technological characteristics.

a) Class I exempt gowns

For purposes of determining classification of a gown under 21 CFR 878.4040(b), the Agency's regulatory approach is that a gown falling within this regulation is not a "surgical gown" if all of the following factors exist:

- it is labeled as a gown other than a surgical gown (e.g., isolation gown);
- it is not described in its labeling as a surgical gown; and
- if it has statements relating to barrier protection, such statements are for only minimal or low barrier protection.

[7] Prior to the existence of ANSI/AAMI PB70, moderate or high barrier protection claims included, but were not limited to, "Prevents Strikethrough," "Highest Fluid Protection," "Impervious," "Highest Level of Protection," and "Impermeable." The Agency discourages the use of these claims because they lack specificity with respect to performance characteristics and test methods. ANSI/AAMI PB70 was developed to address these issues and provide clarity to the user community regarding the levels of liquid barrier protection provided by a gown.

[8] Please see FDA guidance document, *Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff: Guidance for Industry and Food and Drug Administration Staff*. (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf)

In that case, the labeling or descriptions of the device, along with any minimal or low barrier protection (or no barrier protection) claims, show that its intended use is as a nonsurgical gown. Such a gown is considered class I, exempt from premarket notification under 21 CFR 878.4040(b)(2), subject to the limitations in 21 CFR 878.9, as surgical apparel other than surgical gowns and surgical masks. The device is class I exempt because the general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, under section 513(a)(1)(A) of the FD&C Act. The general controls include, but are not limited to, the quality system regulation (21 CFR part 820), registration and listing (21 CFR part 807), medical device reporting (21 CFR part 803), and labeling (21 CFR part 801).

b) Class II gowns

For purposes of determining classification of a gown under 21 CFR 878.4040(b), the Agency's regulatory approach is that a gown falling within this regulation is a "surgical gown" if:

- it is labeled as such;
- it is described as such in its labeling;
- it has statements relating to moderate or high level barrier protection; and/or
- it has statements that it is intended for use during sterile procedures.

In that case, the terminology (e.g., "surgical gown" or "surgical isolation gown"); description in the gown's labeling (e.g., "this gown is suitable as a surgical gown"); and/or Level 3 or 4 barrier protection claims show that the gown is intended for use as a "surgical gown" (which includes "surgical isolation gown"). Such gowns are considered class II devices under 21 CFR 878.4040(b)(1) and are subject to premarket notification. The Agency considers gowns that claim moderate to high level barrier protection, such as ANSI/AAMI PB70 Level 3 or 4, to be a higher risk device than those that claim minimal or low levels of barrier protection, such as ANSI/AAMI PB70 Level 1 or 2, because of such devices' substantial importance in preventing impairment of human health, and, thus, the Agency considers such gowns to be "surgical gowns" within the meaning of 21 CFR 878.4040(b)(1).

Statements in the labeling that a gown is a surgical gown (which includes "surgical isolation gown") provide strong evidence that the gown is a "surgical gown," as that term is used in 21 CFR 878.4040(b)(1), even if there are claims that the gown only provides minimal or low barrier protection.

When a premarket notification (510(k)) for a "surgical gown" (which includes "surgical isolation gown") falling within this section is submitted for FDA review, the 510(k) should contain the following information in addition to the items identified in FDA's *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes* (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081305.pdf):

1. Evidence that the gown complies with the claimed barrier performance criteria of the currently FDA-recognized version of ANSI/AAMI PB70, or equivalent standard.

ANSI/AAMI PB70 establishes barrier performance and documentation requirements for gowns and their materials.

2. Performance test data to demonstrate that the gown is an effective barrier in accordance with ANSI/AAMI PB70 barrier performance specifications. For both single use and reusable gowns, barrier performance testing should be completed on the final, finished, pre-shipment gown, at the end of the stated shelf life of the gown. If the gown is intended to be reusable, barrier performance testing should also be performed at the end of the labeled use-life (maximum reprocessing cycles).

3. Representative engineering drawing(s), schematics, illustrations and/or figures of the gown that are clear, legible, labeled with the barrier protection levels of the gown, and include dimensions and the location of the critical and non-critical zones.

4. Sample labeling that clearly identifies the level of liquid barrier protection per ANSI/AAMI PB70.

5. Sample labeling that includes the direction(s) for use and indication(s) for use.

Current Agency policy is to require the submission of a premarket notification (510(k)) for manufacturers proposing to begin the introduction or delivery for introduction into interstate commerce for commercial distribution a gown falling within section IV.b. The Agency does not intend to enforce compliance with premarket notification requirements for gowns marketed on or before June 26, 2015 that fall within section IV.b. and do not have an existing 510(k) clearance when manufacturers: 1) submit a 510(k) for the gown to the Agency within 60 days of publication of the final guidance; 2) have a 510(k) submission for the gown accepted by the Agency for review within 75 days of publication of the final guidance;[9] and 3) obtain 510(k) clearance for the gown within 180 days of publication of the final guidance. Manufacturers can bundle multiple gowns within a single 510(k) submission.[10] FDA intends to work interactively with manufacturers, as appropriate, during the review process. If a manufacturer has complied with steps 1 and 2 above, but has not received clearance for its device within 180 days because the submission remains under active review, the manufacturer should contact FDA to discuss whether the Agency intends to continue to defer enforcement under these circumstances.

[9] Please see FDA guidance document, *Refuse to Accept Policy for 510(k)s*. (http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf) In order to be considered administratively complete and accepted for review, submissions should contain the items identified in Section IV.b.

[10] Please see FDA guidance document, *Bundling Multiple Device or Multiple Indications in a Single Submission*. (http://www.fda.gov/RegulatoryInformation/Guidances/ucm089731.htm)