SUMMARY OF FDA GUIDANCE FOR GOWNS AND OTHER APPAREL DURING THE COVID-19 OUTBREAK (Updated through April 6, 2020)

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I. BACKGROUND

- The Department of Health and Human Services (HHS) has determined that the COVID-19 outbreak in the United States is a **public health emergency** and the President has **declared a national emergency.**

- The U.S. Food and Drug Administration (FDA) recognizes the need for additional supplies of personal protective equipment (PPE), including **surgical gowns, surgical isolation gowns, and non-surgical gowns (collectively, "gowns")** and **other apparel (e.g., shoe covers, caps, hoods, and scrubs)** to effectively respond to the COVID-19 outbreak.

- In recent weeks, the FDA has published various resources (including temporary enforcement policies) to **clarify the regulatory landscape** and to **help expand the availability** of gowns and surgical apparel for use by health care providers.

- Those resource **include**:

  - "Medical Gowns" webpage, available at: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns;

  - Letter to Healthcare Providers re: Surgical Mask and Gown Conservation Strategies, available at: https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers;

  - FAQs on Shortages of Surgical Masks and Gowns, available at: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns; and

  - March 30, 2020 Guidance Document re: Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency, FDA-2020-D-1138, which is available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;

  - April 6, 2020 Webinar Presentation re: Emergency Policy for Personal Protective Equipment (PPE) During COVID-19, available at: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-enforcement-policy-personal-protective-equipment-ppe-during-covid-19-immediately-effect**.**

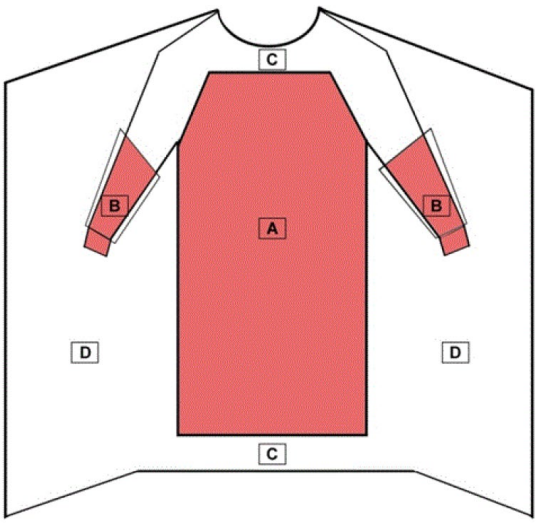
- In general, the FDA has enacted **temporary policies to reduce the regulatory burdens to introduce new PPE, including gowns and other apparel**, to the medical community during the COVID-19 outbreak. Interested companies should **closely follow** FDA requirements for new products. These policies **only apply during the public health emergency**. Companies that want to continue to make and supply products after the public health emergency will likely be required to meet **additional FDA requirements** for medical products.

- The FDA recommends that **health care providers follow Center for Disease Control (CDC) guidance** on the use of PPE, including gowns and other other, during the public health emergency. Additionally, **health care employers must comply with standards of the Occupational Safety and Health Administration (OSHA)** (29 CFR 1910 subpart I), requiring PPE to protect workers.

- This document provides a **general overview and summary** of the FDA recommendations and guidance documents. It is not fact or case specific, and it **does not recommend any particular course of action**. The FDA documents cited herein, and the FDA website, along with any updates, **should be reviewed in consultation** with qualified professionals and/or counsel. Interested parties should also **contact the FDA directly** with questions, and for additional details and guidance.

II. OVERVIEW OF GOWN TYPES

- Gowns are used to **protect health care providers and patients** from transferring microorganisms, bodily fluids, and particulate material.
- They are **tear and puncture resistant**.
- FDA guidance documents generally describe **three categories** of gowns, **defined by their intended use** and the **level of liquid barrier protection** that they provide:
  - surgical gowns;
  - surgical isolation gowns; and
  - non-surgical gowns.
- Each type is **briefly discussed below**.
- **Surgical Gowns**
  - Surgical gowns are used **during surgical procedures**.
  - They provide **moderate or high liquid barrier protection** in "critical zones," defined as:
    - Level 3 or 4 liquid barrier protection under ANSI/AAMI PB70: *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*; or
    - equivalent protection.
  - **Level 3** protection is "moderate" and used for the **widest range** of surgical procedures.
  - **Level 4** protection is "high" and used for **long, fluid-intensive procedures**.
  - The **critical zones** for surgical gowns (which require Level 3 or 4 protection) include most of the front of the gown, **from the shoulders to the knees** (area A, pictured below), and the lower part of the arms, **from the wrist cuffs to above the elbows** (area B, pictured below).

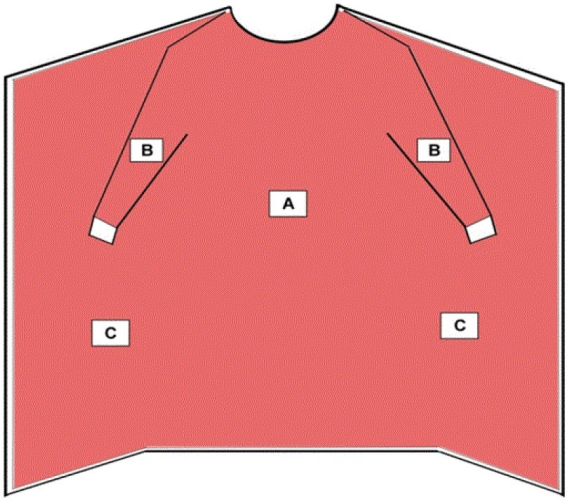


- The **top of the gown** (area C, pictured above) must have **at least Level 1** (i.e., the lowest) liquid barrier protection.

- The **back of the gown** (area D, pictured above) may be **non-protective**.

❖ **Surgical Isolation Gowns**

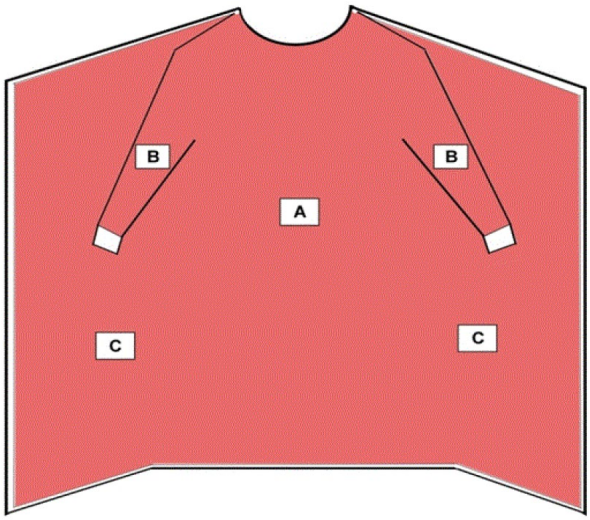
- Surgical isolation gowns are used in **moderate to high risk situations** where larger **zones of protection are needed** than traditional surgical gowns; for example, during arterial blood draw, inserting an intravenous (IV) line, or in the Emergency Room.



- The **entire surgical isolation gown** (areas A, B and C, pictured above), excluding cuffs, hems, and bindings, must have Level 3 or 4 liquid barrier protection.

❖ **Non-Surgical Gowns**

- Non-surgical gowns are used in **minimal to low risk situations**; for example, during basic care, in standard hospital medical units, during blood draw from a vein or suturing, in the Intensive Care Unit (ICU) or a pathology lab.



- As with surgical isolation gowns, the **entire gown** (areas A, B and C, pictured above), excluding cuffs, hems, and bindings, must provide liquid barrier protection. However, **the level of protection is lower**. Non-surgical gowns **provide Level 1 (minimal) or Level 2 (low) liquid barrier protection**.

III. GOWNS AND OTHER APPAREL INTENDED FOR GENERAL PURPOSES

- When gowns and other apparel are marketed to the general public for **general, non-medical purposes**, FDA authorization **is not required** and the requirements of the Food, Drug and Cosmetic (FD&C) Act **do not apply**.

- Gowns and other apparel are **medical devices** and **subject to FDA oversight** when they are "**intended for a medical purpose**," meaning they are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meet[] the definition of 'device' set forth in section 201(h) of the FD&C."

- When **evaluating if products are intended for a medical purpose**, FDA considers:

  - if the product is **labeled for use by health care providers** and/or use **in a health care setting**; and

  - if the product **includes drugs, biologics, or anti-microbial or anti-viral agents**.

IV. FDA EFFORTS TO INCREASE SURGICAL GOWNS AND SURGICAL ISOLATION GOWNS FOR MEDICAL PURPOSES

- Both surgical gowns and surgical isolation gowns are **Class II devices**.
- The FDA has **reduced** the regulatory burdens to **distribute and use (including importation)** of surgical gowns and surgical isolation gowns during the public health emergency provided they **do not create an "undue risk**" to the user.
- Surgical gowns and surgical isolation gowns **do not create an undue risk** where:
  - the product meets **Level 3 or higher liquid barrier protection** consistent with ANSI/AAMI PB70 for critical zone areas:
  - the product meets **flammability requirements for Class I or II textiles** under 16 CFR 1610;
  - the product has been **demonstrated to be sterile, if intended** for sterile surgical settings;[1]
  - the labeling **accurately describes:**
    - the product's **sterile status**, i.e., sterile or non-sterile, and the sterilization method use, if applicable;
    - the **liquid barrier protection** as Level 3 of higher;
    - the **flammability classification** (Class I or Call II); and
    - a list of the **body contacting materials**.
  - the **labeling makes recommendations to sufficiently reduce the risk of use**, including:
    - a general statement that the device **has not been cleared by the FDA**;
    - recommendations **against use if FDA-cleared surgical gowns are available**; and
    - recommendations **against use of non-sterile products in surgical settings**.
  - the product is not recommended or intended for any use that would create an undue risk, for example, the **labeling does not include**:

[1] The performance standards for sterile gowns is describe in Guidance for Industry and FDA Staff, Submission and Review of Sterility Information in Premarket Notification (510(k)), Submissions for Devices Labeled as Sterile, FDA-2008-D-0611, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled.

- uses for antimicrobial or antiviral protection or reduction;
- uses for infection prevention or reduction; or
- claims for Level 4 liquid barrier protection (i.e., current FDA guidance **does not** apply to Level 4 gowns).

❖ Provided that a gown does not create an undue risk, the FDA will **not object if other FDA regulations for medical devices are not satisfied**, including:

- ➢ site registration and product listing under 21 CFR 807;
- ➢ premarket notification under 510(k) of the Food, Drug and Cosmetics (FD&C) Act and 21 CFR 807.81; and
- ➢ device identification requirements under 21 CFR Part 830 and 21 CFR 801.20.

❖ **Compliance with good manufacturing practices** under 21 CFR 820 (design, manufacture, packaging, labeling, storage, and distribution), **and reporting, correction, and product removal** requirements under 21 CFR 806 is **still required**.

❖ The FDA has expressed interest (https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns) working with **manufacturers** to mitigate shortages and indicated that it will **expedite review and authorization (when appropriate)** for gowns.

❖ Interested **manufacturers should email the FDA**[2] at: CDRH-NONDiagnosticEUA-Templates@fda.hhs.gov, or deviceshortages@fda.hhs.gov, with the subject line "Product Code [xxx], Shortage Mitigation Options for FDA Engagement" [3] and, to help facilitate a quick response, **in the body of the email include**:

- ➢ **a description of the product**;
- ➢ **a description of the mitigation steps** that the manufacturer proposes to take**,** including **plans to increase the availability of the product**; and
- ➢ **a description of what the manufacturer wants to discuss with the FDA**, such as, expedited review of a premarket submission or emergency use authorization.

[2] In some cases, the FDA has provided multiple (and different) email addresses, which are listed herein

[3] A list of the classification regulation and associated product codes for gowns and other apparel covered by current FDA guidance is provided in the March 30, 2020 Guidance Document re: Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency, FDA-2020-D-1138, which is available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholder.

- Interested manufacturers also should expect to provide **any proposed labeling** and described **any testing conducted** on the device, including to meet liquid barrier protection, flammability, and sterility performance standards, if applicable. [4]

[4] Besides fluid barrier protection, flammability, and sterility, the performance of gowns is typically tested using consensus standards for: tensile strength; tear resistance; seam strength; lint generation; evaporation resistance; water vapor transmission; and biocompatibility, which are described at: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns. The FDA has not addressed what additional performance testing, if any, gown manufacturers still are expected to perform during the public health emergency. Interested manufacturers should be prepared to discuss this issue with the FDA

V. FDA EFFORTS TO INCREASE NON-SURGICAL GOWNS AND OTHER APPAREL FOR MEDICAL PURPOSES

- The FDA has **reduced** the regulatory burdens to **distribute and use (including importation)** of non-surgical gowns during the public health emergency provided they **do not create an "undue risk**" to the user.

- A non-surgical gown **does not create an undue risk** where:

  - the labeling **accurately describes the product** as a "gown" or "toga" as opposed to a "surgical gown" or "surgical toga";

  - the product includes **a list of the body contacting materials**, which do not include any drugs or biologics;

  - the **labeling makes recommendations to sufficiently reduce the risk of use**, such as, **recommendations against use of the product**, including:

    - in **surgical settings** or where **significant exposure to liquid, bodily, or other hazardous fluids**, may be expected;

    - in clinical settings **where Level 3 or 4 liquid barrier protection is warranted**; or

    - in the presence of a **high intensity heat source or flammable gas**.

  - the product is not recommended or intended for any use that would create an undue risk, for example, the **labeling does not include**:

    - uses for antimicrobial or antiviral protection or reduction; or

    - uses for infection prevention or reduction.

- A non-surgical gown is a **class 1 device** and therefore is **not subject to premarket notification** under Section 510(k) of the FD&C Act.

- Provided that a gown does not create an undue risk, the FDA will **not object if other FDA regulations for medical devices are not satisfied**, including:

  - site registration and product listing under 21 CFR 807;

  - good manufacturing practices under 21 CFR 820 (design, manufacture, packaging, labeling, storage, and distribution);

  - reporting, correction, and product removal requirements under 21 CFR 806; and

  - device identification requirements under 21 CFR Part 830 and 21 CFR 801.20.

- The FDA has expressed interest (https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns) working with

manufacturers to mitigate shortages and indicated that it will **expedite review and authorization (when appropriate)** for gowns.

- Interested **manufacturers should email the FDA**[5] at: CDRH-NONDiagnosticEUA-Templates@fda.hhs.gov, or deviceshortages@fda.hhs.gov, with the subject line "Product Code [xxx], Shortage Mitigation Options for FDA Engagement" [6] and, to help facilitate a quick response, **in the body of the email include**:
  - **a description of the product**;
  - **a description of the mitigation steps** that the manufacturer proposes to take**,** including **plans to increase the availability of the product**; and
  - **a description of what the manufacturer wants to discuss with the FDA**, such as, expedited review of a request for emergency use authorization.
- Interested manufacturers also should expect to provide **any proposed labeling** and described **any testing conducted** on the device, including to meet liquid barrier protection performance standards. [7]
- The FDA has indicated it will take **the same approach for other apparel**.[8]

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[6] A list of the classification regulation and associated product codes for gowns and other apparel covered by current FDA guidance is provided in the March 30, 2020 Guidance Document re: Enforcement Policy for Gowns, Other Apparel, and Gloves During the COVID-19 Public Health Emergency, FDA-2020-D-1138, which is available at: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholder.

[7] Besides fluid barrier protection, the performance of gowns is typically tested using consensus standards for: tensile strength; tear resistance; seam strength; lint generation; evaporation resistance; water vapor transmission; and biocompatibility, which are described at: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns. The FDA has not addressed what additional performance testing, if any, gown manufacturers still are expected to perform during the public health emergency. Interested manufacturers should be prepared to discuss this issue with the FDA