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Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

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Guidance for Industry and Food and Drug Administration Staff

May 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20033 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-800-INFO-FDA or CDRH-COVID19-SurgicalMasks@fda.hhs.gov.

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Guidance for Industry and Food and Drug Administration Staff

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide recommendations for sponsors of decontamination and bioburden reduction systems about what information should be included in a pre-Emergency Use Authorization (pre-EUA) and/or EUA request to help facilitate FDA's efficient review of such request. This guidance provides these recommendations based on the device's intended use with respect to the level (tier) of decontamination or bioburden reduction, based on the sponsor's available data. Decontamination and bioburden reduction systems play an important role in the ongoing efforts to help address shortages of surgical masks and respirators intended for a medical purpose during COVID-19 or reduce the bioburden of surgical masks and filtering facepiece respirators (including N95 respirators) used as personal protective equipment (PPE) by

healthcare personnel[1] (hereinafter, "surgical masks and respirators") for the duration of the COVID-19 public health emergency.[2]

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," available at https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, 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

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named Coronavirus Disease 2019 (COVID-19). On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[3] In

[1] As used in the three EUAs for filtering facepiece respirators in effect at the time of this guidance, healthcare personnel (HCP) refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

[2] In the context of this guidance document, use of the term "surgical masks and respirators" with a decontamination/bioburden system refers to use of FDA-cleared or authorized surgical masks and respirators that are "compatible" with the decontamination or bioburden reduction system.

[3] Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[4]

FDA believes the recommendations set forth in this guidance may help address these urgent public health concerns by providing FDA's current thinking regarding the information that FDA believes should be included in a pre-EUA submission or an EUA request, including recommended labeling for different categories of decontamination and bioburden[5] reduction systems for surgical masks and/or respirators used during the COVID-19 outbreak, to help facilitate efficient review of such systems. These recommendations supersede the recommendations pertaining to the decontamination of face masks and respirators previously included in FDA's April 2020 guidance, Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) (hereinafter, "Face Masks and Respirators Guidance").[6]

FDA recognizes that the need for surgical masks and respirators may outpace the supply available to healthcare organizations during the COVID-19 public health emergency. In addition to outlining recommendations about pre-EUA submissions and EUA requests, including labeling, for decontamination and bioburden reduction systems in this guidance and issuing EUAs authorizing the emergency use of decontamination systems, FDA has also communicated conservation strategies[7] that are intended to augment, but not replace, specific controls and procedures developed by healthcare organizations, the Centers for Disease Control and Prevention (CDC), or CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) to aid in infection control and prevention.[8] In addition, the CDC has issued strategies for optimizing the supply of N95 respirators.[9]

FDA recommends that whenever possible, surgical masks and respirators should be used according to their labeling, and federal, state and local requirements.

III. Scope

This guidance applies to devices intended to decontaminate or reduce the bioburden of surgical masks and/or respirators intended for use as personal protective equipment (PPE) by healthcare

[4] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

[5] The term "bioburden" is commonly used to describe the population of viable microorganisms on a product and/or a sterile barrier system.

[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health. Concurrently with issuance of this guidance, the Face Masks and Respirators Guidance has been revised to remove FDA's recommendations regarding EUAs for decontamination of face masks and face filtering respirators.

[7] https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers.

[8] https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html and https://www.cdc.gov/hicpac/index.html.

[9] https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html.

personnel (HCP) during the COVID-19 public health emergency. FDA has issued emergency use authorizations (EUAs) during the COVID-19 public health emergency for certain decontamination systems for PPE.[10] There are no cleared or approved devices for the decontamination or bioburden reduction of surgical masks and/or respirators for these intended purposes. The pre-EUA and EUA submission recommendations outlined in this guidance apply to systems intended to decontaminate or reduce the bioburden of surgical masks and/or respirators during the COVID-19 public health emergency. These recommendations are intended to assist sponsors in providing FDA with information to support that their decontamination system or bioburden reduction system meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

IV. Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators

FDA is responsible for the oversight of reprocessed[11] single-use medical devices and generally requires the submission of a 510(k) for devices intended for use in reprocessing single-use medical devices. Wherever possible, FDA recommends that during the COVID-19 public health emergency, healthcare facilities should continue to use FDA-cleared or authorized, or National Institute for Occupational Safety and Health (NIOSH)-approved, respirators and FDA-cleared or authorized surgical masks consistent with the product's labeling. However, to help address shortages and to help facilitate the safe reuse and conservation of surgical masks and respirators for a medical purpose, for the duration of the public health emergency, FDA is interested in interacting with sponsors about systems that may be effective at decontaminating[12] or reducing the bioburden of otherwise single-use, disposable surgical masks and respirators and to facilitate distribution and emergency use of such systems under an EUA when certain criteria for issuance are met.

This guidance outlines FDA's recommendations on the information sponsors should consider including in the pre-EUA submissions and EUA requests based on the decontamination or bioburden reduction systems' intended use, including recommended labeling. FDA believes that

[10] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

[11] The term 'reprocessed', "with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient" (Section 201(*ll*)(2)(A) of the FD&C Act). For more information on FDA's recommendations concerning reprocessing of single-use devices, please see FDA's guidance "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification, and FDA's guidance "Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/labeling-recommendations-single-use-devices-reprocessed-third-parties-and-hospitals.

[12] As defined in ANSI/AAMI ST79:2017, "Comprehensive guide to steam sterilization and sterility assurance in health care facilities," decontamination is the "process of cleaning and disinfecting soiled medical devices to render them safe for handling and to the extent necessary for subsequent processing."

these recommendations will help facilitate FDA's efficient review of these EUA requests which will in turn help expand the availability of decontaminated surgical masks and respirators for use during the COVID-19 emergency.

In reviewing EUA requests for decontamination and bioburden reduction systems for surgical masks and/or respirators, FDA considers information such as the intended use of the decontamination or bioburden reduction system, the level of evidence supporting such decontamination or bioburden reduction, evidence supporting user safety with respect to exposure to decontamination or bioburden reduction process residuals, and evidence supporting the continued effectiveness of compatible surgical masks and respirators following decontamination or bioburden reduction with regard to filtering, fit, and breathability, and the product labeling. FDA reviews this information, and other required information,[13] to determine whether the device may be authorized under an EUA.

A. Overview of FDA's Approach to EUA Requests for Decontamination and Bioburden Reduction Systems for Surgical Masks and/or Respirators During the COVID-19 Public Health Emergency

For any decontamination or bioburden reduction system issued an EUA, FDA will include appropriate conditions of authorization in addition to the mandatory conditions outlined in section 564(e)(1)(A) of the FD&C Act. Although this is a case-by-case determination, based on current information and experience, FDA will likely include the following conditions of authorization:

- Appropriate conditions of authorization to ensure that users of the decontamination or bioburden reduction system are informed of the following:
    - that FDA has authorized the emergency use of the device;
    - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
    - of the alternatives to the device that are available, and of their benefits and risks.

- Appropriate instructions for users of the decontamination or bioburden reduction system and facilities regarding:
    - Identification of surgical masks and/or respirators that are compatible with the decontamination or bioburden reduction system;
    - Limitations of use of the decontamination or bioburden reduction system to FDA-cleared or authorized surgical masks and/or respirators only;
    - Collection, sorting, discarding, and decontamination or bioburden reduction of compatible surgical masks and/or respirators;

[13] See Section 564 of the FD&C Act. See also FDA's guidance, Emergency Use Authorization of Medical Products and Related Authorities, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

  - Tracking number of decontamination or bioburden reduction cycles per compatible surgical mask and/or respirator; and
  - User safety with respect to exposure to decontamination or bioburden reduction process residuals.

- Appropriate conditions of authorization for the monitoring and reporting of adverse events. FDA intends to include conditions of authorization that require adverse event reporting consistent with 21 CFR Part 803, including the following:
  - Reporting of adverse events associated with healthcare personnel who use decontaminated or bioburden-reduced surgical masks and/or respirators.
  - Reporting of adverse events for operators of the decontamination or bioburden reduction system and individuals involved in the decontamination or bioburden reduction process.

- For manufacturers of the decontamination or bioburden reduction system, appropriate conditions of authorization concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.

Sponsors should send pre-EUA and EUA requests for decontamination and bioburden reduction systems for surgical masks and respirators to CDRH-COVID19-SurgicalMasks@fda.hhs.gov. FDA will work with sponsors through its EUA process to facilitate expedited evaluation of the request.

B. Overview of Hierarchy for Decontamination and Bioburden Reduction Systems for Surgical Masks and/or Respirators

The recommendations below apply to decontamination and bioburden reduction systems that utilize processes with well-controlled critical cycle parameters and process monitors (e.g., biological indicators (BI), chemical indicators (CI), parametric monitoring) and that follow the known descending order of resistance of microorganisms to germicidal chemicals ("hierarchy")[14] shown in Figure 1 below.[15] FDA recommends that sponsors provide evidence that the critical parameters of the process are well-controlled and predictably follow the hierarchy in Figure 1 when utilizing these recommendations. These evidence levels are presented as "tiers" below.

Sponsors pursuing an EUA for a decontamination or bioburden reduction system for surgical masks and/or respirators should identify the intended use(s) they are seeking and provide corresponding evidence to support the intended use(s) based on which tier their system most

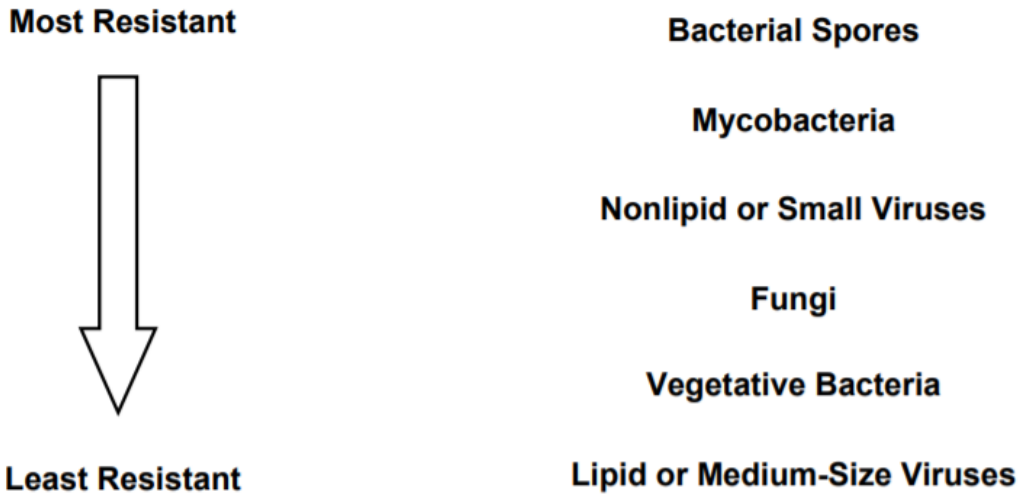
[14] The use of "hierarchy" and "tier" as used in this guidance are not intended to convey any meaning with respect to FDA's prioritization of EUA requests. Hierarchy and tier are used throughout this guidance in the context of microbiology.

[15] Please see FDA's Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

likely falls under. This tiered system will help FDA reviewers more efficiently evaluate EUA requests and identify any additional information the Agency needs from the sponsor.

Although the hierarchy in Figure 1 is generally applicable to most established microbicidal processes, FDA notes that there may be some processes that do not follow this hierarchy. Sponsors utilizing processes for decontamination or bioburden reduction systems that do not follow this hierarchy should contact FDA at CDRH-COVID19-SurgicalMasks@fda.hhs.gov.

Sponsors of decontamination or bioburden reduction systems utilizing processes that follow the hierarchy in Figure 1 should follow the recommendations below for the corresponding tier applicable to their system, in addition to the applicable recommendations in Sections IV.C and IV.D below. Sponsors that have questions regarding the applicable tier for their system should contact FDA at CDRH-COVID19-SurgicalMasks@fda.hhs.gov. Additionally, FDA encourages sponsors to discuss any alternatives to these recommendations with FDA.



Modified from Favero, M.S. and Bond, W.W., Chemical Disinfection of Medical and Surgical Materials. In: Disinfection, Sterilization, and Preservation, 5th Ed Phila: Lippincott Williams & Wilkins 2001: 881-917.

Figure 1. Descending Order of Resistance of Microorganisms to Germicidal Chemicals.

1. Tier 1: Decontamination of Surgical Masks and/or Respirators for Single- or Multiple-Users

FDA considers "Tier 1 systems" to be those systems intended for decontamination of surgical masks and/or respirators for either multiple-users or single-users. Use of surgical masks and/or respirators between multiple-users may increase unintended transmission of SARS-CoV-2 or other pathogens if not adequately decontaminated. For this reason, FDA recommends that sponsors seeking to label their system for decontamination of compatible surgical masks and/or respirators that may be suitable for single- or multiple-users should demonstrate sporicidal or mycobactericidal decontamination with either:

- ≥ 6-log spore reduction of the most resistant spore for the proposed process

  OR

- ≥ 6-log reduction of a Mycobacterium species (e.g., *M. terrae* or *M. abscessus*).

In general, FDA believes that data should demonstrate decontamination corresponding to the highest level of resistance in the hierarchy in Figure 1 when a decontamination system is intended to decontaminate surgical masks and/or respirators for multiple-users because of the increased risk of sharing a person's bioburden when used across multiple-users, as described above.

2. Tier 2: Decontamination of Surgical Masks and/or Respirators for Single-Users Only

FDA considers "Tier 2 systems" to be those systems intended for decontamination of surgical masks and/or respirators for single-users only. "Single-user" means that the same person should use the surgical mask or respirator following decontamination. Use of surgical masks and/or respirators by single-users poses less risk of unintended transmission of SARS-CoV-2 or other pathogens than by multiple-users. For this reason, FDA recommends that sponsors seeking to label their system for decontamination of compatible surgical masks and/or respirators only suitable for single-users should be able to demonstrate viral or vegetative bacterial decontamination with either a

- ≥ 6-log reduction of 3 non-enveloped viruses

  OR

- ≥ 6-log reduction of two gram-positive and two gram-negative vegetative bacteria

In general, FDA believes that data should demonstrate decontamination corresponding to moderate level of resistance in the hierarchy in Figure 1 where the decontamination system is intended to decontaminate surgical masks and/or respirators for reuse by a single-user and the user is unable to supplement this level of decontamination with existing CDC reuse

recommendations.

3. Tier 3: Bioburden Reduction of N95 Respirators for Single-Users Only to Supplement Existing CDC Reuse Recommendations

The CDC has issued specific recommendations on the reuse of N95 respirators under Crisis Capacity Strategies (during known shortages).[16] As such, sponsors may wish to pursue EUAs for systems intended for bioburden reduction of N95 respirators for single-users only to supplement existing CDC reuse recommendations ("Tier 3 systems"). FDA recommends that sponsors seeking an EUA under this Tier should provide labeling that makes clear use of the bioburden reduction system is in addition to and not in lieu of CDC reuse recommendations.

FDA believes that sponsors seeking to label their system for bioburden reduction of compatible N95 respirators only suitable for single-users to supplement CDC reuse recommendations should be able to demonstrate viral or vegetative bacteria bioburden reduction with either a

- ≥ 3-log reduction of a non-enveloped virus

  OR

- ≥ 3-log reduction of two gram-positive and two gram-negative vegetative bacteria

  OR

- Other evidence demonstrating that the bioburden reduction system will reliably achieve ≥ 3-log reduction in non-enveloped virus or vegetative bacteria, which could include, where appropriate, published scientific literature, and scientific and engineering studies.

C. Recommended Content of Pre-EUA Submissions for Decontamination and Bioburden Reduction Systems for Surgical Masks and/or Respirators

To help facilitate pre-EUA discussions, we recommend that you send FDA as much of the following information you have available:

1) Proposed intended use of the decontamination or bioburden reduction system (as discussed in Section IV.B. above).

2) A description of the technology (e.g., materials of construction, chamber size, maximum intended load per cycle, etc.).

[16] https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html

3) A description of the process for decontamination or bioburden reduction controls, including:
    a. Critical cycle parameters (e.g., concentration, time, heat, relative humidity) required for appropriate decontamination or bioburden reduction.
    b. Information on process monitors (e.g., chemical indicator (CI), biological indicator (BI), temperature probes, relative humidity monitors) used to demonstrate your cycle is appropriately implemented and continues to be executed as intended. Process monitors should be placed evenly throughout the load to demonstrate that at all areas of a chamber the critical process parameters have been achieved. If a CI and/or BI are applicable to the process, the CI and/or BI should provide a worst-case challenge to the cycle.
    c. Evidence supporting that the process is controlled and can reliably achieve and maintain critical cycle parameters.
    d. For energy-based methods requiring direct line-of-sight to the device surface, evidence supporting that there are process controls to prevent shadowing and allow line-of-sight access to all device surfaces.

4) Validation of decontamination or bioburden reduction, including:
    a. Evidence to demonstrate a robust ability to reliably decontaminate or reduce bioburden on compatible surgical masks and/or respirators. FDA recommends this include demonstration of appropriate level of validation as described in Section IV.B. of this guidance.
    b. Evidence to demonstrate that soils (e.g., blood, mucus, sebum, saliva) are either removed or do not interfere with the decontamination or bioburden reduction processes. This information is important as it may limit the ability of the surgical masks or respirators contaminated with certain soils to undergo a specific process. For example, blood will rapidly degrade hydrogen peroxide. Therefore, the surgical mask or respirator soiled with blood should not undergo decontamination with hydrogen peroxide.
    c. Protocols and acceptance criteria for scale-up of the process, if applicable.

5) Material compatibility, including:
    a. A description of the materials used in both the filters and the straps (elastic bands) that are compatible with the proposed decontamination or bioburden reduction system, and evidence to support their compatibility.
    b. Identification of any surgical mask and respirator materials known to be incompatible with your method of decontamination or bioburden reduction. For example, cellulose-based materials are incompatible with hydrogen peroxide as hydrogen peroxide will degrade cellulose.

6) Evidence to demonstrate that any process residues (e.g., residuals of the agent from decontamination) remaining on the decontaminated surgical mask or respirator are insignificant to cause a health hazard or deleterious effect to the user. This may include relevant toxicological information on the agents used in decontamination. For example, testing such as exhaustive extraction of decontaminated and aerated respirators to confirm that they are below the limits set forth by applicable international standards or

health hazard information from a safety data sheet prepared in accordance with the Occupational Safety and Health Administration (OSHA)'s Hazard Communication standard (29 CFR 1910.1200) with an OSHA permissible exposure limit or action level or the National Institute for Occupational Safety and Health (NIOSH) recommended exposure limit.

7) Surgical Mask or Respirator compatibility
   Surgical masks and respirators may be composed not only of different materials but may consist of different designs. Therefore, a decontamination or bioburden reduction system that is effective for one make/model may not necessarily be effective for other makes/models. Sponsors seeking authorization of EUAs should provide information, including:
   a. Identification of surgical masks and/or respirators compatible with the decontamination or bioburden reduction system, and evidence to support their compatibility;
   b. Identification of any surgical masks and/or respirators known to be incompatible with the decontamination or bioburden reduction system.
   c. A rationale for the proposed compatibility of the surgical masks and/or respirators with their system.

8) Number of decontamination/bioburden reduction cycles
   FDA is currently not aware of an approach to determining the maximum possible number of decontamination or bioburden reduction cycles for safe use of a surgical mask or respirator as a generic number to be applied in all cases. Safe use of a surgical mask or respirator after decontamination or bioburden reduction is affected by a number of variables that may impact function, fit, and contamination over time. However, sponsors seeking authorization for decontamination or bioburden reduction of surgical masks or respirators should provide testing to support their labeling regarding compatible surgical mask or respirator use with their product, including:
   a. Identification of the number of times a compatible surgical mask or respirator may be decontaminated or undergo bioburden reduction by the proposed system;
   b. A method for tracking the number of decontamination or bioburden reduction cycles to which the surgical mask or respirator has been exposed. If you are proposing to mark the surgical mask or respirator during the decontamination or bioburden reduction cycle to track the number of cycles a surgical mask or respirator has undergone, FDA recommends including data to demonstrate that the markings are indelible (e.g., will not deface, smudge, change color, otherwise be removed) on the surgical mask or respirator or strap surface, and that the markings do not affect the filtration performance of the device.
   c. Identification of the number of repeated cycles that the surgical mask or respirator and the straps (elastic bands) can withstand.
   d. Repeat cycle testing should also assess, as applicable:
      i. Filtration performance
      ii. Breathability
      iii. Fit test data:
         1. Evidence to demonstrate that repeated exposure to your

decontamination or bioburden reduction cycle steps does not decrease the respirator's ability to form a tight seal to the wearer's face.

2. Evidence to demonstrate that the decontamination or bioburden reduction cycle does not compromise the integrity of the elastic bands to maintain an appropriate fit to the wearer.

iv. If a surgical mask is the decontaminated device, performance testing to demonstrate the product meets the performance criteria described in the Face Masks and Respirators Guidance.[17]

e. Evidence to demonstrate that decontamination or bioburden reduction does not damage or reduce the performance (i.e., filtration performance, breathability, and fit, as applicable) of the surgical mask or respirator following the number of identified decontamination or bioburden reduction cycles.

9) Description of chain of custody and safeguards to prevent inadvertent exposure of healthcare personnel and decontamination or bioburden reduction staff to contaminated devices, including:
   a. Details regarding the chain of custody of the contaminated surgical masks and/or respirator(s) from the point of collection in the healthcare facility, to the decontamination or bioburden reduction facility or site, through the decontamination or bioburden reduction cycle, repackaging, and distribution back to the healthcare facility or site.
   b. For processes used in a healthcare setting, a description for how contaminated surgical masks and/or respirators are collected, isolated from the surrounding environment, transported through the healthcare facility to the decontamination or bioburden reduction system, and returned to healthcare personnel.
   c. For processes labeled for single-users, a description of how the chain of custody will ensure that the surgical masks and/or respirators will be returned to their original user.
   d. A description of the safety considerations through each step. At the facility where decontamination or bioburden reduction will occur, also include a description of the safety considerations which will be in effect, including but not limited to the following:
      i. What are the protective measures, including engineering and administrative controls and PPE, required for staff carrying out the decontamination or bioburden reduction processing of surgical masks and/or respirators?
      ii. Will this be performed under biosafety level (BSL)-2 or BSL-3 type conditions?
      iii. If this will occur under other conditions, what additional precautions will be implemented?
      iv. Will staff performing decontamination or bioburden reduction processes be routinely screened for COVID-19 to ensure that personnel have not been exposed due to implementation of processes and that surgical masks

[17] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health.

or respirators are not contaminated by personnel?

e. Describe how the surgical masks or respirators will be handled to ensure they are not contaminated or mixed with surgical masks or respirators to be processed after the surgical mask or respirator has undergone the proposed decontamination or bioburden reduction.
f. Describe how the decontamination or bioburden reduction system will be cleaned and disinfected to prevent transmission of more resistant organisms to processed surgical masks or respirators.

D. Labeling for Decontamination and Bioburden Reduction Systems for Surgical Masks and/or Respirators

As part of your pre-EUA submission or EUA request, we recommend that you send FDA a copy of the labeling for the decontamination or bioburden reduction system, as well as the product labeling for compatible FDA-cleared or authorized surgical masks and/or respirators that are decontaminated using your system. Examples of this labeling can be found on FDA's EUA website[18] by looking at existing authorized decontamination systems.

FDA recommends that labeling for systems intended for decontamination or bioburden reduction of compatible surgical masks and/or respirators should:

1) Be labeled according to their intended use:

   - Tier 1 – Labeling of "Tier 1 systems" should include limitations of the system for the decontamination of compatible surgical masks and/or respirators that may be suitable for single- or multiple- users.

   - Tier 2 – Labeling of "Tier 2 systems" should include limitations of the system for the decontamination of compatible surgical masks and/or respirators that are only suitable for single-users.

   - Tier 3 – Labeling of "Tier 3 systems" should include limitations of the system for the bioburden reduction of compatible N95 respirators that are only suitable for single-users to supplement CDC reuse recommendations.

2) Identify compatible FDA-cleared or authorized surgical masks and/or respirators.

In addition, FDA recommends that product labeling for compatible FDA-cleared or authorized surgical masks and/or respirators should:

1) Clearly state the surgical mask or respirator is decontaminated (Tiers 1 and 2) or undergone bioburden reduction (Tier 3).

[18] https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

2) Identify how many times the surgical mask or respirator may be processed via decontamination or bioburden reduction.
3) Advise users to discard surgical masks or respirators that are visibly damaged, visibly soiled, or that fit poorly and not perform decontamination or bioburden reduction.
4) Identify materials (including filter and strap/elastic band) that are incompatible with your proposed decontamination or bioburden reduction approach.
5) For surgical masks or respirators that are decontaminated with a potential carcinogen, teratogen, or mutagen or chemicals known or suspected of having sensitizing effects, include appropriate warnings to alert users of potential health effects.

As explained in Section IV.A. of this guidance, and as allowed by Section 564(e) of the FD&C Act, FDA may require additional labeling as part of a device's EUA as conditions of authorization.