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FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Respirators for Health Care Personnel Use During the COVID-19 Pandemic

June 9, 2020

Welcome

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Agenda

- Webinar Series Objectives
- Introductions
- Terminology and Overview of Face Masks and Respirators
- FDA Emergency Use Authorizations for Respirators - UPDATE
- Strategies for Optimizing the Supply of N95 Respirators
- Policies and Authorizations for Respirator Decontamination and Bioburden Reduction - UPDATE
- Q&A

Webinar Series Objectives

- Share information and answer questions about safe and effective use of respirators during the COVID-19 emergency.
- Provide updates on important actions impacting use and availability of respirators.
- Provide support for external customers to help assure health care personnel on the front lines have the information they need and the supplies they need to meet demand.

Background

- The FDA, the CDC's National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA) collaborate to assure safe use of respirators.

- The COVID-19 pandemic presents significant challenges to the availability of personal protective equipment (PPE), including respirators, in health care facilities.

- The FDA has authorized the emergency use of certain respirators and decontamination systems and has issued guidance on enforcement policies. Together these approaches provide substantial regulatory flexibility to help facilitate access to critical, quality medical supplies.

Introductions

Overview of Organizational Responsibilities

FDA	NIOSH	OSHA
Suzanne Schwartz, MD, MBA Acting Director, Office of Strategic Partnerships & Technology Innovation Center for Devices and Radiological Health (CDRH) **William Maisel, MD, MPH** Chief Medical Officer Director, Office of Product Evaluation and Quality (OPEQ), CDRH **CAPT Elizabeth Claverie** Assistant Director, Personal Protective Equipment, Reprocessing & Disinfection Devices, OPEQ/CDRH **John Verbeten** Acting Deputy Director Office of Enforcement and Import Operations Office of Regulatory Affairs	**John Howard, MD** Director, NIOSH **Maryann D'Alessandro, PhD** Director, National Personal Protective Technology Laboratory (NPPTL) / NIOSH **John Powers, BS** Branch Chief, Evaluation and Testing Branch, NPPTL/NIOSH **Colleen Miller, BS** Deputy Branch Chief, Conformity Verification and Standards Development Branch, NPPTL/NIOSH **Ed Fisher, MS** Biologist, Research Branch, NPPTL/NIOSH	**Amanda L. Edens** Deputy Assistant Secretary for OSHA **Andrew Levinson, MPH** Deputy Director, OSHA Directorate of Standards and Guidance **Dionne Williams, DrPH, MPH** Deputy Director**,** OSHA - Directorate of Enforcement Programs

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Terminology and Overview of Respirators

Terminology and Overview of Face Masks and Respirators

Face Mask

A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks are to be used for source control only, and are not PPE.

N95 Respirator

A disposable half-mask filtering facepiece respirator (FFR) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Generally, an N95 FFR used in a health care setting is regulated by the FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification or is a class II cleared device.

Terminology and Overview of Face Masks and Respirators

Face Shield

A face shield is a device used to protect the user's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. Generally, a face shield is situated at the crown of the head and is constructed with plastic to cover the user’s eyes and face.

Surgical mask

A mask that covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests, CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.

Face Masks and Respirators Guidance

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency

- Provide regulatory flexibility while assuring products are appropriate for their use.
- Enforcement Discretion as to certain FDA requirements
- In effect for the duration of the public health emergency

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Emergency Use Authorizations for Respirators

Emergency Use Authorization

- EUA authority allows the FDA to help strengthen the nation's public health protections by facilitating the availability and use of critical medical products during public health emergencies when certain criteria are met.
- Criteria for issuance
  - Serious or Life-Threatening Condition
  - Evidence of Effectiveness ("May be Effective") in diagnosing, treating, or preventing the serious or life-threatening disease or condition
  - Risk-Benefit Analysis
  - No Adequate, Approved, Available Alternatives (includes if there are insufficient supplies)

Emergency Use Authorization of Medical Products and Related Authorities

Emergency Use Authorizations for Respirators

- Authorizes emergency use of certain respirators for use in health care settings by HCP when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the COVID-19 outbreak.
- Must meet certain criteria for eligibility, and follow the conditions of authorization and other requirements as described in the EUA
- 3 Current Respirator EUAs:
  - **NIOSH-Approved Air Purifying Respirators for Use in a Health Care Setting**
  - **Imported Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (updated)**
  - **Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (updated)**

Emergency Use Authorizations for Respirators

NIOSH-Approved Air Purifying Respirators for Use in a Health Care Setting

Includes:

1) Non-powered air-purifying particulate FFR and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the NIOSH Certified Equipment List (CEL)
2) Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, and that are listed on the NIOSH CEL
3) FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles
4) Authorized respirators in (1) and (3) above that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system

Emergency Use Authorizations for Respirators

Imported Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Updated

Includes:

1) Authorized respirators listed in Exhibit 1 of the EUA
2) Authorized respirators listed in Exhibit 1 of the EUA that do not have an exhalation valve and have been decontaminated pursuant to the terms and conditions of an authorized decontamination system

The manufacturer or importer should send a request to be authorized under this EUA by email to FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov with the information requested in the EUA.

Emergency Use Authorizations for Respirators

Imported Non-NIOSH-Approved Disposable Filtering Facepiece Respirators

Filtering Facepiece Respirators (FFR) meeting at least one of the criteria in the following three categories are authorized under this EUA (updated):

1. Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications, as follows:

Jurisdiction[7]	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

2. Disposable FFRs that conform to Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that confirm to PPE regulation (European Union (EU) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE mark, and the CE mark has been authenticated and verified by FDA

3. Disposable FFRs that are manufactured by entities that hold one or more NIOSH approvals, that have been verified by FDA, for FFRs, and that are produced by the NIOSH approval holder in accordance with the applicable standards of authorization in another country.

Emergency Use Authorizations for Respirators

Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China

A disposable non-NIOSH-approved respirator manufactured in China is authorized under this EUA if it meets any of the following criteria (updated):

1) The respirator is manufactured by an entity that holds one or more NIOSH approvals, that have been verified by FDA, for FFRs, and that are produced by the NIOSH approval holder in accordance with applicable standards of authorization in another country.

2) The respirator: a) Has a registration certification, reflecting regulatory authorization, under the jurisdiction of the Chinese National Medical Products Administration (NMPA) and that is given by an appropriate provincial or municipal authority, and that has been authenticated and verified by FDA, or b) Conforms to the Personal Protective Equipment (PPE) Directive 89/686/EEC (for those placed into distribution before April 21, 2019) or that conforms to PPE Regulation (European Union (EU) 2016/425 (for those placed into distribution after April 21, 2019), as evidenced by a CE Mark, and the CE mark has been authenticated and verified by FDA.

3) The respirator was previously listed in Appendix A under the April 3, 2020 letter of authorization as an authorized respirator because it demonstrated acceptable performance to applicable standards as documented by test reports, has had particulate filtration efficiency assessed by NIOSH using a modified version of NIOSH's Standard Test Procedure (STP) TEB-APR-STP-0059 within 45 calendar days of the date of issuance of the May 7, 2020 letter, and has results of NIOSH testing that indicate a minimum and maximum filtration efficiency greater than or equal to 95 percent.

   A respirator authorized under this EUA because it meets the above criteria (3), is no longer authorized if it has been sampled by FDA, tested by NIOSH via a modified version of STP TEB-APR-STP-0059, and results according to NIOSH that indicates one or more of the 30 sampled respirators has a filtration efficiency of less than 95%.

Summary of Emergency Use Authorizations for Respirators

- 3 Current Respirator EUAs:
  - **NIOSH-Approved Air Purifying Respirators for Use in a Health Care Setting**
  - **Imported Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (see Exhibit 1)**
  - **Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (see Appendix A)**

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Strategies for Optimizing the Supply of N95 Respirators

Strategies for Optimizing the Supply of N95 Respirators

- Review CDC recommendations Strategies for Optimizing the Supply of N95 Respirators which includes Conventional Capacity, Contingency Capacity and Crisis Capacity strategies.
- FDA-cleared or NIOSH-approved N95 respirators should be used when they are available.
- When they are not available, FDA recommends using FDA-authorized respirators before any other alternatives.
- FDA does NOT recommend using a product as a respirator if it has not been FDA-cleared, NIOSH-approved, or authorized by FDA for Emergency Use as a respirator.
- HCP should ensure that respirators fit adequately before every use.
- It may be difficult to achieve an adequate fit with respirators that have ear loops instead of head straps.

Enforcement Policy for Face Masks and Respirators Guidance (Revised)

Policies and Authorizations for Respirator Decontamination and Bioburden Reduction

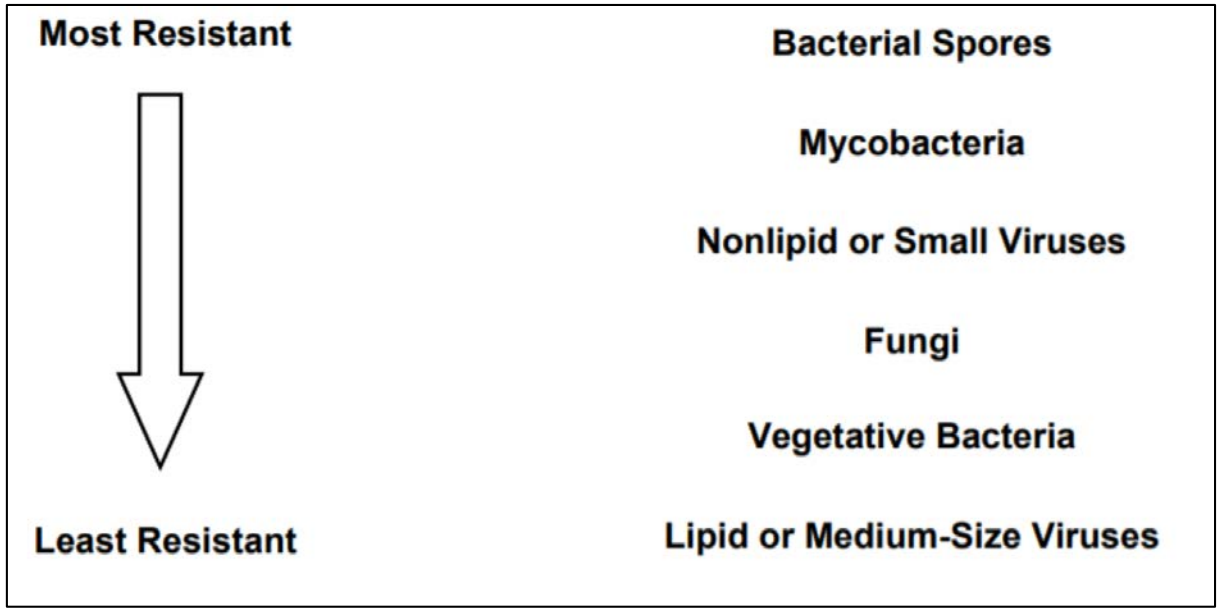
Decontamination and Bioburden Reduction

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

- Evidence-Based Approach to Decontamination and Bioburden Reduction
- Overview of Tiered Approach for Decontamination and Bioburden Reduction Systems
- Recommended Content of Pre-EUA submissions and EUA requests

Evidence-Based Approach to Decontamination and Bioburden Reduction

Descending Order of Resistance of Microorganisms to Germicidal Chemicals



- Hierarchy applicable to most established microbicidal processes
- Tiered approach for processes that follow hierarchy
- Recommend discussion with FDA for processes that do not follow this hierarchy (CDRH-COVID19-SurgicalMasks@fda.hhs.gov)

Tiered Approach for Decontamination and Bioburden Reduction Systems

TIER	Name	Intended Use	Recommended Evidence of Decontamination
Tier 1	**Decontamination** of Surgical Masks and/or Respirators for Single- or Multiple-Users *	**Multiple-Users or Single-Users**	– ≥ 6-log spore reduction of the most resistant spore for the proposed process **OR** – ≥ 6-log reduction of Mycobacterium species (e.g. M. terrae or M. abscesses
Tier 2	**Decontamination** of Surgical Masks and/or Respirators for Single-Users Only	**Single-User**	– ≥ 6-log reduction of 3 non-enveloped viruses **OR** – ≥ 6-log reduction of two gram-positive and two gram-negative vegetative bacteria
Tier 3	**Bioburden Reduction** of N95 Respirators for Single-Users Only to Supplement CDC Reuse Recommendations	**Single-User Only to Supplement Existing CDC Reuse Recommendations**	– ≥ 3-log reduction of non-enveloped virus **OR** – ≥ 3-log reduction of two gram-positive and two gram-negative vegetative bacteria **OR** – other evidence demonstrating similar effect

*Applies to respirators that are non-cellulose and compatible for decontamination

Recommended Content of Pre-EUA Submissions and EUA Requests

Requests should include:

1. Proposed Intended Use
2. Description of the Technology
3. Description of the Process Controls including Critical Cycle Parameters
4. Validation of Decontamination or Bioburden Reduction (Tiered Approach)
5. Material and Respirator Compatibility
6. Process Residues
7. Number of Decontamination/ Bioburden Reduction Cycles
   - Filtration performance
   - Breathability
   - Fit test data
8. Chain of Custody and Safeguards to Prevent Inadvertent Exposure
9. Labeling

EUAs for Decontamination and Bioburden Reduction Systems

- Authorized for compatible N95 respirators (must meet all criteria):
  - Non-cellulose respirators AND
  - Without an exhalation valve AND
  - Either: 1) authorized in the NIOSH-Approved Air Purifying Respirator EUA, OR 2) authorized and identified in Exhibit 1 of the EUA for Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators
- Only when there are insufficient supplies of Filtering Facepiece Respirators (FFRs) resulting from the COVID-19 pandemic

Emergency Use Authorizations

EUAs for Decontamination and Bioburden Reduction Systems

- Battelle Decontamination System
- STERIS Sterilization Systems for Decontamination of N95 Respirators
- Advanced Sterilization Products (ASP) STERRAD Sterilization System
- Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle
- Sterilucent, Inc. Sterilization System
- Duke Decontamination System
- STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers
- Stryker Sustainability Solutions VHP Decontamination System

Emergency Use Authorizations

Questions?

CDRH-COVID19-SurgicalMasks@fda.hhs.gov

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Under Heading: Specialty Technical Topics; Sub-heading: Personal Protective Equipment (PPE)”

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