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Decontaminating Respirators for Health Care Personnel Use during the COVID-19 Pandemic

Center for Devices and Radiological Health (CDRH)
U.S Food and Drug Administration (FDA)

Decontaminating Respirators for Health Care Personnel Use during the COVID-19 Pandemic

- Methods for decontamination and bioburden reduction of N95 respirators
- Evidence of potential effectiveness
- Recommendations/Observations and common challenges in Emergency Use Authorization (EUA) request submissions

Decontamination and Bioburden Reduction

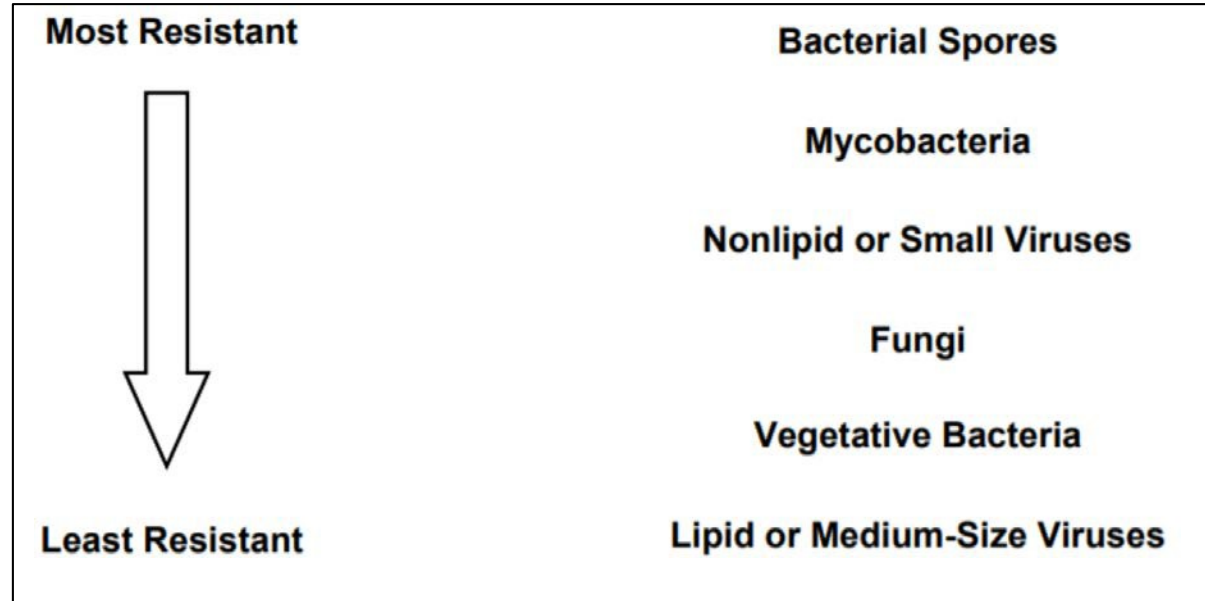
[Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency](#)

- 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	<ul style="list-style-type: none"> – ≥ 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	<ul style="list-style-type: none"> – ≥ 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	<ul style="list-style-type: none"> – ≥ 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

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Questions?

CDRH-COVID19-SurgicalMasks@fda.hhs.gov

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