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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

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

*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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