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Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators during the COVID-19 Pandemic

Office of Health Technology 4: Surgical and Infection Control Devices
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)



Enforcement Policy

To help address the urgent public health concerns caused by personal protective equipment (PPE) shortages, the FDA does not intend to object to the use of dry heat systems to reduce bioburden and support single-user reuse of compatible filtering facepiece respirators (FFRs) without marketing authorization when existing Centers for Disease Control and Prevention (CDC) reuse recommendations are followed, where such devices do not create an undue risk in light of the public health emergency.

Bioburden Reduction Systems

- Bioburden reduction systems are those which could achieve
 - ≥ 3 -log reduction of non-enveloped virus **OR**
 - ≥ 3 -log reduction of two gram-positive and two gram-negative vegetative bacteria
- These systems are to be used only to supplement CDC reuse recommendations (such as, ≤ 5 donnings, storing respirator for 5 days in a paper bag, etc.)
- For more information on decontamination and bioburden reduction, please refer to:
 - [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](#)



Filtering Facepiece Respirators (FFRs) within the Scope of the Policy

- FFRs that:
 - do **not** have exhalation valves, and
 - do **not** incorporate a duck-bill design, and
 - do **not** contain antimicrobial/antiviral agentsand
 - have been authorized under the emergency use authorization (EUA) for NIOSH-approved FFRs, or
 - have been authorized under the EUA for non-NIOSH-approved FFRs that are not manufactured in China, or
 - are FDA-cleared as intended for use by healthcare personnel (HCP) (“compatible respirators” or “compatible FFRs”)

Critical Cycle Parameters for Dry Heat

- Consistent exposure of 70°C for 60 minutes or 75°C for 30 minutes
- Note:
 - Chamber temperature should be monitored closely and recorded throughout the cycle to confirm accurate and even distribution of heat;
 - The system should have highly controlled convective heat transfer (for example, laboratory oven, industrial convection oven) to avoid the risk of localized over-temperature; and
 - Household appliances (for example, home ovens, pressure cookers, multicookers) should not be used due to the lack of accuracy and precision in temperature control and the risks of cross-contamination from mixed use.

Labeling – Bioburden Reduction System



- Necessary labeling should be provided to convey important information to help users better understand the device either by:
 - a manufacturer if manufacturing ovens for bioburden reduction of FFRs or
 - a healthcare organization that is repurposing ovens for bioburden reduction.
- For example, the following information should be included:
 - What is bioburden reduction?
 - What are critical cycle parameters?
 - What are the compatible FFRs?
 - “Only to be used to supplement CDC’s reuse recommendations of FFRs”

Labeling – Handling Instructions

- Handling instructions include:
 - Instructions for the handling of both contaminated and bioburden-reduced compatible FFRs should be provided by the healthcare organization to personnel managing the process
 - A description of chain of custody and safeguards (for example, ensuring that personnel involved in use of the dry heat system utilize appropriate personal protective equipment (PPE)) to prevent inadvertent personnel exposure to contaminated FFRs and eliminate potential cross-contamination between FFRs (for example, individual packaging and labeling for respirators)

Labeling – Bioburden Reduced FFR

- Healthcare organizations should provide labeling of the compatible FFRs that have been bioburden-reduced using dry heat to inform healthcare personnel (HCP) of proper procedures and precautions for using bioburden-reduced FFRs as described in the guidance. For example:
 - Healthcare personnel should follow CDC’s recommendations, as appropriate
 - Bioburden reduced FFRs are only to be reused by single user
 - Respirators that have been bioburden-reduced are no longer considered NIOSH-approved unless the NIOSH-approval holder confirms otherwise, and their performance (that is, fit, filtration, and breathability) might not meet NIOSH-approved N95 standards; in accordance with CDC recommendations, users should perform visual and tactile inspection of the respirator to verify no loss of respirator fit or function and should perform seal checks
 - When to discard respirators
 - [Report Adverse events to FDA MedWatch](#) by submitting the FDA Form 3500 or by calling 1-800-FDA-1088.

Resources

- [Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the COVID-19 Public Health Emergency Guidance](#)
- [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](#)
- [Implementing Filtering Facepiece Respirator \(FFR\) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators](#)
- [Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings](#)

Questions?

Email: CDRH-COVID19-SurgicalMasks@fda.hhs.gov

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