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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 Coronavirus Disease 2019
(COVID-19) Public Health
Emergency**

**Guidance for Industry, Healthcare
Organizations, Healthcare
Personnel, and
Food and Drug Administration Staff**

November 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 20044 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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Enforcement Policy for Bioburden Reduction Systems Using Dry Heat to Support Single-User Reuse of Certain Filtering Facepiece Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry, Healthcare Organizations, Healthcare Personnel, and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

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.

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FDA is issuing this guidance to provide a policy for bioburden¹ reduction systems that use dry heat to help support the single-user reuse² of certain particulate filtering facepiece respirators³ (FFRs). This policy applies to FFRs that do not have exhalation valves, do not incorporate a duck-bill design, and do not contain antimicrobial/antiviral agents and 1) have been authorized under the emergency use authorization (EUA) for NIOSH-approved FFRs,⁴ or 2) have been authorized under the EUA for non-NIOSH-approved FFRs that are not manufactured in China,⁵ or 3) are FDA-cleared as intended for use by healthcare personnel (HCP)⁶ (“compatible respirators” or “compatible FFRs”). Bioburden reduction systems play an important role in the ongoing efforts to help address shortages of FFRs intended for a medical purpose or used as personal protective equipment (PPE) by HCP for the duration of the COVID-19 public health emergency.

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 (PHS 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.

¹ The term “bioburden” is commonly used to describe the population of viable microorganisms on a product and/or a sterile barrier system.

² For the purposes of this guidance, “single-user” means that the same person should use the respirator following bioburden reduction.

³ For the purposes of this guidance, the terms “respirators” and “filtering facepiece respirators” (FFRs) are used interchangeably.

⁴ Letter of Authorization regarding “NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe>.

⁵ Letter of Authorization regarding “Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidppe>.

⁶ As used in the two emergency use authorizations (EUAs) for FFRs that may be relevant under this policy and in effect at the time of publication 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 HCP 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).

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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, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.⁷ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.⁸

FDA recognizes that the need for FFRs may outpace the supply available to healthcare organizations during the COVID-19 public health emergency. While HCP should continue to use a properly fitting, new, FDA-cleared or authorized respirator when available according to existing healthcare organization protocols, in the case that there is a supply shortage, reuse of decontaminated or bioburden-reduced respirators are potential options. To help support the reuse of otherwise single-use, disposable FFRs, FDA has issued [EUAs for certain decontamination systems for decontaminating compatible FFRs](#).⁹ Additionally, FDA has outlined a tiered approach to categorizing systems for decontaminating or reducing bioburden of FFRs based on the level of evidence available to support such systems.¹⁰ In general, FDA believes that decontamination systems should demonstrate a high level of inactivation (i.e., ≥ 6 -log reduction) of microorganisms corresponding to the highest and moderate resistance levels (i.e., Tier 1 and Tier 2, respectively), whereas bioburden reduction systems should demonstrate at least a moderate reduction (i.e., ≥ 3 -log reduction) of moderate resistance level microorganisms (i.e., Tier 3) and are only suitable to support single-user reuse of compatible FFRs in addition to, and not in lieu of, the Centers for Disease Control and Prevention (CDC) reuse recommendations.¹¹ In general, decontamination or bioburden reduction systems may employ various modalities (e.g., vaporized hydrogen peroxide, steam, dry heat) to achieve the intended level of decontamination or bioburden reduction. The policy set forth in this guidance applies to bioburden reduction systems (as opposed to decontamination systems) that only use dry heat (e.g., laboratory oven, industrial convection

⁷ Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists (originally issued on Jan. 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

⁸ 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/>.

⁹ <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

¹⁰ [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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks>.

¹¹ See <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html> for additional information regarding CDC's reuse recommendations for FFRs.

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oven¹²) as a means of reducing bioburden to support the single-user reuse of compatible FFRs when existing CDC reuse recommendations are followed during the COVID-19 outbreak. FDA encourages firms to discuss with FDA any alternatives to the recommendations outlined in this guidance. Please note that NIOSH-approved FFRs which have undergone decontamination or bioburden reduction are no longer considered NIOSH-approved unless the NIOSH approval holder for the respirator confirms that the post-decontamination/bioburden reduction-treated respirator meets the NIOSH approval criteria. This means that, unless otherwise specified in the FFR labeling, NIOSH-approved respirators that have undergone decontamination or bioburden reduction might not consistently meet NIOSH N95 FFR fit, filtration, and breathability standards.

III. Scope

The enforcement policy in this guidance only applies to certain bioburden reduction systems as described above that use dry heat and are intended to reduce the bioburden of compatible FFRs for single-user reuse to supplement existing CDC reuse recommendations (i.e., Tier 3 systems)¹³ during the COVID-19 public health emergency. Manufacturers that wish to make decontamination claims (i.e., Tier 1 or 2) as opposed to bioburden reduction claims (i.e., Tier 3) for their dry heat systems should follow the recommendations outlined in FDA's guidance [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](#).¹⁴ FDA has issued EUAs for certain decontamination systems for decontaminating compatible FFRs, but, as of the date of this guidance, has not authorized for emergency use any bioburden reduction systems utilizing dry heat for reducing bioburden of compatible FFRs. As of the date of this guidance, there are also no cleared or approved devices for decontamination or bioburden reduction of compatible respirators for these intended uses, and any such devices would generally require marketing authorization.

IV. Policy

A. Overview

In the context of the COVID-19 public health emergency, it is important to maintain an adequate supply of PPE such as FFRs for use by HCP to reduce the risk of transmission of SARS-CoV-2. Under certain circumstances, single-use, disposable FFRs may be reused for a limited number of times¹⁵ if properly decontaminated or have undergone sufficient bioburden reduction.

¹² This policy does not apply to home ovens, pressure cookers, multicookers, or other types of household appliances.

¹³ [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](#), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks>.

¹⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks>.

¹⁵ Based upon current CDC recommendations, respirators should not be reused for more than five donnings. (See <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html> for additional information regarding CDC's reuse recommendations for FFRs.)

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To help address the urgent public health concerns caused by PPE shortages, FDA does not intend to object to the use of dry heat systems to reduce bioburden and support single-user reuse of compatible FFRs without marketing authorization when existing CDC reuse recommendations are followed, such as storing the respirator in a breathable paper bag for a minimum of five days between each use and limiting the number of donnings to no more than five per respirator, where such devices do not create an undue risk in light of the public health emergency. FDA believes that the use of dry heat systems as a bioburden reduction method to support single-user reuse of compatible respirators will not create such an undue risk where the critical cycle parameters and labeling elements in Sections IV.B and IV.C, respectively, are met.

B. Critical Cycle Parameters for Dry Heat Systems Intended to Reduce Bioburden of Compatible FFRs

This section provides recommendations regarding critical cycle parameters relevant to the enforcement policy set forth above. Based upon information available to the Agency at this time, FDA believes bioburden reduction systems that use dry heat to support single-user reuse of compatible respirators will not create such an undue risk where:

- The system can ensure respirator exposure to consistent temperatures of 70 °C for 60 minutes or 75 °C for 30 minutes¹⁶ to guarantee sufficient bioburden reduction (i.e., ≥ 3 -log reduction in non-enveloped viruses or vegetative bacteria) while maintaining respirator integrity;¹⁷
- Chamber temperature can be monitored closely and recorded throughout the cycle to confirm accurate and even distribution of heat;
- The system has highly controlled convective heat transfer (e.g., laboratory oven, industrial convection oven) to avoid the risk of localized over-temperature; and
- The system is not a household appliance (e.g., home ovens, pressure cookers, multicookers) due to the lack of accuracy and precision in temperature control and the risks of cross-contamination from mixed use.

¹⁶ Based on currently available evidence [Refs. 1-6], dry heat at $T = 70$ °C for duration $t = 60$ minutes or $T = 75$ °C for $t = 30$ minutes should reliably achieve ≥ 3 -log reduction in non-enveloped virus or vegetative bacteria on respirators. This level of bioburden reduction is consistent with Tier 3 in the hierarchy for decontamination and bioburden reduction systems for respirators as described in FDA's guidance [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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks) (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks>) and should be employed only for single-user reuse of respirators in addition to, and not in lieu of, CDC reuse recommendations (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>).

¹⁷ Based on currently available evidence [Refs. 7-8], dry heat at $T = 70$ °C for 60 minutes or $T = 75$ °C for 30 minutes should not affect the filtration efficiency, breathability, and fit of respirators.

C. Labeling

This section provides labeling recommendations relevant to the enforcement policy described above.

Bioburden Reduction System Labeling

Consistent with the general recommendations above, FDA also recommends that the bioburden reduction system's labeling, as provided either by a manufacturer if manufacturing ovens for bioburden reduction of FFRs or a healthcare organization that is repurposing ovens for bioburden reduction, convey important information to help users better understand the device. For example:

- Bioburden reduction systems that use dry heat on respirators have not demonstrated ≥ 6 -log reduction in microorganisms of the highest or moderate level of resistance (i.e., decontamination). However, dry heat systems operated within well-controlled critical cycle parameters (i.e., temperatures of 70 °C for 60 minutes or 75 °C for 30 minutes) may achieve ≥ 3 -log reduction in non-enveloped viruses or vegetative bacteria and may be sufficient to reduce the bioburden on compatible FFRs. Bioburden reduction is only intended to supplement existing single-user reuse recommendations from the CDC (e.g., store respirator in a breathable paper bag for a minimum of five days between each use). Bioburden reduction should not be used in lieu of or as an alternative to existing CDC recommendations. Please refer to the CDC recommendations for [Decontamination and Reuse of Filtering Facepiece Respirators](#),¹⁸ [Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings](#),¹⁹ and [Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response](#).²⁰ In addition, HCP should follow existing healthcare organization protocols regarding FFR use and reuse.
- The bioburden reduction system should only be used to reduce the bioburden of compatible FFRs, which are those FFRs that do not have exhalation valves, do not incorporate a duckbill design, and do not contain antimicrobial/antiviral agents and 1) have been authorized under the EUA for NIOSH-approved FFRs, or 2) have been authorized under the EUA for non-NIOSH-approved FFRs that are not manufactured in China, or 3) are FDA-cleared as intended for use by HCP.

Handling Instructions

Instructions for the handling of both contaminated and bioburden-reduced compatible FFRs should be provided by the healthcare organization to personnel managing the process and include a description of chain of custody and safeguards (e.g., ensuring that personnel involved in use of the dry heat system utilize appropriate PPE) to prevent inadvertent personnel exposure to contaminated FFRs and eliminate potential cross-contamination between FFRs (e.g., individual packaging and labeling for respirators).²¹

¹⁸ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>

¹⁹ <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

²⁰ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>

²¹ For additional recommendations regarding the description of chain of custody and safeguards to be included in bioburden reduction system labeling, please also see Section IV.C.9 of FDA's guidance [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](#), available at <https://www.fda.gov/regulatory->

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Bioburden-Reduced FFR Labeling

FDA recommends that the healthcare organization provides labeling of the compatible FFRs that have been bioburden-reduced using dry heat to inform HCP of proper procedures and precautions for using bioburden-reduced FFRs, such as the following:

- Users should continue to use a new respirator, if available, according to existing healthcare organization protocols. Bioburden reduction systems should be used only in situations when there is a shortage of new respirators.
- Any compatible respirator that has undergone bioburden reduction is only to be reused by a single user, in conjunction with, not in lieu of, the existing CDC reuse recommendations for these respirators (e.g., store respirator in a breathable paper bag for a minimum of five days between each use). Please refer to the CDC recommendations for [Decontamination and Reuse of Filtering Facepiece Respirators](#),²² [Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings](#),²³ and [Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during the COVID-19 Response](#).²⁴
- Respirators that have been bioburden-reduced are not NIOSH-approved and their performance (i.e., fit, filtration, and breathability) might not meet NIOSH-approved N95 standards. The end user should perform visual and tactile inspection of the respirator after each bioburden reduction cycle to verify there is no loss of respirator fit or function. User seal checks should be performed after each donning. If available, end users should follow any instructions or guidance from the respirator manufacturer in addition to the CDC reuse recommendations (e.g., limiting the number of donnings to no more than five per respirator).
- Discard respirators following use during aerosol-generating procedures.
- Discard respirators contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.
- Discard respirators following close contact with any patient co-infected with an infectious disease requiring contact precautions.
- Discard respirators that are damaged, discolored, or visibly soiled.
- Discard any respirator that becomes hard to breathe through.
- Report Adverse events to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088.

[information/search-fda-guidance-documents/recommendations-sponsors-requesting-euas-decontamination-and-bioburden-reduction-systems-face-masks.](#)

²² <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>.

²³ <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>.

²⁴ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>.

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