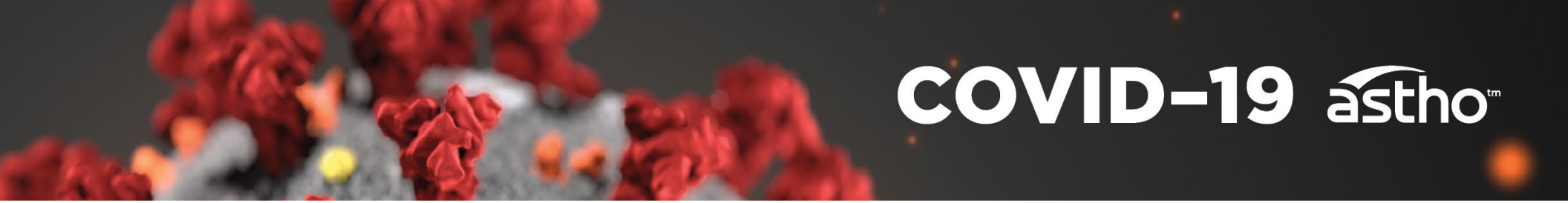

Issue Brief

Regulations of Personal Protective Equipment (PPE) in Healthcare Settings During the COVID-19 Response

April 28, 2020 (Updated as of 12 p.m. ET)

OVERVIEW

The Occupational Safety and Health Administration (OSHA) requires healthcare employers to provide personal protective equipment (PPE) to protect workers; however, maintaining an adequate stockpile of PPE is becoming increasingly difficult as healthcare facilities across the country experience shortages of PPE and disinfectants during the COVID-19 pandemic. Wherever possible, health care facilities should continue to use regulated PPE. As states and territories work to improve supply chain availability, some jurisdictions are exploring alternative solutions to the current shortage. This matrix provides recent guidance and information to assist state health agencies with supply shortages during the COVID-19 pandemic.

	Current Product List	Regulatory Agency	Temporary Guidance and Pathway for Approval During COVID-19	Extended Use or Use of Expired Product During COVID-19	Decontamination of Product During COVID-19
Facemasks	Surgical mask, (with or without liquid barrier protection) Surgical mask with antimicrobial/anti viral agent	Regulated by FDA under 21 CFR 878.4040. FDA Surgical Masks - Premarket Notification [510(k)] Submissions identifies the classification, regulation, and product codes for surgical masks.	FDA released its Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised), which provides guidance for expanding the availability of general use face masks during the pandemic. FDA issued Emergency Use Authorizations (EUA) for the use of surgical masks as PPE in healthcare settings.	CDC released Strategies for Optimizing the Supply of Facemasks, which includes recommendations for limited re-use of facemasks and homemade masks.	FDA is open to interacting with manufacturers regarding the decontamination of otherwise disposable face masks.
N95 Filtering Facepiece Respirators (FFRs)	NIOSH Certified Equipment List NIOSH Approved List of Respirators	Regulated by FDA as a Class II device under 21 CFR 878.4040 and CDC-NIOSH under 42 CFR Part 84. FDA and CDC-NIOSH	FDA issued EUA that allow certain NIOSH-approved respirators not currently regulated by the FDA and imported non-NIOSH-approved disposable FFRs to be used in	CDC released several guidance documents: Strategies for Optimizing the Supply of N95 Respirators	CDC released guidance on Decontamination and Reuse of Filtering Facepiece Respirators.

	FFR Certified Equipment List	have a Memorandum of Understanding to outline the framework for coordination and collaboration. OSHA issued temporary Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to COVID-19 Pandemic. CDC unveiled its Standard Application Procedure for the Approval of Air-Purifying Filtering Facepiece Respirators Under 42 CFR Part 84.	healthcare settings during the COVID-19 outbreak. • March 28: Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators • March 28: NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency (Clarification Letter) • April 3: Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (FAQ Document) FDA released its Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised), which provides guidance for expanding the availability of particulate filtering facepiece respirators (including N95 respirators) for health care professionals during the pandemic.	Considerations for Release of Stockpiled N95s Beyond the Manufacturer-Designated Shelf Life Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings	CDC does not recommend decontamination and reuse of disposable FFRs for routine use. For crisis standards of care, CDC lists three FFR decontamination methods that have shown promise for patient care (excluding aerosol-generating procedures): • Ultraviolet germicidal irradiation • Vaporous hydrogen peroxide (VHP) • Moist heat FDA approved EUAs for VHP decontamination of N95s using the following systems: • Battelle Decontamination System • Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle • Advanced Sterilization Products STERRAD Sterilization System • STERIS Sterilization Systems
Eye Protection	Face shields Goggles	Face shields are regulated by FDA under 21 CFR 878.4040. FDA recommends following CDC and OSHA guidelines.	FDA issued an EUA for the use of face shields as PPE in healthcare settings. FDA released its Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised), which provides guidance for expanding the availability of face shields for medical purposes.	CDC suggests use of eye protection beyond shelf-life for patient care as a crisis capacity strategy	CDC suggests following manufacturer instructions for cleaning and disinfection. For products without manufacture instructions, CDC provides instructions for reprocessing equipment.

Surgical Isolation Gowns	Disposable gown Cloth (washable) gown	Regulated by FDA as a Class II medical device that requires a 510(k) premarket notification. FDA recommends following CDC and OSHA guidelines.	FDA released its Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency, which provides guidance for expanding the availability of surgical gowns during the pandemic. If isolation gowns are not available, CDC suggests using the following substitutes as a last resort: • Disposable lab coats, washable lab coats, washable patient gowns, disposable aprons; Long sleeve aprons in combination with long sleeve patient gowns or lab coats; Open back gowns with long sleeve patient gowns or lab coats; Sleeve covers in combination with aprons and long sleeve patient gowns or lab coats	CDC suggests that disposable and cloths gowns can be worn for extended use by a single HCP between multiple patients with the same infectious disease. It is not clear if HCP should reuse or share cloth gowns without laundering between uses.	Washable cloths gowns and lab coats can be safely laundered according to routine procedures. Disposable gowns are not recommended for decontamination and reuse.
Medical Gloves	Non-sterile examination gloves Surgical gloves	Regulated by FDA as Class I reserved medical devices that require a 510(k) premarket notification. FDA recommends following CDC and OSHA guidelines.	FDA released its Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency, which provides guidance for expanding the availability of examination gloves and surgical gloves during the pandemic.	FDA suggests using medical gloves beyond shelf-life during crises where risk of transmission is low. During extended use of medical gloves between patients with no known infectious diseases, gloved hands should be cleaned between patients. Alcohol-based hand sanitizers may degrade vinyl gloves. If a glove becomes damaged or no longer provides a liquid barrier, replace it.	FDA suggests using radiographic protective gloves or radiation attenuating surgeon's gloves that are clean and offer fluid protection. These gloves cannot be sterilized but can be cleaned following the manufacturer's labeling.
Environmental and Surface Disinfectants	EPA List of Disinfectants for Use Against SARS-CoV-2	Surface disinfectants are regulated by the EPA. Hand sanitizers, antiseptic washes, and antibacterial soaps are	EPA activated its Emerging Viral Pathogens Guidance for Antimicrobial Pesticides to provide product registrants with a voluntary process to claim and use certain EPA-registered	WHO advises, “Some disinfectants with strong bactericidal and antiviral activity, such as Lysol (50% cresylic acid), may have an	N/A

	FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices	regulated by FDA (see below).	products against COVID-19.	expiry date. If this date has passed, the material can still be used for general disinfection purposes at an appropriate dilution decided by a pharmacist..."	
Hand Sanitizer Products	Eligible active ingredients: • Alcohol 60-95% • Benzalkonium chloride • Isopropyl alcohol 70-91.3%	Regulated by FDA as an over-the-counter topical drug; rules are separated into health care antiseptics and consumer antiseptics.	FDA produced guidance documents in 2020: • Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency, • Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency • Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry	FDA does not have information on the stability or effectiveness of drug products past their expiration date (see 21 CFR 211.137). Hand sanitizer produced under the temporary policies for hand sanitizer production and compounding may not have an expiration date listed because they are expected to be used during this public health emergency.	N/A

Notes:

- CDC does not recommend decontamination and reuse of disposable respirators for standard care, but recognizes that this may need to be considered as a crisis capacity strategy FDA authorized for emergency use a decontamination system for disposable N95 respirators.
- FDA suggests that as part of crisis strategy, gloves can be worn for extended use when washed between non-infectious patients. CDC recommends that gloves be removed and disposed between use by each patient.

For questions or feedback, please email preparedness@astho.org.