Personal Protective Equipment

The health care workers who are on the frontlines of responding to the coronavirus disease (COVID-19) outbreak are currently grappling with severe shortages of personal protective equipment (PPE). Such equipment includes eye protection, isolation gowns, facemasks, and N95 respirators. These products are critical to protecting the individuals caring for, testing, and screening patients with COVID-19. Many providers have taken proactive steps themselves to procure more supplies, taking to social media seeking donations of PPE. Politico and other news outlets are currently tracking hospital capacity, patient surge, and providers' ability to obtain PPE, and collecting stories about how COVID-19 is impacting providers' own health.

Public Health Emergency Determination and Personal Respiratory Device EUA

On February 4, 2020, U.S. Department of Health and Human Services Secretary Alex Azar determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the HHS Secretary declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak. Health care personnel can access a list of authorized respirators here. On May 11, 2020, the FDA announced the respirator models that had been on the list of authorized respirators but no longer meet the EUA eligibility criteria and thus are no longer authorized.

PREP Act Declaration

On March 10, 2020, Secretary Azar took further action by issuing a declaration pursuant to the Public Readiness and Emergency Preparedness (PREP) Act, which authorizes the Secretary to provide liability immunity for activities related to medical countermeasures against COVID-19.

DPA Invocation

On March 18, 2020, President Trump invoked the Defense Production Act (DPA), which allows the federal government to compel companies through loans, loan guarantees, purchases and purchase commitments to prioritize and expedite the manufacture of medical supplies that are in short supply. The President delegated the key authority for implementing the DPA to Secretary Azar.

Separately, General Motors Co. Chief Executive Officer Mary Barra offered to manufacture hospital ventilators in auto factories closed because of the coronavirus outbreak, according to top White House economic adviser Larry Kudlow.

FDA Recommendations Regarding Gowns and Surgical Masks

On March 11, 2020, the Food and Drug Administration (FDA) issued a letter to health care providers intended to aid in the management of gowns and surgical masks. The letter outlines recommended conservation strategies for use by health care organizations and personnel. For surgical masks and gowns, the FDA recommends that health care providers follow these strategies based on the supply needs of their health care organization. Gowns that are ANSI/AAMI PB70 Level 1 and 2 barrier protection are considered non-surgical isolation gowns. Gowns

that have ANSI/AAMI PB70 Level 3 and 4 barrier protection and/or can be used for a sterile procedure are considered surgical gowns or surgical isolation gowns.

The FDA notes that it is collaborating with manufacturers of surgical masks and gowns to better understand the current supply chain issues related to the COVID-19 outbreak, and to avoid any widespread shortages of these products. According to an FAQ issued by the FDA on shortages of surgical masks and gowns, the agency is also collaborating with manufacturers of PPE to help facilitate mitigation strategies related to the COVID-19 outbreak. Medical device manufacturers are not required to notify the FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the United States.

For potential or actual supply issues, email information to the FDA at deviceshortages@fda.hhs.gov. Anyone – user, patient, manufacturer, or organization within the supply chain – who is aware of a delay in distribution of a product, and/or anticipates a potential or actual shortage, can notify the agency.

FDA Recommendations Regarding Gloves

On March 20, 2020, the FDA issued a letter to health care providers intended to aid in the management of surgeons' gloves and patient examination gloves. The conservation strategies for use by health care organizations and personnel are categorized for a range of needs and supply levels and are intended to assist health care organizations as they determine procedures during the COVID-19 pandemic.

The conservation strategies described in the letter are intended to augment, and not intended to replace, specific controls and procedures developed by health care organizations, the Centers for Disease Control and Prevention (CDC), or the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) to aid in infection prevention and control. These strategies are not limited to use in the care of patients infected with COVID-19. Health care organizations may find additional useful information in guidelines on modifications to medical standards of care during a crisis.

CDC COVID-19 Interim Infection Prevention and Control Recommendations

The CDC has issued guidance for health care personnel caring for patients with confirmed or possible COVID-19 infection. Based on the current COVID-19 situation and availability of PPE, CDC has issued specific recommendations. CDC instructs health care personnel to adhere to Standard, Contact, and Airborne Precautions when caring for patients with COVID-19 infection. These precautions include the use of PPE.

PPE Availability

CDC communicates regularly with health care industry partners, as well as PPE manufacturers and distributors, to assess availability of PPE. Given decreases in exports from select countries and increases in demand due to the global outbreak, manufacturers of select types of PPE are reporting increased volume of orders and challenges in meeting order demands. Specific challenges are being reported for N95 respirators and facemasks. Orders received are up to 10-fold normal demand for these items. The CDC states that plans for surge manufacturing globally are underway.

Distributors of select types of PPE are also reporting an increased volume of orders from customers and challenges in meeting order demands for PPE, specifically for N95 respirators and facemasks. Due to decreased exports from overseas by manufacturers, distributors are reporting that these items are being placed on allocation, and orders are being filled based on historical demands for existing customers. At present, shortfalls may be anticipated to continue for the next 3–4 months.

The CDC has stated that U.S. health care systems are reporting higher than normal use for N95 respirators, due to fit testing and stockpiling, to prepare for possible widespread COVID-19 transmission. Orders are being placed in higher volumes to meet these needs. Some health care systems have begun reporting that orders for N95 respirators and facemasks are not being filled or are only being partially filled by distributors. In addition, major pharmacy chains have reported stock outs of N95 respirators and facemasks with delays in replenishment of inventory.

CDC is encouraging health care systems to implement the following strategies to conserve supplies:

- Strategies for Optimizing the Supply of Eye Protection
- Strategies for Optimizing the Supply of Isolation Gowns
- Strategies for Optimizing the Supply of Face Masks
- Strategies for Optimizing the Supply of N95 Respirators

In addition to the CDC's Interim Infection Prevention and Control Recommendations for COVID-10, the agency has issued and FAQ on Infection Control and an FAQ About PPE.

FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices

On March 22, 2020, the FDA issued an immediately in effect guidance outlining a policy intended to help increase availability of ventilators and their accessories as well as other respiratory devices during the COVID-19 pandemic.

First, the guidance describes the agency's intention to exercise enforcement discretion for certain modifications to these FDA-cleared devices. Normally, any time a manufacturer or user makes a modification to a ventilator device, those modifications can often trigger an FDA premarket review, which can delay the time it takes to get these devices to the bedside. The guidance also helps manufacturers ramp up their manufacturing by adding production lines or alternative sites to start manufacturing ventilator parts. In recognition of the current pandemic situation, and to ease regulatory burden on manufacturers, the FDA is being flexible in not enforcing the premarket review requirement for these modifications. Second, hospitals and health care professionals may use ventilators intended for other environments. The FDA also provides recommendations for other alternatives that should be considered such as devices for treating sleep apnea, continuous positive airway pressure (CPAP), devices. The FDA's policy also applies to health care facilities that use ventilators beyond their indicated shelf life, which should increase ventilator capacity. Finally, the agency encourages manufacturers, whether foreign or domestic, to talk to FDA about pursuing an EUA, which would allow them to distribute their ventilators in the United States. This includes U.S.-based manufacturers that were previously engaged in making medical devices, but which have capabilities to increase supply of these devices.

FDA Recommendations Regarding Ventilators and Accessories and Other Respiratory Devices

The FDA also issued a letter to health care providers and facilities providing recommendations based on the recently issued guidance, regarding the use of devices with patients who develop respiratory compromise from COVID-19 or other respiratory disorders.

The FDA notes that it is collaborating with manufacturers of ventilators, ventilator accessories, and other respiratory devices to better understand the current supply chain issues related to the COVID-19 outbreak and to avoid any widespread shortages of these devices.

For potential or actual supply issues, email information to the FDA at deviceshortages@fda.hhs.gov. Anyone – user, patient, manufacturer, or organization within the supply chain – who is aware of a delay in distribution of a product, and/or anticipates a potential or actual shortage, can notify the agency.

FDA Instructions for PPE and Device Manufacturers

On March 24, 2020, the FDA issued instructions to manufacturers importing PPE and other devices to increase U.S. supplies to support the U.S. response to COVID-19. These instructions to importers clarify the types of PPE that can be imported without engaging with FDA. They also include information about the type of information importers can submit to facilitate their entries. The agency has adjusted its import screening to further expedite imports of legitimate products and will continually monitor import systems to prevent and mitigate any potential issues.

FDA EUA Relating to Ventilators

On March 24, 2020, the FDA issued an EUA for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors, and ventilator accessories. The products that are eligible for inclusion under this EUA are those that are not currently marketed in the U.S., or that are currently marketed in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA. Manufacturers and other stakeholders may submit a request to FDA under the process outlined in the EUA to have their device(s) added to the EUA.

CDC PPE Burn Rate Calculator

The CDC has created a spreadsheet-based model that provides information for health care facilities to plan and optimize the use of PPE for response to COVID-19. Similarly, non-healthcare facilities may find this tool useful for planning and optimizing PPE use as part of the response to COVID-19. This tool can also be used for planning PPE use outside the context of COVID-19, where PPE shortages may also occur due to supply chain issues related to the COVID-19 response.

The PPE Burn Rate Calculator is now also available as a mobile app. The app is available for both iOS and Android devices. This video tutorial guides users through the tool.

FDA Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers

On March 29, 2020, the FDA issued guidance to provide a policy to help expand the availability and capability of sterilizers, disinfectant devices, and air purifiers during this public health emergency.

To help ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, during the declared public health emergency, FDA does not intend to object to limited modifications to the indications or functionality of FDA-cleared or FDA-approved sterilizers, disinfectant devices and air purifiers pertaining to a device's virucidal effectiveness against SARS- CoV-2, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.8112 or submission of a Premarket Approval Application (PMA) Supplement under section 515 of the FD&C Act and 21 CFR 814.3913, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20.

In addition, during the declared public health emergency, FDA does not intend to object to the distribution and use of sterilizers, disinfectant devices, and air purifiers that are intended to be effective at killing the SARS-CoV-2

virus but do not already have FDA marketing authorization, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81 or submission of a PMA Supplement under section 515 of the FD&C Act and 21 CFR 814.39, Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20.

The guidance gives recommendations regarding design, evaluation, and validation of performance relevant to the enforcement policies. FDA encourages firms to discuss any alternatives to these recommendations with FDA. FDA also recommends that the devices described in the guidance include labeling that helps users better understand device modifications.

FDA EUA for the Battelle Decontamination System

On March 29, 2020, the FDA issued an EUA for the emergency use of the Battelle CCDS Critical Care Decontamination SystemTM at the Battelle Memorial Institute, for use in decontaminating compatible N95 or N95-equivalent respirators for reuse by health care personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of FFRs during the COVID-19 pandemic. Upon issuance of the EUA, Secretary Azar released the following statement: "Getting PPE to the heroic health care workers on the frontlines of the pandemic is one of President Trump's top priorities. FDA's quick action in authorizing Battelle's technology will help hospitals get the maximum use out of their N95 respirators, while we work on multiple fronts to expand supplies available to them. FDA worked closely with the company and responded rapidly to each of their requests, as the agency has done with all emergency use authorizations during this crisis. If you're a company who wants to help get our healthcare workers what they need to stay safe—or help fight the pandemic in any other way—our door is open to you."

FDA Enforcement Policy for Gowns, Other Apparel, and Gloves

On March 30, 2020, the FDA issued guidance to provide a policy to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during this pandemic.

To help foster the availability of gowns and apparel during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of gowns not intended for use as "surgical gowns" and other low-to-minimal barrier protection surgical apparel that does not comply with the following regulatory requirements where the gowns and apparel do not create an undue risk in light of the public health emergency: Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports of corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR Part 801.20. FDA does not intend to object to the distribution and use of ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns that do not comply with the following regulatory requirements, where such surgical gowns do not create an undue risk in light of the public health emergency: Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,20 Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

Additionally, FDA does not intend to object to the distribution and use of patient examination gloves that do not comply with the following regulatory requirements, where the gloves do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,26 Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports of corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. Finally, FDA does not intend to object to the distribution and use of

surgeon's gloves that do not comply with the following regulatory requirements where the surgeon's gloves do not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81,31 Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20.

Optimizing Ventilator Use during the COVID-19 Pandemic

On March 31, 2020, the HHS Assistant Secretary for Health and U.S. Surgeon General issued an open letter to the health care community on how to best optimize ventilator use during the coronavirus outbreak. The open letter stresses the need to aggressively implement the following four measures:

1. Rigorous adherence to all social distancing measures, including limitations on gatherings and travel. This is the best way to reduce infections and thus demand for ventilators.
2. Following guidelines to optimize the use of mechanical ventilators. This includes canceling elective surgeries, using equipment from state regions not experiencing outbreaks, as well as transition of anesthesia machines and other respiratory devices for use as mechanical support for those in respiratory failure from COVID-19 and other diseases.
3. Judicious, data driven requests and usage of the Strategic National Stockpile (SNS) of ventilators and equipment. To be able to allocate ventilators where they are most needed, all states must be data-driven in their requests based on the actual capacity for mechanical ventilation, including anesthesia machine conversions.
4. Increasing the capacity of the SNS through federal procurement. The SNS will receive at least an additional 20,000 mechanical ventilators by mid-May 2020.

Decontamination and Reuse of Filtering Facepiece Respirators

The CDC has issued resources on decontamination and reuse of filtering facepiece respirators (FFRs). Disposable FFRs are not approved for routine decontamination and reuse as standard of care. However, FFR decontamination and reuse may need to be considered as a crisis capacity strategy to ensure continued availability. Based on the limited research available, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat showed the most promise as potential methods to decontaminate FFRs.

FEMA Ventilator Request Process

On April 1, 2020, the Federal Emergency Management Agency (FEMA) announced its adoption of a new process to manage federal ventilator resources to ensure the ventilators are shipped to the states in the amount needed to manage the immediate crisis. FEMA is asking states and tribes to request ventilators from the SNS through their FEMA and HHS regional leadership. The request should include detailed responses to five questions:

- How many usable ventilators, ICU beds and convertible ventilators are currently available within the state/tribe?
- What is the current hospital bed and ICU bed occupancy rate in the state/tribe?
- How many new ICU beds does the state/tribe estimate it can stand-up and the number of ventilators, or FDA-approved ventilator alternatives, it can or is standing up?
- What is the decompression ability of hospitals in the state/tribe?
- How many anesthesia machines are in the state/tribe and have they been converted?

OSHA Enforcement Guidance for Respiratory Protection and the N95 Shortage

On April 3, 2020, the Department of Labor's (DOL) Occupational Safety and Health Administration issued an enforcement memo regarding respiratory protection and the N95 shortage due to the COVID-19 pandemic. The memo provides interim guidance to Compliance Safety and Health Officers (CSHOs) for enforcing the Respiratory Protection standard, 29 CFR § 1910.134, and certain other health standards, with regard to supply shortages of

disposable N95 filtering facepiece respirators. Specifically, it outlines enforcement discretion to permit the extended use and reuse of respirators, as well as the use of respirators that are beyond their manufacturer's recommended shelf life. This guidance applies in all industries.

CMS Updated Infection Control Guidance

On April 8, 2020, the Centers for Medicare and Medicaid Services (CMS) issued a series of updated guidance documents focused on infection control to prevent the spread of COVID-19 in a variety of inpatient and outpatient care settings. The guidance includes new instructions for dialysis facilities as well as hospitals, Critical Access Hospitals (CAHs), psychiatric hospitals, Ambulatory Surgical Centers (ASCs), Community Mental Health Centers (CMHCs), Comprehensive Outpatient Rehabilitation Facilities (CORFs), Outpatient Physical Therapy or Speech Pathology Services (OPTs), Rural Health Clinics (RHCs), Federally Qualified Health Centers (FQHCs), Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs), and Psychiatric Residential Treatment Facilities (PRTFs).

Additional FDA EUAs to Decontaminate N95 Respirators

On April 10, 2020, the FDA issued the second EUA to decontaminate compatible N95 or N95-equivalent respirators for reuse by health care workers in hospital settings. This EUA will support decontamination of approximately 750,000 N95 respirators per day in the U.S. The EUA was issued to STERIS Corporation for the STERIS V-PRO 1 Plus, maX and maX2 Low Temperature Sterilization Systems using the STERIS N95 Decontamination Cycle (non-lumen cycle), which uses vaporized hydrogen peroxide.

On April 12, 2020, the FDA issued an EUA to Advanced Sterilization Products (ASP) for the STERRAD Sterilization Cycles (STERRAD 100S Cycle, STERRAD NX Standard Cycle, or STERRAD 100NX Express Cycle), which uses vaporized hydrogen peroxide gas plasma sterilization. The EUA has the potential to decontaminate approximately 4 million N95 or N95-equivalent respirators per day in the U.S. for reuse by health care workers in hospital settings.

National Healthcare Safety Network COVID-19 Module

The CDC has launched new pathways for Healthcare Worker Staffing and Healthcare Supply in the National Healthcare Safety Network (NHSN) COVID-19 Model. These additional pathways are mean to enable hospitals in reporting critical information to NHSN on health care personnel shortages and COVID-19 treatment supplies shortages, such as ventilator supplies, N95 masks, and gloves.

FDA EUA for Face Masks (Non-Surgical)

On April 18, 2020, the FDA issued a face mask EUA in response to concerns relating to insufficient supply and availability of face masks for use by members of the general public, including health care personnel in health care settings as PPE, to cover their noses and mouths, in accordance with CDC recommendations, to prevent the spread of the SARS-CoV-2 virus during the pandemic. On April 24, 2020, the FDA updated and re-issued the EUA to clarify that face masks, including cloth face coverings, that are authorized by the EUA are only authorized for use by the general public and health care personnel as source control. These face masks are not authorized to be PPE, meaning they are not a substitute for filtering face piece respirators or surgical face masks. The FDA has also published an FAQ regarding its EUA for face masks (non-surgical).

FDA Surgical Mask and Gown Conservation Strategies – Letter to Health Care Providers

On April 27, 2020, the FDA issued a letter to health care providers outlining conservation strategies for surgical masks and gowns for use by health care organizations and personnel. The strategies are categorized for a range of needs and supply levels and are intended to assist health care organizations as they determine operating

procedures during the COVID-19 outbreak. They do not cover N95 respirators and are not limited to use in the care of patients infected with COVID-19.

Allocation of Scare Resources During Pandemics: Strategies for Policy Makers

On April 28, 2020, the Agency for Healthcare Research and Quality (AHRQ) noted that it will update a 2012 evidence review that identified strategies for allocating medical resources in a mass casualty event for policy makers, with a focus on pandemics, in a rapid review. AHRQ will search the databases PubMed, Web of Science, and Cochrane Database of Systematic Reviews. Included studies will focus on population, interventions and comparators, outcomes and study design, timing, and settings.

FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic

On May 7, 2020, the FDA released FAQs on EUAs for non-National Institute for Occupational Safety and Health (NIOSH) approved respirators during the COVID-19 pandemic. The page provides both general information about the devices as well as information for manufacturers, importers, and health care personnel about non-NIOSH approved respirators manufactured in China.

A letter to health care providers from the FDA also dated May 7 explains that the FDA is reissuing its EUA for non-NIOSH approved disposable filtering facepiece respirators manufactured in China to revise one of the eligibility criteria – the criterion for authorization of respirators based on review of test reports from recognized independent test laboratories submitted to the FDA by the manufacturer or importer – and accordingly removed the respirators that had been authorized under that criterion, regardless of whether they passed or failed the NIOSH testing. The FDA took this action because a number of these respirators failed to demonstrate a minimum particulate filtration efficiency of 95 percent in testing conducted at NIOSH. The list of authorized imported, non-NIOSH approved respirators manufactured in China can be found here.

Risk of Misinterpreting Hydrogen Peroxide Indicator Colors for Vapor Sterilization - Letter to Health Care Providers

On May 7, 2020, the FDA issued a letter to health care providers regarding the potential for health care facility staff that reprocess and sterilize medical devices to misinterpret the indicators used to validate the sterilization of medical devices because there is no standard indicator color to indicate a sterilized device. The FDA recommends health care facilities and reprocessing staff review the manufacturer's instructions for the particular indicator bar or card being used and know the significance of the indicator colors and enhance staff training on the indicators for all sterilization systems employed in the facility and reinforce that training with prominently displayed visual reminders.

Face Masks and Surgical Masks for COVID-19: Manufacturing, Purchasing, Importing, and Donating Masks During the Public Health Emergency

On May 11, 2020, the FDA issued an FAQ for people and organizations who are new to working with the FDA about face masks and surgical masks for COVID-19. The resource details which masks are medical devices regulated by the FDA, the difference between a mask and a respirator, and the processes surrounding the manufacturing, importation, purchasing, donation, and reuse of face masks and surgical masks for COVID-19.

Medical Gloves for COVID-19

The FDA is providing regular updates about medical gloves in the context of COVID-19, answering FAQs about the basics on medical gloves and COVID-19, shortages of medical gloves during COVID-19, manufacturing gloves for

COVID-19, importing, purchasing, or donating gloves for COVID-19, and reporting shortages or problems with gloves. To help expand the availability of medical gloves, the FDA is also providing regulatory flexibility, as described in the enforcement policy for gloves that is in effect during the COVID-19 public health emergency.

EUA in Response to Concerns Relating to Insufficient Supply and Availability of Gowns and Other Apparel

On May 22, 2020, the FDA issued an EUA in response to concerns relating to insufficient supply and availability of gowns and other apparel, such as operating-room shoe covers, for use by health care personnel as PPE for use in health care settings in accordance with DCD recommendations to protect both health care personnel and patients from the transfer of SARS-CoV-2, the virus that causes COVID-19, in low or minimal risk level situations to prevent the spread of COVID-19.

Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

On May 26, 2020, the FDA issued guidance to provide recommendations for sponsors of decontamination and bioburden reduction systems about what information should be included in a pre-EUA and/or EUA request to help facilitate FDA's efficient review of such request. This guidance provides these recommendations based on the device's intended use with respect to the level (tier) of decontamination or bioburden reduction, based on the sponsor's available data. Decontamination and bioburden reduction systems play an important role in the ongoing efforts to help address shortages of surgical masks and respirators intended for a medical purpose during COVID-19 or reduce the bioburden of surgical masks and filtering facepiece respirators (including N95 respirators) used as PPE by health care personnel for the duration of the COVID-19 public health emergency.

Use the Correct Cycle and Compatible N95 Respirators When Decontaminating Respirators with STERRAD Sterilization Systems - Letter to Health Care Providers

On May 27, 2020, the FDA issued a letter to health care providers to remind reprocessing staff in health care facilities to use the correct decontamination cycle associated with certain models of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and to only decontaminate compatible N95 or N95-equivalent respirators for reuse during the COVID-19 pandemic. The FDA recommends that reprocessing staff in health care facilities:

- Recognize that new N95 and N95-equivalent respirators, when available, are always the first choice for health care personnel.
- Confirm the N95 or N95-equivalent respirators you are decontaminating do not contain cellulose (i.e., paper-based materials). Respirators that contain cellulose are incompatible with vaporized hydrogen peroxide decontamination.
- Use only the Express cycle for the STERRAD 100NX System. Do not use other cycles available on the STERRAD 100NX System to decontaminate compatible N95 respirators.
- If your system currently does not have the Express cycle, consider the software upgrade available from the manufacturer to add this cycle to the STERRAD 100NX System at your facility.
- Use only the 100S cycle to decontaminate compatible N95 respirators with the STERRAD 100S System.
- Use only the Standard cycle to decontaminate compatible N95 respirators with the STERRAD NX System.
- Review the Fact Sheet and Instructions associated with the EUA.

FDA Enforcement Policy for Face Masks and Respirators

On May 25, 2020, the FDA issued revised guidance to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for healthcare personnel (HCP)1 for the duration of the COVID-19 public health emergency.

FDA COVID-19 Resources for Health Professionals

The FDA has created a new web page to help health professionals quickly and easily access FDA resources. This page contains links to FDA emergency use authorizations; information about personal protective equipment and other medical products for use during COVID-19.

FDA Reissues Emergency Use Authorizations Revising Which Types of Respirators Can Be Decontaminated for Reuse

In response to public health and safety concerns about the appropriateness of decontaminating certain respirators, the agency is reissuing certain EUAs to specify which respirators are appropriate for decontamination. Based on the FDA's increased understanding of the performance and design of these respirators, the FDA has decided that certain respirators should not be decontaminated for reuse by health care personnel. In addition, the FDA is also revising relevant EUAs to no longer authorize decontamination or reuse of respirators that have exhalation valves.

WH Projects Adequate Supply of PPE Through Fall

The U.S. supply of N95 respirator masks will exceed demand in each month from August through October, according to projections from the White House Supply Chain Task Force released by the office of Sen. Maggie Hassan (D-N.H.). The estimates also indicate that the country will be able to meet the demand for surgical masks, nitrile gloves, and face shields. Hassan was given permission from FEMA Administrator Pete Gaynor to release the document during a congressional hearing.

The Physiological Burden of Prolonged PPE Use on Healthcare Workers during Long Shifts

NIOSH has published a new science blog on the long, physically and mentally exhausting shifts worked by health care workers and first responders as they provide care for patients, especially during a public health emergency. According to NIOSH, when wearing PPE such as respirators there may be a physiological burden on the worker which can be exacerbated by long work hours without adequate breaks for eating, hydration and self-care.

Personal Protective Equipment EUAs

To help address concerns about availability during the COVID-19 pandemic, the FDA has issued EUAs for certain PPE products including face shields, other barriers, and respiratory protective devices such as respirators. The FDA has compiled a table of EUAs for PPE.

Webinar Series - Respirators for Health Care Personnel Use during COVID-19 Pandemic

On Tuesday, July 7, 12:00 p.m. - 1:00 p.m. ET, the FDA, along with the CDC's NIOSH and OSHA, hosted a webinar on the topic of Decontaminating Respirators for Health Care Personnel Use during the COVID-19 Pandemic.

Summary Strategies to Optimize the Supply of PPE During Shortages

The CDC has published a quick reference table summarizing strategies to optimize PPE supplies in health care settings and providing links to CDC's full guidance documents on optimizing supplies.

Decontamination Systems for PPE EUAs

The FDA has issued EUAs authorizing the emergency use of some decontamination systems to decontaminate certain respirators, recognizing that availability of PPE is an integral part of routine patient care during the COVID-19 pandemic. The FDA has published a table including authorization information for the use of decontamination systems to decontaminate certain PPE devices during the COVID-19 public health emergency.

FDA Webinar Series on the Regulation of Certain PPE for Health Care Personnel Use

The FDA has convened a series of webinars on the regulation of respirators, importing respirators, decontaminating respirators, and face masks and surgical masks for health care personnel use during the COVID-19 pandemic. This webpage contains meeting information for each webinar, including presentations, printable slides, and transcripts.

Prioritization and Allocation of Certain Scarce and Critical Health and Medical Resources for Domestic Use

In April, FEMA issued a temporary final rule to allocate certain health and medical resources for domestic use, so that these resources may not be exported from the United States without explicit FEMA approval. The rule covered five types of PPE. FEMA is proposing an extension of this rule and to modify the types of PPE covered. The notice of proposed rulemaking is open for public comment through December 31, 2020.

Manufacturing and Distributing Respirators for Health Care Use in the United States Under an Existing EUA During the COVID-19 Pandemic

The FDA has posted a new webpage providing additional information on the manufacture and distribution of respirators for health care use in the United States under an existing EUA during the COVID-19 public health emergency. It also provides links to more detailed information from the FDA, CDC, and NIOSH.

Considerations for Selecting Respirators for Your Health Care Facility

In accordance with CDC Strategies for Optimizing the Supply of N95 Respirators, the FDA has posted new information illustrating which EUA applies to specific respirator types and providing links to information on performance factors for each type to consider when selecting respirators for use in health care facilities in the United States. The FDA, in conjunction with the CDC and NIOSH, continues to evaluate respirator performance.

Webinar Series – CDC/NIOSH's Surgical N95 Respirator Guidance

On Tuesday, September 1, the FDA and the CDC's NIOSH hosted a webinar to review CDC/NIOSH's Surgical N95 respirator guidance. CDC NIOSH has begun accepting applications to implement the coordinated regulatory process for a subset of single-use disposable N95 filtering facepiece respirators that have been exempted from the FDA's premarket notification requirements. A transcript, recording, and slide presentations from the webinar will be posted here.

Respirators and Other PPE for Health Care Personnel Use During the COVID-19 Pandemic

On September 29, the FDA, along with NIOSH and OSHA, will host a webinar on Respirators and Other PPE for Health Care Personnel Use during the COVID-19 Pandemic. During this webinar, representatives from the FDA, the CDC, and OSHA will be available to answer questions. A transcript, recording, and slide presentations from the webinar will be posted here.

FDA Battelle Memorial Institute Warning Letter

On October 7, the FDA, sent a warning letter to Battell Memorial Institute regarding its Critical Care Decontamination System (CCDS). CCDS is was authorized for emergency use in decontaminating compatible N95 respirators for multiple-user reuse by health care personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of filtering facepiece respirators resulting from the COVID-19 pandemic.

FDA Reissues EUA for Certain Non-NIOSH-Approved Filtering Face-Piece Respirators Manufactured in China

On October 15, the FDA reissued the EUA for certain filtering FFRs that are manufactured in China and are not approved by NIOSH Under the June 6, 2020 version of this EUA, a respirator was authorized if it met any of three predetermined eligibility criteria. Effective immediately, the reissued EUA no longer includes the three eligibility criteria, meaning the FDA will no longer review requests nor add to the list of authorized respirators–known as Appendix A—of this EUA based on those criteria. The FDA recognizes there is still a shortage of FFRs, and to provide additional capacity as needed, the agency is continuing the EUA of respirator models that are already included in Appendix A of this reissued EUA.