Cal/OSHA Interim Guidance on COVID-19 for Health Care Facilities: Severe Respirator Supply Shortages

Note: This Interim Guidance is Subject to Change as the Situation Evolves

Summary

This guidance is for healthcare and other employers covered by Cal/OSHA’s Aerosol Transmissible Diseases (ATD) Standard (title 8 section 5199). It discusses respirator requirements for covered employers who care for suspected or confirmed COVID-19 patients when there are severe respirator shortages.

WARNING: Respirators must always be immediately available to health care workers who may be called upon to perform emergency aerosol generating procedures on suspected or confirmed COVID-19 patients.

Engineering and Work Practice Controls

Regardless of respirator availability, employers must comply with all other provisions of Section 5199 at all times, including but not limited to:

- Engineering controls to minimize the number of employees exposed to suspected and confirmed COVID-19 patients and infectious aerosols. This includes using barrier enclosures that cover a patient’s head and upper body that are authorized by the U.S. Food and Drug Administration.

- Source control procedures whenever employees are not using a respirator, including the masking of suspected and confirmed COVID-19 patients unless not possible for medical reasons.

- Work practices that minimize the number of employees exposed to suspected and confirmed COVID-19 patients and infectious aerosols.

- Training employees on additional precautions and changes to the ATD Plan when respirators cannot be obtained to care for suspected and confirmed COVID-19 patients.

- Informing employees and their representatives that the changes are only in effect until respirator supplies can be restored, and keeping them updated on status changes

- Full compliance with all respirator requirements in the ATD Standard, once respirator supply chains are restored

NIOSH-Certified Respirator Requirements

In situations where there is no critical shortage, covered employers must provide to and ensure the use of NIOSH-certified particulate respirators by all employees occupationally exposed to novel pathogens such as SARS-CoV-2, the virus that causes COVID-19.
Respiratory Protection During Severe Shortages

Where severe respirator shortages make it impossible to provide NIOSH-certified filtering facepiece respirators, employers must protect employees with the best available methods in the order listed below. A mixture of the respiratory protection methods may be used, provided higher-level protections are implemented first. Use of surgical masks cannot be used until all other respiratory protection options have been exhausted.

WARNING: Elastomeric respirators should not be used in sterile fields. Other respirators with exhaust valves should normally not be used in sterile fields, but in light of shortages, use of a respirator with a valve covered by a mask would be acceptable if PAPRs or valveless respirators are not available. Discontinue if this causes any breathing difficulties.

1.0 Use reusable NIOSH certified respirators instead of disposable filtering facepiece respirators

Elastomeric half-mask, full-facepiece respirators and powered air-purifying respirators (PAPRs) equipped with particulate filters can be disinfected and reused multiple times.

2.0 Use NIOSH certified industrial filtering facepiece respirators

On March 2, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) allowing the use of certain industrial N95 respirators in health care settings.

3.0 Allow employees to wear their own respirator if it complies with Cal/OSHA requirements

Title 8 section 3380 permits employee-provided personal protective equipment (PPE) as long as the employer ensures the PPE complies with Cal/OSHA standards and is properly maintained. Employers cannot prohibit employee-provided PPE in compliance with Cal/OSHA standards when the employer fails to provide it. Disciplinary actions against employees who wear their own PPE may subject the employer to retaliation claims under Labor Code sections 1102.5 and 6310 through 6312.

4.0 Use certain expired NIOSH certified filtering facepiece respirators

NIOSH has approved the use of certain expired filtering facepiece respirators under specific conditions. See Release of Stockpile N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Considerations for the COVID-19 Response.

5.0 Use methods to extend the use of existing stocks of filtering facepiece respirators.

5.1 Extended use of respirators

Extended use occurs when health care employees use the same respirator during encounters with several patients without removing the respirator between patient encounters. Employers must ensure that the respirators are kept clean, sanitary, and in good working order at all times.

Extended use is practiced when multiple patients are infected with the same respiratory pathogen and patients are placed together in dedicated areas (cohorting). When patients are cohorted together:
• The maximum recommended respirator extended use period is 8–12 hours.
• Respirators should be removed and carefully stored in a clean paper bag for re-donning and worn through the remainder of the shift or processed for reuse as described below in 5.2 and 5.3 before activities such as meals, restroom breaks, and other breaks.

5.2 Reuse filtering facepiece respirators that have not been disinfected
Filtering facepiece respirators can be reused without disinfection only if at least seven full days pass between each respirator use. Most (greater than 99%) of the virus that may be on the respirator should become non-viable after seven days.

Employers must establish procedures and provide effective training to ensure filtering facepiece respirators are reused safely and properly. Procedures and training must include the following:
• **CDC and CDPH** recommendations are followed when reusing respirators.
• Employees perform a user seal check every time a respirator is put on.
• Respirators are:
  o Kept clean, sanitary and in good working order at all times.
  o Protected from contamination by a face shield or facemask.
  o Protected during storage from damage or deformation, contamination, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals.
  o Inspected prior to putting them on after storage for proper function, tightness of connections, and the condition of the facepiece, straps and valves.
  o Checked for proper fit by a user seal check each time they are put on.
  o Used by one employee only, never shared (do not write on the filtering material with a permanent marker; rather, attach a label or tag securely to the respirator strap).
  o Discarded if contaminated with a hazardous substance, blood, or bodily fluids; after use during an aerosol-generating procedure or surgery; if wet or visibly dirty; when they no longer form an effective seal to the user’s face; or when breathing becomes difficult.

5.3 Use approved methods to disinfect filtering facepiece respirators
If employers decide to reuse filtering facepiece respirators without waiting seven days, the respirator must be disinfected between uses. Employers must use a procedure authorized by the FDA and demonstrate that off-gassing of disinfectant will not occur during respirator use. Ethylene oxide cannot be used. The FDA approved procedures are:
• **Battelle Decontamination System** (hydrogen peroxide)
  o Fact Sheet for Healthcare Providers
  o Instructions for Healthcare Facilities
  o Instructions for Healthcare Personnel
- **STERIS Sterilization Systems for Decontamination of N95 Respirators** (hydrogen peroxide)
  - Fact Sheet for Healthcare Providers
  - Instructions for Healthcare Facilities
  - Instructions for Healthcare Personnel
- **Sterilucent, Inc. Sterilization System** (hydrogen peroxide)
  - Fact Sheet for Healthcare Personnel
  - Instructions for Healthcare Facilities
  - Instructions for Healthcare Personnel
- **Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle** (hydrogen peroxide and ozone)
  - Fact Sheet for Healthcare Personnel
  - Instructions for Healthcare Facilities
  - Instructions for Healthcare Personnel
- **Advanced Sterilization Products STERRAD Sterilization System** (hydrogen peroxide)
  - Fact Sheet for Healthcare Personnel
  - Instructions for Healthcare Facilities
  - Instructions for Healthcare Personnel
- **Duke Decontamination System** (hydrogen peroxide)
  - Fact Sheet for Healthcare Personnel
  - Instructions for Decontamination Facility
  - Instructions for Healthcare Facilities
  - Instructions for Healthcare Personnel

Writing on the filtering material of a filtering facepiece respirator with a permanent marker voids NIOSH approval. The solvents in the marker may damage the filtering material and degrade its filtering efficiency. Use a label or tag securely attached to the respirator strap.

- Disinfection must be done in accordance with title 8 article 111 Fumigation.
- Filtering face piece respirators must be aerated for at least 4 hours after disinfection is complete to protect users from off-gassing of hydrogen peroxide and ozone. Employers should use real-time monitors to confirm there is no off-gassing from respirators.
- After disinfection, the respirator should only be used by the person who previously used the respirator.

## 6.0 Use filtering facepiece respirators certified to a foreign standard

The FDA issued EUAs for respirators certified to standards from other countries. Although not NIOSH certified, the following FDA authorized foreign certified respirators are allowed temporarily during the current COVID-19 crisis:

- April 14, 2020 **FDA EUA**
May 7, 2020 FDA EUA

The following foreign certified respirators are not allowed regardless of FDA approval:

- Respirators with ear loops. Only respirators with headbands are allowed.
- Respirators that provide less than 95 percent filtering efficiency as reported by NIOSH. See https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html for further information.

Before use, employees must be fit tested with the same make, model, style, and size of respirator that will be used.

Due to reports of counterfeit and defective respirators, employers must inspect samples from each batch of foreign standard respirators upon receipt for damage including visible holes when held up to the light, defects that limit a close seal to the face, appearance that they are counterfeit, or some other obvious problem. Provide training to employees so they can check their own respirators.

Further information on counterfeit respirators that are listed as NIOSH-approved (does not cover foreign certified respirators) is available at: https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html.

7.0 Use surgical masks only when all the above attempts to provide respiratory protection have been exhausted

For the current COVID-19 crisis, when all attempts to provide respiratory protection, including the measures listed above, are exhausted, covered employers must provide surgical masks to protect employees.

Surgical masks are not respirators. It is illegal to discipline, discharge or lay off an employee for exercising their health and safety rights. Please see Labor Code sections 1102.5, 6310 and 6311 for information on prohibited discriminatory action against employees.

When surgical masks are used by employees caring for suspect or confirmed COVID patients, the employer must also comply with all recommendations in the Centers for Disease Control and Prevention (CDC) guidelines: Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings.

Respirators, not surgical masks, must be used for the following regardless of respirator shortages:

- High-hazard tasks and aerosol generating procedures, which require use of powered air-purifying respirators whenever possible instead of a filtering facepiece respirator.
- Procedures that require close interaction with patients, such as collecting specimens by nasopharyngeal swabs or oropharyngeal swabs.
Additional Resources

- Centers for Disease Control and Prevention. Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies
- Centers for Disease Control and Prevention. Decontamination and Reuse of Filtering Facepiece Respirators using Contingency and Crisis Capacity Strategies
- National Institute for Occupational Safety and Heath, Centers for Disease Control and Prevention. Respiratory Protection During Outbreaks: Respirators versus Surgical Masks
- National Institute for Occupational Safety and Heath, Centers for Disease Control and Prevention. Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings
- National Institute for Occupational Safety and Heath, Centers for Disease Control and Prevention. Release of Stockpile N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life: Consideration for the COVID-19 Response
- National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. International Assessment Results – Not NIOSH-approved
- National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. Assessment Of Filter Penetration Performance For Non-Niosh Approved Respirators
- National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. International Respirator Assessment Request
- National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. Factors to Consider when Planning to Purchase Respirators from Another Country, Including KN95 Respirators from China (Webinar, May 7, 2020)
- Cal/OSHA. Aerosol Transmissible Diseases Standard, title 8 section 5199
- U.S. Food and Drug Administration. Protective Barrier Enclosures
  - Fact Sheet for Healthcare Providers
  - Fact Sheet for Patients
- U.S. Food and Drug Administration. Letter to Manufacturers of Imported, Non- NIOSH-Approved Disposable Filtering Facepiece Respirators
- U.S. Food and Drug Administration. Personal Protective Equipment EUAs
- U.S. Food and Drug Administration. Non-NIOSH Approved Respirator EUA FAQ
- U.S. Food and Drug Administration news release. Coronavirus (COVID-19) Update: FDA and CDC take action to increase access to respirators, including N95s, for health care personnel