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DEPARTMENT OF PUBLIC HEALTH

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Respiratory Protection and Filtering Facepiece Respirator (FFR) Fit Testing – May 27, 2020

SARS-CoV-2, the coronavirus that causes COVID-19, is transmitted by respiratory (saliva and mucus) droplets that can spread while talking, sneezing, or coughing. SARS-CoV-2 can also be transmitted via aerosolized respiratory secretions; aerosolization most often occurs during aerosol-generating procedures (AGPs). AGPs are performed in a variety of medical care settings and include CPAP, BiPAP, open suctioning, and nebulizer treatments, among others. CDC has a detailed list of these procedures.[1] Filtering Facepiece Respirators (FFRs), including N95 respirators, are necessary to protect healthcare personnel during the administration of AGPs with patients with suspected or confirmed COVID-19.

A surgical or procedure mask can protect wearers from respiratory droplets during non-AGP situations. During patient care for patients with suspected or confirmed COVID-19, in addition to a gown and gloves, eye protection (goggles or a face shield) is also required; face shields that reach below the chin offer additional protection during activities that might involve splashes or sprays. Surgical and procedure masks are also used as source control – blocking droplets expelled from the mouth and nose – preventing droplets potentially containing SARS-CoV-2 from reaching others.

Surgical and procedure masks can block droplets and small splashes, but not aerosols. The air pressure generated during AGPs breaks up secretions (saliva and mucous) into tiny particles as small as 0.3 microns in diameter, much smaller than droplets. These aerosols, which can possibly contain SARS-CoV-2, can be easily breathed deep into the lungs of healthcare staff performing AGP. A tightly-sealed respirator over the mouth and nose is needed with filtering capability to protect the health care worker's respiratory system from the tiny particles.

FFRs are just one (though key) component in the prevention of coronavirus transmission. "Engineering controls" and "administrative controls" are our first line of defense against COVID-19 exposure via aerosols:

1. **Avoid AGPs where possible.** AGPs are frequently necessary for healthcare. Sometimes a different or modified procedure that does not generate aerosols can be substituted, such as metered dose inhalers (MDI) with spacers in place of nebulizers.
2. Perform AGPs in negative pressure rooms (airborne infection isolation rooms - AIIR) to keep aerosolized coronavirus from accumulating in the vicinity of healthcare workers, reducing the likelihood of it being breathed in. Most healthcare setting don't have enough (or any) negative pressure rooms available however. Doors should be closed during AGPs to prevent contaminated air from readily spreading into the facility.
3. Restrict the number of staff in the room during AGPs, and keep the door closed during AGPs.
4. Limit staff engaged in AGPs to only those staff who have been fit tested to the make and model of respirator that the staff person is wearing during the AGPs.
5. Consider assigning only SARS-CoV-2-immune staff (staff who have recovered from COVID-19) to perform AGPs. These staff still require respiratory protection, as we do not know enough about immunity at this time.

Respirators protect the mucus membranes from droplets and aerosols. Some cover the full face, such as elastomeric respirators or powered air purifying respirators (PAPR). For healthcare personnel caring for patients with suspected or confirmed COVID-19, respirators should be worn when available, and definitely worn for AGPs. When a patient's COVID status is unknown and there is widespread community transmission of COVID-19, it is reasonable to wear a respirator when performing AGPs for that person.

Respiratory Protection Programs (RPPs) and FFR Fit Testing

The federal Occupational Safety and Health Administration (OSHA) is responsible for setting and enforcing federal laws and standards that protect workers in the workplace. OSHA sets and enforces standards for employers to establish respiratory protections programs (RPP) for their workers. RPPs include the following key elements:[2]

1. The employer has a written RPP compliant with the OSHA standard.
2. The employer has a RPP administrator responsible for developing and implementing the plan.
3. Employees at risk are identified and are covered under the employer's plan (hazard analysis).
4. Covered employers have a one-time medical evaluation to ensure they can safely wear the respiratory protection. Respirators increase the work of breathing and could be dangerous for certain individuals with certain underlying health conditions. The medical evaluation is performed by a physician, but usually only requires a written survey. A physical examination may be needed, but this is uncommon.
5. Workers are trained on the plan, their risks, and their respiratory protection equipment (e.g. N95 FFR).
6. Workers are annually "fit tested" to find a respirator make (manufacturer), model, and style that reliably filters out aerosols-size particles. The most common method of fit testing is a qualitative test using a hood and bitrex (bitter) or saccharine (sweet) aerosols to determine whether a tight seal is being achieved (and therefore, not tasted).
7. The worker practices "fit checking," which is a procedure to determine whether an effective seal has been achieved each time the respirator is donned (put on).

Any worker, regardless of job title or licensure, who performs AGPs in any setting (hospitals, nursing homes, and home health settings) should comply with OSHA respiratory protection standards. Facilities and agencies that are not implementing an up-to-date RPP are out of compliance with OSHA standards and are subject to citation by federal OSHA (private employers) or Connecticut OSHA (public-sector employers).

RPPs and FFR Use During the COVID-19 Pandemic and Time of Shortage

Severe shortages in the supply chain and a surge of patients with possible COVID-19 throughout our healthcare system is putting tremendous pressure on the availability of N95s. While the recommendation is to avoid APGs, it is understood many patients will need AGPs that cannot be avoided, such as intubation, suction, and cardiopulmonary resuscitation, especially considering the significant impact of COVID-19 on respiratory systems.

Gaps in RPPs before the COVID-19 pandemic

Prior to the pandemic, some healthcare employers did not have respiratory protection plans that met existing OSHA respiratory protection standards, or they were out of date. Filling this gap in RPPs during the pandemic puts additional strain on resources for fit testing to institute OSHA-complaint FFR use.

OSHA annual fit test waiver

Due to the COVID-19 public health emergency, on March 14, 2020 OSHA waived the annual fit testing requirement.[3] However, **OSHA has NOT waived the requirement for an initial fit test for the make and model a worker is to use**. If the employees receive new makes and models of the N95 during the shortage, and the workers are not fit tested successfully to those new makes and models, they may not be maximally protected against SARS-CoV-2 infection.

DPH Recommendations for RPP and Fit Testing

It is unlikely that all employers will be able to create an OSHA-compliant RPP with competing priorities during the coronavirus pandemic. There may not be enough time to complete the many necessary steps in the plan, considering the status of the pandemic and the immediate needs to protect workers who might be exposed to COVID-19. OSHA standards require employers to explore and implement all practical engineering and work practice controls to protect workers prior to issuing respiratory protection and other PPE. During contingency and crisis operations, employers should rely heavily on engineering and other controls if an OSHA compliant RPP is not in place.

During the Public Health Emergency, a **contingency plan** may be put in place to complete certain key elements:

1. Identify staff who have exposures to aerosols (who perform AGPs).
2. **Make changes to minimize the risk of staff to aerosols of respiratory secretions.** See page 1 for examples. Change protocols and work practices to the extent possible without compromising medical care and putting patients at risk of medical complications.
3. Perform an expedited medical check: interview staff and ask them to check with their health provider to determine if they can tolerate a respirator or if they have any underlying medical conditions that may make respirator use unsafe. Other types of respirators (e.g. elastomerics or PAPRs, if available) may be considered for those who cannot tolerate FFRs. Note that certain facial hair or facial shapes can make a successful FFR fit impossible.
4. Obtain a fit test kit and perform just-in-time fit test.
   a. Fit testers: Competency for testers must be demonstrated after training (but not necessarily certification).
   b. Fit test equipment: Standardized equipment that is available from various manufacturers, consistent with OSHA standards, must be used. The equipment includes uniquely designed and engineered hoods, aerosol pump sprayers, and test solutions (e.g., bitrex and saccharine) with standardized concentrations.
   c. Resources: Possible sources of trainers and equipment include local health departments, the Connecticut Fire Academy, occupational health consultants (private sector), and health systems/hospitals. These resources may be unavailable, especially during this crisis, and occupational health consultants may be expensive.

Crisis plan. It is possible that the resources to perform just-in-time fit tests will not be available. If AGPs are to be done, they will need to be done without fit testing. A non-fit tested respirator is potentially more protective than a standard surgical or procedure mask to prevent exposure to aerosols. Staff must be aware that performing AGPs without fit testing poses a risk to their health.

1. Staff should perform fit checks as they would with every donning. This does not address the particles that can pass through the filter, but it does at least address the significant concern about leaks around the mask that can be avoided by assiduous fit checking.
2. In the event workers need to use an N95 without a RPP in place, detailed documentation is needed that verifies the steps that were taken to examine and implement engineering and work-practice controls in an attempt to avoid exposing workers as much as possible to situations where they need to use non-fit tested N95s.

Recordkeeping is essential for either the contingency or crisis plan. Key elements include

1. Employee name
2. Hazard information: Employee's exposure (type of AGP) and **Engineering/Administrative controls (noted on page 1) undertaken to avoid use of N95 respirators that have not been fit tested in compliance with OSHA standards.**
3. Medical check information
4. Training and instructions: topics covered, fit checking instructions and demonstration of competency. It is important to document that staff were notified of the risks to them for any deviation from OSHA standards (especially if non-fit-tested FFRs are used), and that they understand and accept those risks
5. Fit test Information: Completed or not completed. For each fit test completed: name of employee, make and model of N95 that passed qualitative test.
6. Make and model of N95 each employee uses when performing APGs after fit testing (this must be the same as the make and model the employee had successfully fit tested).
7. Dates of medical check, training, and fit testing (records must be maintained 30 years)

Though just-in-time fit testing might be conducted during the COVID-19 emergency, **a full OSHA-compliant RPP should be developed and implemented as soon as time and resources permit**. It is likely we will experience one or more subsequent waves of COVID-19, and healthcare workers need to be prepared.

- Agencies and Facilities with existing RPPs who have not completed annual fit testing for 2020 should complete this as soon as possible. Issues raised by this wave of COVID-19 should be addressed through after-action analysis and incident action plans which should be incorporated into the RPP.
- Agencies and Facilities that have not had an RPP and with staff that need to use FFRs: plans should begin NOW to write and implement a RPP and to perform annual fit testing as soon as resources become available.

Approach to Foreign-Sourced Respirators such as "KN95"

The Food and Drug Administration (FDA) ensures the safety of a wide range of drugs and medical products and has an important enforcement role in determining the safety and authorizing the use of different types of personal protective equipment (including N95 FFRs). FDA works in concert with CDC's National Institute for Occupational Safety and Health (NIOSH) on the regulation of personal protective equipment to ensure its safety.

OSHA standards require NIOSH-certified masks be used. NIOSH engages in research on occupational safety and health, tests protective equipment using certain scientific standards, and certifies protective equipment. NIOSH tests various makes and models of N95 FFRs to ensure those certified can filter out fine aerosol-sized particles down to 0.3 micron in diameter. NIOSH has tested and certified use of certain N95 respirators that have exceeded their manufacturer's shelf life,[4] and NIOSH has tested but not certified respirator devices approved in other countries.[5]

Although FDA has approved the import of a subset of "KN95" from certain manufacturers for use in the US, FDA has only stated that the filter media of those KN95s is likely to be as effective as the media used for N95s. NIOSH assessments show that KN95s do not always provide the expected level of filtration, and there can be substantial variation in filtration efficiency between the devices.[6] KN95 products are NOT NIOSH-certified, however CDC's Strategies for Optimizing the Supply of N95 Respirators includes (in Crisis Alternate Strategies) the option: "Use of respirators approved under standards used in other countries that are similar to NIOSH-approved N95 respirators".[7]

> "Non-NIOSH-approved products developed by manufacturers who are not NIOSH approval holders, including only products approved by and received from China, should only be used in crisis situations when no other NIOSH-approved N95 respirator (or a listed device from one of the other countries identified within the FDA EUA) is available; they should not be used during aerosol generating medical procedures unless the alternative is a loose-fitting surgical mask or improvised device."[7]

CDC also outlines factors to consider when planning to purchase respirators from another country.[8] OSHA and CDC have agreed that the tight-seal fit around the face required of NIOSH-approved N95 respirators cannot be obtained in most cases with KN95 face masks, especially those with "ear-loop" strap designs. Non-NIOSH approved respirators, including KN95 masks, are not an acceptable substitute for NIOSH-approved N95 respirators and should never be used during aerosol-generating procedures if N95 respirators are available. Any products not recognized by FDA[9] or NIOSH[5] (including "KS95" products) should not be used for anything other than source control.

DISCLAIMER

DPH recognizes that the contingency and crisis recommendations outlined here do not comply with OSHA regulations in important ways, and that confers an unfortunate risk to workers. OSHA standards should always be rigorously followed; however, recommendations that do not comply with OSHA standards are included because situations have arisen where full compliance is not possible during this public health emergency. DPH's intent in offering this guidance is to help the employer come as close as possible to OSHA compliance when full compliance is not possible, and to lessen the risk to employees to the greatest extent possible considering the barriers to full compliance during this time.

Because the crisis and contingency recommendations in this document are not in full compliance with OHSA standards, it should be understood clearly that employers risk a citation from OSHA for any non-compliance. Considering the public health emergency, it is conceivable that OSHA will take the public health emergency into account, however DPH we cannot offer any guarantees on this.
Agencies and facilities should be ready to explain and document decisions and actions, should an OSHA compliance investigation be opened. Documentation does not exempt an entity from liability for OSHA citations, but not documenting the decision-making process is an additional violation in and of itself.

It should be clearly understood that DPH does not have standard setting, certifying, or enforcement authority in the area of workplace respiratory protection. Those responsibilities and authorities lie with OSHA, FDA, and NISOH. If there is any conflict between this guidance and OSHA, NIOSH, or FDA standards, the federal standards and enforcement supersedes DPH guidance.

References

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