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Technical Bulletin

June, 2020

Optimizing Supplies of Filtering Facepiece Respirators: U.S. Non-Healthcare Workplaces

Background

This general document is not specific to any particular airborne contaminant, including viruses and bacteria, and is intended for a sophisticated occupational audience.

During disease outbreaks such as COVID-19, recommendations are often made to provide healthcare workers with respirators at least as protective as an N95, FFP2, or similar filtering facepiece respirator (FFR). The increased use of FFRs by healthcare workers may impact the availability of these respirators in non-healthcare sectors. The purpose of this document is to help non-healthcare industrial workplaces optimize use of their supply of FFRs. During times when organizations are not able to obtain their usual respirator models or respirator type, alternative controls and respirator options may need to be considered.

Note, this document references the US Centers for Disease Control and Prevention (CDC) Interim Guidance for Conserving and Extending Filtering Facepiece Respirator Supply in Non-Healthcare Sectors. Other local or national guidance documents may be available. In the absence of other guidance, the CDC guidance highlights many considerations and best practices that may be suitable for non-healthcare employers outside of the US.

Potential Strategies for Optimizing Use of FFRs During Shortages

In the Interim Guidance for Conserving and Extending Filtering Facepiece Respirator Supply in Non-Healthcare Sectors, the CDC suggested 9 steps to help reduce reliance on FFRs in non-healthcare workplaces based on the hierarchy of controls, with steps 3-7 for consideration during periods of expected FFR shortages, and steps 8-9 for consideration during known shortages:

1) Evaluate longer term strategies for the elimination and substitution of hazards that require the use of FFRs.
2) Implement feasible engineering and administrative controls to minimize exposures requiring FFRs (control to below any recognized occupational exposure limit (OEL) etc.).
3) Use qualitative fit test methods instead of quantitative fit tests to conserve FFR supply.
4) Transition to other alternatives types of respirators, including reusable (elastomeric) half and full facepiece respirators, and powered air-purifying respirators (PAPRs).
5) After non-PPE control options and alternate respirators are exhausted, conserve FFRs by extending schedule for when FFRs are replaced, where acceptable and consistent with product user instructions.
6) Use FFRs that are beyond the manufacturer's stated shelf life for fit testing and training.
7) Use respirators approved under standards used in other countries that are similar to NIOSH-approval.
8) Use of FFRs beyond their manufacturer's stated shelf life for work operations.
9) Suspending work when no appropriate respiratory protection is available.

Prioritizing Respirator Use via Hierarchy of Controls

Prioritization of respirator use can help optimize supplies and promote availability of N95, FFP2 or similar respirators for those who need them most. Review your risk assessments and determine if respiratory protection is required for each application or task included in the site-specific respiratory protection program. Where respiratory hazard exposures are above acceptable levels, evaluate and consider implementing alternative control strategies where feasible to reduce reliance on respiratory protection, especially for processes currently requiring the use of FFRs. Where respiratory hazard exposures are at or below acceptable levels and voluntary use is allowed, consider if voluntary use will continue to be allowed during periods of significant FFR shortages. For resources on implementing a respiratory protection program, please visit the 3M Center for Respiratory Protection.

Resources to help investigate longer term engineering control strategies are available from several agencies, including NIOSH, https://www.cdc.gov/niosh/engcontrols/default.html and the British Health and Safety Executive, https://www.hse.gov.uk/pubns/guidance/index.htm.

Per the Interim Guidance for Conserving and Extending Filtering Facepiece Respirator Supply in Non-Healthcare Sectors, the CDC suggests the following steps could be considered to implement feasible engineering and administrative controls to help reduce respiratory hazards and therefore minimize or eliminate workplace exposures requiring FFRs or other respirators:

1) Shifting work to ventilated enclosures (fume hoods, biological safety cabinets, etc.)
2) Altering the process to reduce exposures, such as wet methods instead of dry
3) Rescheduling non-essential work which requires FFR use
4) Adjusting schedules to reduce the quantity of respirators needed
5) Limiting the number of workers to the minimum needed to complete a job safely, where task requires respirator use

Additionally, the U.S. Occupational Safety and Health Administration (OSHA) has recommended engineering and administrative controls that may be effective in reducing the risk of employees being exposed to the virus that causes COVID-19, including staggering schedules and adjusting work practices to allow for adequate social distancing.

For help with evaluating whether respiratory protection is needed to help protect against the virus which causes COVID-19, see 3M Technical Bulletin - Evaluating the Need for Respirators during COVID-19 Pandemic – Non-healthcare Workplaces. The US CDC, OSHA, and the American Industrial Hygiene Association (AIHA) have also created guidelines for specific industries, such as airlines, construction, food processing, manufacturing, retail, transit, and package delivery services.

Considerations for Fit Testing During a Pandemic

During periods of significant shortages, per the Interim Guidance for Conserving and Extending Filtering Facepiece Respirator Supply in Non-Healthcare Sectors , the CDC suggests that qualitative fit testing may be considered over quantitative if hazard ratios allow and where fit testing guidance permits (see applicable local or national standards and regulations). Qualitative fit testing is not destructive to the respirator used during the test and may help conserve FFRs.

As fit testing supplies may also be limited, see a summary of OSHA's position on fit testing in a pandemic, in 3M Technical Bulletin - U.S. OSHA Position on Fit Testing during COVID-19. For further information on fit testing and your local standards and regulations, contact your local 3M Personal Safety Division representative.

While completing fit testing during a pandemic, concerns may arise about additional sanitation of fit testing equipment and close contact work. See 3M Technical Bulletin - Fit Test Hygiene During COVID-19 Pandemic for additional information.

Evaluating Available Respiratory Protection Options

The US CDC and OSHA have suggested to transition respiratory protection from FFRs to other alternative types of respirators, including reusable (elastomeric) half and full facepiece respirators, and powered air-purifying respirators (PAPRs) Examples of respirator types that may be available when availability of N95, FFP2 or similar respirators is limited include:

		
Filtering facepiece respirators with alternative filter classifications such as P95, P100, FFP3	Reusable (elastomeric) respirators	Powered air-purifying respirators (PAPRs)

The following table outlines factors to help organizations determine whether these other respirator types might work within their respiratory protection program.

	Key Attributes	Key Potential Advantages	Key Potential Limitations
Other filtering facepiece respirators 	• Effectively filter particulates as well as airborne biological particles such as viruses and bacteria • Designed to fit tightly to the face • Wide variety • Certified as particu-late respirator	• Low Cost • Minimal care and maintenance	• Wearer to be clean shaven in area of the faceseal • Fit with certain safety glasses
Elastomeric respirators with particulate filters 	• Effectively filter particulates as well as airborne biological particles such as viruses and bacteria • Designed to fit tightly to the face • Multiple sizes • Cleaned and reused	• Low Cost • Reusable – longevity / replacement parts • Eye protection (Full-face only)	• Wearer to be clean shaven in area of the faceseal • Fit with certain safety glasses (half face) • Communication • Storage, cleaning, maintenance • Prescription in-facepiece eyewear (Full-face)

	Key Attributes	Key Potential Advantages	Key Potential Limitations
Powered air-purifying respirators (PAPRs) 	• Effectively filter particulates as well as airborne biological particles such as viruses and bacteria • Designed to fit over some facial hair • Variety of styles and facepiece/headtop offerings	• Wide variety of head-tops – Limited facial hair permitted for loose-fitting headgear – Eye protection (certain head-gear) – More of face visible • Low breathing burden and increased comfort for longer wear time	• Storage, cleaning, maintenance • Care, charging, and life of PAPR batteries • Weight and size • Communication
Welding PAPRs with high efficiency (HE) filters (for welding applications) 	• Effectively filter welding fumes as well as airborne biological particles such as viruses and bacteria • Auto darkening filter • Designed to fit over some facial hair • Hard hat options	• Wide variety of head-tops – Limited facial hair permitted for loose-fitting headgear – Eye protection (certain head-gear) – More of face visible • Low breathing burden and increased comfort for longer wear time	• Storage, cleaning, maintenance • Care, charging, and life of PAPR batteries • Weight and size • Communication
Supplied air respirators	• Air is supplied from a qualified source • Designed to fit over some facial hair • Variety of styles and facepiece/headtop offerings	• Wide variety of head-tops (same as above) • No replacement filters needed	• Worker is “tethered” to air supply via airline • Employer needs to certify breathing air • System can be costly to install

Filter Options

When considering filter options during shortages of FFRs, filters which provide similar or greater performance to N95s, FFP2s, KN95 can be considered. Particulate respirators are classified by their performance against local certification standards. In the US, testing and approval is done by the National Institute for Occupational Safety and Health (NIOSH). In Europe respirators are tested against the relevant European Standard and are approved to the PPE Directive 89/686/EEC or the replacement PPE Regulation (EU) 2016/425.

Filtration efficiency is one of the performance parameters evaluated for certification. Table 1 contains some of the minimum filtration efficiency requirements according to US, Europe and China standards. There are many test variables that affect performance such as type of aerosol, particle size, flow rate, whether the aerosol has been charge-neutralized to the Boltzmann equilibrium state, etc.

The US NIOSH, and other countries such as Canada, Mexico, China also categorize filters by their resistance to oil mists. Resistance to oil mists is indicated by a letter (N, R or P). N-class filters are not resistant to oil. R-class filters are oil-resistant, but they may only be used against oil mists for up to eight hours. P-class filters are oil-proof; time-use limitations against oil mists must be determined by the manufacturer. For use against oil mists, 3M recommends 40 hours of use or 30 days, whichever occurs first, for its P-class filters. European FFP2/ FFP3, and P2/P3 are all tested against oil mists, and do not have a not resistant to oil category. For a more detailed comparison of global filtering facepiece respirator regulations, see 3M Technical Bulletin - Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes.

PAPR filters provide filtration for all particulates at a 99.97% filter efficiency, including oil mists.

Table 1: Filtration Efficiency Requirements Per U.S., European, and China Standards

Standard	Classification	Filter Efficiency
NIOSH 42 CFR 84 (US)	N95/R95/P95	≥ 95%
NIOSH 42 CFR 84 (US)	N99/R99/P99	≥ 99%
NIOSH 42 CFR 84 (US)	N100/R100/P100	≥ 99.97%
NIOSH 42 CFR 84 (US)	HE (PAPR)	≥ 99.97%
EN 149:2001	FFP2 (filtering facepiece)	≥ 94%
EN 149:2001	FFP3 (filtering facepiece)	≥ 99%
EN 143:2000, EN 140:1999, EN 136:1998	P2 (elastomeric facepiece)	≥ 94%
EN 143:2000, EN 140:1999, EN 136:1998	P3 (elastomeric facepiece)	≥ 99.95%
EN12942 7.14.1	TH3 P (PAPR)	≥ 99.8%
GB2626-2006	KN/KP90	≥ 90%
GB2626-2006	KN/KP95	≥ 95%
GB2626-2006	KN/KP100	≥ 99.97%
GB 30864-2014	P95 (PAPR)	≥ 95%
GB 30864-2014	P100 (PAPR)	≥ 99.97%

Consult local standards and regulations for guidance on alternative filter options.

Extended Wear and Limited Re-Use of FFRs in Non-Healthcare Workplaces

US OSHA recently provided enforcement guidance on extended use or reuse of N95s, during a pandemic health crisis, Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic. in an April 3, 2020 memo.

The following information is taken directly from that guidance:

"In the event extended use or reuse of N95 FFRs becomes necessary, the same worker is permitted to extend use of or reuse the respirator, as long as the respirator maintains its structural and functional integrity and the filter material is not physically damaged, soiled, or contaminated (e.g., with blood, oil, paint). Employers must address in their written RPPs the circumstances under which a disposable respirator will be considered contaminated and not available for extended use or reuse. Extended use is preferred over reuse due to contact transmission risk associated with donning/doffing during reuse. When respirators are being re-used, employers should pay particular attention to workers' proper storage of the FFRs in between periods of reuse.

Users should perform a user seal check each time they don a respirator and should not use a respirator on which they cannot perform a successful user seal check. See 29 CFR § 1910.134, Appendix B-1, User Seal Check Procedures.

Employers should train workers to understand that if the structural and functional integrity of any part of the respirator is compromised, it should be discarded, and that if a successful user seal check cannot be performed, another respirator should be tried to achieve a successful user seal check.

If reuse of respirators is necessary, an appropriate sequence for donning/doffing procedures should be used to prevent contamination, and training needs to address appropriate donning/doffing procedures. See www.cdc.gov/niosh/npptl/pdfs/PPE-Sequence-508.pdf."

FFRs can be worn until they are dirty, damaged or difficult to breathe through. Note that particles will remain on the filter fibers, and therefore the respirator could become a potential source of contact contamination after use, depending on the nature of the contaminant. When removing an FFR after use, take care not to touch the filter portion of the respirator, and wash your hands immediately after handling the respirator. If it is to be reused, it should be stored in a breathable package. If not, it should be discarded with other potentially contaminated waste, according to your local regulations.

To be effective, a respirator needs to be worn correctly and worn throughout the duration of the hazardous exposure. People using a respirator will need to go to an uncontaminated area to remove the respirator for any reason, including to eat and drink.

Always read and follow the product specific *User Instructions*.

Use of FFRs Beyond Their Stated Shelf Life for Training and Fit Testing

Training activities are a way you can consider using a filtering facepiece respirator that is beyond its shelf life. Before using a respirator model, OSHA requires in 29 CFR 1910.134 that wearers must be trained on correct donning techniques for that model, including headband placement, forming noseclips, and conducting user seal checks (fit checks). While wearers are learning these procedures, each wearer will use at least one respirator. If an organization has access to respirators that are past their shelf life and are the same model as those used by workers, CDC recommends using those respirators which are past their shelf life for training and preserve those respirators within their shelf life for use as respiratory protection.

See 3M Technical Bulletin - Respirators Beyond Their Shelf Life – Considerations for more information.

Use of Respirators Approved in Other Countries

In OSHA's "Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic", OSHA requires that employers must make a good-faith effort to ensure that their workforce is provided with the most appropriate respiratory protection available to help protect against the hazards from which the workers need protection. OSHA is advising that the following priority be used to accomplish this task:

- Implement the hierarchy of controls in an effort first to eliminate or substitute out workplace respiratory hazards,

- Use engineering controls, administrative controls, and safe work practices to prevent worker exposures to respiratory hazards.

OSHA further prescribes that employers seek to acquire and use PPE "in the following order:

1) NIOSH-certified equipment; then
2) Equipment certified in accordance with standards of other countries or jurisdictions except the People's Republic of China, unless equipment certified in accordance with standards of the People's Republic of China is manufactured by a NIOSH certificate holder[6]; then
3) Equipment certified in accordance with standards of the People's Republic of China, the manufacturer of which is not a NIOSH certificate holder[6]; then
4) Facemasks (e.g., medical masks, procedure masks)."

Regulatory standards often dictate the physical and performance properties that respirator products are required to have in order to obtain certification or approval in a particular country. Standards in different countries or regions may have slightly different requirements for certification or approval of respirators.

Most regulatory standards for FFRs have similar, but not identical, test methods and respirator classes. The most commonly used respirator class descriptor is filtration efficiency. This is the ability of a respirator to filter a specific particle in a controlled laboratory test. Because of similarities in standard requirements, the following respirator classes, from various countries and regions, all have approximately 94-95% filtration efficiency, are designed to form a seal with the face, and may be considered to be functionally similar for most uses against non-oil airborne particles:

- Australia/New Zealand - P2
- Brazil - P2
- China - KN95, KP95
- Europe - FFP2
- Japan - DS2, DL2
- India - BIS P2
- Korea - 1st class
- US NIOSH - N95, R95, P95

For more information, see 3M Technical Bulletin - Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator Classes.

Use of FFRs Beyond Their Manufacturer's Stated Shelf Life for Work Operations

US OSHA has included the following statement in their April 3, 2020 guidance to enforcement officers, Enforcement Guidance for Respiratory Protection and the N95 Shortage Due to the Coronavirus Disease 2019 (COVID-19) Pandemic for non-healthcare sectors during the current COVID-19 pandemic; "When these alternatives are not available, or where their use creates additional safety or health hazards, employers may consider the extended use or reuse of N95 FFRs or use of N95 FFRs that were NIOSH-approved but have since passed the manufacturer's recommended shelf life." OSHA provides the following additional guidance:"In the event that N95s are not available and the employer has shown a good faith effort to acquire the respirators or to use alternative options, as outlined below, Compliance Safety and Health Officers (CSHOs) should exercise enforcement discretion for the use of N95 FFRs beyond the manufacturer's recommended shelf life, including surgical N95s.

- Employers may use only previously NIOSH-certified expired N95 FFRs found at www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html. Workers should be notified that they are using expired N95s.

- Purchasers and users of personal protective equipment should not co-mingle products that are past their manufacturer's recommended shelf life (i.e., expired) with items that are within their shelf life.
- Employers should visually inspect, or ensure that workers visually inspect, the N95 FFRs to determine if the structural and functional integrity of the respirator has been compromised. Over time, components such as the straps, nose bridge, and nose foam material may degrade, which can affect the quality of the fit and seal.
- Where an employer has expired N95s available from their own stored cache (i.e., not from the U.S. Strategic National Stockpile or other government stockpiles), the employer should seek assistance from the respirator manufacturer or independent lab regarding testing of those stored respirators prior to use."

See 3M Technical Bulletin - Respirators Beyond Their Shelf Life – Considerations for more information.

Use of Surgical Masks or Cloth Face Coverings in Industrial Settings

Cloth face coverings and surgical masks do not serve as respiratory protection devices and do not provide the same protection as respirators. Unlike government-approved respirators, cloth face coverings and surgical masks are not designed to seal to the users' face and are not tested to reduce wearers' exposure to airborne particulates. Tight-fitting respirators, such as filtering facepiece respirators, are designed to seal to the user's face and are tested to meet minimum filtration efficiency requirements and other government regulatory standards. While cloth face coverings and surgical masks do not serve as respiratory protection devices, they may serve other purposes. They could help wearers remember not to touch their nose and mouth, and they may help contain spit or phlegm expelled by the wearer, like covering a cough or sneeze with a face tissue.

The following video may be helpful for employees to understand the differences between respirators and surgical/procedural masks: 3M Video - Fluid Resistance Testing.

See the following 3M Regulatory Update for more information on OSHA guidance by risk category, "OSHA Respiratory Protection Program Guidance during COVID-19 Pandemic".

Closing

A range of options may be considered for non-healthcare employers in the event of limited supply of FFRs during disease outbreaks. Employers should review their risk assessments and the hierarchy of controls. Should there still be a requirement to issue respiratory protective equipment to employees, a variety of options may be available to employers to optimize use of existing supplies or to utilize alternative respiratory protection products. When all options have been exhausted, and exposures to hazards cannot be adequately controlled, a temporary suspension of work may be required.

References

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2) US Centers for Disease Control and Prevention. 2020 "COVID-19 Businesses and Workplaces: Plan, Prepare, and Respond", https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/businesses-employers.html Accessed 8 May 2020
3) Occupational Safety and Health Administration (OSHA). "Safety and Health Topics/COVID-19" https://www.osha.gov/SLTC/covid-19/ Accessed 8 May 2020
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5) Occupational Safety and Health Administration (OSHA). "Enforcement Guidance for Use of Respiratory Protection Equipment Certified under Standards of Other Countries or Jurisdictions During the Coronavirus Disease 2019 (COVID-19) Pandemic" April 3, 2020, https://www.osha.gov/memos/2020-04-03/enforcement-guidance-use-respiratory-protection-equipment-certified-under Accessed 8 May 2020

6) U.S. Centers for Disease Control and Prevention (CDC). "Strategies for Optimizing the Supply of N95 Respirators: Conventional Capacity Strategies"; reviewed Feb 29, 2020; downloaded March 30, 2020. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/conventional-capacity-strategies.html

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