Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators
Decontamination & Reuse

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A previous version of this content, Decontamination and Reuse of Filtering Facepiece Respirators, has been archived and is no longer being maintained.

CDC's Strategies for Optimizing the Supply of N95 FFRs were written to follow a continuum using the surge capacity approach in the order of **conventional** (everyday practice), **contingency** (expected shortages), and **crisis** (known shortages) capacities. N95 FFRs are meant to be disposed after each use. CDC developed contingency and crisis strategies to help healthcare facilities conserve their supplies in the face of shortages.

When the availability of N95 FFRs become limited due to an expected shortage, supplies first should be conserved using contingency strategies.

Contingency Strategies

- With extended use, N95 FFRs are worn for a prolonged period, for multiple patient contacts, before being removed and discarded (unlike conventional strategies in which an N95 FFR is used for one patient contact then discarded). This will slow the N95 FFR burn rate to help alleviate supply concerns.
- N95 FFRs are used beyond the manufacturer designated shelf-life for fit testing and training.

After attempting the above contingency strategies and there is still a known shortage of N95 FFRs and available supplies cannot meet needs based on the current burn rate, crisis capacity strategies can be used.

Crisis Capacity Strategies

- Respirators (including N95 FFRs and other types of respirators) are used beyond the manufacturer-designated shelf life for health care delivery.
- Respirators are used that are similar to NIOSH-approved respirators but are not NIOSH approved and are approved according to standards used in other countries. The performance of some internationally approved respirators was evaluated by NIOSH and the results can be found here.
- Respirators are used that have reached the manufacturer-designated shelf life but have not been evaluated by NIOSH.
- With limited reuse, an N95 FFRs is donned for one patient contact, then doffed and stored before being used for another patient contact for a limited number of donnings.
- The use of N95 FFRs and facemasks is prioritized by healthcare activity type.

This guidance provides information on how to determine if, and when, a healthcare facility should be operating under N95 FFR crisis capacity situations during the COVID-19 pandemic and how to appropriately implement limited reuse of N95 FFRs, including their reuse after decontamination.

How to determine if an N95 FFR crisis capacity strategy is needed

Because crisis capacity strategies are not compatible with US standards of care, crisis capacity strategies should only be implemented when there are known shortages of N95 FFRs and only after conventional and contingency strategies have been implemented.

The ability to implement specific crisis capacity strategies will depend on the on-hand inventory. The following flow chart can assist healthcare facility respiratory program managers in determining if their healthcare facility should operate under a crisis capacity situation. Use the Personal Protective Equipment (PPE) Burn Rate Calculator to help you plan and optimize the use of PPE.

Flowchart to Determine if an N95 FFR Crisis Capacity Strategy Is Needed

Evaluate Adequacy of Current N95 FFR Inventory and Supply Chain

Is your current N95 FFR inventory and supply chain equal to or greater than your PPE needs?

Are there N95 FFRs available from local healthcare coalitions and federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) that can cover your PPE needs based on your burn rate and ability to procure more PPE when needed?

Use the Personal Protective Equipment (PPE) Burn Rate Calculator, available here, to help you plan and optimize the use of PPE during the response to coronavirus disease 2019 (COVID-19).

Evaluate Availability of Other Respirators in Your Inventory

Are there NIOSH-approved respirators that meet or exceed the level of protection of N95 FFRs available in your inventory or from the supply chain to cover your PPE needs?

Are there NIOSH-approved respirators available from local healthcare coalitions and federal, state, and local public health partners (e.g., public health emergency preparedness and response staff) that can cover your PPE needs?

Other devices that can be used include N99, N100, P95, P99, P100, R95, R99, and R100 FFRs, elastomeric respirators, and powered air-purifying respirators (PAPRs).

The use of these devices is included in the conventional capacity strategies to conserve the supply of N95 FFRs. More information on other NIOSH-approved respiratory protective devices can be found here.

Evaluate Extended Use of N95 FFRs

Can extended use of N95 FFRs (using the same N95 FFR for more than one patient contact) cover your PPE needs based on your burn rate and ability to procure more PPE when needed?

More information on extended FFR use and other contingency capacity strategies can be found here.

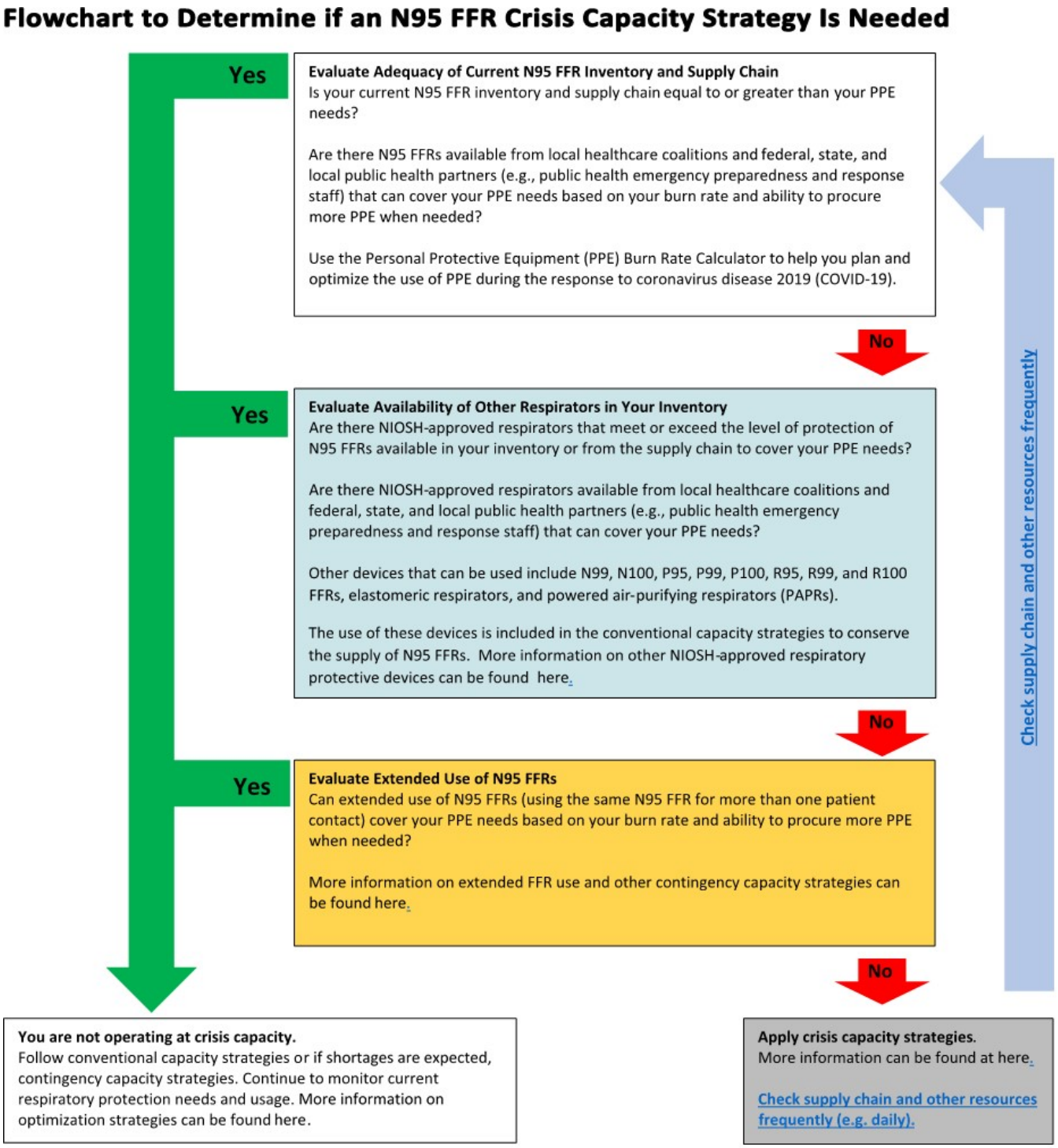
If Yes to any scenario
You are not operating at crisis capacity.

Follow conventional capacity strategies or if shortages are expected, contingency capacity strategies. Continue to monitor current respiratory protection needs and usage. More information on optimization strategies can be found here.

If No to any scenario
Apply crisis capacity strategies.

More information can be found here.

Check supply chain and other resources frequently (e.g. daily).



What is limited FFR reuse?

Limited FFR reuse refers to the practice of using the same N95 FFR or other filtering facepiece respirator for multiple encounters with patients but removing it (doffing) after each encounter [1]. This is different than extended use of an FFR where the same FFR is worn continuously for encounters with multiple patients. During limited reuse, the FFR is stored in between encounters to be put on again (donned) prior to the next encounter with a patient. Decontamination of N95 FFRs may be considered as part of limited reuse strategies. Extended use may also be considered as part of limited reuse strategies whereby an N95 FFR is worn for multiple patient contacts then stored or decontaminated before being reused. More information on implementing reuse and extended use can be found here.

The number of times that an FFR can be reused is limited by:

- Fit
- Filtration performance
- Contamination and soiling
- Damage

FFRs visibly contaminated with blood, respiratory or nasal secretions, or other bodily fluids should be discarded and not reused. FFRs that are damaged (e.g. broken straps, broken nose piece), malformed, or are unable to pass a fit check should also be discarded and not reused.

More information on limited FFR reuse can be found here.

When should limited reuse be implemented?

Limited FFR reuse is just one of several strategies available for addressing an N95 FFR crisis capacity situation when there is a known shortage of devices after conventional and contingency capacity strategies have been implemented. It should only be considered during a crisis capacity situation during a declared public health emergency. When an N95 FFR crisis situation no longer exists, limited FFR reuse should not be utilized.

Before deciding to implement FFR reuse, facilities should explore opportunities to switch to respirators that are designed to be decontaminated and reused (e.g., elastomeric respirators or powered air-purifying respirators) to reduce demand for FFRs and the need for crisis capacity strategies.

Limitations for Limited FFR reuse

Decrease in N95 FFR fit and filtration performance

NIOSH-certified N95 FFRs are designed to filter 95% of particles when appropriately fitted to the wearer's face. This means that an N95 that is not properly fitted to the face will likely give the wearer less protection. N95 FFRs are designed to be single-use devices but may be used multiple times under crisis capacity strategies. N95 FFR performance will decrease as the number of hours and number of donnings and doffings increase.

The number of times that an FFR can be reused will likely be limited by its fit because the tethering straps can become weaker or stretched after each donning. Each time an N95 FFR is donned or doffed, the integrity of the straps may be impacted. Repeated donning and doffing will result in the straps no longer being able to generate enough force to create a tight seal with the face. The resulting poor seal will allow unfiltered air to enter the N95 FFR and into the wearer's breathing zone.

CDC recommends limiting the number of donnings for an N95 FFR to no more than five per device. It may be possible to don some models of FFRs more than five times [2]. One study reported that fit performance decreased over multiple, consecutive donnings and fit varied among the different models of FFRs examined [3]. If manufacturer guidance on how many times a particular FFR can be donned is not available, the CDC recommends limiting the number of uses to no more than five per device based on published data on changes in FFR fit from a limited number of FFR models over multiple donnings.

A recent observational study conducted in a hospital emergency room during the COVID-19 pandemic found that extended use and reuse of N95 FFRs as measured by the total hours and shifts the mask was worn and the number of donnings and doffings was associated with an increase in the fit failure of the respirators. This study also showed that it

may be possible to don some models of FFRs more than five times [2]. Fit performance during limited reuse should be monitored by the respiratory protection program manager or appropriate safety personnel. Information about how to assess N95 FFR fit during limited reuse can be found below. More information on limited FFR reuse can be found here.

N95 FFR contamination and self-contamination risk

FFRs, which are typically made of multiple layers of materials, can become contaminated while filtering the inhaled air of the wearer during exposures to pathogen-laden aerosols. Studies [4-6] have shown that:

- The outer layer of the FFR, which is the layer furthest from the wearer's face, can become contaminated when exposed to virus aerosols.
- The inner layer of the FFR, which is the closet to the wearer's face, is unlikely to be contaminated.
- The electret filtering layer, which is found between the inner and outer layers of the FFR, captures most of the aerosolized virus particles.

Pathogens captured by the FFR's electret filtering layer are not readily dislodged due to the attractive forces between the particles and the electret filtering media [7]. Physical contact with the filtering layer by the wearer is unlikely due to its location within the FFR. The outer surface, the surface furthest from the wearer's face, presents the highest risk for pathogen transfer to the wearer. Wearers should practice hand hygiene before and after handling any FFR to avoid potentially contaminating the outside layer of the FFR with their hands.

Wearers of new or reused FFRs should be careful to avoid contaminating them when:

- Donning and doffing the FFR
- Adjusting the fit or placement of the FFR
- Performing a user-seal check when redonning a previously worn FFR

A limited reuse strategy to reduce the risk of self-contamination

One strategy to reduce the risk of contact transfer of pathogens from the FFR to the wearer during FFR reuse is to issue five N95 FFRs to each healthcare staff member who care for patients with suspected or confirmed COVID-19. The healthcare staff member can wear one N95 FFR each day and store it in a breathable paper bag at the end of each shift with a minimum of five days between each N95 FFR use, rotating the use each day between N95 FFRs. This will provide some time for pathogens on it to "die off" during storage [8]. This strategy requires a minimum of five N95 FFRs per staff member, provided that healthcare personnel don, doff, and store them properly each day.

As a caution, healthcare personnel should treat reused FFRs as though they are contaminated, while preventing FFR contamination prior to donning by following the precautions outlined in the reuse recommendations found here. Hand hygiene with soap and water or an alcohol-based hand sanitizer with at least 60% alcohol should be performed before donning and after touching or adjusting the FFR while in use (if necessary for comfort or to maintain fit) or after doffing. More information about ways to minimize the risks of FFR reuse can be found here.

CDC recommends limiting the number of donnings for an N95 FFR to no more than five per device. It may be possible to don some models of FFRs more than five times [2]. Fit performance during limited reuse should be monitored by the respiratory protection program manager or appropriate safety personnel. Information about how to assess N95 FFR fit during limited reuse can be found below.

If supplies are even more constrained, and five respirators are not available for each worker who needs them, N95 FFR limited reuse with FFR decontamination may be necessary.

What is FFR decontamination?

Decontamination is a process to reduce the number of pathogens on used FFRs before reusing them. It is used to limit the risk of self-contamination. Decontamination and subsequent reuse of FFRs should only be practiced where FFR shortages exist. Decontamination should only be performed on NIOSH-approved FFRs without exhalation valves.

At present, FFRs are considered one-time use products, and there are currently no manufacturer-authorized methods for FFR decontamination before reuse. Only respirator manufacturers can reliably provide guidance on how to decontaminate their specific models of FFRs. In the absence of manufacturer's recommendations, third parties, such as decontamination companies, safety organizations, or research laboratories, may also provide guidance or procedures on how to decontaminate respirators without impacting their performance.

An effective FFR decontamination method should reduce the pathogen burden, not harm the fit or filtration performance of the FFR, and should present no residual chemical hazard. NIOSH reviewed the literature on decontaminating FFRs because of these considerations. NIOSH found that, **as of April 2020, ultraviolet germicidal irradiation, vaporous hydrogen peroxide, and moist heat have shown the most promise as potential methods to decontaminate FFRs.**

On March 29, 2020, the U.S. Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a process to decontaminate, and subsequent EUAs have been issued. Healthcare facilities should check the FDA Emergency Use Authorizations website for the most up-to-date information.

The effectiveness of using any of the methods mentioned in this guidance should be explored with specific FFR models and with the manufacturer and, if needed, third party expert input and support to better understand the impact on respirator performance, including filtration and fit, and structural integrity, including integrity of head straps and other parts.

Employers should be able to demonstrate effectiveness of any decontamination methods used against the likely contaminants (i.e., pathogens) of concern including SARS-CoV-2. Employers should also ensure that any decontamination methods used, including those for which an FDA EUA has been issued, do not produce additional safety hazards (e.g., electrical arcs resulting from placing FFRs with metal parts into microwaves), or that workers are adequately protected from those hazards through appropriate engineering and administrative controls, safe work practices, and personal protective equipment.

Decontamination might cause poorer fit, reduced filtration efficiency, and reduced breathability of disposable FFRs as a result of changes to the filtering material, straps, nose bridge material, or strap attachments of the FFR. Decontamination may produce chemical inhalation risks and should be evaluated for off-gassing.

While decontamination and subsequent reuse of FFRs void the NIOSH approval and are not permitted under OSHA's respiratory protection standard during normal conditions of use, these options may need to be considered during a crisis capacity situation when FFR shortages exist.

Considerations before deciding to decontaminate FFRs

FFR Decontamination is one strategy available during an N95 FFR crisis capacity situation

Other strategies to conserve supplies of respirators during an N95 FFR crisis capacity situation should be utilized first

before FFR decontamination is implemented. Other crisis capacity strategies to conserve supplies of respirators can be found here.

- Use respirators identified by CDC as performing adequately for healthcare delivery when beyond their manufacturer-designated shelf life.
- Using respirators that are similar to NIOSH-approved respirators and not NIOSH approved but that are approved according to standards used in other countries.
- Implement limited reuse of N95 FFRs by one healthcare staff member for multiple encounters with different patients, but have the staff member remove it after each encounter.
- Prioritize the use of N95 FFRs and facemasks by activity type with and without masking symptomatic patients.

N95 FFR decontamination will not increase the number of times or hours that an FFR can be worn

Decontamination of an N95 FFR inactivates viruses and bacteria on the device, but does not restore the N95 FFR to "new" performance. Decontamination studies have evaluated the effect of the decontamination process on the fit and filtration performance of N95 FFRs; however, these studies did not consider the likelihood that N95 FFRs worn by healthcare personnel are likely donned and doffed multiple times before undergoing decontamination. N95 FFR performance will decrease as the number of hours and number of donnings and doffings increase. Repeated decontamination and handling of FFRs can damage the fit and filtration performance of N95 FFRs. Fit performance during limited reuse, including decontaminated FFRs, should be monitored by the respiratory protection program manager or appropriate safety personnel. Information about how to assess N95 FFR fit during limited reuse can be found below.

The effects of N95 FFR decontamination may vary by model

Only respirator manufacturers can reliably provide guidance on how to decontaminate their specific FFR models. In the absence of manufacturer's recommendations, third parties may also provide guidance or procedures on how to decontaminate respirators without impacting respirator performance.

Decontamination methods should be evaluated **for each FFR model** currently being used under a facility's respiratory protection program. The method should be evaluated, or data should be made available from third party decontaminators, that demonstrate:

- The method can inactivate viruses and bacteria.
- Filtration performance is not affected after each cycle of decontamination.
- Fit performance of the respirator is not affected after each decontamination cycle.
- Off-gassing of decontamination chemicals falls below the permissible range.

NIOSH has evaluated the filtration and fit performance for some models of N95 FFRs using a variety of decontamination methods. These assessments were made on new, unused respirators that had been decontaminated and did not include the efficacy of the method for inactivating viruses or bacteria. Results of these assessments are available here.

Decontaminated FFRs should be monitored and tracked

There are approximately 500 NIOSH-certified N95 FFR models, and each one has its individual set of construction materials and characteristics, including surface area and "dead space." It is important to check with the manufacturer to make sure the respirator used has been evaluated to determine if the decontamination method is appropriate: Just because a method is effective for one respirator does not mean it will be effective for a different respirator.

Healthcare facilities using multiple FFR models should develop a process to ensure appropriate decontamination methods are used for their current FFR models. This process should include several pieces of data related to the decontamination process, FFR use, and tracking of any adverse reactions such as skin irritations, headaches, and respiratory distress. This process should include:

- A listing of current FFR models in use and the ability of each model to be decontaminated using the current decontamination method
- The number of FFRs available and a plan for decontamination that will not result in additional shortages
- The number of cycles each FFR has been decontaminated
- Collection of data related to any adverse effects such as skin irritation, smells or off-gassing, physiological complaints such as headaches or respiratory distress, etc.
- Sampling decontaminated respirators to measure filtration efficiency and fit performance
- Frequent evaluation of fit performance of decontaminated FFRs

All employees should receive proper training on how to reuse FFRs including how to decontaminate FFRs if implemented

Facilities should provide healthcare personnel with required education and training, including having them demonstrate competency when donning and doffing, with any PPE ensemble that is used to perform job responsibilities, such as provision of patient care. Employees should be properly trained to reuse FFRs and use decontaminated FFRs. Training should address the following:

- The risks of self-contamination during reuse
- Limitations of decontaminated FFRs
- How to properly store and label FFRs
- How to properly don and doff FFRs
- When to discard FFRs
- How to perform a user seal check

More information on how to reuse FFRs can be found here.

How to assess the performance of reused FFRs including decontaminated FFRs

FFR wearers should perform a user seal check each time they don an FFR. More information about conducting a user seal check can be found here and may be included with the user instructions provided by the manufacturer. For FFRs that have been donned more than 5 times, FFR program managers should consider implementing a qualitative FFR fit performance evaluation. A qualitative FFR fit performance evaluation is not the same as a qualitative fit test, but can be conducted using the same agents and exercises used for qualitative fit testing. A qualitative FFR fit performance evaluation is an abbreviated evaluation where each exercise is conducted for 15 seconds [9]. If the wearer detects the test agent while performing these exercises, the fit of the reused FFR may be compromised. When the availability of pre-made fit test solutions are limited, many can be prepared using commercially available chemicals following the instructions here.

A qualitative FFR performance evaluation is conducted as follows:

1. The FFR wearer should don their previously used FFR (for reuse) or be wearing an FFR (extended use).
2. The wearer dons the test hood.

3. The test agent is released within the hood (add more test agent every 30 seconds).
4. The wearer performs 7 exercises for 15 seconds each:
    a. Breathe normally
    b. Breathe deeply
    c. Move head side to side
    d. Move head up and down
    e. Talk
    f. Bend over at the waist
    g. Breathe normally

When to stop using crisis capacity strategies and return to normal operations

As soon as new supplies can meet the projected demand, all reuse and decontamination of respirators should be discontinued. FFRs should only be reused when operating at crisis capacity due to the inability of FFR supplies to meet the burn rate. Current rates of usage and FFR availability should be monitored daily. Additionally, supply chain options should be checked regularly to determine if more FFRs or other suitable forms of respiratory protection can be acquired. Other devices that can be used include N99, N100, P95, P99, P100, R95, R99, and R100 FFRs, elastomeric respirators, and powered air-purifying respirators (PAPRs). The use of these devices is included in the conventional capacity strategies to conserve the supply of N95 FFRs. More information on the use of other NIOSH-approved respiratory devices can be found here. FFR decontamination should only be implemented as a crisis capacity strategy during a declared public health emergency and should not be practiced when other devices are available or there are enough N95 FFRs to exit crisis capacity strategies. Facilities wishing to incorporate respirators that can be decontaminated and reused into their long-term strategy should consider using reusable respirators such as elastomeric respirators or PAPRs.

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