Technical Data Bulletin

OH&ESD

#176 Pandemic Influenza Preparedness Planning: Practical Considerations for Respirator Use in a Health Care Setting

Published: March, 2007

Background

On October 17, 2006, the Centers for Disease Control and Prevention (CDC) issued a guidance document titled "Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic."[1] The intent of the guidance is to provide health care operations a framework to assist in the planning process for use of surgical masks and respirators during an influenza pandemic. The CDC recommendations apply to settings where pandemic influenza patients may receive health care services such as hospitals, emergency departments, out-patient facilities, residential care facilities, emergency medical services, and home health care delivery.

According to the CDC, lack of immunity to a pandemic influenza strain and potential for a high case-fatality rate makes it advisable to take additional precautions beyond those typically recommended during a seasonal influenza outbreak. Use of respiratory protection during an influenza pandemic is one of those additional precautions. The primary consideration for use of respiratory protection in a health care setting during an influenza pandemic is the reduction in exposure needed or desired for the situation. For most types of patient care a "N95" respirator may be used. However, the CDC has described certain activities as "high risk" due to the likelihood of generating infectious respiratory aerosols and indicates a higher level of respiratory protection may be considered.[1] Examples of high risk activities as defined by the CDC include aerosol generating procedures such as endotracheal intubation, nebulizer treatment, and bronchoscopy performed on patients with confirmed or suspected pandemic influenza; emergency intubation or cardiac pulmonary resuscitation of a confirmed or suspect pandemic influenza patient; and providing direct care of a patient with confirmed or suspected pandemic influenza-associated pneumonia due to the potential for the individual to produce an increased amount of respirable infectious particles when they cough. The CDC also indicates that it would be prudent for health care workers to wear respiratory protection for other direct care activities involving patients with confirmed or suspected pandemic influenza. An example cited includes housekeeping staff that may enter rooms of influenza patients to mop floors or clean patient equipment.

In the guidance document, several types of respiratory protection are referenced as potentially utilized by health care workers during a pandemic situation. The purpose of this technical data bulletin is to describe the types of respirators available and considerations for use in a health care setting during an influenza pandemic. It is important to remember that use of respirators is only one of many strategies to help reduce exposure to biological hazards. Since no respirator will completely prevent the inhalation of all particles, use of respirators may help reduce, but not eliminate, the risk of exposure, infection, illness or death. Reading and understanding the CDC guidance document prior to selecting and using respiratory protective equipment is recommended.

Types of Respiratory Protection

A respirator is a protective device designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.[2] In a pandemic influenza scenario, the hazards are airborne infectious biological particles, or bioaerosols. Bioaerosols can be filtered by respirators with particulate filters.[3-7] For use in the United States, respiratory protective equipment must be certified by the

National Institute for Occupational Safety and Health (NIOSH), the federal agency tasked with testing and certification of respirators. NIOSH has nine approval categories for respirators designed to reduce exposure to particles.

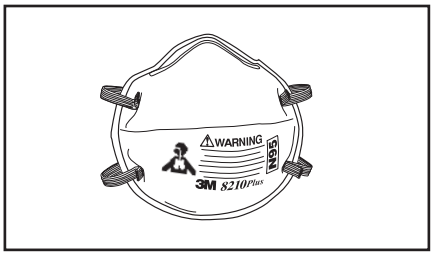
The NIOSH approval categories for particulate filters include N95, N99, N100, R95, R99, R100, P95, P99 and P100 and, for powered air purifying respirators (PAPRs), a high efficiency (HE) filter designation similar in filter efficiency to the 100 level category. The 95, 99 and 100 (99.97) refer to the percentage of particle filtration efficiency when tested according to the NIOSH laboratory test methods.[2] An N-certified respirator can only be used in environments that do not contain oil aerosols. R and P-certified respirators can be used in both oil and non-oil containing environments. Healthcare settings normally do not contain oil aerosols and in most healthcare applications respirators from any of the approval categories and filtration efficiencies could be selected to help reduce exposure to bioaerosols.

It should be noted that penetration of particles through the filter is only one of the possible sources of respiratory exposure. Other potential sources such as face seal leakage, improper maintenance, or not wearing the respirator when necessary may contribute more to exposure than filter penetration. Each of these must be addressed and controlled. Wearers must be trained how to properly maintain their respirators and the importance of wearing them during all times of exposure.

It is also important to emphasize that respirators only reduce exposure. Types or classes of respirators are given an "assigned protection factor" or APF. APF is the expected ability of the respirator to reduce exposure when used according to an effective respiratory protection program. For example, an APF of 10 means that a respirator is expected to reduce exposure by a factor of 10 (or 90%) when properly selected, maintained, fitted and worn. Therefore, even if a filter is 100% efficient, the expected amount of exposure reduction would be limited by the APF. Because no respirator will prevent the inhalation of all particles, they cannot eliminate the risk of exposure, infection and illness.

Use of respirators in the workplace, including health care facilities, is regulated by the Occupational Safety and Health Administration (OSHA) and requires a complete respiratory protection program including fit testing, training and medical evaluation.[8]

Filtering Facepiece Respirator
A particulate filtering facepiece respirator has an integral part, if not all, of the respirator comprised of the filter material. This type of respirator fits from the nose to just beneath the chin and is called a half facepiece respirator. OSHA has given half facepiece respirators an APF of 10.[9] Filtering facepiece respirators are available with or without exhalation valves. Some filtering facepiece respirators have also been cleared by the FDA and these respiratory protective devices are classified as N95 surgical respirators.

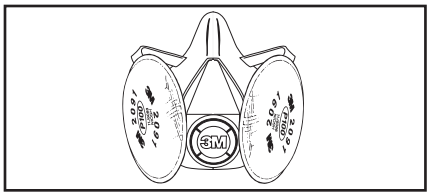


3M™ Filtering Facepiece Respirator Without Exhalation Valve

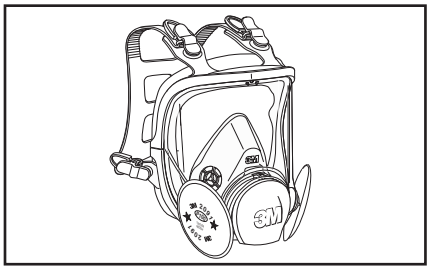
3M™ Filtering Facepiece Respirator With Exhalation Valve

Elastomeric Respirator
An elastomeric respirator's facepiece is normally made of an elastomer or "rubber-like" material. The appropriate filter is then attached to the facepiece and in most styles can be removed and replaced. Elastomeric respirators are available as half facepiece and full facepiece respirators. A half facepiece respirator fits from the nose to just beneath the chin and has an OSHA APF of 10.[9] A full facepiece respirator fits from the upper portion of the forehead to just beneath the chin.

Full facepiece respirators have an APF of 10 when qualitatively fit tested and an APF of 50 when quantitatively fit tested.[9] A full facepiece respirator provides additional area for the face to facepiece seal compared to a half facepiece respirator and hence can offer a higher level of protection, or greater reduction in exposure. The particulate filters for elastomeric respirators are also tested and certified per the NIOSH approval categories described above.



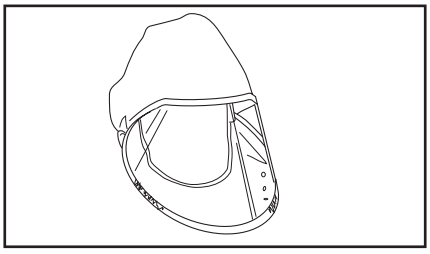
Half Facepiece Elastomeric Respirator



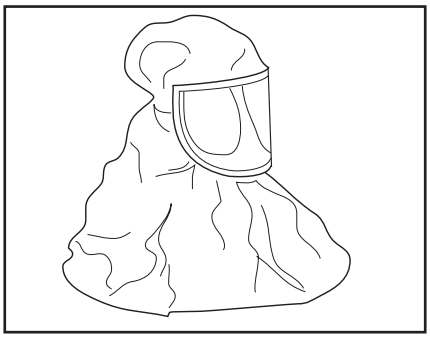
Full Facepiece Elastomeric Respirator

Powered Air Purifying Respirator (PAPR)

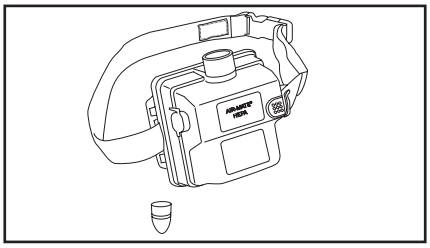
A powered air purifying respirator relies on a battery operated motor blower, rather than the person's lungs, to draw air through the filter material. The motor blower and filter are often attached to a belt and worn at the waist. The filtered air is then delivered through a "breathing tube" to a loose-fitting facepiece or hood worn by the individual. A loose-fitting facepiece is designed to seal loosely and forms a partial seal with the face. A PAPR used with a loose fitting facepiece has an OSHA APF of 25.[9] A hood, on the other hand, completely covers the head and neck and may also cover a portion of the shoulders. A PAPR used with a hood can achieve an OSHA APF of up to 1000.[9] PAPRs, where the air is flowing out from the respirator, make it more difficult for particles to enter the breathing zone and offer a higher level of protection than a half facepiece respirator. PAPRs suitable for particles such as bioaerosols carry a NIOSH high efficiency (HE) approval, similar in filter efficiency to the 100 level categories described above.



3M™ Loose-fitting Facepiece for Powered Air Purifying Respirator



3M™ Hood for Powered Air Purifying Respirator



3M™ Motor Blower with Enclosed Filter

Additional Considerations for Use

Fit Testing

Respirators which rely on a face to facepiece seal require fit testing per OSHA regulations. This requirement includes the filtering facepiece respirators as well as the half and full facepiece elastomeric respirators. Respirators which do not rely on a seal to the face, such as PAPRs with loose-fitting facepieces and hoods do not require fit testing.

Fit test methods that are acceptable to OSHA are listed in Appendix A of 1910.134. These include qualitative fit test methods such as the saccharin or bitter aerosol methods or quantitative fit test methods where a device gives a numerical measurement of the fit.

Employees with facial hair cannot wear respirators which rely on a face to facepiece seal such as the filtering facepiece respirators and the half and full facepiece elastomeric respirators. This needs to be considered during respirator selection. A PAPR with a hood can be used by most employees with facial hair, such as a full beard. A PAPR with a loose-fitting facepiece can be used with limited facial hair, as long as the facial hair does not come between the face and the respirator faceseal.

The need to fit test individuals also involves logistical considerations. During a pandemic event, it may be necessary to utilize staff that may not have been previously fit tested on filtering facepiece

or elastomeric respirators. From a preparedness perspective, the preferred scenario is that all potentially affected employees will have been properly fit tested and trained in preparation for such an event well in advance of a potential occurrence. If this has not transpired, logistical considerations could include a plan to fit test these employees at the time of an event (prior to use of the respirator) as well as potential use of PAPRs with loose fitting facepieces or hoods. Training, medical evaluation and all other requirements of the respirator standard are, however, required for use of PAPRs.

It is also important to note that the CDC encourages measures to minimize the number of personnel who come into contact with suspected or confirmed pandemic influenza patients in order to minimize the number of workers exposed as well the demand for respirators.

Reuse of Respiratory Protection

Filtering Facepiece Respirators:
Any reuse of a filtering facepiece respirator during a pandemic event is restricted to use by a single person, not to be shared between employees and only done if absolutely necessary. In its guidance document the CDC indicates that a disposable N95 respirator (i.e. a filtering facepiece respirator) should be discarded once worn in the presence of a patient with pandemic influenza. They also site an Institute of Medicine (IOM) suggestion that if it is necessary to reuse a disposable N95 respirator, precautions should be taken to cover the respirator with a medical mask or protective faceshield, to store the respirator carefully between uses and to wash hands before and after handling the respirator and the mask or faceshield used to cover the respirator.[10] Filtering facepiece respirators are not designed to be washed. Storage of filtering facepiece respirators in re-sealable plastic bags may not be appropriate due to moisture after use and the potential for microorganism survival on filters. Paper bags have been utilized in some healthcare facilities as a storage container.

Elastomeric Facepiece Respirators and PAPRs:
In Appendix B of the guidance document, the CDC explains that elastomeric respirator facepieces and PAPRs can be "cleaned, disinfected, and fitted with new filters for reuse." They do caution that care must be taken to prevent exposure of the wearer to any infectious material that may be on the outside surface of the respirator. The CDC directs facilities to follow the manufacturer's instructions for cleaning PAPRs and the assumption is that would be true for elastomeric respirator facepieces as well. Used filters should be discarded. Filters and cartridges cannot be washed and reused.

Cleaning of 3M elastomeric respirators is often accomplished by removing the filters and then immersing the facepiece, loose-fitting facepiece, or hood in warm water with a neutral detergent and scrubbing with a soft brush if needed. Solvents and strong detergents may damage 3M respirators and respirator components and should not be used for cleaning. 3M half and full facepieces can be sanitized by soaking in a quaternary ammonia disinfectant, sodium hypochlorite, or other disinfecting agent. Hoods and loose-fitting facepieces can be wiped with similar disinfecting agents. The sodium hypochlorite solution used to sanitize respirators, 1 ounce (30ml) of household bleach in 2 gallons (7.5L) of water, may be less concentrated than the sodium hypochlorite solution used in a health care setting. The directions that accompany the quaternary ammonia solutions or other disinfecting agents should be followed, including mixing instructions and the appropriate contact time. Contact times of disinfecting agents may be several minutes in duration and should be included in the logistics of cleaning and maintenance.

Although elastomeric facepieces and components can be submerged, this is not true for many PAPR components such as motor blowers, batteries and breathing tubes that have a "muffler" inside for sound dampening. Submersion of these components in any liquid will likely result in damage and instead should be wiped with a disinfecting solution. One exception is the motor blower of the 3M GVP PAPR, which is designed to be sealed or capped

and then submerged for cleaning. Filters and cartridges should not be submerged or washed.

In an industrial setting, once an elastomeric respirator or a PAPR with a loose-fitting facepiece or hood has been cleaned and sanitized per the user instructions, it is returned to inventory and can be used by another person. Although sharing disinfected respirators between employees is not specifically addressed by the CDC, it is an additional factor for consideration in the event of an influenza pandemic.

Inspection
All respirators, including brand new respirators, and components must be inspected prior to each use and any damaged or deteriorated components replaced. Refer to the User Instructions provided with each respirator system for specific cleaning, sanitizing, inspection and maintenance procedures.

Storage
The CDC did not provide guidance regarding storage; however, OSHA requires that respirators be stored in an area free from potential contamination and in a method that will not cause any damage. Elastomeric respirators and PAPRs dedicated to specific individuals should be identifiable to the person (e.g. write name on headband of respirator, store in a specified location, etc.)

Maintenance
Filtering facepieces respirators have no replaceable parts and are considered disposable. Elastomeric facepiece respirators and PAPRs, however, do have parts and filters that need to be available when a replacement is needed. Planning for a pandemic event should include not only the respirator system but any replacement parts and filters that may be required. In addition, PAPR systems operate on a battery which requires a battery charging and maintenance program be in place or detailed in preparedness plans. For guidance on battery charging and maintenance of 3M PAPRs refer to 3M OH&ESD Technical Data Bulletin 151 titled "PAPR Management and Planning for First Responders."

Infection Control
CDC's guidance indicates if a respirator that provides protection from splashes of blood or body fluids is needed, an FDA-cleared surgical respirator should be selected. Currently, only filtering facepiece respirators have been cleared by the FDA as surgical respirators.

An additional infection control consideration is that PAPRs and respirators with exhalation valves allow the air, including the person's exhaled breath, to be released into the environment. If worn by an infected person, these respirators would not prevent transmission of a virus from the wearer. PAPRs and respirators with exhalation valves should not be used in healthcare environments requiring a sterile environment such as the operating room.

Ability to Perform Job Duties
Selection criteria may also include which style respirator will be least likely to affect the person's ability to perform job duties. The ability to communicate to co-workers and patients is perhaps least affected by filtering facepiece respirators. Speaking while wearing elastomeric facepiece respirators may sound slightly more muffled. PAPRs also have some noise associated with the motor blower which may interfere with the ability to hear while using a stethoscope. It is not recommended to use a stethoscope with a hood as the stethoscope tubing may interfere with the sealing area.

Summary
Many aspects of respirator use and selection must be considered while planning for the possibility of a pandemic influenza event.
Table 1 is a summary of the considerations described in this document. Preparedness planning may require a combination of approaches and perhaps even selection of a variety of respiratory protection products. Respirator use in a health care setting, as in any occupational setting, must be in compliance with a complete respiratory protection program in accordance with OSHA regulations (29 CFR 1910.134).

Table 1: Summary of Consideration

Consideration	Filtering Facepiece Respirator	Elastomeric Half Facepiece Respirator	Elastomeric Full Facepiece Respirator	PAPR with Loose-fitting Facepiece	PAPR with Hood
Reduction in Exposure Desired	APF of 10	APF of 10	APF of 50 (if quantitatively fit tested)	APF of 25	APF of 1000 (consult manufacturer)
Requires Fit Testing	Yes	Yes	Yes	No	No
Can be Used with Facial Hair	No	No	No	Limited facial hair	Yes
Reusable	No	Yes, with cleaning and disinfection. Dispose of used filters	Yes, with cleaning and disinfection. Dispose of used filters	Yes, with cleaning and disinfection. Dispose of used filters	Yes, with cleaning and disinfection. Dispose of used filters
Maintenance Required	No	Yes	Yes	Yes	Yes
Batteries to Charge	No	No	No	Yes	Yes
Exhaled Breath Released into Environment	No (without valve), Yes (with valve)	Yes	Yes	Yes	Yes
Compatibility with stethoscope	Yes	Yes	Yes	Yes, but noise from motor blower may interfere	No

References

1. Centers for Disease Control and Prevention. Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic; October 2006.
2. "Approval of Respiratory Protective Devices," *Code of Federal Regulations Title 42*, Part 84, 1996. p.533.
3. Chen, S.K., Vesley, D., Brosseau, L.M., and J.H. Vincent. Evaluation of single-use masks and respirators for protection of health care workers against mycobacterial aerosols. *Am. J. Infect. Control* 22:65-74; 1994.
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7. Willeke, K., Qian, Y., Donnelly, J., Grinshpun, S.A. and V. Ulevicius. Penetration of airborne microorganisms through a surgical mask and a dust/mist respirator. *AIHA Journal 57*; 348-355; 1996.
8. "Respiratory Protection," *Code of Federal Regulations Title 1910,* Part 134. 2005. pp. 419-444.
9. "Assigned Protection Factors," Federal Register 71:164 (August 24, 2006) pp. 50122-50192.
10. Institute of Medicine. Reusability of facemasks during an influenza pandemic: facing the flu. Report of the Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic. Washington, D.C.: The National Academics Press, 2006. http://www.nap.edu/catalog/11637.html

Additional Resources:

CDC Website: www.cdc.gov
OSHA Website: www.osha.gov

3M OH&ESD Technical Data
- Bulletin #174, March 2007, Respiratory Protection Against Biohazards
- Bulletin #151, March 2002, PAPR Management and Planning for First Responders

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