



May 3, 2009

Respiratory Protection for Exposures to the H1N1 Influenza Virus

Frequently Asked Questions (FAQs) for the General Public

3M has received a number of inquiries regarding the selection of appropriate respirators for use by the general public against potential exposures to the H1N1 influenza (previously referred to as “swine flu”) virus. Following are responses to many of the most commonly asked questions. It is important to note this FAQ is not a substitute for the guidance of the Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO). Please frequently consult their websites for the most current information and infection control procedures regarding H1N1 influenza.

CDC: <http://www.cdc.gov/h1n1flu/>

WHO: <http://www.who.int/en/>

What does CDC recommend for respiratory protection against the virus that causes H1N1 influenza for the General Public?

The CDC updated the guidance “Caring for a Sick Person in Your Home” on May 1, 2009. In regards to respiratory protection use, the CDC suggests that those caring for sick persons wear an N95 disposable respirator during close contact with the sick person including during the administration of respiratory treatments. Those caring for sick individuals should review the guidance carefully to understand all CDC recommendations.

On April 27, 2009 the CDC updated their guidance issued “Facemask and Respirator Use.” In regards to respiratory protection use, the CDC suggests that respirators should be considered, along with other measures, for use by individuals for whom close contact (within six feet) with an infectious person is unavoidable. The CDC mentions that this can include selected individuals who must care for a sick person (e.g., family member with a respiratory infection) at home. They state that unless otherwise specified, “respirator” refers to an N95 or higher filtering facepiece respirator certified by the U.S. National Institute for Occupational Safety and Health (NIOSH). The complete guidance should be reviewed carefully to understand all CDC recommendations.

A copy of the CDC documents can be accessed at <http://www.cdc.gov/H1N1flu/>

Can a European or Australian/New Zealand or other approved respirator be used for H1N1 flu?

The World Health Organization (WHO) has not issued guidance for respirator use for those in the general public who are exposed to the H1N1 influenza virus. At the present time, the Centers for Disease Control and Prevention’s (CDC) guidance states that a National Institute for Occupational Safety and Health (NIOSH)-certified N95 particulate respirator, or one with an equivalent or higher level of protection, should be used in by the general public and in community settings in specific situations.

At this time, we are not aware of any recommendations for general public use of respirators approved by other government agencies. The World Health Organization is recommending European CE approved particulate respirators (EN149:2001 approved FFP2 or FFP3 disposable respirator or EN143:2000 P2 filters or respirators with higher levels of protection), for use outside the United States to help reduce health care worker's exposures to airborne organisms in certain situations.

The World Health Organization, the CDC and your local health authority should be referenced for the most current information and guidelines.

What is a type N95 respirator?

N95 is one of nine classifications for National Institute for Occupational Safety and Health (NIOSH) certified particulate respirators.

Can respirators protect you from the virus that causes H1N1 influenza?

It is probable that H1N1 influenza is spread from person to person in several ways. A particulate respirator is just one of several preventative measures that can be used to help reduce exposure to the virus that causes H1N1 influenza. The CDC has recommended frequent hand washing, following good respiratory hygiene practices, not sharing cups and utensils and applying routine cleaning and disinfection practices used during influenza season. The CDC is recommending that ill individuals stay home from work and school to help avoid the spread of infectious diseases.

Particulate respirators are designed to help reduce exposures of the wearer to airborne particles. A particulate respirator's ability to help reduce wearer exposure to airborne germs depends on the filtration capabilities of the materials it is made of and on how well it fits the wearer. It is important to select a respirator that is government approved since it will be tested for filtration efficiency (refer to questions above). It is also important to follow all directions on how to use and put on a respirator. Putting the respirator on correctly means more of the air you breathe goes through the respirator filter. Although a respirator can help reduce the number of germs you breathe, it cannot eliminate the breathing in of all germs in the air and does not eliminate the possibility of contracting infection, illness, or disease.

Can 3M's Respirators For Use by the General Public in Public Health Medical Emergencies, be used to help reduce exposures to biological agents?

Yes. A respirator is just one of several preventative measures that can be used to help reduce exposure to airborne viruses. The CDC has recommended frequent hand washing, following good respiratory hygiene practices, not sharing cups and utensils and applying routine cleaning and disinfection practices used during influenza season. The CDC is recommending that ill individuals stay home from work and school to help avoid the spread of infectious diseases.

The US FDA has cleared two 3M respirators for use by the general public to help reduce wearer exposure to airborne germs in public health medical emergencies. These respirators are NIOSH N95 certified filtering facepiece respirators. Information regarding these respirators and their proper use can be found at the following website.

<http://multimedia.3m.com/mws/mediawebserver?66666UuZjcFSLXTtNXtc5XM2EVuQEcuZgVs6EVs6E666666-->

What 3M respirators can the General Public use to reduce exposure to the virus that causes H1N1 influenza?

Individuals in the general public should use NIOSH N95 filtering facepiece particulate respirators that have been cleared by the FDA for use by the general public in the event of a public health medical emergency (Models 8612F and 8670F). Individuals should carefully read the User Instructions that come with the respirators and should practice putting on the respirator and checking its seal before they use the respirator in an area where they may be exposed to someone with H1N1 influenza. If FDA-cleared N95 general public respirators are not available and an individual chooses to use another NIOSH-approved N95 filtering facepiece particulate respirator, refer to the 3M website, www.my3MN95.com for instructions developed specifically for the General Public on how to use and fit an N95 respirator.

Can medical facemasks be used to help reduce exposures to airborne biological agents?

Medical, surgical and patient care masks are not designed to protect the wearer from inhaling airborne hazards; therefore 3M recommends that they not be used for this purpose, or in place of an approved respirator.

What is the difference between a government-certified respirator and a surgical mask?

Respirators are designed to help reduce the wearer's exposure to airborne particles. The primary purpose of a surgical facemask is to help prevent biological particles expelled by the wearer from going into the environment. Surgical masks are also designed to be fluid resistant to splash and splatter of blood and other infectious materials. Surgical facemasks are not necessarily designed to seal tightly to the face and therefore the potential of air leakage around the edges exists. Even those masks that appear similar to respirators have not been designed to protect the wearer from airborne hazards or tested to the same level of filtration efficiency; therefore they should not be considered an equivalent substitute to government-approved respirators. Some approved respirators are designed to have the characteristics of both an approved respirator and a surgical mask. In the U.S., these products are both approved by the National Institute for Occupational Safety and Health (NIOSH) and cleared by the U.S. Food and Drug Administration (FDA) as surgical masks.

Are there any medical restrictions for wearing a respirator?

If a person has pre-existing lung disease such as asthma or emphysema, underlying heart disease such as heart failure or other health conditions, they may have difficulty breathing through respirators and should consult their healthcare provider (doctor) before use.

What are the limitations of using respirators for potential exposures to the H1N1 influenza virus?

Respirators are not a guarantee that the user will not contract H1N1 influenza. The following items need to be carefully read and understood.

- Respirators may help reduce exposure to the number of airborne disease causing organisms (germs), but they don't eliminate the breathing in of all germs in the air and do not eliminate the possibility of contracting, infection, illness, or disease.
- For greatest effectiveness respirators need to be worn whenever the person is exposed to germs during a public health medical emergency.
- Respirators may help reduce exposure to the number of germs, however, they will not prevent entry of germs through the skin, eyes or other parts of the body and other protective equipment may be needed.

- Fit of the respirator to the face is very important. If it does not fit properly, airborne contaminants will penetrate (enter underneath) the facepiece seal.
- 3M respirators are not designed for children.
- Anything that comes between the respirator and face will make the respirator less effective by interfering with its fit. Men should shave every day that they may use the respirator. Hair, jewelry and clothing should not be between the face and the respirator.
- Individuals in the general public should use FDA-cleared N95 respirators and carefully read the *User Instructions* that come with the respirators and should practice putting on the respirator and checking its seal before they use the respirator in an area where they may be exposed to germs. If FDA-cleared N95 respirators are not available and another N95 respirator is obtained, refer to the 3M website, www.my3MN95.com for instructions developed specifically for the General Public on how to use and fit an N95 respirator.
- If a person has pre-existing lung disease such as asthma or emphysema, underlying heart disease such as heart failure or other health conditions, they may have difficulty breathing through respirators and should consult their healthcare provider (doctor) before use.

Each individual should use the best available information to determine appropriate respiratory protection for exposures to the virus that causes H1N1 influenza. For further assistance, see 3M's website www.mmm.com/swineflu.

Can children use respirators?

Respirators have not been evaluated for use by children. Respirators are designed according to government performance standards for use by healthy adults who work in an occupational/workplace setting. There are no government performance standards today which specify criteria for designing respirators for children, such as breathing resistance.

The 3M Respirators For Use by the General Public in Public Health Medical Emergencies were cleared by the FDA for use by adults and not for use by children. Current 3M respirators are not sized to fit the smaller face of a young child. In addition, children may have difficulty breathing through a respirator and wearing the respirator without shifting it around or lifting it off of the face. "Fidgeting" or restlessness, common to children could cause a leak during exposure. The effectiveness of a respirator is dependent upon the wearer being able to continuously wear the respirator without breaking the seal. Infants and toddlers should not be given respirators due to the risk of choking or suffocation.

Nevertheless, under certain special circumstances, such as with a child who is immuno-compromised, government approved respirators have been used by children under the advisement and care of the child's physician. If you are considering use of a respirator for a child, consult your personal physician regarding your specific situation.

Are multiple sizes of respirators needed?

Multiple sizes of respirators are not mandatory. Multiple sizes or alternative facepiece designs can provide the individual with additional options for obtaining a good fit and seal. What is important is that the respirator fit the wearer.

How important is fit?

Fit is very important. If a respirator does not seal tightly to the face, airborne hazards can penetrate or enter underneath the facepiece seal and into the breathing zone. It is very important to always follow the donning instructions and do a user seal-check or fit-check before entering a contaminated environment or taking care of a sick person. A good fit can only be obtained if the face is clean-shaven in the area where the respirator seals against the face. Beards, long mustaches, and stubble may cause leaks into the respirator. Hair, jewelry and clothing should not be between the face and the respirator. Many medical facemasks, not approved as respirators, do not seal tightly to the face allowing airborne hazards to enter the breathing zone. Even those medical facemasks that appear to seal tightly to the face have not been designed to protect the wearer from airborne hazards. Therefore, they should not be considered an equivalent substitute for government-approved respirators.

What if I have a beard or stubble and want to wear a respirator?

A tight sealing respirator, one where the sealing surface contacts the face, will not provide an adequate seal when placed over any amount of facial hair. A bearded individual will typically require a powered air-purifying respirator (PAPR) with a hood or helmet.

How do I put on the respirator and check for proper fit?

The *User Instructions* for a 3M respirator contain the proper procedures for putting on the respirator and checking for fit and seal. It is very important to read and follow the donning instructions very carefully and to conduct a fit check or user seal check every time the respirator is put on. The user instructions are provided with the original packaging of the respirator.

Instructions on how to put on the respirator and check for proper fit can be found on the following websites:

[3M: Particulate Respirator 8612F, Wear it Right info - English](http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66SQ6DCOrrrrQ-)
<http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66SQ6DCOrrrrQ->

[3M: Particulate Respirator 8612F, Wear it Right info - Spanish](http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66sTofCOrrrrQ-)
<http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66sTofCOrrrrQ->

<http://mothra.implex.net/3MOccupationalHealth/748350/8612F.wmv> Video

[3M: Particulate Respirator 8670F, Wear it Right info - English](http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66SQ6ECOrrrrQ-)
<http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66SQ6ECOrrrrQ->

[3M: Particulate Respirator 8670F, Wear it Right info - Spanish](http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66sTo2COrrrrQ-)
<http://multimedia.mmm.com/mws/mediawebserver.dyn?6666660Zjcf6IVs6EVs66sTo2COrrrrQ->

<http://mothra.implex.net/3MOccupationalHealth/748350/8670.wmv> Video

How is a user seal check/fit check performed on a disposable respirator?

The *User Instructions* for a 3M respirator contain the proper procedures for putting on the respirator and checking for fit and seal. It is very important to read and follow the donning instructions very carefully and to conduct a fit check or user seal check every time the respirator is put on. The user instructions are provided with the original packaging of the respirator. Additionally, the websites listed in the previous question contain the procedures to properly put on the respirator and check for fit and seal for 3M filtering facepiece respirators.

If, during the *user seal check* (fit check), you notice air leakage around the edges of the respirator you should readjust the respirator. If you still notice air leakage, you should remove the respirator (in a clean area only). Review the instructions, if necessary, to make sure that you are putting it on correctly. Inspect the respirator to make sure that there is no damage to the respirator. You must be clean-shaven. Be sure that there is no hair, clothing or jewelry between your skin and the edge of the respirator. Put the respirator on again, according to the manufacturer's directions. Do a *user seal check* (fit check). If you still cannot achieve a proper seal, do not enter an area where you may be exposed to germs. You may need to obtain a different size, make or model respirator.

Can disposable respirators be shared between people?

Disposable respirators should never be shared.

What is BFE, and what does it measure?

BFE stands for Bacterial Filtration Efficiency. This test is most commonly used for surgical masks and evaluates how well a respirator or surgical mask can prevent biological particles from being expelled by the wearer from entering into the environment. Bioaerosol particles generated during the BFE test are "large," on the order of 1 to 5 microns in size. For comparison, particles used for respirator filter efficiency tests are much smaller, approximately 0.3 microns in size. The BFE test is a relative indicator of the performance of a medical, surgical or patient care mask but the results are not comparable to respirator certification filtration efficiency.

Are government-certified respirators tested for BFE?

Respirators are not necessarily tested for Bacterial Filtration Efficiency (BFE). The BFE result has little meaning for government-certified respirators. More stringent filter efficiency tests are used for certification testing of respirators. Manufacturers of combination approved respirator/surgical masks will publish BFE results. BFE results are not necessarily useful for applications outside of the health care industry.

Can a valved respirator be used for protection from the virus that causes H1N1 influenza?

A valved respirator is designed to allow for easy exhalation through a one-way exhalation valve. If a person is wearing a respirator to help reduce his or her exposure to airborne viruses, a respirator with an exhalation valve would be acceptable. It would not be acceptable for someone to wear a valved respirator if they have a suspected/probable/confirmed case of H1N1 influenza, as they may exhale airborne viruses into the environment.

Respirators should not be worn by a person whose respiratory system has been compromised or who may have trouble breathing through a respirator, unless otherwise advised by your personal physician.

Should an influenza patient wear a respirator?

The CDC's "Interim Guidance on Infection Control and Antiviral Recommendations for Patients with Confirmed or Suspected Swine Influenza A Virus Infection" updated on April 24, 2009 states that an "*ill person should wear a surgical mask when outside of the patient room,*". Additionally the CDC recommends frequent hand washing, following good respiratory hygiene practices, not sharing cups and utensil and applying routine cleaning and disinfection practices used during influenza season.

The CDC is not recommending the use of respirators by H1N1 influenza patients at this time. 3M recommends that patients, and any individual, whose respiratory system has been

compromised or who may have trouble breathing through a respirator, consult with their personal physician before wearing a respirator.

What precautions should visitors take when visiting facilities with H1N1 influenza patients?

Prior to entering a health care setting, visitors should consult with the facility's Infection Control Practitioner regarding visitor policies.

Can I clean or wash a disposable respirator?

Under no circumstances should an attempt be made to clean or wash a disposable respirator.

Can I reuse a disposable respirator?

Filtering facepiece respirators should be disposed of after use unless directed otherwise by a federal or local health authority. 3M's respirators for the General Public are FDA-cleared as "single use respirators" and must be disposed of after use.

How should respirators be disposed of after use?

You should immediately replace the respirator if it is damaged, has been splashed or sprayed with body fluids, or if it becomes harder to breathe through. Filtering facepiece respirators should be disposed of after use unless directed otherwise by a federal or local health authority. Wearers should remove their respirator only when they are in an area that is considered free of airborne hazards, including confirmed or suspected H1N1 influenza patients. Touch only the straps and not the surface of the respirator when removing. Dispose of the respirator by carefully placing it in a closed waste container. Wearers should wash hands after disposal of a used respirator. Please also consult recommendations of the federal or local health authority.

3M's respirators for the General Public are FDA-cleared as "single use respirators".

What is the risk of inhaling biological particles, such as the H1N1 influenza virus, that have been collected by the respirator filter?

The risk of inhaling particles that have been collected by the filter is very low, particularly in very clean areas (such as a patient care setting or a home). When particles are collected on a filter they are strongly held to the filter. Breathing through a filter has not been shown to dislodge the particles collected in that filter. However, it is important to understand that proper use of respirators only reduces your exposure to particles and does not prevent the risk of some exposure.

Can particles, such as bacteria or viruses, be reaerosolized from the respirator filter?

When particles are collected on a filter they are strongly held to the filter. Proper and normal use of a respirator has not been shown to reaerosolize the particles collected in that filter. Just because particles may not reaerosolize, does not mean that a respirator can be reused. The recommendations of the local health authority and the facility's infection control practitioner regarding reuse should be followed.

Do 3M disposable respirators contain natural rubber latex?

None of 3M's National Institute for Occupational Safety and Health (NIOSH) approved N95, N100, R95, P95, or P100 disposable respirators contain components made from natural rubber latex. This is stated on each original packaging of these respirators. Many 3M respirators sold outside the U.S. do not contain components made from latex. However, there are some that

contain natural rubber latex components and these respirators carry a statement on the primary packaging similar to the following: “This product contains components which contain natural rubber latex which may cause allergic reaction.” If you require information on which 3M products contain natural rubber latex components, please contact your local 3M office.

What do N, R, and P stand for?

For the following National Institute for Occupational Safety and Health (NIOSH) filter designations N stands for Not Resistant to oil; R stands for Resistant to oil; and P stands for oil Proof.

Do any of 3M’s disposable respirators contain fiberglass material?

No. All 3M disposable respirators have filter media made from polypropylene and coverings typically made from a combination of polypropylene and polyester.

For more information, visit www.my3MN95.com or www.3M.com/swineflu .