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Respiratory Protection for Airborne Exposures to Biohazards

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

Abstract

Diseases can be transmitted via many routes, including inhalation of aerosols. When properly fitted, selected, used, and maintained, particulate-removing respirators have been demonstrated to reduce the amount of aerosols – both bioaerosols and non-biological aerosols – that are inhaled by the wearer. In contrast, most surgical masks are not designed to seal tightly to the face, and research has shown that they do not achieve the level of contaminant reduction provided by a certified respirator that is used correctly. Although questions have been raised as to whether or not biological particles can be filtered as well as non-biological particles, research shows that a respirator filter will remove bioaerosols in a similar manner as it removes non-biological aerosols from air that passes through it.

When respiratory protection is needed to help reduce exposure to bioaerosols, the user should select a certified particulate respirator according to recommendations from CDC, WHO or applicable local agencies. Once a respirator has been selected, a continuing, effective respiratory protection program as specified by applicable local regulations must be implemented. This includes training on the respiratory hazards, fit testing, and proper maintenance and disposal of the respirators.

Introduction

Recently there has been growing interest in the use of respirators to help protect against certain airborne biohazards. Diseases that may be caused by inhalation of airborne biological organisms include tuberculosis (TB), Hantavirus, anthrax, coronaviruses (including SARS, MERS and others), and influenza. Biohazards may become airborne, perhaps as the agent itself, such as an anthrax spore, or as the agent riding on some other material that becomes airborne, such as dusts, mists or droplet nuclei. Hantavirus infection has been caused by people inhaling soil dust that became airborne after rodents shed virus via urine, feces or other materials into the soil. In fact, it is generally thought that airborne viruses are normally attached to other particles and rarely exist as naked organisms.[1]

Inhalation of these bioaerosols may be reduced by wearing respirators. The US Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO), and national health authorities have made numerous recommendations for respirator use where they believed the potential for the spread of disease through the airborne route exists. Considerations for selection and use of respirators to help reduce exposure to bioaerosols include:

- Filtration
- Microorganism survival on the filter
- Potential reaerosolization of the bioaerosol
- Reuse of the respirator
- Fit and the assigned protection factor of the respirator

These topics are addressed in this bulletin.

Routes of Exposure

Inhalation is not the only route of exposure for biohazards. Infection can occur from other routes of exposure, such as ingestion, skin and mucous membrane penetration (including the eyes) and animal and insect bites. Skin and mucous membrane penetration can occur by direct contact with aerosols or secondarily – e.g., a hand touching a contaminated surface and then touching a mucous membrane.

How a disease is spread informs what types of controls are useful in preventing its spread. If the disease can be spread by contact, preventing surfaces from becoming contaminated and effective hand hygiene will be very important. Surgical masks may be worn by infected people in order to help reduce the spread via exhaled aerosols. Surgical masks, safety glasses or goggles, and faceshields may be used to help shield the healthcare worker's mucous membranes (eyes, nose, and mouth) from large sprays of blood and other body fluids. Use of respirators may also be appropriate.

Particles ranging in size from submicron to 100 µm can remain airborne for extended periods of time.[2] Particles smaller than 100 µm in size can enter the nose, mouth and throat and are considered "inhalable." Particles smaller than 10 µm can reach the large bronchioles and are considered the "thoracic" fraction, and particles smaller than approximately 5 µm can enter the deep lung and are considered the "respirable" fraction.[3]

Certain diseases can be spread through the airborne route. This means that if the organism that causes the disease is aerosolized the potential exists for illness. Tuberculosis is one disease that is spread through the airborne route. Healthcare workers have been known to acquire tuberculosis infections during care for tuberculosis patients. In one particular case, it is believed by investigators that the transmission occurred during an aerosol-generating procedure that a healthcare worker performed without wearing a respirator, according to guidance at the time.[4] Evidence has been presented that indicates the airborne route is one of the ways that severe acute respiratory syndrome (SARS) and seasonal influenza can be spread.[5-9] Analysis of various typical ventilation systems in surgical suites suggests that airborne particles are quickly and evenly distributed throughout the room.[10] When airborne, viruses and bacteria can be filtered by properly selected and worn respirators with particulate filters. Because no respirator will prevent the inhalation of all particles, including viruses and bacteria, respirators cannot eliminate the risk of exposure, infection, and illness. With so many respirator use recommendations being made on websites and other sources, it is important to understand respirators and the role they have in helping to reduce exposures to bioaerosols.

Terminology

Bioaerosols are those airborne particles that are living or originate from living organisms.[11] They include microorganisms and fragments, toxins, and particulate waste from all varieties of living things.

A **respirator** is a device designed to help provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.[12] For bioaerosols, particulate-removing respirators are often recommended to help reduce exposure.

Particulate respirators are available as:

1. A filtering half facepiece (sometimes called a disposable respirator), where the filter is virtually the entire respirator
2. An elastomeric (reusable) half facepiece with a particulate filter
3. An elastomeric (reusable) full facepiece with a particulate filter
4. A powered air purifying respirator (PAPR) that includes a particulate filter

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 A 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. For a more detailed comparison of global filtering facepiece respirator regulations, see the 3M Technical Bulletin - Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes.

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

Standard	Classification	Filter Efficiency
NIOSH 42 CFR 84 (US)	N95	≥ 95%
NIOSH 42 CFR 84 (US)	N99	≥ 99%
NIOSH 42 CFR 84 (US)	N100	≥ 99.97%
EN 149:2001	FFP1 (filtering facepiece)	≥ 80%
EN 149:2001	FFP2 (filtering facepiece)	≥ 94%
EN 149:2001	FFP3 (filtering facepiece)	≥ 99%
EN 143:2000, EN 140:1999, EN136:1998	P1 (elastomeric facepiece)	≥ 80%
EN 143:2000, EN 140:1999, EN136:1998	P2 (elastomeric facepiece)	≥ 94%
EN 143:2000, EN 140:1999, EN136:1998	P3 (elastomeric facepiece)	≥ 99.95%
GB2626-2006	KN/KP90	≥ 90%
GB2626-2006	KN/KP95	≥ 95%
GB2626-2006	KN/KP100	≥ 99.97%

Please note that penetration of particles through the filter is only one of the possible sources of exposure to contaminants. Other potential sources such as faceseal leakage, leakage as a result of improper maintenance, or not wearing the respirator when necessary may contribute more to exposure than filter penetration. Each of these factors must be addressed and controlled. For example, all particulate respirators that are designed to seal to the face (including filtering facepiece respirators) can be fit tested using the saccharin or Bitrex™ qualitative fit test methods, or using appropriate quantitative fit test methods such as the ambient particle counting method using the TSI® PortaCount®. Wearers must be trained how to properly use and maintain their respirators and the importance of wearing them at all times during potential exposure.

Please also note that respirators help reduce exposure to airborne contaminants but do not prevent the inhalation of all particles. As a result, when properly selected, used and maintained, respirators can lower exposures to concentrations considered safe for most non-biological particles. However, they do not eliminate the risk of exposure, infection, or illness since safe exposure levels have not been established for biological particles. In many countries, 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 may reduce exposure by a factor of 10 (or 90%) when properly selected, used, and maintained. Therefore, even if a filter could be hypothetically 100% efficient, the expected amount of exposure reduction would be limited by the APF. Because no respirator will prevent the inhalation of all particles, none can entirely eliminate the risk of exposure, infection, and illness.

For more information on the proper selection, use, and maintenance of respiratory protection, please see the United States (US) OSHA standard for respiratory protection (29 CFR 1910.134), EN 529 Respiratory protective devices: Recommendations for selection, use, care and maintenance — Guidance document,[13] or any applicable local standards and guidance.

A surgical mask is an infection control device designed to help prevent the spread of infection from the wearer’s exhaled breath to potentially susceptible persons.[14] A surgical mask may help reduce contamination of the environment by providing a barrier for large droplets expelled by the wearer. However, since surgical masks are not tested in the same way as respirators, any “filtration efficiency” claims cannot be directly compared to those for a respirator.[15-16] A surgical mask may also be tested for its ability to reduce exposure of the wearer against fluid splashes or high velocity streams. Most surgical masks are not designed to seal tightly to the face, and research has shown that they do not achieve the level of contaminant reduction provided by a NIOSH-certified respirator.[16-17] This has been found to be true both in laboratory studies[16] and in healthcare

workplaces.[17] When infection rates were tracked among workers who wore N95 respirators, workers who wore medical masks, and workers who wore neither, N95 respirators were found to be significantly protective against bacterial and viral infections, while surgical masks were not.[17] Surgical masks have not been assigned protection factors by OSHA and should not be relied upon to help reduce exposure to inhalable airborne particles. For a more detailed comparison, see the 3M Technical Bulletin - Surgical Masks, Standard N95s, Surgical N95s: A comparison.

In a few cases, a certified respirator may also have the attributes of a surgical mask. These are sometimes referred to as "Surgical Respirators." These products can help block large droplets expelled by the wearer, but also have been shown to have efficacy at filtering smaller particles and are designed to fit tightly to the face. Because of the additional use as a respirator, this type of surgical mask (i.e. surgical respirator) must also be fit tested. For an exploration of additional information concerning when surgical N95 respirators may be needed, see 3M Technical Bulletin - Surgical Masks, Standard N95s, Surgical N95s: A comparison.

Filtration

A number of questions have been raised regarding the use of respirators against biological agents. The primary question is whether or not particulate respirators can filter small particles such as fungal spores (2 to 5 µm), bacteria (0.3 to 10 µm), or viruses (0.02 to 0.3 µm).[17] The physical size of various organisms is shown in Table B. As noted previously, biological organisms may be carried on other particles including dust, blood, saliva, etc.

Droplets generated from coughing, sneezing and talking will quickly dry in the air to form droplet nuclei. Droplet nuclei generated from coughs, sneezes, and speaking have been found to range from submicron to over 20 microns.[18-19] Influenza viruses, and other viruses, have been collected from exhaled breath.[20] It is thought that droplet nuclei that contain Mycobacterium tuberculosis may range from less than 1 µm to greater than 5 microns.[21-22] Airborne particles containing influenza viruses have been sampled from the air of hospital rooms containing influenza patients and found to be in the size range from less than 1 µm to greater than 4 µm.[5] Understanding filtration mechanisms can help answer whether or not these particles can be filtered by particulate respirators.

Many particulate respirators use a non-woven fibrous filter media to capture particles. Fibers ranging in size from less than 1 µm up to 100 µm in size crisscross to form a web of many layers which is mostly air due to the spaces between the fibers. It is these spaces between fibers that allow for breathability. Particles are trapped, or captured, when flowing through the layers of filter media, and that capture can happen through several different mechanisms. These are gravitational settling, inertial impaction, interception, diffusion, and electrostatic attraction.[1]

Table B. Size of Various Microorganisms

Microorganism (common name or disease)	Physical Size (µm)
Hepatitis virus (Hepatitis B)	0.042 - 0.047
Adenovirus (respiratory infections)	0.07 - 0.09
Filoviruses (Ebola)	0.08 diameter 0.79 - 0.97 length
Bunyaviridae (Hantavirus)	0.08 - 0.12
Orthomyxoviridae (Influenza A, B, & C)	0.08 - 0.12
Coronaviridae (SARS–CoV, MERS-CoV & SARS-CoV-2)	0.12
Variola Virus (Smallpox)	0.14 - 0.26 diameter 0.22 - 0.45 length
Mycobacterium tuberculosis (TB)	< 1 to > 5 diameter
Bacillus anthracis spore (Anthrax infection)	1.0 - 1.5 diameter

To understand how a particle is captured, one must first consider the movement of air through the filter media. The path of the air around a fiber may be described in terms of imaginary streamlines. Any particle carried by the air may or may not stay within the streamlines depending largely upon the particle's size (aerodynamic diameter).

Very large particles (> 100 µm) in slow moving airstreams may settle out due to gravity. However, most respirable particles are too small for this mechanism. Respirable particles above 0.6 µm in diameter are typically captured efficiently by interception and inertial impaction.[23] Inertial impaction occurs when a particle cannot follow an air streamline around a fiber because of its inertia and instead impacts into the fiber. In the interception mechanism, the particle holds to the streamline, but that streamline will naturally bring the particle close enough to come in contact with the fiber. In contrast, diffusion is typically very efficient for particles smaller than 0.1 µm. Random movements of air molecules collide with these very small particles and cause them to wander across streamlines until they come in contact with a fiber.

Because of the various mechanisms by which particulate filtration occurs, the smallest particles are typically not the most difficult to filter. Most particulate filters have a region of lower filtration efficiency somewhere between 0.05-0.5 µm.[1] Particles in this range are large enough to be less effectively captured by diffusion and are also small enough to be less effectively captured by interception or impaction. The most penetrating particle size (MPPS) will depend on the filter media, air flow, and electrostatic charge on the particle. Filters that use electrostatic attraction may have a MPPS shifted to a slightly smaller size range.

An often-expressed question is whether biological aerosols are captured by respirator filters the same as non-biological aerosols. Due to concerns on the efficacy of respirator filters for Mycobacterium tuberculosis (TB), many studies have been conducted using bioaerosols. These filter evaluations were conducted over a range of test conditions (flow, humidity), biological species representing various shapes (spheres, rod, and rod/sphere shape) and sizes, filter performance levels and varying filter media (mechanical and electret; polypropylene and fiberglass). These experiments[24-29] found no significant difference in the filtration of biological aerosols and non-biological aerosols with similar physical properties – in other words, filtration efficiency is based on particle size rather than the nature of the particle's origin.[30-33] Spherical particles were found to be usually more penetrating than rod-shaped particles with equivalent aerodynamic diameter over a range of particle sizes. Studies in which researchers challenged NIOSH-approved N95 and P100 filtering facepiece respirators and filter cartridges with viable virus aerosols – including H1N1 influenza aerosols – indicated that respirators capture viable H1N1 influenza and other virus aerosols as well as or better than their respective N95 or P100 filtration efficiency rating.[30-31] Other studies have investigated the filtration efficiency of respirator filters challenged with nanometer-sized particles. These studies have found that NIOSH-approved respirators show filtration efficiencies similar to what would be expected based on their approval category.[34, 35] Where penetrations have slightly exceeded 5%, the results were not statistically significantly higher than 5%.[35]

The effectiveness of approved respirators against biological aerosols and the impact of most penetrating particle size can be seen in Figures 1 and 2. The filtration efficiencies against aerosols containing two different types influenza virus particles (H1N1 and H5N1) were measured for five different models of 3M filtering facepiece respirators. Testing was conducted at the University of Nebraska Medical Center in collaboration with 3M.[36-38] The products tested included respirators with NIOSH N95 approval (US) and with EN149 FFP2 and FFP3 approvals (Europe). Previous research has shown that, for 3M filtering facepiece respirators, European FFP2-approved products have similar or slightly higher filtration efficiencies than NIOSH N95-approved products.

Figure 1. Filtration Efficiency of Four 3M Filtering Facepiece Respirators at 85 Liters per Minute Against an Aerosol Containing H1N1 Virus Particles.

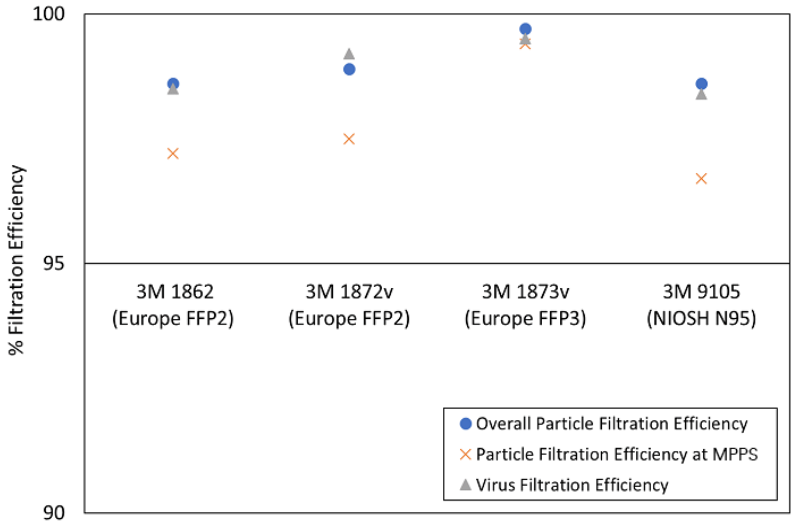
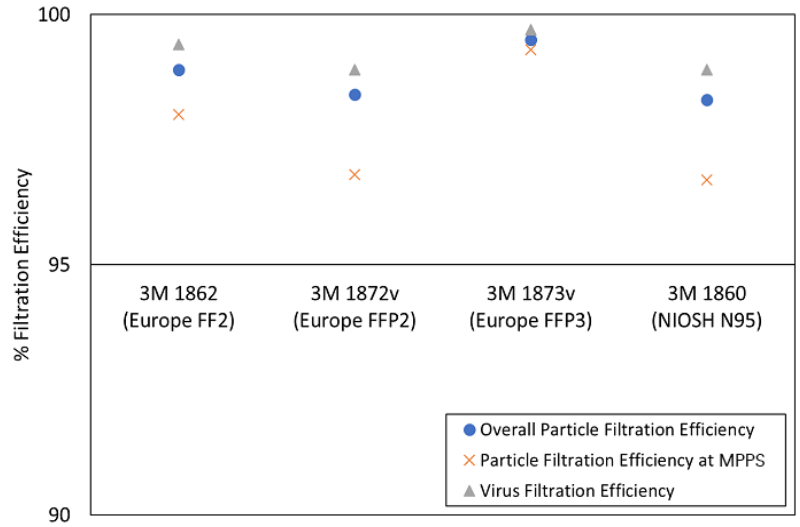


Figure 2. Filtration Efficiency of Four 3M Filtering Facepiece Respirators at 85 Liters per Minute Against an Aerosol Containing H5N1 Virus Particles



Three different filtration efficiency values are depicted in Figures 1 and 2 for each respirator model. Overall particle filtration efficiency is the filtration efficiency for particles of all sizes in the influenza virus test aerosol, ranging from less than 0.010 µm to approximately 0.5 µm. Particle filtration efficiency at most penetrating particle size (MMPS) is the filtration efficiency for those particles in the influenza virus test aerosol which represented the most penetrating size, typically about 0.04 µm for the tested respirators. Finally, virus filtration efficiency is the filtration efficiency for virus particles based on a quantitative reverse transcription-polymerase chain reaction (qRT-PCR) assay for the influenza HA gene.

All of the respirator models tested show high overall particle filtration efficiency and virus particle filtration efficiency (≥ 98%). As would be expected, the filtration efficiency at the most penetrating particle size for each of the respirator models is lower than the corresponding overall particle filtration efficiency. However, each respirator model tested still had high filtration efficiency at the most penetrating particle size (≥ 95%). The respirator model demonstrating the highest filtration efficiencies was the 3M 1873V, which has an EN149 FFP3 approval. This higher filtration performance is expected as the FFP3 approval has a higher filtration performance requirement.

Filtration claims, especially regarding bioaerosols, can be complex. To help you maximize your level of protection, make sure to use a respirator that has been tested and approved per all applicable local regulations. And, as mentioned above, filtration efficiency is just one of the required components that needs to be considered when selecting and using a respirator.

Microorganism Survival on Filters

Another area of interest is regarding the survival of microorganisms on respirator filters. This could impact storage and handling procedures. Several studies have been conducted regarding survival on filters. Over 18 types of respirator filters and five surgical masks have been studied using several types of microorganisms followed by storage at various humidities.[39-43] In these studies the filters were typically loaded with the microorganisms at experimental concentrations that were higher than those typically expected in most work environments.

The polypropylene filters used in these studies were then checked for survival of microorganisms ranging from immediately after loading to as many as 28 days later, depending on the experiment. These studies found there were surviving organisms immediately after loading and that they survived for varying lengths of time depending on the storage conditions of the study. Usually storage under high-humidity conditions was the most favorable for long term survival. However, these storage conditions are not typical of respirator storage practices in most respirator programs. Storing filtering facepieces used against bioaerosols in resealable plastic bags may be inappropriate, since the filters may be moist from use, and storage in plastic will keep the humidity level high.

One of these studies looked for migration of the organism to the inside of the filtering facepiece respirator and concluded that respirators may be reused over time with little risk of internal contamination, even after a week's time, provided the respirator is carefully handled and stored (handled by non-filter components, e.g., straps).[42] The investigators felt any internal contamination from environmental bacteria was due to handling (removal from bag to sample).

One study looked at two high efficiency filters with varying percentages of cellulose.[43] These filters were inoculated with Stachybotrys atra and stored at relative humidity (RH) as high as 100% for 86 days. S. atra grew and produced toxins on these cellulose filters at the high RH conditions. Again, these conditions are not typical during most normal respirator use and storage.

These concerns have prompted some to state that a traditional filter without a nanoparticle coating of a biocide would turn into a breeding ground for a virus or bacterial agent. The studies mentioned above do not support this claim. While it may be relatively easy to load a filter with a biocide, determining its efficacy is more difficult. Close examination of the claim needs to be made. Claims often relate to protection of the product, such as from microbial decay rather than protection of the wearer. Many countries require that a product claim of biocidal effectiveness for protecting the wearer must be in compliance with local regulations. In the US, claims are regulated by the Environmental Protection Agency (EPA). In Europe, claims must be in compliance with the Biocide Product Regulation (EU) (528/2012). If the claims have not been approved or are not in compliance, they may be inappropriate. Very little peer-reviewed research has been conducted on respirators that currently claim antimicrobial properties.

One investigation of respirators incorporating antimicrobial-treated filter media found that there was non-detectable or no effect on the viability of penetrating particles.[44] Another study found an insignificant difference in the fractions of surviving organisms captured on untreated filters and those filters treated with iodine and similar environmental conditions.[45]

Having the filter treated with a biocide may only be beneficial in extending the useful life of the filter. While most of the virus would be deposited on the filter as a result of breathing through the filter, bioaerosols may also be deposited on the straps, exhalation valve cover (if present), and nose clips etc. Thus caution in handling the respirator must still be taken and a biocide filter treatment may not prevent the spread of disease by contact with these respirator components.

Overall, these studies suggest careful consideration for filter handling, reuse and respirator disposal, especially where the organism can be spread by contact. Precautionary measures might include the use of gloves and washing hands after handling the respirator. For organisms transmitted only by inhalation, respirator handling may not be critical. One investigator suggested

training for respirator users might be necessary to recognize when exposures would require immediate disposal of respirators.[44]

Reaerosolization of Microorganisms Collected on Respirator Filters

Once a particle is captured on a filter fiber, it will adhere to the fiber due to Van der Waals forces. Therefore, filters are generally good collectors of small particles. In contrast, reaersolization is the process by which any aerially deposited material on the filter can be re-suspended into the air. It could be hypothesized to happen if there was high air flow back through the filter such as if the wearer were to cough or sneeze while wearing the respirator. In this regard, one experiment investigating this possibility used three microorganisms and two surrogate particles [NaCl and Polystyrene latex (PSL) particles] of various size ranges from 0.6 µm to 5.10 µm.[46] They were loaded onto three models of filtering facepiece particulate respirators. The reentrainment velocity was 300 cm/sec. Reaerosolization was significant only for larger test particles (3 and 5 µm) into dry air. There was no reaerosolization when the RH levels were greater than 35%. These authors concluded that reaerosolization of collected TB bacteria and other particles less than a few microns in size is insignificant at conditions encountered in respirator wear. They also speculated that the conclusions were valid for other fibrous filters as well.

In a second study, investigators used 1µm PSL particles to simulate anthrax spores.[47] Two models of filtering facepiece particulate respirators were loaded with approximately 20 million particles. The respirators were then dropped three feet onto a hard surface. The amount released ranged from 0 to 0.5% and the average release measured 0.16% and 0.29% for the two models tested. While this loading represents a much higher degree of loading than would be expected in typical work environments, this study indicates a small, but consistent fraction of 1 µm particles captured by a respirator filter may be released into the air. These results suggest caution in handling and disposing of respirators contaminated with anthrax spores.

Selection and Use

When respiratory protection is used to reduce exposures to bioaerosols, the user should select a certified/approved particulate respirator according to recommendations from CDC, WHO or applicable local authorities. Remember that the NIOSH particulate filter rating does not include faceseal leakage – only filter penetration. European EN performance standards do include a Total Inward Leakage performance requirement, however, these are not necessarily good indicators of product performance in the workplace. Therefore, the assigned protection factor must be considered to ensure the expected reduction in respiratory exposure is adequate for your intended application.

Once a respirator has been selected, a continuing, effective respiratory protection program as specified by applicable local regulations must be implemented. This includes training on the respiratory hazards, as well as the respirator fit testing, maintenance, disposal, etc. Of course, all respirators must be used in accordance with the applicable user instructions.

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