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Respiratory Protection for Airborne Exposures to Biohazards

Formerly titled "Respiratory Protection Against Biohazards"

Introduction

Recently there has been growing interest in the use of respirators for certain airborne biohazards. Diseases that may be caused by inhalation of airborne biological organisms include tuberculosis (TB), Hantavirus, anthrax, sudden acute respiratory syndrome (SARS) and influenza. Biohazards may become airborne; perhaps as the agent itself such as an anthrax spore, 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 Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO) and many 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 for 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 may 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 may 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 indicates what types of controls are useful in preventing its spread. If the disease can be spread by contact, preventing surfaces from becoming contaminated and hand hygiene will be very important. Surgical masks may be worn by infected people in order to reduce the spread via exhaled aerosols. Surgical masks, safety glasses and face shields may be used to 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 from submicron to 100 µm in size can remain airborne. (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. 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. [4-8] When airborne, viruses and bacteria can be filtered by respirators with particulate filters. Because no respirator will prevent the inhalation of all particles, such as 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. [9] 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. [10] For bioaerosols, particulate removing respirators are often recommended to help reduce exposure. Particulate respirators are available as:

1. a filtering half facepiece respirator where the filter is the entire respirator
2. an elastomeric (reusable) half mask with a particulate filter
3. an elastomeric (reusable) full facemask 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 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 as category 3 devices under the PPE Directive 89/686/EEC.

Filtration efficiency is one of the performance parameters evaluated for certification. These tests are designed to be very stringent or "worst case." Following are some of the minimum filtration requirements according to US and European standards. However, it is often inappropriate to compare results from the different tests as 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.

Standard	Classification	Filter Efficiency
NIOSH 42 CFR 84	95	≥ 95%
NIOSH 42 CFR 84	99	≥ 99%
NIOSH 42 CFR 84	100	≥ 99.97%
EN149:2001	FFP1 (filtering facepiece)	≥ 80%
EN149:2001	FFP2 (filtering facepiece)	≥ 94%
EN149:2001	FFP3 (filtering facepiece)	≥ 98%
EN143:2000 EN140:1999, EN136:1998	P1 (elastomeric facepiece)	≥ 80%
EN143:2000 EN140:1999, EN136:1998	P2 (elastomeric facepiece)	≥ 94%
EN143:2000 EN140:1999, EN136:1998	P3 (elastomeric facepiece)	≥ 99.95%

It should be noted that penetration of particles through the filter is only one of the possible sources of exposure to contaminants. Other potential sources such as face seal 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 designed to seal to the face (including filtering facepiece respirators) can be fit tested using the saccharin or Bitrex™ qualitative fit test methods. Wearers must be trained how to properly maintain their respirators and the importance of wearing them all of the time during potential exposure.

It is important to recall that respirators help reduce exposure to airborne contaminants but do not prevent the inhalation of all particles. As a result, when properly used and maintained, respirators can lower exposures to concentration considered safe for most non-biological particles. However, they do not eliminate the risk of exposure, infection or illness where biological particles where safe exposure levels have not been established. 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, 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.

For more information on the proper selection and use 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 [11] or any applicable local standards.

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. [12] 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 the same as respirators any "filtration efficiency" claims can not be directly compared to those for a respirator. [13,14] A surgical mask may also be tested to for its ability to reduce exposure of the wearer against fluid splashes. 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 as provided by a NIOSH-approved respirator in laboratory studies. [14] Surgical masks have not been assigned protection factors by OSHA and should not be relied upon to help reduce exposure to inhalable airborne particles.

In a few cases, an approved respirator may also have the attributes of a surgical mask. These are typically referred to as "Surgical Respirators". This means it can help block large droplets expelled by the wearer, but has also been shown to have efficacy at filtering smaller particles, and is designed to fit tightly to the face. Because of its additional use as a respirator, this type of surgical mask must also be fit tested.

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). [15] The physical size of various organisms is shown in Table 1. As noted previously, biological organisms may be carried on other particles including dust, blood, saliva, etc. Droplets generated from talking, coughing or sneezing 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. [15,16] Influenza viruses, and other viruses, have been collected from exhaled breath. [17] It is thought that droplet nuclei that contain *Mycobacterium tuberculosis* may range from less than 1 µm to greater than 5 microns. [18,19] 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. [4]. 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 from less than 1 µm to 100 µm in size crisscross to form a web of many layers which is mostly air due to the large spaces between the fibers. It is the spaces between fibers that allow for breathability. Therefore, a particle does not become trapped because it tries to go through a hole that is too small. Rather, while flowing through the layers of filter media, a particle becomes attached to a fiber due to a number of different mechanisms. The most common of these are gravitational settling, inertial impaction, interception, diffusion, and electrostatic attraction. [1]

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 captured efficiently by interception and inertial impaction. [20] 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 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 complex methods by which particulate filtration occurs, the smallest particles are not the most difficult to filter. Most particulate filters have a region of lesser filtration efficiency somewhere between 0.05-0.5 µm. [1] Particles in this range are large enough to be less effectively pushed around by diffusion, but 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.

Filtration efficiencies of six different commercially available US N95 filtering facepiece respirators as tested by 3M are shown in the left side of Figure 1. (Previous research has shown that for 3M products, European FFP2 respirators have equivalent or better filtration efficiency in tests representative of health care environments.) Averaged filtration efficiencies are shown as a function of different sized sodium chloride particles at a flow rate of 85 liters per minute.

While there was variability between different samples of the same model respirator, and between different models, the MPPS included particles with a diameter between 0.04 and 0.1 µm. As seen in Figure 1, particles that are smaller or larger than the MPPS are captured with higher filtration efficiency. Filtration via diffusion (most noticeable for particles smaller than 0.1 µm) actually increases as particle size decreases. Other research has confirmed that filter efficiency increases with decreasing particle size, even for particles as small as 0.003 µm (much smaller than that of virus). (21)

A size distribution from a sneeze is shown on the right side of Figure 1. (22) It should be noted that most of the droplet nuclei are larger than the MPPS. In other words, droplet nuclei that may contain microorganisms will be filtered by these respirators with high efficiency.

There has been much confusion regarding the MPPS. Some of this may be due to the different methods used to describe the size of particulate aerosols. For bioaerosols, microbiologists may cite the size of the physical organism as shown in Table 1. Industrial hygienists often use the shape and density of the particle to calculate an aerodynamic diameter. The aerodynamic diameter is used to estimate how a particle travels through air or is deposited in the human respiratory tract. Filtration research with smaller particles is often done using a device which selects different sized particles according to the particle's ability to move through an electric field while falling. This size is called a mobility diameter.

Another possible source of confusion is the statistical terms used to describe aerosols in respirator test methods. Respirators are tested against aerosols that contain a range of different sized particles. For example, in the US, the median size of the sodium chloride aerosol used in the NIOSH 42 CFR 84 particulate filter test is 0.075 µm. However, if the same aerosol was characterized by mass instead of by count, the mass median aerodynamic diameter would be approximately 0.3 µm. Therefore, care needs to taken when comparing filtration claims. To be safe, 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.

An often-expressed question is whether biological aerosols are removed by respirator filters the same as non-biological aerosols. Due to concerns on the efficacy of respirator filters for *Mycobacterium tuberculosis* (TB), many studies were 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 (23-28) have demonstrated that there is no significant difference in the filtration of biological aerosols and non-biological aerosols with similar physical properties. Spherical particles were usually more penetrating than rod-shaped particles with equivalent aerodynamic diameter over a range of particle sizes. Studies have confirmed that nonbiological particles of similar aerodynamic diameter can be used for assessing the performance of respirators against biological aerosols. (29-30) Additionally, more studies have been published evaluating 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. [31-32] Where penetrations have slightly exceeded 5%, the results were not statistically significantly different from 5%. [32]

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. [33-37] The filters were typically loaded with the microorganisms at experimental concentrations that were probably higher than those expected in work settings.

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 have demonstrated that 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 in respirator programs. Storage of filtering facepieces used against bioaerosols in resealable plastic bags may not be appropriate. The filters may be moist from use and storage in plastic will keep the humidity level high. These studies also indicate that while the microorganisms can remain viable on the filter, they were unable to grow.

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 even after a week's time of internal contamination provided the respirator is carefully handled and stored (handled by non-filter components, e.g., straps). [37] 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. [36] These filters were inoculated with *Stachybotrys atra* and stored at 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 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 Directive (98/8/EC). 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 which 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. [38]. 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. [39]

Having the filter treated with a biocide may only be beneficial in extending the shelf life of the filter. While most of the virus would be deposited on the filter as a result of breathing through the filter, bioaerosols will 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.

Reaerosolization of Microorganisms

Once a particle is collected onto a fiber, it will adhere to the filter fiber due to Van der Waals forces. Therefore, filters are likely to be good collectors of small particles. In contrast, reaersolization is the process by which any aerially deposited material on the filter can be re-suspended. 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 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. [40] 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. [41] The two models of filtering facepiece particulate respirators were loaded with ~ 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 2 models. 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 needed for exposures to bioaerosols, the user should select a certified / approved particulate respirator according to recommendations from CDC, WHO or applicable local agencies. Remember that the NIOSH particulate filter rating does not include face seal leakage, only filter penetration. Therefore, the assigned protection factor must be considered to ensure the expected reduction in respirator exposure is adequate for your intended application. Although the European certification testing includes face seal leakage, some countries have assigned protection factors that are lower than the nominal protection factors calculated from the certification tests.

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, maintenance, disposal, etc.

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Table 1. 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)	0.10-0.12
Variola Virus (Smallpox)	0.14-0.26 diameter 0.22-0.45 length
Mycobacterium tuberculosis (TB)	< 1 to > 5 µm diameter
Bacillus anthracis spore (Anthrax infection)	1.0-1.5 diameter

Figure 1. Averaged Filtration Efficiency for Six N95 respirators (on the left), and Size Distribution of Droplet Nuclei from a Sneeze (on the right).