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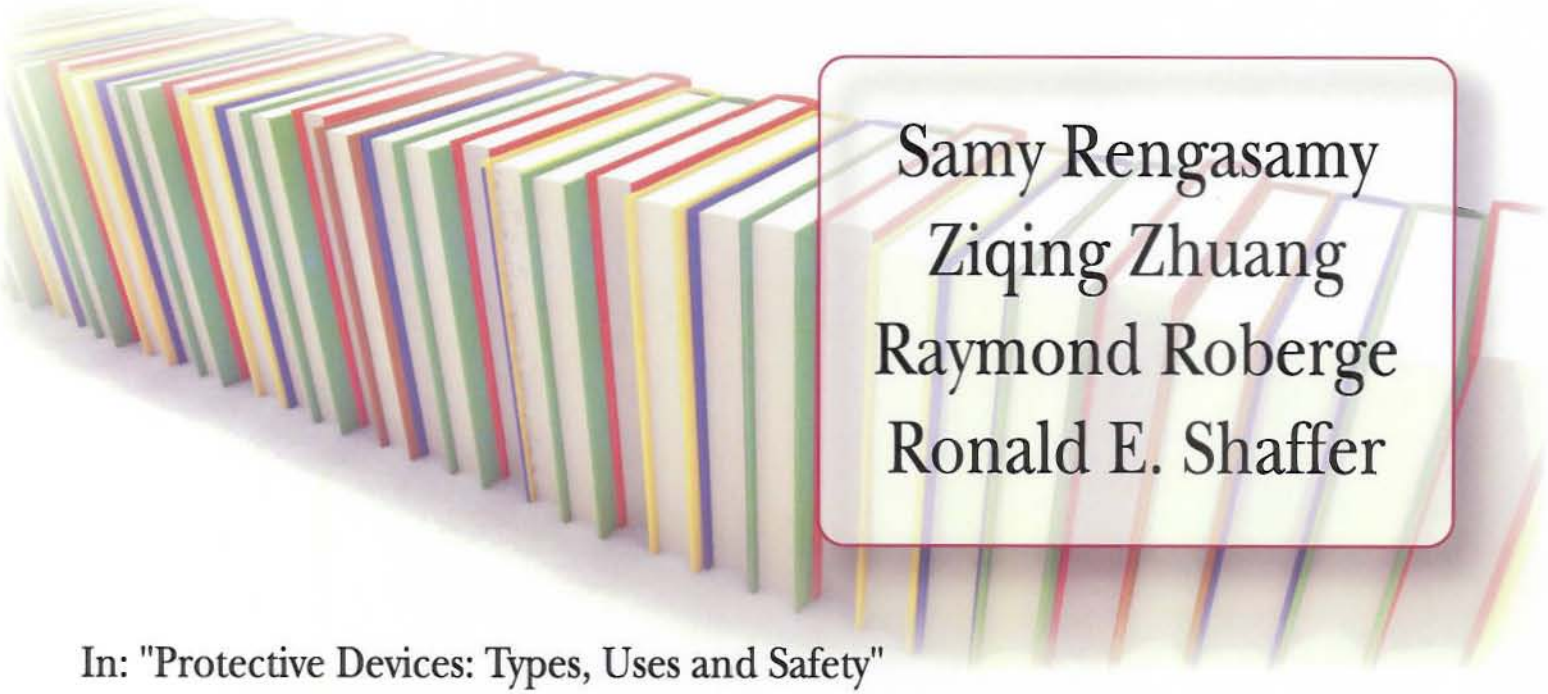
PARTICULATE RESPIRATORY PROTECTION-OVERVIEW, EMERGING ISSUES AND RESEARCH NEEDS



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Chapter 3

PARTICULATE RESPIRATORY PROTECTION – OVERVIEW, EMERGING ISSUES AND RESEARCH NEEDS

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ABSTRACT

This chapter is a brief review of respiratory protective devices for harmful airborne particulates. Particles in the breathing air present serious health hazards to civilians and workers in occupational settings. To reduce the inhalation of particles, respiratory protection is required when other control measures are not feasible or not yet implemented. For many years respiratory protection devices were used in industrial workplaces to minimize particulate exposures, then extended to other workplaces including healthcare. Respirators are required to reduce the exposure to airborne infectious diseases, including severe acute respiratory syndrome (SARS), pandemic influenza and multi-drug resistant diseases because implementation of administrative and engineering controls is not always feasible. Similarly, bioterrorism incidents involving viruses, bacteria and spores require respiratory protection. Another emerging area of concern is the recent technological developments in the nanotechnology industry for producing engineered nanomaterials. Nano-sized particles may potentially be more toxic than equal quantities of larger-sized particles.

The exposure to harmful nonbiological and biological aerosols can be addressed by proper selection of air-purifying respirators (APRs) recommended by regulatory agencies and other organizations. The National Institute for Occupational Safety and Health (NIOSH) and other standards organizations have developed performance standards for APRs. The NIOSH-certified APRs will provide expected protection levels when properly used. However, these devices do not fit all wearers equally well and impose varying

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levels of discomfort when fitted to the face. Poor fit of a respirator causes face seal leakage and compromises the respiratory protection levels. To address this issue, NIOSH has recently characterized face sizes and shapes characteristic of the current U.S. work force and developed new respirator fit test panels. Advanced respirator design for different facial features could improve respirator fit leading towards consistent protection.

Also, the physiological impact of some forms of respiratory protective equipment upon wearers has not been adequately examined. Re-use of disposable equipment is also an issue of recent importance given that supplies of disposable respirators may be insufficient in a pandemic-like setting. Recent technological developments have produced nanofibers which can be employed for producing efficient filters. Similarly, antimicrobial components can be incorporated into the filter media used for respirators to kill/ inactivate the microorganisms, as they pass through or are captured in the filter. The need for further research and developments in the different areas of respiratory protection are discussed.

I. INTRODUCTION

Particles are generated by a wide variety of natural, domestic, and industrial activities including construction, agriculture, and mining. Environmental particles are associated with a broad spectrum of acute and chronic health effects ranging from irritation to death (WHO 2000). Indoor air pollution also contributes to the increase in risks of respiratory diseases (WHO 2005). Similarly, workplace airborne contaminants are associated with diseases including pneumoconiosis, cancer, asthma and allergic alveolitis (WHO 1999; Hoet et al. 2004). The health effects of particulates are primarily reduced by implementing engineering (fume-hoods, biosafety cabinets, containment systems) and administrative controls. However, these measures may not be sufficient to reduce the inhalation of nonbiological as well as biological particles including multi-drug resistant tuberculosis, SARS, and avian and pandemic influenza viruses. Thus, respiratory protection is an essential line of defense to reduce the inhalation of harmful nonbiological and biological aerosols. In the United States, over three million workers are required to wear respirators in 282,000 establishments (BLS/NIOSH 2003) as a consequence of their work.

The increased production of engineered nanoparticles in workplaces also raises concern on their effects on human health and environment. Nanoparticles are defined as particles with at least one dimension <100 nm. Nanoparticles are generated by various natural as well as industrial processes including combustion, milling and grinding (Biswas and Wu 2005). Engineered nanoparticles are intentionally produced with specific properties including shape, size, surface and chemistry to meet specific applications in different areas (Biswas and Wu 2005). The chemical and physical properties of engineered nanoparticles can differ from the properties of the bulk form of the same materials. Workers generating or handling engineered nanoparticles in some situations have been shown to be exposed to high levels of nanoparticles (Bello et al. 2009). Exposures to different levels of nanoparticles have been shown to produce respiratory and systemic health effects in animal models (Maynard and Kuempel 2005; Oberdorster et al. 2005; Schulte et al. 2008; Fanning et al. 2009; Shvedova et al. 2009). The characteristics of engineered nanomaterials present new challenges to understand and manage potential health risks to workers in different workplaces.

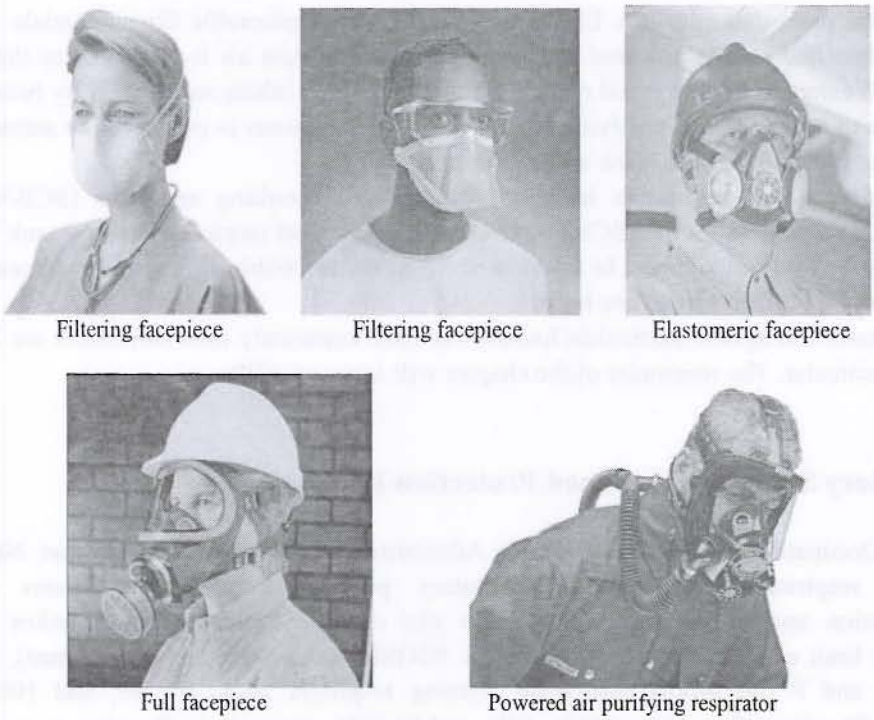

Figure 1. Various types of NIOSH-approved respirators (with permission from manufacturers Moldex, Kimberly Clark, MSA, and North Safety Porducts).

Respiratory protection is a complex, dynamic and evolving field addressing filtration, face seal leakage, physiology and other factors necessary to support the use of respirators for protection against various types of particulates. Respirator manufacturers, standard development organizations and government regulators need to work together to develop "easy to use" respirators that provide maximum protection while minimizing burden to workers. This chapter provides an overview of respiratory protection programs and current research areas. The chapter concludes with an update on recent advances in biocidal filters, nanofilters, and other possible improvements to respiratory protection equipment.

II. Elements of Respiratory Protection Program

Types of Respirators

Two main classes of respirators namely air-purifying and air-supplied respirators are used for respiratory protection in workplaces. Air-purifying respirators (APRs) remove contaminants from ambient air while supplied-air respirators use breathing grade air from a source other than ambient air. Tight-fitting air-purifying respirators are divided into half-facepiece and full-facepiece respirators. Half-facepiece respirators cover the face from the nose to under the chin area, and full-facepiece respirators fit on the entire face covering from the hairline to under the chin area **(Figure 1)**. Among the APRs, some are called disposable filtering facepiece respirators (FFRs) because the entire respirator is made up of the filter

material and discarded after use. Elastomeric APRs have replaceable filter materials. APRs are also classified as non-powered and powered based on how air is presented to the filter material. Wearers of non-powered respirators including FFR inhale ambient air by breathing. In the case of a powered air-purifying respirator (PAPR) a blower is used to force ambient air through the filters to the face mask inlet covering.

The air-supplied respirators include self-contained breathing apparatus (SCBA) and supplied-air respirators (SAR). SCBA user carries a source of respirable air in a tank which can supply air for limited times. In the case of SAR, the respirable air source is connected to the respirator up to 300 feet airline hose.

For protection against particulate hazards the most commonly used respirators are APRs, FFRs in particular. The remainder of the chapter will focus on APRs.

Respiratory Selection / Assigned Protection Factor (APF)

The Occupational Safety and Health Administration (OSHA) requires that NIOSH-approved respirators be used for respiratory protection against particulates where administration and engineering controls do not reduce worker exposure below some regulatory limit or target level (OSHA 2008). NIOSH certifies N (non-oil resistant), R (oil resistant), and P (oil proof) particulate filtering respirator types 95, 99, and 100 with minimum filtration efficiencies of 95%, 99%, and 99.97%, respectively. Respirators are tested for filtration performance under "worst-case" test conditions (e.g., 85 L/min flow rate, charge neutralized particles, etc.) by measuring the maximum penetration values throughout 200 mg aerosol loading (Federal Register 1995). According to the NIOSH respirator certification test protocol, N type respirators are tested with polydisperse NaCl aerosol particles with a count median diameter (CMD) of 75±20 nm (NIOSH 2007a), while P and R type respirators are tested with polydisperse dioctyl phthalate (DOP) aerosol particles with a CMD of 185±20 nm (NIOSH 2007b).

Respirator selection process for a given workplace is based on the assigned protection factor (APF) for the respirators (Federal Register 2006). The APF of a respirator reflects the level of protection that a properly functioning respirator used in the context of an OSHA-compliant respiratory protection program would be expected to provide to a population of properly fitted and trained users. The APFs provide employers information when selecting respirators for protection against contaminants in workplaces (Federal Register 2006). The APF takes into account all expected sources of facepiece penetration including penetrations through the face seal, filter and valve leakage. For example, an APF of 10 for a respirator means that a user could expect to inhale no more than one tenth of the airborne contaminant present in a given workplace. Proper selection of respirators using APFs is an important component of the respiratory protection program. **Table 1** shows OSHA assigned APFs for different types of respirators. Appropriate respirators are selected based on the criteria described in the NIOSH respirator selection logic based on toxicologic, safety and other relevant information (NIOSH 2004). Selection of respirators for infectious aerosols requires consideration of expert opinion in addition to the traditional exposure assessment approaches. Further, a respirator selection method for infectious aerosols has been described (McCullough and Brosseau 1999). The toxicity of bioaerosols was determined from risk ranking proposed by a variety of organizations including Centers for Disease Control and Prevention (CDC),

National Institute of Health (NIH), European Commission, Canadian Laboratory Centre for Disease Control and the World Health Organization (WHO). A ranking of airborne concentration of bioaerosols was obtained from the individual's activity, room volume and airflow rates. From the concentration and toxicity ranks, a minimum APF was determined and the corresponding respirator class suggested.

Respirator Training

OSHA requires employers to provide effective training to employees who are required to use respirators (OSHA 2008). OSHA also requires that all new employees should receive training within the last 12 months immediately prior to joining a respiratory protection program. Employers are required to evaluate proper implementation of the respirator program. The training must be comprehensive, understandable, and recur annually and more often if necessary. Employers shall ensure that employees learn how to inspect, don and doff, and check face seal leaks of the respirator.

Table 1. Assigned protection factors (APFs).

Type of respirator[1]	Quarter mask	Half-mask	Full face-piece	Helmet/ hood	Loose-fitting face-piece
1. Air-purifying respirator (APR)	5	10	50	-----	-----
2. Powered air-purifying respirator (PAPR)	-----	50	1,000	25/1000[2]	25
3. Supplied-air respirator (SAR)					
Demand mode	-----	10	50	-----	-----
Continuous mode	-----	50	1,000	25/1000[2]	25
Pressure demand and other positive pressure mode	-----	50	1,000	-----	-----
4. Self-Contained Breathing Apparatus (SCBA)					
Pressure mode	-----	10	50	50	-----
Pressure demand and other positive pressure mode	-----	-----	10,000	10,000	-----

[1] The assigned protection factors in Table 1 are only effective when the employer implements a continuing, effective respirator program as required by this section (29 CFR 1910.134), including training, fit testing, maintenance, and use requirements.

[2] The employer must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. The level of performance can be demonstrated by performing a workplace protection factor (WPF) or simulated workplace protection factor (SWPF) study or equivalent testing. Absent such testing, all other PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Fit Testing

Respiratory protection is dependent on minimizing both the penetration of particles through filter media as well as leakage around the face mask interface. The high filtration efficiency levels measured for particulate respirators under laboratory test conditions do not necessarily imply high levels of respiratory protection in workplaces. Face seal leakage is a major component of the total inward leakage of particles. For tight fitting APRs, a proper seal between the respirator sealing surface and wearer's face is crucial to reduce leakage. Several studies demonstrated the importance of fit-testing for achieving highest levels of simulated workplace protection factors (Coffey et al. 1999a; Zhuang et al. 2003). OSHA requires fit testing annually either by a qualitative or a quantitative method (OSHA 2008). OSHA-accepted qualitative methods employ the use of isoamyl acetate (IAA), saccharine, Bitrex™ and irritant smoke along with the wearer's senses for determining respirator fit pass/fail criteria. Quantitative fit factor measurements utilize instrumentation to determine leakage using aerosol particle concentration and negative pressure measurements to provide a numerical assessment.

III. Filtration Performance

Filtration Mechanisms

Particles are captured by fibrous filters through interception, impaction, diffusion and electrostatic mechanisms. According to the single fiber theory, mechanical filters capture particles >300 nm size by interception and inertial impaction mechanisms, while Brownian diffusion efficiently filters <200 nm particles (Hinds 1999). However, the intermediate size particles, where none of the mechanisms are dominant, show maximum penetration through filters. The size of the particles at the minimum efficiency is the most penetrating particle size (MPPS). Many studies have shown that the MPPS for mechanical filters is >100 nm (Lee and Liu 1980; Lee and Liu 1982). The MPPS is dependent on several factors including filter charge, particle charge, fiber diameter, packing density and flow rate (Lee and Liu 1980; Lee and Liu 1982; Martin and Moyer 2000). Developments in filter technology enabled the introduction of electric charges onto filter media by corona or triboelectric charging mechanisms to enhance particle capturing efficiency. Electret filters capture particles via coulombic attraction and polarizing forces in addition to other common filtration mechanisms (Hinds 1999). Electret filters are designed with less weight and are widely employed in respirators because of the tremendous increase in filtration efficiency with only modest increase in resistance (pressure drop). Electret filters shift the MPPS towards smaller size (<100 nm) particles (**Figure 2**) (Martin and Moyer 2000; Balazy et al. 2006a; Huang et al. 2007; Rengasamy et al. 2007; Rengasamy et al. 2009).

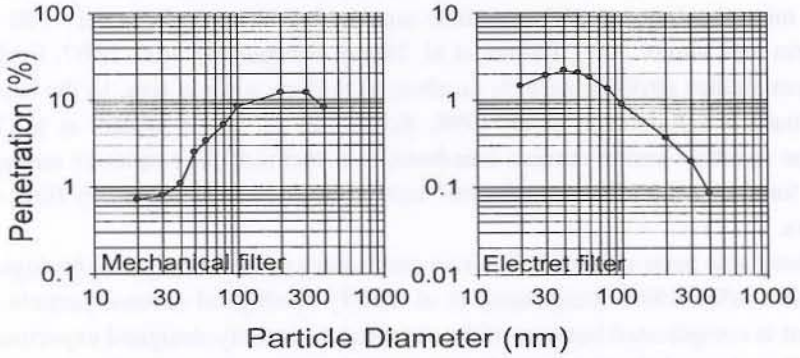

Figure 2. Typical penetration curves for mechanical and electret filters.

Filtration Efficiency

The filtration performance of APRs against particulates has been reviewed in detail elsewhere and only a cursory review will be provided here (Hodous and Coffey 1994; Brown 1995; Rengasamy et al. 2004; Shaffer and Rengasamy 2009). Most studies published in literature employed particulate N95 and P100 FFRs because of their widespread use in many workplaces. For simplicity, these research studies measured the initial penetration levels of polydisperse or monodisperse particles for a short time, such as one minute. The laboratory filtration performance of N95 and P100 FFRs is well-characterized for various size ranges of particles (Qian et al. 1998; Martin and Moyer 2000; Balazy et al. 2006a; Rengasamy et al. 2007; Rengasamy et al. 2008; Eninger et al. 2008a; Eshbaugh et al. 2009). Most of these studies measured the penetration of solid and liquid aerosol particles of different size monodisperse or polydisperse aerosols. The penetration levels were within the NIOSH allowed penetration levels for the different types of respirators at 85 L/min flow rate and the MPPS was in the 50 nm range. One research group reported monodisperse NaCl particle as well as MS2 virus aerosol particle penetration levels > 5% for the MPPS (50 nm observed in the studies) for one of the two N95 FFR models tested in their studies (Balazy et al. 2006a; Balazy et al. 2006b). Subsequent studies measured the filter penetration levels for five N95 FFR models using monodisperse NaCl particles from 20 nm to 400 nm (Rengasamy et al. 2007). Some models showed penetration levels up to 5.2% at the MPPS (40 nm observed in the study) which was not statistically different from 5%. One study reported 3-5% penetrations at the MPPS (approximately 40-60 nm) for N99 FFRs (Eninger et al. 2008a). The discrepancy between the penetration levels measured by the NIOSH particulate test method and other studies can be explained by the difference in the test methodologies. NIOSH respirator certification employs polydisperse aerosols (NaCl, 75±20 nm CMD and DOP, 185±20 nm CMD) for penetration measurements throughout 200 mg loading. Particle penetration is obtained by measuring light scattering of particles using a photometric technique, which is not sensitive to particles <100 nm (Eninger et al. 2008b). On the other hand, many researchers measured penetration levels of different size monodisperse particles for a shorter time using highly sensitive equipment with no loading.

Several of the investigators measured monodisperse aerosol penetrations for durations as low as one minute using a sensitive particle number-based method for the <100 nm particle range (Martin and Moyer 2000; Balazy et al. 2006a; Rengasamy et al. 2007; Eshbaugh et al. 2009). Recent studies attribute particle number, as well as surface area, to the harmful health effects of humans (Donaldson et al. 1998; Schulte et al. 2008; Waters et al. 2009). This indicates that number- and/or surface area-based test methods for respirator testing should be considered for future "worst-case scenario" test methods for contemporary filter media used in respirators.

There have also been several reviews on respiratory protection against biological aerosols (Hodous and Coffey 1994; Rengasamy et al. 2004). Biological aerosol particle penetration measurement is complicated because of the need for a specially-designed experimental set up. Several studies showed that biological aerosols behave the same way as inert aerosols with respect to filtration (Willeke et al. 1996; Brosseau et al. 1997a; McCullough et al. 1997; Eninger et al. 2008c). In one study, bacterial penetrations were compared with those of spherical corn oil particles of the same aerodynamic particle sizes (Willeke et al. 1996). The authors showed that respirator filters had the same penetration values for spherical *Streptococcus salivarius* of 0.8-1.0 μm diameter and spherical corn oil particles (0.9-1.7 μm diameter). This finding was confirmed using *Mycobacterium abscessus* aerosol and similar size polystyrene latex (PSL) particles (Brosseau et al. 1997a; McCullough et al. 1997). Recent studies showed that size-fractionated physical penetration of MS2 virus was similar to the viable penetrations in the electrical mobility diameter (22-29 nm) of MS2 virus (Eninger et al. 2008c).

Because of their small size, questions have been raised against the performance of APRs against nanoparticles generated in the workplace. A recent review discussed the current knowledge and limitations (Shaffer and Rengasamy 2009). Furthermore, NIOSH published recommendations for respiratory protection against nanoparticles (NIOSH 2009). The primary concern was that the thermal velocity of small size particles can exceed their capture velocity (Dahneke 1971) leading to increased worker exposure. This suggests that small size particles approaching molecular sizes may not be captured and that thermal rebound of particles <10 nm size will increase penetration levels as predicted (Wang and Kasper 1991). However, single fiber filtration theory predicts that small size particles will be effectively captured by diffusion. Studies were needed to measure the performance of filter media in general and filters used in APRs in particular to determine single fiber filtration theory predicted performance for particles below <10 nm size.

To better understand the penetration of smaller size nanoparticles, experimental studies used glass fiber, composite and membrane filters and challenged them with monodisperse silver (4-10 nm) and dioctyl phthalate (32-420 nm) aerosols to measure particle penetrations at different face velocities (VanOsdell et al. 1990). Penetration levels decreased with decreasing particle size and there was no evidence for thermal rebound for particles of 4 nm size at face velocities up to 15 cm/s. Further studies showed no measurable thermal rebound of particles until 3 nm size (Ichitsubo et al. 1996). The authors also showed that the penetration of nanoparticles below 2 nm was higher than the theoretical results, thus suggesting thermal rebound. A recent study confirmed the thermal rebound for particles <2 nm size at a face velocity of 2.5 cm/s (Kim et al. 2006). Recent studies using different test systems confirmed the absence of any thermal rebound effect for particles >2 nm size (Heim

et al. 2005; Kim et al. 2007a). These studies indicated that respirators made from fibrous filter media would be efficient for capturing particles down to 2 nm.

Historical measurements of respirator efficiency have used aerosol particles >20 nm size, and the lack of information for smaller size particle penetration has remained a concern. Recently, the filtration efficiency of respirators against smaller size particles <20 nm was investigated to determine if any thermal rebound effects could be observed. The filtration performance of respirators against NaCl nanoparticles in the 4.5 nm to 10 μm range aerosols was investigated using one model each of NIOSH-approved N95 and CE-marked European FFP1 respirators (Huang et al. 2007). The authors showed that particles below 10 nm were collected efficiently by the respirators. Another study employed monodisperse silver nanoparticles in the range of 4-30 nm to measure penetration levels for NIOSH-approved N95 and P100 respirators (Rengasamy et al. 2008). Filtration performance of five models of N95 and two models of P100 increased with decreasing particle size down to 4 nm with no thermal rebound. Similar trends in penetrations were obtained for two models each of Conformite Europeen (CE)-marked FFP2 and FFP3 respirators (Rengasamy et al. 2009). All the respirators tested in the study showed no deviation from single fiber filtration theory for particles as small as 4 nm.

Filter Degradation

Filtration performance of FFRs exposed to physical processes and chemicals in workplaces was not well understood until recently. Intermittent aerosol particle loading onto electret filters was shown to decrease filtration efficiency (Moyer and Bergman 2000). Electret filter degradation by gamma- (Walsh and Stenhouse 1998) and X-ray- radiations (Janssen et al. 2003) have been described. In another study, UV irradiation of one N95 and one P100 FFR for up to 8 hrs showed that the penetration levels remained within NIOSH allowed levels (Viscusi et al. 2007). The authors also showed that microwave treatment up to two minutes had no significant changes in filtration performance on the two models tested. Some studies showed that electret filter media degrade at temperatures up to 65°C and relative humidity (RH) up to 90% (Ackley 1982). In other studies, dry heat at a temperature of 80°C for one hour (Viscusi et al. 2007) and dry heat up to 90°C for one hour (Viscusi et al. 2009) showed no visible damage or significant change in filtration efficiency for N95 and P100 FFRs.

Electret filters have been shown to undergo filtration performance degradation upon exposure to certain chemicals. For example, exposure to oils such as DOP decreased the filtration performance of electret filters by mechanisms including neutralization and masking of charge (Tennal et al. 1991; Barrett and Rousseau 1998). Liquid isopropanol treatment increased particle penetration levels with a shift in the MPPS towards higher diameter size particle indicating the removal of electric charges (Chen et al. 1993; Chen and Huang 1998; Martin and Moyer 2000). The removal of electric charges from liquid isopropanol-treated electret respirators was confirmed by electrostatic force microscopy measurements (Kim et al. 2007b). Some studies attributed swelling and dissolution of low-molecular weight polymers for the increase in particle penetrations (Myers and Arnold 2003). In contrast, no measurable release of particles from isopropanol-treated FFRs was reported (Rengasamy et al. 2009). Interestingly, some studies demonstrated that organic solvents in vapor form did not degrade

electret filters (Jasper et al. 2006). While great progress has been made, further studies are still needed to better understand the mechanism of electrical charge removal by different treatments.

IV. Particle Leakage

Face seal leakage is a major component of total inward leakage of particles in addition to particle penetration through filter media. Until recently, the relative contribution of face seal leakage to total inward leakage was not well understood for tight fitting APRs. To address this issue, various studies have been conducted with both manikin head forms, and human subjects performing a set of exercises simulating workplace maneuvers in the laboratory, and with subjects performing their normal work activities in real world workplaces.

Face Seal Leakage with Manikin Head

Several studies measured particle leakage into the breathing zone using a manikin set up **(Figure 3)** (Cooper et al. 1983; Tuomi 1985). The respiratory protection by common clothing and household items such as handkerchief and toweling materials was also studied using a manikin head (Cooper et al. 1983). The authors showed 0-65% leakage around the face/mask interface, and 0.6-39% penetration through filtering media at a flow rate of 37 L/min, indicating that leakage is significantly contributing to particle penetration. In another manikin study, face seal leakage produced higher levels of penetration for particles >5 μm diameter (Tuomi 1985). Subsequent studies showed that aerosol penetration through the filter was strongly dependent on particle size and flow rate, while particle leakage was dependent strongly on particle size and less strongly on pressure drop (Hinds and Kraske, 1987). Based on their results, a model was developed to predict the overall penetration as a function of particle size for any work rate and overall total mass penetration and exposure aerosol size distribution (Hinds and Bellin 1987).

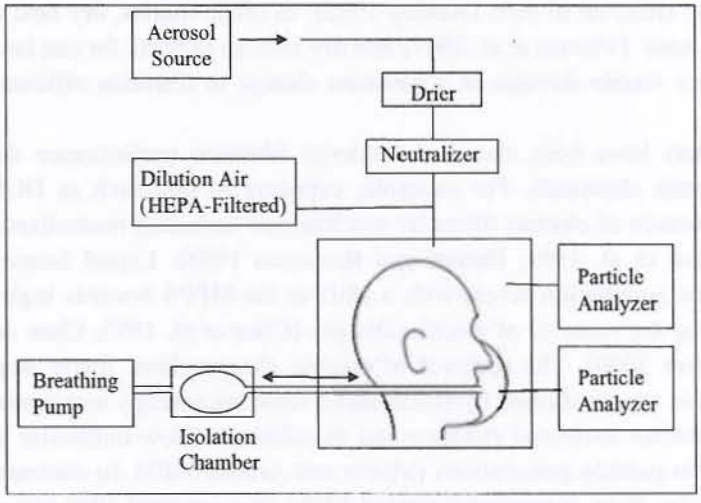

Figure 3. A typical manikin set up to measure particle penetration through filter and face seal.

Some studies compared the face seal leakage of aerosols with gases. In a manikin study, face seal leakage was measured as a function of leak size and particle size with polystyrene latex (PSL) particles and acetone vapor as challenge agents (Myers et al. 1991). Leakage of PSL particles decreased with increasing diameter size from 0.36 to 2.5 μm. The authors also showed that the leakage of acetone vapor was higher than that of PSL particles, indicating that a gaseous challenge agent may be better for fit testing purpose. This possibility was tested with PSL (0.72 μm) particles and vapors including sulfur hexafluoride (SF_6) and isoamyl acetate (IAA) using a manikin head form (Gardner et al. 2004). The simulated respiratory fit factor measurements for PSL particles correlated with those for SF_6 and IAA, suggesting that submicron particle leakage was similar to that of vapor challenges.

Simulated Workplace Protection Factor (SWPF)

Artificial static leaks introduced in manikin head studies may not represent the more dynamic leaks created while a respirator-worn human face is moving during normal work activities (Krishnan et al. 1994; Janssen and Weber 2005; Janssen et al. 2007). Because of the difficulties in measuring particle leakage for subjects wearing respirators in a real workplace, SWPF measurements are made in laboratories using test exercises designed to simulate normal workplace activities. SWPF is measured as the ratio of test atmosphere aerosol concentration outside to the inside of a properly functioning respirator worn properly by a subject in the laboratory.

Several studies investigated the SWPF for N95 FFRs (Coffey et al. 1999b; Coffey et al. 2004; Zhuang et al. 2005). In one study, the performance of 20 N95 FFRs and one elastomeric respirator with replaceable filters was measured in a laboratory setting using a PortaCount Plus (Coffey et al. 1999b). The 95th percentile of the total penetration with fit-testing for all of the respirators combined was 4%, which indicated higher than expected protection levels for N95 respirators. However, the 95th percentile of the total penetration was 33% without fit-testing indicating the importance of fit testing to achieve high levels of workplace protection. In a similar study, 12 N95 FFRs passing a PortaCount Plus fit test method showed 5th percentile SWPF value ≥10 (Coffey et al. 2004). Further studies confirmed this finding by measuring the SWPF for 18 models of N95 (Zhuang et al. 2005). The results showed geometric means (GM) of SWPF 25 and 22 for men and women, respectively. Using a similar methodology, Lawrence and colleagues measured the SWPF for N95 elastomeric and N95 FFRs (Lawrence et al. 2006). For N95 elastomeric and FFRs, the GM values were 35.5 and 20.5 with 5th percentile values of 7.3 and 3.3, respectively. None of these devices as a group provided the expected protection levels for a half-facepiece respirator.

Recently, the SWPF for particles <100 nm was investigated for four different models of N95 FFRs using an Electrical Low Pressure Impactor (ELPI) (Lee et al. 2008). In general, the protection factor (PF) increased with increase in particle size. The authors obtained GM values of 21.5 for four commercially available N95 FFR models (A, B, C, and D) over the eight particle size ranges tested in the study. Nine samples of N95 FFRs for each model A, B, C, and D were tested and the PF values were <10 for 13.9%, 63.95%, 11.1% and 22.2% of the respirators, respectively, suggesting that the OSHA assigned APFs may overestimate their measured PF. Similarly, PF values <10 were reported for some N95 FFRs in a previous study

(Coffey et al. 2004). Interestingly, PF values were less for particles in the 40-200 nm range compared to 200-1300 nm range (Lee et al. 2008). The increasing concern on nanoparticle exposure in workplaces suggests that further studies are needed to better understand the workplace protection factor (WPF) for nanoparticles.

Workplace Protection Factor (WPF)

WPF is a measure of the protection provided in a workplace, under the conditions of that workplace, by a properly selected, fit tested and functioning respirator while it is properly worn and used (AIHA et al. 1985). The number of WPF studies is limited because of the difficulties in simultaneously measuring the contaminant concentrations inside and outside of the respirator on subjects working in real workplaces.

Several studies measured the WPF for different types of APRs used for protection against particulates. In one study the WPF of N95 FFRs in a steel foundry was evaluated (Janssen et al. 2007). Individual WPF values ranged from 5 to 753. The GM was 119 with a 5^{th} percentile value of 19 showing a consistent performance of FFRs with the APF for half-facepiece respirators. Another study investigated the WPF of half-facepiece non-powered air purifying elastomeric respirators equipped with P100 filters in a steel foundry (Zhuang et al. 2003). The GM of the WPFs values was 920 with a geometric standard deviation (GSD) of 17.8 ensuring expected protection levels. On the contrary, one study showed WPFs <10 for N95 FFRs against microorganisms in the 0.7-2 μm and 2-10 μm range sizes representing most bacteria and most fungi, respectively, in agricultural farms (Lee et al. 2005). The low WPF values obtained for some microorganisms are less than the APF value of 10 expected for FFRs. The low WPF values are in agreement with the SWPF obtained for some N95 FFRs (Lawrence et al. 2006). Studies on WPF in healthcare environment are not available to assess the effectiveness of respirators against infectious microorganisms in that occupational setting (Radonovich et al. 2008). However, the low concentration of infectious aerosol particles in healthcare facilities makes WPF measurement difficult.

Fit Test Panels, Anthropometric Analysis, Respirator Design

As noted earlier, face-fitting characteristics are by far the most important aspect for tight fitting respirators to ensure the reliability and level of the protection they offer. Yet, until recently the database of facial dimensions that was used for sizing respirators to fit workers' faces was more than three decades old. For example, the respirator fit test panels used by NIOSH for respirator certification are based on the 25-subject panels developed by the Los Alamos National Laboratory (LANL) in the early 1970's based on U.S. military personnel data. The changing U.S. demographics have resulted in the test panels becoming less representative of the current U.S. workforce of respirator users. Problems with the LANL panel have been reported elsewhere (Zhuang et al. 2005).

In 2001, NIOSH initiated a study to develop an anthropometric database of the heads and faces of civilian respirator users in the U.S. workforce to update the respirator fit test panels. A total of 3,997 subjects were recruited from industries and public services in which workers routinely or occasionally use respirators. Although the sampling plan did not call for

sampling specific geographic regions, subjects were obtained at 41 separate sites, located in 8 states from the east to west coasts of the United States. All subjects were measured for 21 dimensions using traditional measurement tools, and 1013 of the total were scanned with a state-of-the-art 3D scanner (Zhuang and Bradtmiller 2005). The researchers established a database containing anthropometric measures that are representative of U.S. population who rely on respirators to prevent work-related respiratory illnesses, injuries, and death.

Based on the data collected, two new fit test panels for half- and full-face respirator fit testing were developed (Zhuang et al. 2007). One of the new panels (NIOSH bivariate panel) included the same linear measurements used in the LANL panel currently used by NIOSH in the respirator certification program (**Figure 4**). The other panel was based on establishing the appropriate facial features by using principal component analysis (PCA) to identify the combination of facial dimensions that best represented the variation among the faces in the data set (**Figure 5**). The new panels have been incorporated into the International Organization for Standardization (ISO) respiratory protective devices standards (ISO 2009). The use of the new bivariate panel to assess respirators ability to fit a range of facial sizes has been considered in the concept development of a total inward leakage requirement for respirator certification (NIOSH 2007). Based on the new anthropometric data collected, five digital 3-D headforms representative of the current U.S. work force have also been developed (Zhuang et al. 2010).

A similar anthropometric survey of Chinese civilian workers was conducted in 2006 (Du et al. 2008). A total of 3000 subjects (2,026 male and 974 female) between the ages of 18 and 66 years old was measured using traditional techniques. Through comparison with the facial dimensions of American subjects, the study indicated that Chinese civilian workers have shorter face length, smaller nose protrusion, larger face width and longer lip length. Two respirator fit test panels were developed specifically for Chinese workers with the same techniques used to create the NIOSH panels (Chen et al. 2009). Another research group collected facial anthropometric data on 451 Chinese university students and teachers and found that Chinese may have shorter and wider facial characteristics than American civilian workers and military personnel (Yang et al. 2007)

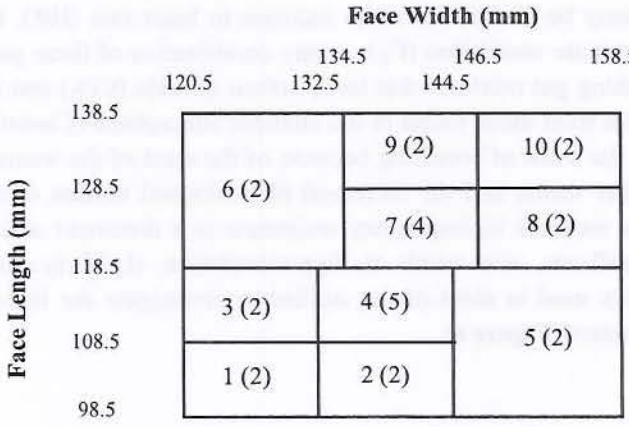

Figure 4. NIOSH fit test panel based on face length and face width. The numbers in each cell represent cell number and the numbers in parentheses indicate the number of subjects to be sampled from each cell.

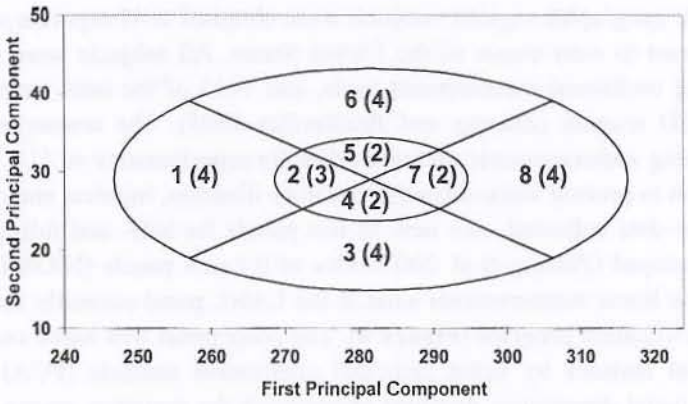

Figure 5. NIOSH fit test panel based on two principal components. The numbers in each cell represent cell number and the numbers in parentheses indicate the number of subjects to be sampled from each cell.

In the 2007 Institute of Medicine (IOM) report, "Assessment of the NIOSH Head and Face Anthropometric Survey of U.S. Respirator Users", the IOM recommended that "NIOSH [...] perform research to determine which facial features have the greatest impact on respiratory protection of face masks in the workplace, using quantitative measures." (IOM 2007). To address these concerns, NIOSH has developed a research roadmap documenting short- and long-term strategies for facial anthropometrics and respirator fit research.

V. Physiological Impact of FFRs on Wearers

Only a modest amount of data exist on the physiological burden associated with FFRs by workers at low-to-moderate work rates (e.g., healthcare workers, nursery care staff, etc.). There are also few human studies addressing the overall physiological impact of air-purifying respirators (APR) and their impact on wearers will not be included in this review. The impact of wearing a FFR may be manifested as an increase in heart rate (HR), breathing rate (f_B), tidal volume (V_T), minute ventilation ($\dot{V}_E$), or any combination of these parameters. FFR use also results in breathing gas mixtures that have carbon dioxide (CO_2) and oxygen (O_2) levels significantly different from those found in the ambient atmosphere (Caretti and Coyne 2008). FFR also increases the work of breathing because of the need of the wearer to overcome the resistance of the filter media and the increased physiological burden of the respirator dead space ($V_{D\ resp}$). The increase in inspiratory resistance is a dominant effect (Martyny et al. 2002) and, if significant, can result in hypoventilation (Lafferty and McKay 2006). Treadmills have been used in most of the studies to investigate the impact of FFR use on physiological parameters (**Figure 6**).

Breathing Resistance

Breathing resistance in FFRs is a function of filter media parameters (e.g., packing density of fibers, orientation of fibers, thickness of the filter, particulate loading), degree of

airflow (higher airflows generally result in greater resistance), and FFR fit (leakage associated with poor fit will impact resistance). Resistance to airflow in FFRs is moderated by decreasing air velocity through manipulation of the shape of the FFR to increase surface area (e.g., duckbill FFR, pleated FFR, etc.). Also, the use of electrically charged (electret) filter fibers results in more efficient FFR that are thinner and offer less resistance to airflow. NIOSH breathing resistance maximums for FFR are 35 mm and 25 mm H_2O pressure, respectively, for inhalation and exhalation at a constant flow rate of 85 L/min (OSHA 2008). One study documented FFR-associated average peak inhalation and exhalation pressures of 1.24 cm and 1.19 cm H_2O pressure, respectively, at a moderate work rate using subjects who did not routinely use FFR (Jones 1991). Others have suggested that the work of breathing associated with the use of FFR is minimal (Fennelly and Nardell 1998).

Breathing Rate (f_B)

Use of respiratory protective equipment generally results in a variable increase in the breathing rate (f_B) that is a factor of the respirator's filter resistance, dead space, work rate, physical fitness of the wearer, respirator-induced anxiety and CO_2 retention (Lange 2000; Szeinuk et al. 2000; Martyny et al. 2002). As the f_B increases, there is less time, per breath, for O_2 extraction and CO_2 expulsion. Previous respirator studies utilized exertion levels (e.g., industrial workers with air-purifying respirators) that are greater than those of many of today's FFR wearers (e.g., healthcare workers, etc.) (Harber et al. 2009), consequently there is little data with respect to current FFR use. Studies using past generation FFRs suggested that low resistance FFRs with small $V_{D\ resp}$ preferentially result in an increase in f_B over V_T because it is more energy efficient (for respirators with small $V_{D\ resp}$ compared to larger $V_{D\ resp}$) and might offer the advantage of increased heat dissipation (Jones 1991). Wearing a N95 FFR for four hours at sedentary activity increased the breathing rate by two breaths per minute over baseline values (Kao et al. 2004). Further improvements in FFR design could bring about decrements in breathing resistance and, by extension, decrease the impact on f_B.

Figure 6. Measurement of physiological parameters of a subject wearing a FFR walking on a treadmill (with permission from NIOSH).

Heart Rate (HR)

Use of respirators places a physiological burden on the user that can affect the heart rate. Wearing a N95 FFR during qualitative fit testing of approximately 30 minutes duration (Lafferty and McKay 2006) or during low to moderate treadmill exercise over 80 minutes (Li et al. 2005) did not significantly increase HR. Further studies are needed to address the cardiovascular impact of FFR worn over periods of several hours.

Tidal Volume (V_T)

Tidal volume (V_T) is the amount of air inhaled or exhaled in each breath and is an indicator of the level of respiratory exertion. Increase in the work of breathing can be manifest as an increase in V_T, breathing rate, or both. The effect of $V_{D\ resp}$ on the FFR user is an increase in V_T (or f_B) (James 1976; Caretti and Coyne 2008). Relatively small amounts of $V_{D\ resp}$ can increase V_T. (Jones 1991); respirators with >100 mL of dead space cause a compensatory increase in the depth of respiration (Hinds and Bellin 1993). Wearing a FFR adds its dead space ($V_{D\ resp}$) to the anatomical V_D of the respiratory tract, functionally resulting in the creation of significantly augmented physiological V_D and the associated increased physiological burden and compensatory requirements. Human respiratory V_D averages 1 mL per pound of body weight. Average $V_{D\ resp}$ of a FFR is dependent upon its configuration (e.g., cup, duck bill, flat fold) and the facial anthropometic features of the wearer. The resultant compensatory increase in V_T ranges from 50% - 90% of the $V_{D\ resp}$ (for respirators having a $V_{D\ resp}$ of 100 mL or more) (James 1976). Duck bill and cup-shaped FFR have greater $V_{D\ resp}$ than flat fold N95, but the $V_{D\ resp}$ differences of these various FFR upon the physiological burden of wearers has not been evaluated in depth. For example, it is theoretically possible that the lower $V_{D\ resp}$ associated with flat fold FFR might offer physiological benefit when worn over extended periods or during intense physical activity.

Respirator Dead Space ($V_{D\ RESP}$) Gases

The $V_{D\ resp}$ of FFR serves as a repository for exhaled and inhaled gases and houses mixtures that are significantly different from the ambient atmosphere (Caretti and Coyne 2008). Inhalation of CO_2 that is higher, or O_2 that is lower, than ambient levels results in compensatory mechanisms to maintain the body's acid-base status within its normally tight boundaries. OSHA ambient workplace standards for CO_2 are <0.5% (as an eight hour time-weighted average), and <19.5% O_2 is considered oxygen deficient (though some have argued, not without merit, that partial pressures should be the dominant consideration rather than O_2 percentages). Interestingly, previous studies have noted that the microenvironment of FFR (i.e., $V_{D\ resp}$) does not conform to the OSHA ambient workplace standards. Lafferty and McKay measured $V_{D\ resp}$ gases during N95 FFR qualitative fit testing exercises and noted mean CO_2 levels of 4.2% (±0.4%) and mean O_2 levels of 15.5% (±0.6%) (Lafferty and McKay 2006). Huang and Huang (2007) taped N95 FFRs to the faces of volunteers (to eliminate face seal leakage) and reported mean $V_{D\ resp}$ O_2 levels as low as 15.21% (±0.21) (Huang and Huang 2007). Thus, it is quite evident that the microenvironment gases of the

FFR can have significant impact on the wearer and additional research is warranted to attempt to address more fully this physiological burden.

Oxygen Saturation

Oxygen saturation (SaO_2) reflects the percentage of hemoglobin binding sites occupied by O_2. Normal SaO_2 levels range from 95% - 100% at sea level. The impact on SaO_2 of wearing an FFR has been studied to a limited degree. One study noted that SaO_2 decreased <1% while wearing an N95 FFR during qualitative fit testing exercises. This correlates with a recent study of surgeons wearing surgical masks (Beder et al. 2008) that noted the SaO_2 baseline of 97.3% declined to 96.3%, a finding that was significant only during surgical procedures > 60 minutes duration. A drop in arterial O_2 of 9 mm Hg, following four hours of FFR wear during hemodialysis, has also been reported (Kao et al. 2004). More data will be required before the full effect of FFR on O_2 parameters is fully elucidated.

Effect of FFR use on CO_2 Levels

Normal carbon dioxide levels in arterial blood range from 35-45 mm Hg pressure. Exhalation causes the expulsion of metabolically-produced CO_2 to the environment, but the use of FFR results in the retention of variable amounts of CO_2 in the $V_{D\ resp}$ that is subsequently re-breathed with successive inhalations. Unfortunately, the impact of this re-breathed CO_2, while wearing FFR, has not been studied in significant detail. Future studies will need to address effects on CO_2 following longer periods of wear and at higher work rates. Also, the impact on CO_2 of different FFR models (e.g., duck bill, flat fold, cup shaped) will need to be investigated.

VI. Emerging Issues

Respirator Shortage/Reuse

Exposure to airborne infectious diseases including the SARS and influenza virus can be reduced by using respiratory protection devices and are often recommended by various public health agencies. During the outbreak of SARS in 2003, large numbers of different size respirators were needed to meet the demand because policy indicates that FFRs worn by healthcare workers should be discarded after examining an infectious patient. Recently, experts predicted the occurrence of an influenza pandemic and a possible shortage of respirators for healthcare personnel and civilian population. The need for more than 90 million N95 FFRs for the protection of healthcare workers against a 42-day influenza pandemic outbreak is predicted (IOM 2006; CDC 2006). In addition, respirators are needed for workers in other sectors and may also be used by the civilian population. Most healthcare facilities only keep a limited number of respirators in stock (Roberge 2008). For these reasons, the U.S. and other countries have stockpiled the most commonly used respiratory

devices. The performance of respirators after long-term storage is not well understood, nor is the degree of risk posed by a respirator exposed to an infectious aerosol (e.g. act as a fomite). One possible option to extend supplies would be to decontaminate an FFR and reuse it, which needs further research on evaluating the effects of decontamination on FFR performance. These issues will be discussed in the next three sections.

Storage

OSHA requires that the employer shall ensure that respirators are stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and that they shall be packed or stored to prevent deformation of the facepiece and exhalation valve (CFR 2003). The storage of respirators should be in accordance with any applicable manufacturer instructions.

The effect of long-term storage of FFRs on filter performance was not investigated until recently. In one study, lifetimes between 1.8 to 2.3 years were calculated for two corona-charged polypropylene filters under high voltage conditions (Motyl and Lowkis 2006). The authors showed that conditioning the samples at a higher humidity influences the changes of the equivalent voltage and the life time of the electret filter. Recently the long-term storage of 21 models of N95 FFRs for at least 6 to ~10 years in warehouses at 15-32°C and relative humidity (RH) 20-80% was studied (Viscusi et al. 2009). These FFRs were tested for initial, as well as maximum penetrations with 200 mg NaCl loading according to the NIOSH particulate respirator certification protocol (Federal Register 1995). Nineteen out of 21 models showed <5% initial, as well as maximum penetration levels. The results from this study indicated that storage for up to 10 years will likely maintain the filtration performance of FFRs. Further studies are needed to better understand the aging effect of the other components of the respirator (e.g. straps, sealing surfaces).

Microbial Contamination and Survival

The survival of microorganisms in the contaminated respirators is a potential health problem should respirators be reused. Microbial contamination of past generation respirators stored in humid environments facilitated microbial growth and increased particle penetration, especially if the filter material is biodegradable (Lacey et al. 1982; Pasanen et al. 1993). In one study, 18 types of respirators and 5 surgical mask models were challenged with different microorganisms and then the percentage of culturable microorganisms recovered from filters was calculated (Brosseau et al. 1997b). A wide variation in the culturability of *Mycobacterium abscessus* (1-60%), *Staphylococcus epidermidis* (0-100%) and *Bacillus subtilis* (87-100%) was obtained after 5 days storage.

Further studies with N95 FFRs using *Mycobacterium smegmatis* showed that the microorganism survived only three days even under ideal growth conditions (Reponen et al. 1999). The authors also reported that the viability of *Pseudomonas fluorescens*, a vegetative bacterium was lost in 3 days, while *Bacillus subtilis*, a spore-forming bacterium remained viable for 13 days (Wang et al. 1999). Both organisms failed to multiply and grow. These

studies suggested that respirators exposed to different microorganisms need careful consideration before potential reuse.

Decontamination

Cleaning and decontamination are important steps in disinfecting respirators other than disposable FFR, which can reduce the spread of diseases during reuse of a respirator by the same or a different user. Respirator maintenance, cleaning and disinfection are required for respirator reuse in the workplace (CFR 2003). Employers must provide for the cleaning and disinfecting, storage, inspection, and repair of reusable respirators used by employees. Employers also must provide each user a respirator that is clean, sanitary and in good working order. Respirator cleaning and disinfection involve removal of components as recommended by manufacturer, washing with a mild detergent in warm water, rinsing thoroughly, drying and reassembling of components before reuse. Decontamination generally involves additional treatment to kill infectious organisms that have been captured by the filter. However, decontamination of disposable FFRs was not considered until recently.

An Institute of Medicine (IOM) report recommended that Department of Health and Human Services (DHHS) sponsor and/or conduct research on simple decontamination procedures for FFRs to meet the demand during a pandemic influenza (IOM 2006). One recent paper took a step toward addressing this issue by reporting the investigation of the filtration performance of two FFR models exposed to ten different decontamination methods (Viscusi et al. 2007). Liquid hydrogen peroxide at 3% for 30 min, vaporized hydrogen peroxide or UV irradiation for up to 8 hours resulted in penetration levels <5% with no significant damage to both N95 and P100 FFRs. On the other hand, bleach treatment up to 5.25% (sodium hypochlorite) concentrations for 30 min showed stiffening of the respirators and tarnishing of the nose pad, with no significant increase in particle penetration levels.

The effectiveness of a variety of decontamination methods for microorganisms applied to FFRs have been investigated (Fisher et al. 2009; Vo et al. 2009). For example, in one study (Fisher et al. 2009), FFR coupons (circular discs, 5 cm^2) were loaded with MS2 aerosol particles and exposed to different concentrations of bleach for 10 minutes. MS2 virus was maximally inactivated at 0.6% bleach and did not vary with the protein concentration in the suspension medium. However, bleach at 0.0006% effectively inactivated MS2 in growth medium containing low, but not high concentration of protein. This suggested that high protein concentration is likely to inhibit the decontamination effect of bleach. Steam treatment was also found to be effective for decontamination of MS2 on filter coupons and was not affected by protein concentration in the suspension medium.

Several decontamination methods including ozone (Kharde and Yousef 2001), chlorine dioxide (EPA 2007), low pressure oxygen-based plasmas (Hury et al. 1998), L-gel (Raber and McGuire 2002) and other technologies (EPA 1994) have been used for decontamination of microorganisms on different substrate materials, but not on respirators. Further research on potential decontamination technologies for FFRs and other types of APRs contaminated with microorganisms should be conducted.

VII. Recent Developments

Biocidal Filters

Handling contaminated respirators may present potential problems of virus transmission. To prevent the spread of infection, a report by the Institute of Medicine (IOM) suggested the need for research in the development of antimicrobial masks that can inactivate the virus (IOM 2006). Respirators incorporated with antimicrobial agents such as iodine, silver, quaternary ammonium and ozone-like compounds can inactivate/kill microorganisms. Some studies showed significant removal/inactivation of MS2 virus aerosol when passed through iodinated filters (Heimbuch et al. 2004; Heimbuch and Wander 2006), while others failed to demonstrate a significant inactivation (Eninger et al. 2008c). The discrepancy between the results obtained in the above studies appears to be due to the difference in the test methodologies employed for measuring the viable virus particles. Iodinated filters were found to be effective for various bacterial species including *Bacillus subtilis, Escherichia coli and Micrococcus luteus* (Lee et al., 2008a; Ratnesar-Shumate et al., 2008). A recent study investigaged MS2 virus decontamination efficacy of respirators using coupons from four manufacturers representing four different antimicrobial agents (Rengasamy et al. 2009). The authors showed that the viability of MS2 was significantly decreased at high temperature and high humidity storage conditions by the iodinated antimicrobial respirator coupon, with no significant effect for the other antimicrobial respirtor coupons. The antimicrobial efficacy of the filter materials for different microorganisms remains to be determined.

Antimicrobial technology in related areas may be applied to respirators. For example, antimicrobial clothing materials incorporated with N-hydantoin derivatives (Sun and Sun 2003) and quaternary ammonium salt (Kim and Sun 2001) were effective for microbial decontamination. The application of similar technologies may be exploited for respirators.

Nanofiber Filters

The non-woven industry generally considers nanofibers as having a diameter less than 0.5 μm with a large surface area-to-volume ratio (Wang et al. 2008). Nanofibers are widely produced by electrospinning (Teo and Ramakrishna 2006) and melt-blown or multi-component fiber spinning techniques (Ward 2005). The physical characteristics of nanofibers, including diameter, surface area and basis weight, have been reported (Grafe and Graham 2002). The increased surface area of nanofibers makes them potential candidates for particle filtration applications. Respirators containing nanofiber filter media have potential to offer excellent filtration performance without an increase in filter air flow resistance. Respirators with smaller air flow resistance are potentially more comfortable to wear for extended periods of time.

Polypropylene nanofibers generated by melt-blown technology were investigated for their collection efficiency against various size particles (Podgorski et al. 2006). The authors showed that addition of thin nanofiber (diameter, 0.74-1.41 μm) layers to the polypropylene filter considerably increased the filtration efficiency, especially in the 200 nm range (MPPS) and 2.6 times increase in the quality factor (QF). QF is a metric of filter performance

represented as a ratio between filter efficiency and pressure drop. This finding was confirmed by measuring the figure of merit (also known as QF) for nanofiber (diameter, 0.15 μm) filters (Wang et al. 2008). The authors showed that nanofiber filters had better figure of merit for particles >100 nm compared to conventional fiberglass filters. However, for particles <100 nm, nanofiber filters did not perform better than conventional filters. Application of nanofibers for respiratory protection needs further investigation.

Novel Respirator Designs

Although respirators are designed to provide a good fit on the human face, some exhibit considerable leakage under working conditions (Coffey et al. 1999a; Zhuang et al. 2003). Developments in better sealing respirators will enhance respiratory protection in workplaces. Toward this goal, NIOSH recently sponsored a workshop to discuss the current state of APR fit and to suggest future technologies that could lead to improved fitting APRs (UMSPH 2008). Recently, some manufacturers have designed masks with adhesives on the face sealing periphery to provide a tight seal on the face of a wearer. Others combined a transparent material with the filter for adjusting the fit of the respirator to the face. Another report discussed new technologies that offer potential improvement for facial seal, cooling and filtration (Richardson et al. 2008). Further improvements in simplifying donning and doffing procedures for respirators are needed.

Conclusion

The need for respiratory protection against biological aerosols such as influenza and SARS, and nonbiological particulate hazards including nanoparticles is growing. Data from several research studies show that respirators approved by NIOSH and other organizations meet their expected filtration performance levels. These respirators efficiently capture particles as small as 4 nm under stringent test conditions with no deviation from single-fiber filtration theory. Most of the respirators on the market are electret filters with enhanced particle capturing efficiency without significant increase in breathing resistance. The MPPS for the FFRs was in the <100 nm range as expected for electret filters.

In spite of the high filtration efficiency levels reported for respirators, face seal leakage remains a major concern to achieve expected levels of respiratory protection in workplaces. WPF and SWPF studies continue to report varying results on the fitting of FFRs to workers faces. Face seal leakage studies using manikin models with artificial static leaks may be of limited value to address workplace protection against particulates. Several studies attempted to delineate the relationship between face seal leakage and particle size with no consistent pattern. Some of the SWPF studies obtained protection factors around 20 for the commonly used N95 FFRs which exhibited variability in achieving those protection factor levels. WPF measurements in a variety of different actual workplaces provided varying protection levels for similar respirators. Many investigators reported WPF values of >10 for APRs, while WPF value of <10 was obtained in one study. Concerns about nanoparticle leakage suggests the need for further studies on measuring WPF for nanoparticles <100 nm. Fit testing is necessary

to ensure that the user is wearing the correct respirator size and model to provide expected levels of protection.

To reduce leakage, design of good fitting respirators is needed. Update of the database of facial feature measurements of workers representing the U.S. workforce instead of the data for the military personnel enabled NIOSH to develop new fit test panels to improve the design of better fitting respirators.

The physiological impact of respiratory protective equipment upon wearers needs further investigation. Recent research has indicated elevated levels of CO_2 and reduced O_2 concentrations could impact the physiological response of users. Further research is needed to assess the impact on user comfort and tolerability issues.

Long-term storage of respirators is needed to meet the demands during pandemic events. Further research on respirator degradation, microbial contamination and decontamination are important to address emerging respirator needs. Technological advances produced biocidal, and nanofiber filters which may be considered for respiratory protection. Further research in similar innovative technologies could provide better respiratory protection to workers through improved fit, better filtration performance, reduced physiological burden, and improved comfort and tolerability.

DISCLAIMER

The findings and conclusions of this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of a commercial product or trade name does not constitute endorsement by the National Institute for Occupational Safety and Health.

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