BETTER RESPIRATORY EQUIPMENT USING ADVANCED TECHNOLOGIES FOR HEALTHCARE EMPLOYEES (PROJECT B.R.E.A.T.H.E.)

An Interagency Working Group of the U.S. Federal Government

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Sponsored and Chaired by the Office of Public Health and Environmental Hazards in the Veterans Health Administration at the U.S. Department of Veterans Affairs

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Executive Summary

The **B**etter **R**espiratory **E**quipment using **A**dvanced **T**echnologies for **H**ealthcare **E**mployees (**Project BREATHE**) Working Group (WG) is a U.S. Federal government interagency effort, initiated by the Department of Veterans Affairs, whose purpose is to develop a set of consensus recommendations that aim to improve respiratory protective equipment used by healthcare workers (HCWs). With representatives from nine (9) Federal departments and agencies, this multi-disciplinary team had a broad range of expertise, including pandemic and emergency preparedness, infectious disease medicine and epidemiology, respirator and personal protective equipment policy and regulation, occupational and environmental medicine, respirator and materials science, infection control, respirator physiology and physics and bio-security. The WG was co-chaired by staff from the Veterans Administration (VA) and the Centers for Disease Control and Prevention (CDC). This report consists of 28 consensus recommendations for consideration by respirator manufacturers, research organizations, consensus standards development organizations, and respirator users and their employers.

The activities of the WG build on recommendations issued by the Institute of Medicine (IOM) in November 2007 and articulate the next steps that should be taken toward better respiratory protective equipment for HCWs. Together, this set of recommendations constitutes an *idealized* view of the features included in the next generation of respirators for HCWs. Each of 28 consensus recommendations is included in one of four categories of desirable characteristics:

- **Respirators should perform their intended functions safely and effectively**
  (9 recommendations)

- **Respirators should support, not interfere with, occupational activities**
  (5 recommendations)

- **Respirators should be comfortable and tolerable for the duration of wear**
  (10 recommendations)

- **Respiratory protective programs should comply with Federal standards and guidelines, state regulations, and local policies**
  (4 recommendations)

These recommendations may be regarded as (a) an action and research agenda for the Federal government, (b) a guide for the U.S. health care sector that identifies activities which might yield strong returns on their resource investment, and (c) a research and development roadmap for the next generation of respirators used by the U.S. healthcare workforce.

Reflected in this report is a position held by the WG that clinical assessment tools, such as clinical trials, are preferred over methods performed solely in a laboratory. However, in many instances clinical assessments are not practical, in which case the use of laboratory tools that have been validated against clinical outcomes, are favored. In cases where neither is available, the WG has made suggestions about the types of assessment methods that should be considered for development and validation. The WG favors the development of a **new respirator class called a "B95" (Biological N95)** which connotes protection against biological particulates. Consensus Recommendations issued by the Project BREATHE WG include:

Safety and Effectiveness

(1) Respirators should meet current U.S. Federal government standards for respiratory protective devices (*e.g.*, the CDC National Institute for Occupational Safety and Health (NIOSH) N95 single use negative pressure air purifying respirator) and used as part of an Occupational Safety and Health Administration (OSHA) compliant respiratory protection program, including annual fit testing.

(2) (a) A means should be developed to practically don and doff approved respirators without self-contamination and (b) A test should be developed, validated and standardized that assesses respirator contamination in a clinical environment.

(3) (a) Designs should be utilized that prevent respirator-dependent transmission of infectious pathogens and (b) A test should be developed, validated and standardized that assesses respirator-dependent pathogen transmission in a clinical environment.

(4) Respirators should be capable of providing a Simulated Workplace Protection Factor of 100 that is assessed using a standardized and validated measure (e.g., the NIOSH total inward leakage test) for a majority (ideally 90%) of healthcare workers wearing a "one-size-fits-all" (or as few sizes as possible) configuration.

(5) Blood and body fluid penetration should be assessed with American Society for Testing and Materials (ASTM) F 1862 - 07: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood.

(6) Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after 50 brief worker-patient encounters, if necessary, during a crisis.

(7) Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after 50 disinfections, each taking 60 seconds or less to complete.

(8) Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after being stored in air-conditioned space for at least 10 years at 21-23°C (69-73°F) and 45-55% relative humidity.

(9) Respirators should have a manufacturer-specified fit assessment technique (*e.g.*, a user seal check) that is capable of detecting inadequate fit (Simulated Workplace Protection Factor < 100) with at least 75% accuracy during work activities.

No Interference with Occupational Activities

(10) (a) Specific word intelligibility tests should be developed, standardized and validated to more precisely measure the hearing accuracy of words in the healthcare setting and (b) Respirator wearers should achieve equivalent or higher scores on hearing acuity tests, on average, when wearing a respirator compared to no respirator.

(11) Respirator wearers should achieve equivalent or higher scores on speaking intelligibility tests, on average, when wearing a respirator compared to no respirator.

(12) (a) Visual fields should be assessed with a standardized and validated tool developed for use in the healthcare environment and (b) Healthcare visual field performance criteria should be developed for respirator wearers.

(13) (a) Transparent respirator facepieces should be developed to the extent possible and (b) Transparency should be assessed with an optical clearance test that is standardized and validated.

(14) (a) Respiratory protective equipment should be assessed for inter-equipment compatibility using a practical clinical test that should be developed, standardized, and validated and (b) Healthcare performance criteria for protective equipment compatibility should be developed.

Comfort and Tolerability

(15) (a) Respirators should have a level of breathing resistance that is low enough to be comfortable and tolerable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Breathing resistance should be < 10 mm H_2O pressure drop on average at 85 lpm.

(16) Facial irritation should be assessed using two standardized and validated tests: (a) A clinical assessment utilizing a pain or discomfort scale and (b) A lab-based sensitivity test, such as a transdermal water loss test or an animal skin sensitivity test.

(17) (a) Immune system stimulation should be assessed with a standardized and validated test and (b) Performance characteristics for allergenicity should be developed.

(18) (a) Respirator facial pressure should be low enough to be comfortable and tolerable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Facial pressure should be assessed using two standardized and validated tests: (1) a clinical assessment and (2) a lab-based test.

(19) (a) Respirators should cause a level of facial heat rise that is low enough to be comfortable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Facial heat should not exceed a 7°F rise from baseline, on average, when the wearer is under low level exertion at 21-23°C (69-73°F) ambient temperature.

(20) (a) Respirator CO_2 dead space retention should be low enough to be comfortable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Respirator oral-nasal chamber CO_2 levels at end-inhalation should be < 1%, on average.

(21) (a) Respirator humidity should be maintained at levels perceived as comfortable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Respirator relative humidity levels should be maintained at < 20% above baseline, on average, under low levels of exertion.

(22) (a) Respirator weight should be low enough, and distribution of weight sufficiently symmetrical, to be comfortable and tolerable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Respirator weight and mass distribution should be evaluated with a standardized and validated clinical test for which performance criteria are developed.

(23) (a) Odor should be assessed with a standardized and validated clinical tool and (b) Performance criteria should be developed.

(24) (a) Respirators should be comfortable enough to be worn for 10 consecutive days under the following circumstances: (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Perceived respirator discomfort during prolonged wear should be assessed clinically using a validated and standardized test.

Healthcare System Policies and Practices

(25) Employer interviews, surveys and clinical trials should be conducted to determine respirator features that would lead employers to purchase one respirator over another.

(26) Employee interviews, surveys and clinical trials should be conducted to determine respirator features that would lead employees to choose one respirator over another.

(27) Patient and healthcare visitor interviews and surveys should be conducted to determine respirator features that would lead them to prefer one respirator over another.

(28) (a) Studies that estimate the costs and benefits of respirators across diverse settings should be completed and (b) Health economists and other fiscal experts should be recruited for participation in cost-effectiveness assessments.

An extensive research network makes the VA an ideal organization to marshal the development of one or more new respirators to the U.S. marketplace in partnership with NIOSH and other Federal agencies. An extensive healthcare system in VA hospitals provides an excellent test bed for assessing and guiding prototype design. VA HCWs, who stand to receive the most benefit from a new respirator, are poised to assist with development. Together, this unique set of characteristics should put the VA in a position to demonstrate to Congress and the American taxpayer the benefits of improving respiratory protective equipment for HCWs. The same approach should lead to more cost-effective respirators that deliver a net savings in the near future.

Introduction

The **B**etter **R**espiratory **E**quipment using **A**dvanced **T**echnologies for **H**ealthcare **E**mployees (**Project BREATHE**) Working Group (WG) is an interagency effort of the U.S. Federal government initiated by the Department of Veterans Affairs (VA). The purpose of Project BREATHE is to use a government-academic-private partnership model to bring a new respirator for healthcare workers to the U.S. marketplace (Figure 1). The aim of the WG (phase I of Project BREATHE) is to develop a set of consensus recommendations that, if implemented, should improve the function and utility of respiratory protective equipment used by VA and other healthcare workers (HCWs).

The nation's VA medical centers employ approximately 118,000 HCWs[1] who wear and discard approximately 1.6 million respirators per year[2] at its 900+ outpatient clinics, 150+ hospitals and 136 nursing homes[1]. Provision of a safe workplace where HCWs can carry-out their occupational duties in a secure environment without undue risk, during periods of routine operations and a variety of crises, is considered mission critical.

The primary purpose of this report is to articulate the consensus recommendations of the Project BREATHE WG. These recommendations are based on clinical and laboratory evidence, when it is available, and rely on expert opinion when it is not. These 28 recommendations may be regarded as (a) an action and research agenda for the Federal government, (b) a guide for the U.S. health care sector that identifies activities which might yield strong returns on their resource investment, and (c) a research and development roadmap for the next generation of respirators used by the U.S. healthcare workforce. All 28 recommendations implemented simultaneously would be viewed as "ideal". However, mass producing a respirator in which all 28 stipulations were met, at a cost viewed as reasonable by healthcare systems, might not be plausible.

The WG favors the development of a new respirator class called a **"B95" (Biological N95)** which connotes protection against biological particulates. This designation helps illuminate the differences between the new respirator type and the N95, R95 or P95 (the N, P or R classes of respirators). While the focus of Project BREATHE is on the VA system, it is understood that these recommendations stand to influence the next generation of respirators on a global scale.

Background

Respirators have been used widely by U.S. HCWs since the early 1990s when tuberculosis (TB) saw a global resurgence[3]. The intended primary purpose of respiratory protective equipment in healthcare is to reduce the risk of exposure in order to prevent the human-to-human transmission of airborne infectious diseases[4] via fine particles (bioaerosols) that are emitted from the respiratory tract of infected patients when coughing, sneezing or talking[5]. There may also be secondary benefits from the use of respiratory protective equipment, such as protection against blood and body fluid splashes or facial protection from irritant substances[6]. In 1994, the Centers for Disease Control and Prevention (CDC) recommended that HCWs caring for patients infected with TB should don respiratory protection[3]. This approach, which became the standard of care, was endorsed and later bolstered via regulation by the Occupational Safety and Health Administration (OSHA)[7]. An ensuing policy debate about the level of protection to be afforded HCWs during the course of their occupational duties led to a new respirator classification system (N, P, R nomenclature) that included a more precise identification of the filtration efficiency of each respirator type[7].

As certain types of TB evolved into strains that were resistant to treatment by many of the most common antibiotics[8], HCWs became infected with TB with increasing frequency. In the late 1980s and early 1990s, several HCWs died from occupational exposure to TB[9]. To enhance protection, HCWs began wearing respirators borrowed from other occupational sectors. Dust mist respirators (DMRs), akin to N95 respirators used currently) were used widely by the construction and manufacturing industries[7] to protect against the inhalation of workplace dusts (particulates)[4]. DMRs were shown to be effective in filtering simulant infectious disease particulates[4], although a lack of clear clinical evidence proving the effectiveness of respirators against airborne infectious diseases led to controversy about the necessity of this relatively expensive and intrusive protective measure[10]. This controversy continues today and may be partially responsible for the relative complacency[11] and low compliance rates[11,12,13] with respiratory protection guidelines among HCWs[14]. Further stirring controversy was an act of Congress (Wicker Act) that prevented OSHA from enforcing its annual respirator fit-testing standard[15]. This Act was subsequently abrogated.

Discomfort and intolerance were frequent complaints of HCWs in Toronto who wore respiratory protection during the Severe Acute Respiratory Syndrome (SARS) crisis[14]. During the SARS outbreak, many Canadian public health organizations advised HCWs to use respiratory protection throughout the course of their work shifts, which often lasted 12 hours or longer[16]. Notwithstanding the ostensible protection provided by respirators, HCWs complained about headaches, facial heat and pressure, shortness of breath, interference with occupational duties, among other problems associated with their use[16,17-21]. Respirator-associated discomfort and occupational interference was viewed as a major limiting factor in work performance and, to an unknown extent, occupational absenteeism may have been related[16,18,20]. Concerns have been raised about the same or similar events occurring in the U.S. during future epidemics[14].

In 2006, the National Personal Protective Technology Laboratory (NPPTL) in the National Institute for Occupational Safety and Health (NIOSH) of the CDC made a request to the Institute of Medicine (IOM) for a review of personal protective equipment, with the explicit purpose of recommending how to best protect HCWs during an influenza pandemic[14]. In its report, *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*, the IOM noted a conspicuous lack of evidence behind respirator protective measures, including minimal attention placed on the development of equipment meeting the needs of HCWs. The IOM recommended revisiting elemental aspects of respirator design and development, including a distinct attention to respirators tailored to the jobs performed by HCWs, and pursuing an evidence-based approach to equipment design, to the extent that this is possible (Figure 2). This report stressed the need for urgent action, emphasizing that the next influenza pandemic could occur in the near future.

Building the "BREATHE Team"

VA leadership accepted the call to action by the IOM and directed the initial actions of the Project BREATHE Working Group to study ways to "*Innovate and Strengthen Personal Protective Equipment Design [and] Testing*"[14] (Figure 3). An initial partnership was formed with the National Institute for Occupational Safety and Health (NIOSH) via a memorandum of understanding followed by outreach activities to all other relevant Federal agencies. A common agenda was reflected by productive collaboration among nine Federal agencies:

Project BREATHE — Participating Federal Agencies:
(See Appendix A for a list of individual members)

- The National Personal Protective Technology Laboratory in the National Institute for Occupational Safety and Health in the Centers for Disease Control and Prevention (Department of Health and Human Services)
- Office for Infection Control, Division of Healthcare Quality Promotion in the Centers for Disease Control and Prevention (Department of Health and Human Services)
- National Center for HIV, STD and TB Prevention, Division of Healthcare Quality Promotion in the Centers for Disease Control and Prevention (Department of Health and Human Services)
- The U.S. Army Edgewood Chemical Biological Center (Department of Defense)
- The Occupational Safety and Health Administration (Department of Labor)
- The National Institute of Standards and Technology (Department of Commerce)
- The National Aeronautics and Space Administration
- Biomedical Advanced Research and Development Authority (Department of Health and Human Services)
- Office of Public Health and Environmental Hazards in the Veterans Health Administration (Department of Veterans Affairs)

The Food and Drug Administration (FDA) is notably absent because of legal stipulations raised by their General Council; however, the FDA Center for Devices and Radiological Health reviewed this report before it was made available to the public.

Co-chaired by staff from the VA and the CDC, the WG had a broad range of expertise and experience, including (but not necessarily limited to):

- Pandemic and emergency preparedness;
- Infectious disease medicine;
- Infectious disease epidemiology;
- Infection control and prevention;
- Respirator and personal protective equipment policy and regulation;
- Respirator and materials science;
- Occupational and environmental medicine;
- Respirator physiology;
- Aerosol physics; and
- Biosecurity.

The focus of Project BREATHE was on the development of respiratory protection for HCWs who are employed in hospitals and other clinical settings. It was *not* focused on the unique needs of paramedical personnel, such as ambulance or in-flight rescue medical teams or hazardous materials workers. In scope were respirators that protect against aerosolized infectious particulates (airborne pathogens) to which HCWs may be exposed, such as TB, measles and influenza. Protection against

agents that were perceived to have a high probability for use during terrorist events or biological warfare (Chemical, Biological, Radiological, Nuclear or Explosive events or CBNRE) were *not* specifically considered by the BREATHE WG. However, these agents were not intentionally excluded and may be viewed as included in the WG's considerations to the extent that these agents may also cause naturally occurring infections.

The WG acknowledged that policy makers often seek to reduce risk of adverse events to zero. It should be noted that the WG believes this paradigm is not possible with respiratory protection. By nature, occupational activities in healthcare carry an inherent risk of workplace-acquired infection. Respiratory personal protective equipment is designed to be a last resort to infection control after various administrative and engineering methods are employed[3]. The aim of respirators is to limit the risk of HCW exposure, not to eliminate it. The extent to which risk is limited depends on numerous factors[14] that are discussed in this report. Project BREATHE seeks to improve respirator tolerability, comfort, and other functional characteristics, while maintaining a level of protection equivalent to, or greater than, current standards. If successful, changes that grow out of this report should increase compliance with respiratory protection guidelines and standards among HCWs.

Research for Project BREATHE began with the VA staff interviewing members of the WG to record problems with existing respiratory protective equipment and to record improvements recommended. Four key categories of characteristics emerged:

- **Respirators should perform their intended functions safely and effectively.**
- **Respirators should support, not interfere with, occupational activities.**
- **Respirators should be comfortable and tolerable for the duration of wear.**
- **Respiratory protective programs should comply with Federal standards and guidelines, state regulations, and local policies.**

This framework was used to facilitate discussion among WG members. The team convened in Washington, DC in August 2008 to articulate and form a consensus about recommended features and performance requirements for the next generation of respirators. Only items that met team consensus were included in the final list of characteristics. The WG avoided making recommendations about specific materials used in, or the final appearance of, future respirators. Instead, efforts were directed toward describing the desirable characteristics and identifying ways to assess the performance of respirators (using various laboratory-based and clinical assessment methods) once these characteristics become incorporated. Throughout this report, the WG articulates its preference for clinical assessment methods (*e.g.*, clinical trials; in situ measurements) over methods performed solely in the laboratory (*e.g.*, surrogate biomarkers; correlates of physiologic response). However, in many instances clinical assessments were identified as impractical. In such cases, the WG favors the use of laboratory tools that have been validated against clinical outcomes. The recommendations included in this report have varying levels of urgency and importance; therefore, priority designations (1 through 5, with 1 being the most important) were assigned to each recommendation based on consensus. Collectively, this set of recommendations constitutes an *idealized* view of the features included in next generation of respirators for HCWs.

Following the August 2008 meeting, this consensus report was drafted by the VA authors (LR and AB) and distributed to the WG for review, critique and modification. The review was iterative until consensus was reached about textual changes. While the intended audience for this is the VA, the intent is to share these recommendations widely across the Federal government to propel the research that is needed among the agencies represented on the WG. A subsequent manuscript is planned for publication. The intention is to have future endeavors include discussions with private manufacturers about building one or more prototype respirators based on these recommendations.

The IOM report emphasized that in "this era of moving toward preparedness for a pandemic, it is important to examine the level of rigor employed to ensure that all forms of personal protective equipment are deemed to be safe and effective medical devices".[22] The BREATHE WG viewed safety and effectiveness as closely linked to comfort and tolerability. Even the most sophisticated respirators cannot be fully effective if they are not properly worn. The respirators that emerge from Project BREATHE should be capable of performing effectively under a variety of circumstances, ranging from routine operations to bioterrorism.

Effectiveness of equipment used in the workplace is a characteristic that is often incorporated into policy and regulation. The utility and practical applicability of certain safety measures, such as the Assigned Protection Factor (APF)[4,29] or fit-testing[24], have been studied extensively[7,14,25]. The intention of Project BREATHE is not make value judgments about current regulatory stipulations (Table 1), but instead to issue a list of consensus recommendations that align with, or build upon, current standards.

Consensus 1: Safety and Effectiveness

- **Objective:** Respirators should function safely and effectively.
- **Recommendation:** Respirators should meet current standards.
- **Priority Designation:** 1

Currently, NIOSH certification is required for manufacturers to place the NIOSH seal of approval on their products[26]. OSHA regulates respiratory protective equipment and places safety stipulations on the way it is used in all workplaces, including healthcare settings[26]. The WG agreed that in order for a respirator to work as designed, it needs to be used in the context of an OSHA compliant respiratory protection program (29 CFR 1910.134)[28], including annual fit testing.

Clearance from the FDA is required for manufacturers to make claims about the protective effect against blood and body fluid splash protection fluid resistance, biocompatibility, and flammability. Medical claims can only be made for devices sold in the U.S. that have received FDA clearance or approval[29]. Most respirator manufacturers do not seek such approval. The WG discussed the possibility of including the FDA more formally in the approval process before respirators may be marketed, although a consensus was not reached and a recommendation was not issued.

Consensus 2: Self-Contamination

- **Objective:** Respirators should be capable of being easily donned and doffed without causing self-contamination.
- **Recommendation:** (a) A means should be developed to practically don and doff approved respirators without self-contamination and (b) A test should be developed, validated and standardized that assesses respirator contamination in a clinical environment.
- **Priority Designation:** 1

Doffing and donning are among the most frequent activities associated with self-contamination[30]. Contamination of respirator surfaces with microorganisms may be sources of infection[31], although the extent to which PPE contamination leads to transmission is unknown. Respirators that are designed to diminish self-contamination are desired. There is no standard way to measure the likelihood of contamination; therefore, Federal agencies (*e.g.*, NIOSH and the National Institute of Standards and Technology (NIST)) should consider working together to develop an assessment tool. Similarly, manufacturers should propose means to practically assess self-contamination. The methods described by Casanova[30] may serve as a starting point.

Consensus 3: Fomite Transmission

- **Objective:** Respirators should not be a conduit for transmission of pathogens between persons.
- **Recommendation:** (a) Designs should be utilized that prevent respirator-dependent transmission of infectious pathogens and (b) A test should be developed, validated and standardized that assesses respirator-dependent pathogen transmission in a clinical environment.
- **Priority Designation:** 1

Because materials contaminated with microorganisms (fomites) may transmit infection from one person to another[32], respirators should be constructed with materials that minimize or eliminate this risk (e.g., through the use of an antimicrobial coating). Currently, two respirators approved by NIOSH contain antimicrobial components, however their efficacy at reducing the risks of handling after exposure to an infectious aerosol challenge is unknown. Manufacturers seeking approval for respirators incorporating antimicrobial technologies need to satisfy requirements specified by NIOSH, FDA, and the Environmental Protection Agency (EPA) depending upon the specific claims being made[33]. Assessment methods should be developed because there is no accepted standard. Manufacturers should propose ways to gauge fomite transmission in the healthcare workplace. One option might be the use of MS2 phage assays developed by NIOSH.[34,35, 36]

Consensus 4: Protection / Respirator Fit

- **Objective:** Respirators should be inherently well-fitting and reduce HCWs particulate exposure to expected levels.
- **Recommendation:** Respirators should be capable of providing a Simulated Workplace Protection Factor of 100 that is assessed using a standardized and validated measure (*e.g.*, the NIOSH total inward leakage test) for a majority (ideally 90%) of healthcare workers wearing a "one-size-fits-all" (or as few sizes as possible) configuration.
- **Priority Designation:** 1

There are numerous ways to measure the effectiveness of respirator use by HCWs. Arguably, the most important outcome is to reduce exposures leading to a decrease in infections among those who wear respirators compared to those who do not[37]. However, these types of clinical trials are very difficult and expensive to conduct[38,39,40]. More commonly, exposure to inert particulates in a lab-based environment serves as a surrogate for clinical outcome data. In the workplace, one measurement that has been validated in some occupations (but not healthcare) is the Workplace Protection Factor (WPF)[41]. A similar measure conducted in a laboratory setting under controlled conditions is the Simulated Workplace Protection Factor (SWPF)[25]. Both WPF and SWPF values are calculated by comparing the number or concentration of particulates inside versus outside the filtered space. For many years, media technology has been advanced enough to confidently filter microorganisms[42]. Facial seal is widely understood to be the primary source of respirator leakage[14]. Because definitive clinical trials have not been done to prove the level of protection necessary to prevent infections in HCWs, the APF hazard ratios[4] (the inverse of the probability of exposure ratio, *inside/outside*) are assigned by OSHA somewhat arbitrarily.

One of the reasons some HCWs experience leaks around the facial seal with half-face respirators is because the shape does not approximate all of the curves of the face[14]. Some organizations purchase one or few respirator models for their workforces. In a setting with a large workforce, it would be highly unusual for one respirator to fit every worker — two models in different sizes are often required[43, 44]. If respirators were tailored to fit the facial characteristics of each user without manipulation, the likelihood of leaks might be much lower. Anthropometric tools[45], auto-adjusting ("form fitting") materials,[59] facial adhesives[47] and novel polymers with high plasticity[46] may facilitate development of a "one model fits most" approach.

Current NIOSH certification regulations do not have a fit test requirement for half-mask particulate air purifying respirators. When the current NIOSH certification requirements were published in 1995 (see Federal Register Notice Vol. 60, No. 110 / Thursday June 8th, 1995 pages 30336-30404), it was felt that the fit test protocols in use at that time lacked sufficient validation to include as a requirement. NIOSH has proposed a new total inward leakage test to fill this gap[48]. This Project BREATHE requirement builds upon the proposed NIOSH requirement.

Consensus 5: Blood and Body Fluids

- **Objective:** Respirators should serve as a barrier to protect the wearer from blood and body fluids.
- **Recommendation:** Blood and body fluid penetration should be assessed with ASTM F 1862 - 07: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood.
- **Priority Designation:** 3

While the primary purpose of respirators in healthcare is to filter airborne microorganisms and prevent occupational illness[4], some HCWs may also use them secondarily (and concurrently) as a facial shield against blood and body fluids[29], such as during surgical procedures. Infection control precautions call for fluid and splash

protection whenever there is a possibility that such exposure may occur[49]. In contradistinction to respirators, surgical masks are designed to (a) protect the wearer from exposure to blood and body fluids and (b) protect others from the wearer who may expel infectious particulates when coughing, sneezing or talking[50].

Consensus 6: Reuse

- **Objective:** Respirators should be capable of reuse.
- **Recommendation:** Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after 50 brief worker-patient encounters, if necessary, during a crisis.
- **Priority Designation:** 1

Use of disposable respirators has become a "standard operating procedure" for most U.S. hospitals[22]. Because most respirators are used for brief periods[51] and discarded, there is little need for durable equipment that can be reused (*e.g.*, multiple donnings). However, during a crisis in which respirators may be in short supply, respirators that are durable enough to be repeatedly reused may be necessary[52]. If a sufficient supply of respirators is not available, NIOSH and CDC have previously recommended that healthcare facilities may consider reuse as long as the device has not been obviously soiled or damaged[53]. The WG proposes a definition of "reusable" to mean capable of maintaining or exceeding a SWPF > 100 for up to 50 interactions (each lasting ≤ 10 minutes*) between the healthcare worker who is wearing the respirator and the patients s/he serves.

**Note: the maximum number of times a user could change his/her respirator over an 8 hour shift: 8 hours x 60 minutes/50 changes = maximum HCW-patient interaction time (9.6 minutes) per respirator.*

Consensus 7: Repeated Disinfection Durability

- **Objective:** Respirators should be capable of being repeatedly decontaminated/disinfected during a crisis.
- **Recommendation:** Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after 50 disinfections, each taking 60 seconds or less to complete.
- **Priority Designation:** 1

Because most respirators are used for brief periods[51] and discarded, there is little need for equipment that can be repeatedly disinfected. However, during a crisis in which respirator may be in short supply, respirators that are durable enough to be repeatedly decontaminated (*e.g.*, to render infectious materials on the respirator inactive and thus unable to act as a fomite) may be necessary. Current Federal regulations for certification of respiratory protective devices do not specify a minimum or maximum number of reuses. The only requirement identified in the body of the regulation is that "Mouthpieces, hoods, helmets, and facepieces, except those employed in single-use respirators, shall be constructed of materials that withstand repeated disinfection as recommended by the application in the instructions for use of the device"[26]. OSHA regulations[54] indicate that respirator cleaning procedures "must ensure that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm to the user". The WG proposes using a definition of "reusable" to mean capable of maintaining a SWPF > 100 for up to 50 decontamination/disinfection cycles. Ideally, respirators should be capable of disinfection within 60 seconds. If this proves impossible, it may become necessary to assign each HCW two respirators to allow one to be disinfected while the other is worn. The method(s) of disinfection, including identification of disinfecting agent(s), should (1) be specified by the manufacturer and (2) approved by NIOSH as part of the user instructions, (3) be in compliance with the OSHA requirements (discussed above) for equivalent effectiveness, (4) not cause damage to the respirator, and (5) not harm the user. Mechanisms or tools of disinfection might include an alcohol swab, ultraviolet (UV) light, germicidal solution, microwave, or autoclave[55]. The WG favors an approach in which a standard method of determining "disinfection" evolves using a collaborative exchange of information among interested stakeholders, (*e.g.*, manufacturers, NIOSH, OSHA, FDA, healthcare worker researchers) to avoid placing this burden solely on the manufacturer.

Consensus 8: Shelf-Life Durability

- **Objective:** Respirators should be durable enough to tolerate a long shelf-life.
- **Recommendation:** Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after being stored in air-conditioned space for at least 10

years at 21-23°C (69-73°F) and 45-55% relative humidity.

- **Priority Designation:** 2

Many U.S. agencies' recommendations call for stockpiling of respirators for use during a crisis[8,50, 52,56]. Depending on the frequency of crisis events (an unknown figure), respirators may be in storage for a prolonged period, perhaps many years. Storage time can be limited by regularly using a portion of the stockpile for routine operations and replenishing the stockpile with new items[57]. A specified shelf-life should be identified for all components of the respirator, including accessory items, such as filter cartridges, straps, and air hoses.

Consensus 9: Gauging Fit

- **Objective:** HCWs should have a way to rapidly assess fit in the field.
- **Recommendation:** Respirators should have a manufacturer-specified fit assessment technique (*e.g.*, a user seal check) that is capable of detecting inadequate fit (Simulated Workplace Protection Factor < 100) with at least 75% accuracy during work activities.
- **Priority Designation:** Elastomeric (2); Filtering facepiece (5)

Conducting a brief assessment to determine whether a respirator fit is adequate may help workers become familiar with the type of fit that is most effective[58]. Although the benefit of respirator user seal checks might seem intuitive, recent studies have suggested that this practice may, in fact, not help identify adequate or inadequate facial seal[59,60,61]. Regardless, user seal checks are a current mandatory requirement of an OSHA compliant respiratory protection program [Appendix B-1 to § 1910.134: User Seal Check Procedures][62].

Manufacturers and/or research organizations should develop new and effective ways of rapidly assessing fit in the workplace area of operations ("the field"), and should consider designing signals or indicators (*e.g.*, colorimetric) that identify adequate fit for the user[63].

One of the most frequent complaints about respirators in healthcare is their tendency to interfere with occupational activities[16,18,20,22,64,65]. This may occur in part because the respirators that are commonly used by U.S. HCWs were borrowed from other occupational sectors. Efforts should be made to tailor respiratory equipment to meet the unique needs of HCWs including communications. The respirator should ideally not impair hearing, speech, or non-verbal communication. Another consideration is compatibility with other equipment used in the performance of healthcare delivery.

Consensus 10: Hearing Integrity

- **Objective:** Respirators should not impede, and preferably improve, the wearer's ability to hear.
- **Recommendation:** (a) Specific word intelligibility tests should be developed, standardized and validated to more precisely measure the hearing accuracy of words in the healthcare setting and (b) Respirator wearers should achieve equivalent or higher scores on hearing acuity tests, on average, when wearing a respirator compared to no respirator.
- **Priority Designation:** 1

The ambient noise in hospitals, especially intensive care units, has been shown to be excessive[66]. The ability to hear and to respond to emergency alarms or warning devices may be impaired when wearing a respirator with a hood or helmet that covers the head[67]. The noise of a Powered Air-Purifying Respirator (PAPR) has been shown to be in excess of 70 decibels[68]. This level of noise may interfere with hearing integrity in a clinical setting[69] and possibly lead to medical errors[70]. Hearing impairment, ranging from moderate to significant, was reported by 27% - 42% of HCWs (depending on the PAPR model used) during the SARS outbreak in 2003[19]. Clearly hearing sounds during defibrillation has been shown to be very challenging when wearing a PAPR[71]. Approximately 1 in 10 words are heard incorrectly in the intensive care unit setting with typical ambient noise (about 60 decibels)[72]. The use of a PAPR has been shown to further diminish the intelligibility of words[72]. Respirators should not impede, and preferably improve, the wearer's ability to hear. Measures routinely used to assess hearing interference, such as the Modified Rhyme Test (MRT),[73] lack specificity to the healthcare environment. The SPIN test[74] is one option that uses whole sentences instead of single words.

Consensus 11: Speech Intelligibility

- **Objective:** Respirators should not impede, and preferably improve, the ability of others to hear the wearer's spoken words.
- **Recommendation:** Respirator wearers should achieve equivalent or higher scores on speaking intelligibility tests, on average, when wearing a respirator compared to no respirator.
- **Priority Designation:** 1

Many respirators decrease the intelligibility of words spoken by the respirator wearer[72]. A few half-face elastomeric respirators on the U.S. market are equipped with speech augmentation devices (*e.g.*, "speaking membranes"). Such devices are only available in reusable respirators that are less commonly used than disposable filtering facepiece respirators by HCWs. They have been shown to have little if any effect on intelligibility[72]. New devices should be developed that increase word clarity spoken by the respirator wearer.

Consensus 12: Visual Field

- **Objective:** Respirators should cause minimal or no obstruction of the wearer's visual field.
- **Recommendation:** (a) Visual fields should be assessed with a standardized and validated tool developed for use in the healthcare environment and (b) Healthcare visual field performance criteria should be developed for respirator wearers.
- **Priority Designation:** 2

Respirators have been shown to obstruct the wearer's visual field[75]. The inferior visual fields (looking downward) may be most affected by filtering facepiece respirators[76,77]. Although unproven, this type of interference could lead to occupational injuries[35] or medical errors. Mitigating problems with eyewear fogging may be beneficial. The tests historically used to gauge visual field, such as the "apertometer," specified in the European

standard (EN136:1998) and the NIOSH CBRN standard[78] are cumbersome and require test-administrator training. Obtaining the necessary visual field testing equipment can be difficult[79]. In addition to lab-based tools, visual field determinations should be, at least in part, conducted in clinical settings ("the field") to ensure data produced are applicable to the occupational setting of HCWs. Simple-to-use assessment tools that can be utilized in the field are needed for the healthcare environment.

Consensus 13: Facial Visualization

- **Objective:** Respirators should be transparent, to the extent plausible and feasible, allowing visualization of the wearer's face.
- **Recommendation:** (a) Transparent respirator facepieces should be developed and, if possible, implemented and (b) Transparency should be assessed with an optical clearance test that is standardized and validated.
- **Priority Designation:** 5

Respirators typically prevent visualization of the wearer's mouth and a portion of the face. Improved visualization of the wearer's lips might improve communication. Visualization of the face might also lower barriers to clinician-patient interactions and co-worker communications.

Consensus 14: Equipment Compatibility

- **Objective:** Respirators should not interfere with other equipment (*e.g.*, stethoscope, otoscope) used in the healthcare environment.
- **Recommendation:** (a) Respiratory protective equipment should be assessed for inter-equipment compatibility using a practical clinical test that should be developed, standardized, and validated and (b) Healthcare performance criteria for protective equipment compatibility should be developed.
- **Priority Designation:** 2

During a high-risk intubation of a patient infected with multiple drug-resistant TB, the HCW performing the procedure might wear a gown, goggles or a face shield, shoe coverings, hair covering, and, possibly an N95 respirator underneath a PAPR[80]. The intubation process typically requires an unrestricted range of motion of both arms and the neck[80]. Numerous similar activities in healthcare require equipment compatibility. Careful planning is required to prevent respiratory protective equipment from interfering with other equipment used in healthcare. Current NIOSH certification requirements[26] for half-mask respirators only require that "half-mask facepieces shall not interfere with the fit of common industrial safety corrective spectacles." The requirement recommended here would expand upon the NIOSH baseline requirement to include other items commonly used by HCWs.

Lack of sufficient comfort and tolerability are among the most commonly cited problems with respirators marketed to healthcare workers. A growing interest to improve comfort and tolerance appears to be emerging[14]. As noted by the IOM and the National Research Council in a recent review of the NIOSH Personal Protective Technology program, "Understanding that comfort is fundamentally a *safety* issue is a necessary prerequisite to improvement of the materials, design and engineering of PPT in such as way that critically important human factors are taken into account." When worn over prolonged work shifts, disposable model respirators are associated with facial pressure, irritation, and heat and reusable models are associated with communication and occupational interference[65]. Ideally respirators should be as comfortable to wear as a loose-fitting surgical mask.

Consensus 15: Breathing Resistance

- **Objective:** The breathing resistance of a respirator should be tolerable.
- **Recommendation:** (a) Respirators should have a level of breathing resistance that is low enough to be comfortable and tolerable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Breathing resistance should be < 10 mm H_2O pressure drop on average at 85 lpm.
- **Priority Designation:** 1

Discomfort and intolerance have been two of the most significant barriers to routine[51] and emergency use[16,65] of respirators. HCWs are accustomed to wearing respirators for short durations[51]; however, during crises, they may be called on to wear protective equipment for a prolonged period[22,65] (hours or days) with few exceptions.

The airflow resistance across a respirator filter ("pressure drop") at air flow speeds typical for human breathing[81] is an important contributor to discomfort and intolerance.[82,83] Although the pressure drop seen with commonly used respirators may not lead to excessive exertion in HCWs[84], the psychometric sensation of breathing across filter material is associated with an uncomfortable feeling[85]. To circumvent this problem, positive pressure respirators may be used. For settings in which the use of positive pressure is viewed as too cumbersome, costly or otherwise not possible, an inhalation and exhalation mean pressure drop less than 10 mm H_2O for each maneuver, at an airflow rate of 85 lpm, should be appropriate for assessment under current circumstances. Although this is a signification reduction compared to the requirements in the current NIOSH standard (35 mm H_2O with inhalation and 25 mm H_2O with exhalation), recent unpublished research by NIOSH found that respirators currently in the U.S. strategic national stockpile have filter airflow resistance levels between 6.7 mm H_2O and 9.4 mm H_2O and thus may already meet this lower requirement[57]. A breathing pattern and airflow rate closer to human ventilation physiology (*e.g.*, < 40-80 L/min)[83] may be considered for use (and standardized) in the future. Additional research is needed to establish a quantitative relationship between filter airflow resistance and subjective comfort.

Consensus 16: Facial Irritation

- **Objective:** Respirators should not cause facial irritation.
- **Recommendation:** Facial irritation should be assessed using two standardized and validated tests: (a) A clinical assessment utilizing a pain or discomfort scale and (b) A lab-based sensitivity test, such as a transdermal water loss test or an animal skin sensitivity test.
- **Priority Designation:** 1

Facial irritation, although typically mild, is often a contributing factor to respirator intolerance in HCWs.[86,65] NIOSH respirator certification requirements (section 84.61) specify "respirator components which come into contact with the wearer's skin should be made of nonirritating materials". However, no specific test methods or performance requirements are identified in the standard. There are a variety of factors associated with facial irritation, including skin inflammation due to contact with respirator material(s) or agents used to clean respiratory protective equipment. A portion of facial irritation may be more precisely termed facial allergy or facial pressure — both of which are discussed as separate recommendations. To minimize this problem, respirator

material should be constructed with materials that are typically not irritating to facial skin and do not interact with skin care products. Eventually, it may be possible to use a sole lab-based test to determine facial irritation, once it is validated against clinical outcomes. Since this has not yet been done, two tests (one clinical and one lab) should be performed on each newly developed respirator model.

Consensus 17: Allergenicity

- **Objective:** Respirators should not cause allergic reactions.
- **Recommendations:** (a) Immune system stimulation should be assessed with a standardized and validated test and (b) Performance characteristics for allergenicity should be developed.
- **Priority Designation:** 1

Occupational allergy is commonly cited as a reason for absenteeism[87-93] or loss of work productivity[93-96] although allergy to respiratory protective equipment is thought to be rare[63,97] (unless the materials include latex). Allergic reactions to latex in the workplace can produce severe systemic manifestations including death[98]. Latex should therefore be avoided in personal protective equipment in favor of other polymers. There is no evidence indicating that respirators currently marketed in the U.S. have *not* met this stipulation; however, the WG proposes that an absence of latex would be best articulated as a performance specification. A European biocompatibility test (*e.g.*, ISO 10993) may be appropriate for use in the U.S. to demonstrate absence of reactivity.

Consensus 18: Facial Pressure

- **Objective:** Facial pressure induced by respirators should cause minimal if any discomfort.
- **Recommendation:** (a) Respirator facial pressure should be low enough to be comfortable and tolerable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Facial pressure should be assessed using two standardized and validated tests: (a) a clinical assessment and a lab-based test.
- **Priority Designation:** 2

Pressure on the face is considered one of the more common reasons for intolerance to respirators among HCWs[65,99]. Facial heat, facial pressure, facial irritation, and facial pain (discomfort) are considered individually and discussed separately in this report. Facial heat is often associated with facial pressure because heat leads to sweating and a tight facial seal leads to moisture entrapment inside the sealed respirator chamber. Similarly, facial pain is often associated with facial pressure because a tight facial seal can be painful[69]. To eliminate facial pressure, a loose-fitting respirator could be used. If a tight-fitting respirator is used, facial pressure can be minimized by achieving low particulate leakage using mechanisms other than a tight facial seal (*e.g.*, facial adhesive). Until new methods of assessing facial pressure are developed, both clinical and lab-based tests should be done on each newly developed respirator model. Eventually, it may be possible to use a sole lab-based test to determine facial pressure, once it is validated against clinical outcomes.

Consensus 19: Facial Heat

- **Objective:** The internal environment of respirators should have a comfortable temperature.
- **Recommendation:** (a) Respirators should cause a level of facial heat rise that is low enough to be comfortable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Facial heat should not exceed a 7°F rise from baseline, on average, when the wearer is under low level exertion at 21-23°C (69-73°F) ambient temperature and 45-55% relative humidity.
- **Priority Designation:** 2

Facial heat is often cited as a cause of respirator intolerance[99-102]. It may be more common than previously acknowledged because higher inhaled air temperatures are associated with increased ventilation and shortness of breath[102]. The NPPTL is studying thermal imaging in an effort to better understand these processes[80]. A temperature gain less than 7°F has been associated with improved tolerance and is less likely to trigger a shortness-of-breath sensation[99,102]. Indoor ambient conditions that are typically considered comfortable are a temperature of 21-23°C (69-73°F) and a relative humidity of 45-55%.

Consensus 20: Air Exchange

- **Objective:** Respirators should have adequate air exchange.
- **Recommendation:** (a) Respirator CO_2 dead space retention should be low enough to be comfortable

for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Respirator chamber CO_2 levels at end-inhalation should be < 1%, on average.
- **Priority Designation:** 2

Exchange of air from within the facial chamber (often called "dead space") to the exterior of a half-face respirator serves several functions. It typically diminishes heat, moisture, exhaled gases (such as CO_2) and particulates[103]. Heat, moisture and particulates are discussed under separate recommendations. This section pertains to the effects of CO_2.

During the normal respiratory cycle, exhalation into an air-tight space causes CO_2 concentration to increase within an enclosed area[80]. Whether CO_2 levels rise in a corresponding fashion depends on numerous factors, including the size of the closed space, the respiratory physiology of the user, the quality of the facial seal, the airflow pattern within a confined space and the length of time the respirator is worn without removal. The extent to which respirator dead space CO_2 causes a rise in serum CO_2 is not completely understood and is being evaluated at this time[80]. Nevertheless, Japanese respirator certification calls for less than 1% inspiratory CO_2, which may be viewed as an idealized performance figure[104]. Dead space CO_2 testing could be done in a human subject trial or in a laboratory with an automated breathing and metabolic simulator (ABMS). The reliability of the ABMS tests needs to be examined for this application.

Exhalation valves, one-way valves that permit exhalation of CO_2 but close during inhalation, are one method to decrease intra-mask CO_2 levels*. However, it has been proposed that the use of an exhalation valve could permit an ill HCW to inadvertently expel infectious droplets or droplet nuclei through the valve toward a patient or coworker, causing disease transmission[14]. One approach that may help allay these concerns would be positioning the exhaust valves in such a way that the exhausted air is vented away from the anterior aspect of the respirator. Another option would be to filter the pertinent particles from the exhausted air as before it is expelled.

**Note: one reoccurring question has been whether permitting intra-mask CO_2 to rise above 0.5% would violate OSHA standard 29CFR1910.1000 TABLE Z-1. The position of the WG was that it would not because OSHA standard 29CFR1910.1000 TABLE Z-1 pertains to the ambient environment, not respirators. The intra-mask dead space should not be considered ambient.*

Consensus 21: Moisture Management

- **Objective:** The internal environment of respirators should not be uncomfortably dry or humid.
- **Recommendation:** (a) Respirator humidity should be maintained at levels perceived as comfortable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Respirator relative humidity levels should be maintained at < 20% above baseline, on average, under low levels of exertion.
- **Priority Designation:** 3

Intra-mask moisture (humidity) has not been well studied. Laboratory and clinical studies should be conducted to determine the effect of moisture on comfort and tolerability. Conventionally, relative humidity levels ranging from 30-60% should be relatively comfortable[105]. Although published data are limited, relative humidity can be expected to increase with increasing workload of the wearer[99].

Consensus 22: Mass Features

- **Objective:** Respirators should be positioned on the face in a fashion that is comfortable.
- **Recommendation:** (a) Respirator weight should be low enough, and distribution of weight sufficiently symmetrical, to be comfortable and tolerable for (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Respirator weight and mass distribution should be evaluated with a standardized and validated practical performance test for which performance criteria are developed
- **Priority Designation:** 3

Heavy respirators are typically associated with low tolerance and high discomfort[106]. Balancing a respirator can help decrease facial pressure points and prolong wear times[107]. Respirator designs that are as light as possible and have a symmetrical weight distribution should lend themselves to comfortable positioning. Weight balancing tools, such as a "Center of Gravity" machine, should be used to assess weight and moment of inertia in the prototype development process.

Consensus 23: Odor

- **Objective:** Respirators should be non-malodorous.
- **Recommendation:** (a) Odor should be assessed with a standardized and validated clinical tool and (b) Performance criteria should be developed.
- **Priority Designation:** 3

Malodorous respirators were cited as a problematic for healthcare workers during the SARS crisis, especially among workers who were not accustomed to their use[16]. Respirators that have no odor, or at least are not mal-odorous, should be better tolerated. Clinical trials should be used to assess this subject. A laboratory surrogate measure may also be useful.

Consensus 24: Prolonged Tolerability

- **Objective:** Respirators should be tolerated for a prolonged period during a crisis.
- **Recommendation:** (a) Respirators should be comfortable enough to be worn for *10 consecutive days* under the following circumstances: (1) ≥ 2 hours of uninterrupted wear and (2) ≥ 8 hours with 15 minute break periods every 2 hours and (b) Perceived respirator discomfort during prolonged wear should be assessed clinically using a validated and standardized test.
- **Priority Designation:** 1

Respirators available in the U.S. market are often not tolerated well for more than 3-5 hours of wear, even with interposed break periods[65], at least among wearers who use respirators infrequently or are accustomed to short duration use[51]. Although a respirator that is tolerated for prolonged periods is not always necessary, it may become important during a crisis[16]. Certain psychological characteristics of respirator wear may be related to the length of time worn, such as claustrophobia which is experienced in about 10% of respirator users[69]. Ways to diminish the likelihood of claustrophobia may include decreasing facial pressure and making smaller the size of the facial or head covering[108]. It should be expected that every respirator will be perceived as intolerable by some workers — no respirator has a perfect tolerance record. While tolerance duration of one work shift (approximately 8 hours) is an essential requirement, (as identified in other recommendations), 10 days of consecutive use for 8 hours per day is a secondary objective, such that the respirator may be comfortably used during a prolonged disease outbreak.

Although policies at most U.S. medical centers are written to be in compliance with national, state and local regulatory stipulations, it is widely acknowledged that many institutions do not put the full extent of their policies into practice. The scope of this discrepancy is unknown, but conventional wisdom holds that it involves medical institutions across the U.S. Incomplete compliance probably increases the risk of healthcare associated infections[109] and may lead HCWs to believe the policies are unnecessary, frivolous or ill-advised[11-13].

Perhaps one of the most important shortcomings of respirator science is a lack of clinical evidence demonstrating to what extent respirators diminish the occurrence of infectious diseases. If it were shown that respirators, in fact, significantly diminish the likelihood of illness or death among HCWs, it is probable that fewer workers would be non-compliant and still fewer would favor their removal from healthcare facilities altogether. Therefore, the WG believes that clinical trials should be conducted to improve understanding about the effectiveness of respirators and respiratory protection programs in the healthcare setting.

Consensus 25: Employer Desirability

- **Objective:** Respirators should be viewed by employers as important and desirable components of their protective equipment.
- **Recommendation:** Employer interviews, surveys and clinical trials should be conducted to determine respirator features that would lead employers to purchase one respirator over another.
- **Priority Designation:** 1

The types of respirators purchased for use in medical centers are typically dependent on the opinion of leadership toward respiratory protection (RP) programs. Anecdotally, some employers look to purchase the least expensive respirator model for their RP programs. A cultural change needs to occur such that employers see respirators as an investment in the health and safety of their HCWs and patients. Such a change may be, in part, predicated on clinical trials demonstrating cost effectiveness and cost/benefit of respiratory protection. It may also require qualitative research with healthcare leaders to assess attitudes about RP policies and practices.

Consensus 26: Employee Desirability

- **Objective:** Respirators should be viewed by employees as important and desirable components of their protective equipment.
- **Recommendation:** Employee interviews, surveys and clinical trials should be conducted to determine respirator features that would lead employees to choose one respirator over another.
- **Priority Designation:** 1

Most HCWs do not like to wear respirators[14,16,110]. More comfortable and tolerable respirators may help mitigate this problem[110]. For some HCWs, respirators and personal protective equipment help them feel "safe" in an uncertain environment[11,12]; however, compliance remains poor[14]. Convincing HCWs that certain respirators are more desirable than others may be predicated on clinical trials that demonstrate effectiveness[37]. Modifications to respirators requested by HCWs may also play an important role[14].

Consensus 27: Patient Desirability

- **Objective:** Respirators should be viewed by patients/visitors as important components of HCW protective equipment.
- **Recommendation:** Patient and healthcare visitor interviews and surveys should be conducted to determine respirator features that would lead them to prefer one respirator over another.
- **Priority Designation:** 2

The views of patients, family members and other visitors toward respirator use have not been well studied. However, their views may influence the use and purchase of respirators. Some may be comforted to learn that HCWs serving them and their family members are taking precautions. Still, reports of concern among patients and workers have occurred when HCWs don respirators that have an unusual appearance[74,109,111,112]. Respirators should facilitate the HCW-patient relationship, not interfere with it.

Consensus 28: Cost Effective for Employers

- **Objective:** Respirator usage should be cost-effective.
- **Recommendation:** (a) Studies that estimate the costs and benefits of respirators across diverse settings should be completed and (b) Health economists and other fiscal experts should be recruited for participation in cost-effectiveness assessments.
- **Priority Designation:** 2

Although the purpose of project BREATHE is to issue recommendations about the preferred characteristics of respirators, it is important to acknowledge and discuss the costs of respirators to manufacturers and employers. The cost of respirators transcends all aspects of respirator research, development, production, and practice. Among the more important aspects of cost may be the manufacturer's perceived return on investment prior to researching potential technologies and the employer's return on investment in terms of diminishing occupational illnesses. Further, all aspects of cost are inter-related such that modification of one variable may affect other cost assumptions and outcomes.

Employers are continually faced with decisions on how to allocate resources subject to their budget constraints. Respiratory protection programs compete with many other production inputs in this allocation of resources. If respirators are viewed as an unfunded mandate rather than imperative of safety, then organizations need to be convinced that respirators are essential.

Additional work is needed to link the benefits of respirator usage with the costs. Few cost-benefit studies exist. To date, studies primarily have focused solely on the costs of respirators and respiratory protection programs. One study estimated the median hospital compliance costs related to TB as required by the CDC and OSHA as being $83,900 for respirators and $17,187 for respirator fit-testing programs[113]. However, these findings may not be generalizable as the study was conducted in only five hospitals.

OSHA conducted an economic analysis of respiratory protective equipment as required by its rulemaking process[113]. Annual incremental costs across all industries were estimated to be about $111 million with 90 percent of those costs allocated toward fit testing ($67 million) and training ($36 million). For the health services industry, OSHA estimated that the incremental compliance costs constituted 0.01 % of sales and 0.14 % of profit. OSHA's study did discuss the possible benefits of respirators, such as averted illness, injuries, and death, but did not monetize those benefits or calculate cost benefit ratios.

Conclusion and Next Steps

The Project BREATHE WG was convened to make recommendations on behalf of the U.S. Federal Government to the VA about the characteristics that should be included in the next generation of respirators for healthcare workers. Table 2, A Comparison of Established Federal Agency Specifications and the B95 BREATHE Recommendations, provides a summary of the 28 features and performance characteristics articulated in this report, in the context of current regulations, guidelines and standards. Publication of this document completes Phase I of Project BREATHE (Figure 1). To avoid confusion, it should be noted that several new respirator criteria have also been discussed by regulatory agencies and other stakeholders (Table 3) that were developed using an entirely *different* process than was used by the Project BREATHE WG.

Although these respirator characteristics were parsed into 28 recommendations, in reality many overlap and influence each other. Some are competing objectives. The WG also acknowledges that this set of recommendations offers an *idealized* view of the respirator characteristics to be included in the next generation of respirators for HCWs. It may not be possible to develop a prototype in which all or most of these recommendations are implemented.

Because these recommendations cover a broad range of design and performance characteristics, and many require additional research, it is important that they be shared with manufacturers, academia, and the private sector healthcare community. The development of B95 respirator prototypes may be facilitated via parterships, such as joint governmental and private sector action. Therefore, the WG encourages the VA to publish these recommendations in a peer-reviewed journal to make them widely available.

Given a variety of competing objectives in these recommendations, the WG favors a "*hybrid*" respirator that is *disposable* under routine conditions but could be *reused* if necessary during a crisis. Such models that are *scalable* in complexity are viewed with optimism. This might include a lightweight, relatively simple model for routine use with features (*e.g.*, a powered air supply) that can be temporarily added when necessary.

This report represents an opportunity for VA to shape national policy and establish a strong culture of safety in its institutions. To be successful, however, multiple performance tests need to be developed and validated. Clinical effectiveness studies should be initiated. Demonstration projects should begin soon, possibly using a subset of VA medical centers as a test-bed.

Finally, the WG invites the FDA to join in this effort to the extent that it does not conflict with their regulatory mission. FDA's participation is needed to help ensure that preventive health claims are substantiated with scientific evidence, similar to other products under FDA purview.

Improving respirator tolerability and functionality should lead to wider acceptance of respirators as a means of protection for VA and other HCWs. This report has outlined several steps towards the next phase in the evolution of respirators. For the recommendations in this report to result in meaningful improvements, continuous study and refinement will be essential.

References

1. A brief history of the VA. Department of Veterans Affairs. Available at: http://www1.va.gov/opa/feature/history/index.asp. Accessed 5/11/08.

2. Unpublished data. On file at the Office of Public Health and Environmental Hazards, 810 Vermont Ave, Washington DC. Accessed 11/2/08.

3. Morbidity and Mortality Weekly Report. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care facilities. MMWR Morb Mortal Wkly Rep 1994;43(RR-13):1-132.

4. NIOSH safety and health topics. Available at: Respirator selection logic. NIOSH. Available at: http://www.cdc.gov/niosh/docs/2005-100/chapter1.html. Accessed 1/16/2009.

5. Kowalski. Airborne respiratory diseases and mechanical systems for control of microbes. Kowaski W, Banfleth W. HPAC. 1986.

6. Guidelines for compliance in healthcare facilities and interpretive guidelines for the bloodborne pathogen standard, The OSHA Guidebook. Osello B. OSHA. 2002.

7. Institute of Medicine Report. Tuberculosis in the Workplace p. 129. National Academies of Sciences Press, 2001

8. World Health Organization Report. Clarification: Use of masks by health-care workers in pandemic settings. World Health Organization; 2005. Available at: http://www.who.int/csr/resources/publications/influenza/Mask%20Clarification10_11.pdf. Accessed 1/23/208.

9. Goldman KP. Tuberculosis in hospital doctors. Tubercle 1988; 69:237–40.

10. Adal KA, Anglim AM, Palumbo CL, Titus MG, Coyner BJ, Farr BM. The use of high-efficiency particulate air-filter respirators to protect hospital workers from tuberculosis. A cost-effectiveness analysis. N Engl J Med. 1994 Jul 21;331(3):169-73.

11. Hammond JS, Eckes JM, Gomez GA, Cunningham DN. HIV, trauma, and infection control: universal precautions are universally ignored. J Trauma 1990 May;30(5):555-561.

12. Kelen GD, DiGiovanna TA, Celentano DD, Kalainov D, Bisson L, Junkins E, et al. Adherence to universal (barrier) precautions during interventions on critically ill and injured emergency department patients. J Acquir Immune Defic Syndr 1990;3(10):987-994.

13. Willy ME, Dhillon GL, Loewen NL, Wesley RA, Henderson DK. Adverse exposures and universal precautions practices among a group of highly exposed health professionals. Infect Control Hosp Epidemiol 1990;11(7):351-356.

14. Institute of Medicine Report. Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers. National Academies of Sciences. Washington, DC: National Academies Press; 2008.

15. 29 CFR Parts 1910 and 1926. Respiratory Protection; Final Rule. Department of Labor. Safety and Health Administration; 1998.

16. Yassi AB, Bryce E. Protecting the Faces of Health Care Workers: knowledge gaps and research priorities for effective protection against occupationally-acquired respiratory infectious diseases. Occupational Health and Safety Agency in British Columbia. American Journal of Infection Control. March 2005; 33(2):114-121.

17. Bai Y, Lin CC, Lin CY, et al. Survey of stress reactions among health care workers involved with the SARS outbreak. Psychiatr Serv. Sep 2004;55(9):1055-1057.

18. Farquharson C, Baguley K. Responding to the severe acute respiratory syndrome (SARS) outbreak: lessons learned in a Toronto emergency department. J Emerg Nurs. Jun 2003;29(3):222-228.

19. Khoo KL, Leng PH, Ibrahim IB, Lim TK. The changing face of healthcare worker perceptions on powered air-purifying respirators during the SARS outbreak. Respirology. Jan 2005;10(1):107-110.

20. Nickell LA, Crighton EJ, Tracy CS, et al. Psychosocial effects of SARS on hospital staff: survey of a large tertiary care institution. CMAJ. Mar 2 2004;170(5):793-798.

21. SARS Unmasked: Celebrating Resilience, Exposing Vulnerability: Registered Nurses Association of Ontario, Canada; 2003. Available at: http://www.rnao.org/Storage/24/1891_SARS_Report_June_04.pdf. Accessed 2/26/2008.

22. Institute of Medicine Report Brief: Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers. National Academies of Sciences. Washington, DC: National Academies Press; 2008.

23. 29 CFR 1910.134 App A. Respiratory Protection; Final Rule: Fit Testing Procedures. Department of Labor. Safety and Health Administration; 1998.

24. Federal Register1910; 1915; 1926: Assigned Protection Factors; Final Rule; 71:50121-50192 August 24, 2006 (Volume 71, Number 164)]. 08/24/2006

25. Coffey CC, Campbell DL, Shuang Z. Simulated Workplace Performance of N95 Respirators. AIHA Journal. 1999(60):618-624.

26. 42 CFR Part 84 Respiratory Protective Devices: NIOSH Respiratory Rule; Final Rule; June 8, 1995

27. 29 CFR Parts 1910 and 1926. Respiratory Protection; Final Rule. Department of Labor. Safety and Health Administration; 1998.

28. 29 CFR 1910.134 App A. Respiratory Protection; Final Rule: Fit Testing Procedures. Department of Labor. Safety and Health Administration; 1998.

29. FDA's Role in Regulating PPE. Available at: http://www.fda.gov/cdrh/ppe/fdarole.html. Accessed 1/20/09

30. Casanova L, Alfano-Sobsey E, Rutala WA, Weber DJ, Sobsey M. Virus transfer from personal protective equipment to healthcare employees' skin and clothing. Emerg Infect Dis. 2008 Aug;14(8):1291-3.

31. Centers for Disease Control and Prevention. Sequence for donning and removing personal protective equipment (PPE). 2004 . Available from http://www.cdc.gov/ncidod/sars/ic.htm.

32. Boyce JM. Environmental contamination makes an important contribution to hospital infection. J Hosp Infect. 2007 Jun;65 Suppl 2:50-4.

33. Ahlers and Peterson. NIOSH Vision and Mission. Seminar presentation. Available at: 2008 http://www.cdc.gov/niosh/npptl/pdfs/January24_2008_mfgmtgPresentation.pdf. Pages 44-50.

34. ASTM Standard. ASTM WK19887 - Evaluation of the Effectiveness of Biological Decontamination Procedures for Air Permeable Materials when Challenged by a Viral Aerosol. Available at: www.astm.org.

35. ASTM Standard. ASTM WK19888 - Evaluation of the Effectiveness of Biological Decontamination Procedures for Surfaces When Challenged with Viral Droplets. Available at: www.astm.org.

36. Fisher, E., Rengasamy S., Viscusi D., Vo, E., and Shaffer, RE, Development of a Test Method to Assess the Effectiveness of Biological Decontamination Procedures for Filtering Facepiece Respirators, APPLIED AND ENVIRONMENTAL MICROBIOLOGY, Mar. 2009, p. 1500–1507.

37. Radonovich LJ Jr, Hodgson MJ, Cohen HJ. Do respirators protect health-care workers from airborne infectious diseases? Respir Care. 2008 Dec;53(12):1660-4.

38. Guyatt GH, Sackett DL, Sinclair JC, Hayward R, Cook DJ, Cook RJ.

39. Hayward RS, Wilson MC, Tunis SR, Bass EB, Guyatt G.Users' guides to the medical literature. VIII. How to use clinical practice guidelines. A. Are the recommendations valid? The Evidence-Based Medicine Working Group. JAMA. 1995 Aug 16;274(7):570-4.

40. Richardson WS, Detsky AS. Users' guides to the medical literature. VII. How to use a clinical decision analysis. A. Are the results of the study valid? Evidence-Based Medicine Working Group. JAMA. 1995 Apr 26;273(16):1292-5.

41. Janssen et al, WPF for N95 FFR in Journal of Occupational and Environmental Hygiene 4: 698-707 (2007).

42. Batelle report. Available at: http://www.cdc.gov/niosh/npptl/researchprojects/pdfs/CR-085Gardner.pdf. Accessed 1/19/09.

43. Lee K, Slavcev A, Nicas M. Respiratory protection against Mycobacterium tuberculosis: quantitative fit test outcomes for five type N95 filtering-facepiece respirators. J Occup Environ Hyg. 2004 Jan;1(1):22-8

44. McMahon E, Wada K, Dufresne A. Implementing fit testing for N95 filtering facepiece respirators: practical information from a large cohort of hospital workers. Am J Infect Control. 2008 May;36(4):298-300.

45. Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respirator Users. 2007. National Academies press.

46. Jayaraman, S. New Materials and Designs to Improve Respirator Fit. No Fit-Test Respirator Workshop. November 6, 2008. Pittsburgh, PA.

47. Nelson P. Experiences of Small Business Respirator Innovation, presented at the "no fit test" respirator workshop, Pittsburgh, PA November 6th, 2008. Seminar Presentation. Available at: http://cpheo.sph.umn.edu/img/assets/32459/Nelson.pdf. Accessed 3/18/2009.

48. Newcomb W. Proposed Total Inward Leakage Testing in NIOSH Certification Technical Concept, presented at NIOSH public meeting 6/26/07. Seminar Presentation. Available at: http://www.cdc.gov/niosh/docket/pdfs/NIOSH-036/0036-062607-newcomb_pres_3.pdf. Accessed 3/18/2009.

49. HICPAC. Siegel JD RE, Jackson M, Chiarello L, and the Healthcare Infection, Committee CPA (HICPAC). 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007.

50. Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic. US Dept of Health and Human Services; 2006. Available at: http://www.pandemicflu.gov/plan/healthcare/maskguidancehc.html. Accessed 1/23/2008.

51. Bryce E, Copes R, Gamage B, Lockhart K, Yassi A. Staff perception and institutional reporting: two views of infection control compliance in British Columbia and Ontario three years after an outbreak of severe acute respiratory syndrome. J Hosp Infect. 2008 Jun;69(2):169-76.

52. Guidance on Preparing Workplaces for an Influenza Pandemic. OSHA 3327-02N. Occupational Safety and Hazards Administration; 2007.

53. Institute of Medicine Report. Reusability of Facemasks During an Influenza Pandemic: Facing the Flu. National Academies of Sciences. National Academies Press; 2006.

54. 29 CFR. Respiratory Protection; Final Rule: Fit Testing Procedures, Appendix B-1. Department of Labor. Safety and Health Administration; 1998.

55. Viscusi DJ, King WP, Shaffer RE: Effect of decontamination on the filtration efficiency of two filtering facepiece respirator models. J Intl Soc Resp Protect 2007:24:93-107.

56. VA Pandemic Influenza Plan. Department of Veterans Affairs; 2006. Available at: http://www.publichealth.va.gov/flu/documents/VA-PandemicFluPlan_2006-03-31.pdf. Accessed 1/23/2008.

57. Viscusi DJ(a), Bergman, M., Sinkule, E., and Shaffer, RE, Evaluation of the Filtration Performance of 21 N95 Filtering Facepiece Respirators after Prolonged Storage, American Journal of Infection Control (in press, Corrected Proof, Available online 02 February 2009

58. TB Respiratory Protection Program In Health Care Facilities. Administrator's Guide. U.S. Department of Health and Human Services, Public Health Service. Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. September 1999.

59. Delaney LJ, McKay RT, Freeman A. Determination of known exhalation valve damage using a negative pressure user seal check method on full facepiece respirators. Appl Occup Environ Hyg. 2003 Apr;18(4):237-43.

60. Derrick JL, Chan YF, Gomersall CD, Lui SF. Predictive value of the user seal check in determining half-face respirator fit. J Hosp Infect. 2005 Feb;59(2):152-5.

61. Myers, W.R.; Jaraiedi, M.; Hendricks, L. Effectiveness of Fit Check Methods on Half Mask Respirators. Appl Occup Environ Hyg 10(11):934–942 (1995).

62. 29 CFR D. Respiratory Protection; Final Rule: Fit Testing Procedures, Appendix B-1: User Seal Check Procedures. Department of Labor. Safety and Health Administration; 1998.

63. Frew AJ.Advances in environmental and occupational disorders. J Allergy Clin Immunol. 2003 Mar;111(3 Suppl):S824-8.

64. Johnston AR, Myers WR, Colton CE, Birkner JS, Campbell CE. Review of respirator performance testing in the workplace: issues and concerns. Am Ind Hyg Assoc J. Nov 1992;53(11):705-712.

65. Radonovich LJ Jr, Cheng J, Shenal BV, Hodgson M, Bender BS. Respirator tolerance in health care workers. JAMA. 2009 Jan 7;301(1):36-8

66. Busch-Vishniac IJ, West JE, Barnhill C, Hunter T, Orellana D, Chivukula R. Noise levels in Johns Hopkins Hospital. J Acoust Soc Am. Dec 2005;118(6):3629-3645.

67. Coyne KA(b), et al: Respirator performance ratings for speech intelligibility. Am Indust Hyg Assoc J 1998;59:257-260

68. Adams J: Making hospital triage operations safer. Occup Health Safety 2006;90:92-94.

69. Szeinuk J, Beckett WS, Clark N, Hailoo WL. Medical evaluation for respirator use. Am J Ind Med. 2000 Jan;37(1):142-57.

70. Peng et al: Infection control and anaesthesia: lessons learned from the Toronto SARS outbreak. Can J Anaesthes 2004;50:989-997.

71. Coates et al: Chemical protective clothing: a study into the ability of staff to perform lifesaving procedures. J Accident Emer Med 2000;17:115-118.

72. Unpublished data. Manuscript in preparation: Diminished Speech Intelligibility with Respirators Used by Healthcare Workers. Radonovich L, Yanke R, Cheng J, Bender B. 7/1/09.

73. House AS, Williams CE, Heker MH, Kryter KD. Articulation-Testing Methods: Consonantal Differentiation with a Closed-Response Set. J Acoust Soc Am. Jan 1965;37:158-166.

74. Kalikow DN, Stevens KN, Elliott LL. Development of a test of speech intelligibility in noise using sentence materials with controlled word predictability. J Acoust Soc Am. 1977 May;61(5):1337-51.

75. Understanding respiratory protection against SARS. Available at: http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html. Accessed 1/19/09

76. Eck EK, Vannier A. The effect of high-efficiency particulate air respirator design on occupational health: a pilot study balancing risks in the real world. Infect Control Hosp Epidemiol. 1997 Feb;18(2):122-7.

77. Fennelly KP: Personal respiratory protection against Mycobacterium Tuberculosis. Clinics in Chest Medicine 1997;18:1-17.

78. Chemical, biological, radiological, nuclear (CBRN) respirator standard. Available at: http://www.cdc.gov/niosh/npptl/standardsdev/cbrn/. Accessed 1/21/09.

79. Gardner, P. Pesonal communication., Edgewood Chemical Biological Center. 1/18/09.

80. Personal communication. Unpublished data. Roberge MR, Vojtko MR, Roberge RJ, Vojtko RJ, Landsittel DP NIOSH. August 11, 2008.

81. Powered Air-Purifying Respirator (PAPR) Discussion Topics NIOSH Docket 008-A. Available at: http://www.cdc.gov/niosh/review/public/008-A/. November 2008. Accessed 1/19/2008.

82. Bentley RA, Griffin OG, Love RG, Muir DC, Sweetland KF. Acceptable levels for breathing resistance of respiratory apparatus. Arch Environ Health. 1973 Oct;27(4):273-80.

83. Coyne K, Caretti D, Scott W, Johnson A, Koh F. Inspiratory flow rates during hard work when breathing through different respirator inhalation and exhalation resistances. J Occup Environ Hyg. 2006 Sep;3(9):490-500.

84. Unpublished data. Manuscript in preparation: Discomfort and exertion associated with respirator use during healthcare operations." Radonovich L, Shenal B, Bender B. 7/1/09.

85. Johnson A, et al. How is respirator comfort affected by respiratory resistance. J of Intl Soc for Res Protection. Spring/summer 2005.

86. Foo CC et al. adverse skin reactions to personal protective equipment against severe acute respirator syndrome – a descriptive study in Singapore, Contact Dermatitis. 2006 Nov; 55(5):291-4

87. Cisternas MG, Blanc PD, Yen IH, Katz PP, Earnest G, Eisner MD, Shiboski S,Yelin EH.A comprehensive study of the direct and indirect costs of adult asthma. J Allergy Clin Immunol. 2003 Jun;111(6):1212-8.

88. Gannon PFG, Weir DC, Robertson AS, Burge PS. Health employment and financial outcomes in workers with occupational asthma. Br J Ind Med 1993; 50:491-496.

89. Holness DL, Nethercott JR. Work outcome in workers with occupational skin disease. Am J Ind Med. 1995 Jun;27(6):807-15.

90. Mancuso CA, Rincon M, Charlson ME. Adverse work outcomes and events attributed to asthma. Am J Ind Med. 2003 Sep;44(3):236-45.

91. Smith DH, Malone DC, Lawson KA, Okamoto LJ, Battista C, Saunders WB. A national estimate of the economic costs of asthma. Am J Respir Crit Care Med. 1997 Sep;156(3 Pt 1):787-93.

92. Venables KM, Chan-Yeung M. Occupational asthma. Lancet 1997; 349:1465-1469.

93. Weiss KB, Gergen PJ, Hodgson TA. An economic evaluation of asthma in the United States. N Engl J Med 1992; 326:862-866.

94. Chen H, Blanc PD, Hayden ML, Bleecker ER, Chawla A, Lee JH; TENOR Study Group. Assessing productivity loss and activity impairment in severe or difficult-to-treat asthma. Value Health. 2008 Mar-Apr;11(2):231-9.

95. Crystal-Peters J, Crown WH, Goetzel RZ, Schutt DC. The cost of productivity losses associated with allergic rhinitis. Am J Manag Care. 2000 Mar;6(3):373-8.

96. Lamb CE, Ratner PH, Johnson CE, Ambegaonkar AJ, Joshi AV, Day D, Sampson N, Eng B Economic impact of workplace productivity losses due to allergic rhinitis compared with select medical conditions in the United States from an employer perspective. Curr Med Res Opin. 2006 Jun;22(6):1203-10.

97. Kuschner WG, Chitkara RK, Sarinas PS. Occupational asthma. Practical points for diagnosis and management. West J Med. 1998 Dec;169(6):342-50.

98. Kelly KJ, Walsh-Kelly CM. Latex allergy: a patient and health care system emergency. Ann Emerg Med. 1998 Dec;32(6):723-9.

99. Li Y, Tokura H, Guo YP, et al. Effects of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations. Int Arch Occup Environ Health. Jul 2005;78(6):501-509.

100. Doney B GM, Middendorf, P, Bang KM. Respirator Surveillance at Five Veterans Affairs Medical Centers. American Industrial Hygiene Conference & Exhibition. Abstract. Dallas, TX. May 2003.

101. Jonas-Simpson C. Courage and commitment. Can Nurse. Sep 2003;99(8):9-12.

102. Lind AR. The influence of inspired air temperature on tolerance to work in the heat. Brit J. Ind Med. 12:126(1955).

103. Understanding respiratory protection against SARS. Available at: http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html. Accessed 1/19/09.

104. Suzuki K, Ogawa A, Matsumura Y: Influencing factors of carbon dioxide concentration increase of filtering respirators (abstract). International Society for Respiratory Protection, 12th International Conference, Nov. 9-12, 2004, Yokohama, Japan.

105. ASHRAE Standard 55-2004: Thermal Environmental Conditions for Human Occupancy. American Society of Heating, Refrigerating and Air-Conditioning Engineers. 2004/2008.

106. White MK, Hodous TK. Drug and multi-drug resistant tuberculosis. Available at: http://www.who.int/tb/challenges/mdr/en/index.html. Accessed 1/16/2009.

107. Barker D. Personal communication. Edgewood Chemical Biological Center. 1/18/09.

108. Morgan WP. Psychological problems associated with the wearing of industrial respirators: a review. Am Ind Hyg Assoc J. 1983 Sep;44(9):671-6.

109. Menzies D, et al: Tuberculosis among healthcare workers. New Engl J Med 1995;332:92-98.

110. Baig A, Eagan A, Radonovich L. Unpublished data. Manuscript submitted for publication. 5/2/2009.

111. Nelson HS: USA objections to protective respirators. Lancet 1992;340:1088.

112. Koller DF, et al: When family-centered care is challenged by infectious disease: pediatric health care delivery during the SARS outbreaks. Qualitative Health Research 2006;16:47-60.

113. Kellerman, S., Tokars, T., and Jarvis, W. (1998) The costs of healthcare worker respiratory protection and fit-testing programs. Infect Control Hosp Epidemiol. 19(9):629-34.

Figure 1: Phases of Project BREATHE

- **Phase I:** Formation of a Federal governmental interagency working group that will issue a consensus statement about the types of respirator characteristics believed to be ideal for the healthcare workforce. The consensus statement will include recommendations for "*evidence-based performance requirements (prescriptive standards) for PPE*" and to "*establish measures to assess and compare the effectiveness of PPE.*"[54]

- **Phase II:** Developing one or more respirator prototypes that utilize some or all of the features recommended in Phase I. This phase would occur in collaboration with the private sector and academia in a "*coordinate[d] effort*"[54] Testing the prototype(s) in healthcare workers prior to larger-scale production will "*increase research on the design and engineering of the next generation of PPE.*"[54]

- **Phase III:** Laboratory and field testing of the prototype respirator(s) in an effort to ensure it meets performance requirements and "*increase research on the design and engineering of the next generation of PPE*"[54] and "*strengthen pre-market testing*."[54]

- **Phase IV:** Making the new respirator(s) available to the wider healthcare workforce to "*strengthen post-market evaluation*"[54] using post-development research efforts, aiming to further improve the new design.

Figure 2: Institute of Medicine Recommendations for Evidence-Based Performance Measures

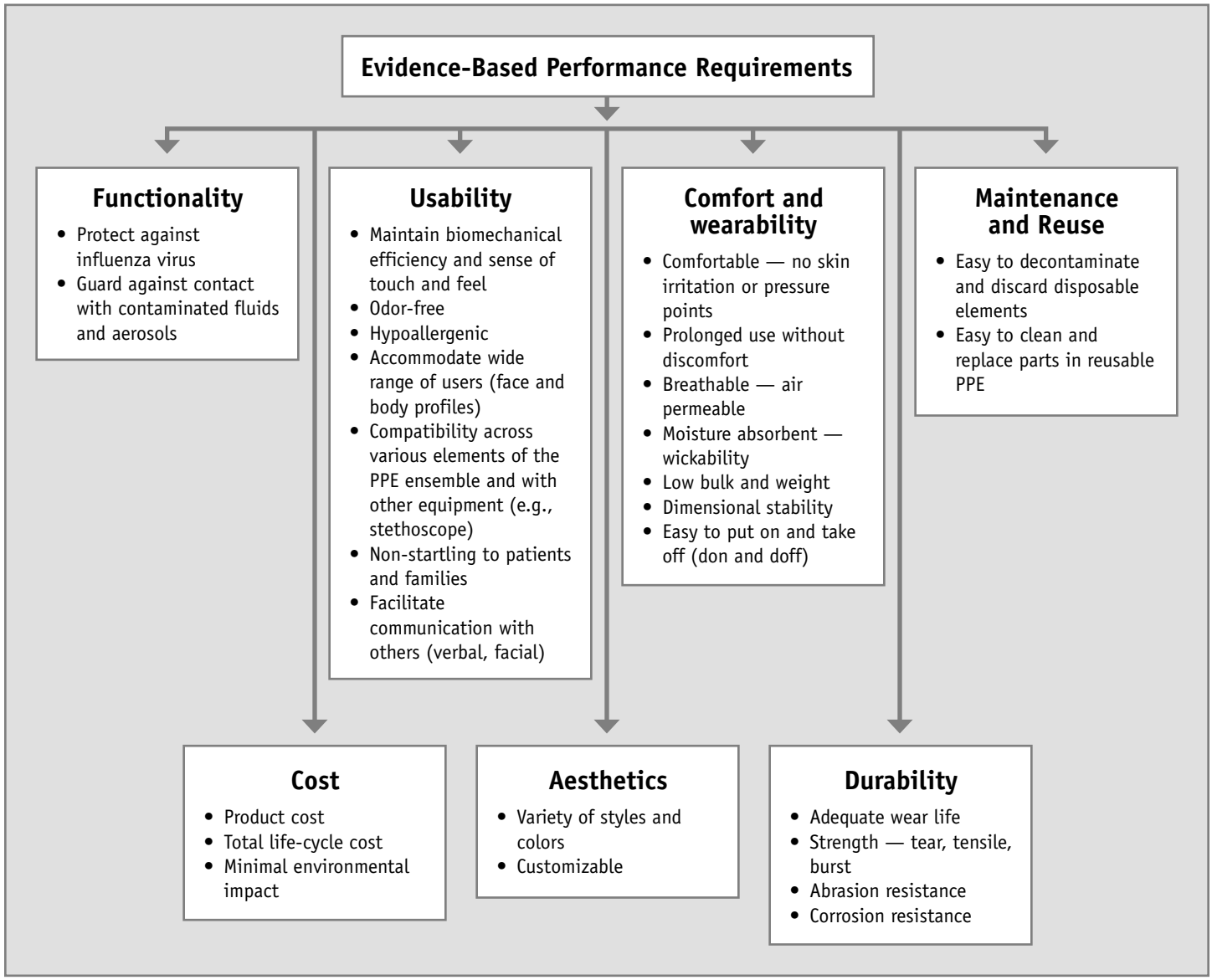

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Figure 3: Institute of Medicine Recommendations* to Innovate and Strengthen PPE Design, Testing and Certification**

- Adopt a Systems Approach to the Design and Engineering of the Next Generation of PPE
- Coordinate Efforts and Expand Resources for Research and Approval of PPE
- Ensure Balance and Transparency of Standards-Setting Processes
- Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE
- Establish Measures to Assess and Compare the Effectiveness of PPE
- Increase Research on the Design and Engineering of the Next Generation of PPE
- Strengthen Pre-market Testing of PPE for Healthcare Workers
- Strengthen Post-market Evaluation of PPE for Healthcare Workers

*Adapted from "Overview of the Report Recommendations" Box S-1 in *Preparing for an Influenza Pandemic: Personal Protective Equipment for Healthcare Workers*

**PPE: Personal Protective Equipment

Table 1: Current Respirator Performance Requirements issued by Pertinent U.S. Governmental Agencies and Oversight Organizations

Feature/ Characteristic \ Agency	CDC/NIOSH/ NPPTL	†FDA	OSHA	VA	ASTM	ISO
Safety and Effectiveness						
Safety and Effectiveness	X	Meets FDA recommendations & NIOSH certified N95 Respirator certification standards	29 CFR Ch. XVII 1910.134 (d) (3) (i) The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements, under routine and reasonably foreseeable emergency situations.	[3]All respirators used will be certified by the National Institute for Occupational Safety and Health (NIOSH) and be used in accordance with the terms of that certification.	X	X
Self-Contamination	X	X	X	X	X	X
Fomite Transmission	X	X	X	X	X	X
Protection/ Respirator Fit	[5]Respirator Selection Logic 2004 (Table 1): Assigned Protection Factor ≥ 10; can only be achieved if the respirator is qualitatively or quantitatively fit tested on individual workers. [4]42 CFR Ch. 1 84.175 (a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either: (1) By providing more than one facepiece size; or (2) By providing one facepiece size which will fit varying facial shapes and sizes.	X	29 CFR Ch. XVII 1910.134 (d) (A) Table 1: APF = 10 for Air-Purifying Respirator, including filtering facepieces, and half masks with elastomeric facepieces.	X	[12]**ASTM F2100-07** - Standard specification for performance of materials used in medical face masks.	X

Abbreviations

AIHA - American Industrial Hygiene Association
ANSI - American National Standards Institute
ASTM - American Society for Testing andMaterials
CDC - Centers for Disease Control and Prevention
FDA - Food and Drug Administration
ISO - International Organization for Standardization
NIOSH - National Institute for Occupational Safety and Health
NIST - National Institute of Standards andTechnology
NPPTL - National Personal Protective Technology Laboratory
OSHA - Occupational Safety and Health Administration
VA - Department of Veterans Affairs

References

[1]OSHA Standard 29 CFR Ch. XVII 1910.134
[2]VA Tuberculosis Exposure Control Plan, August 14, 2008
[3]VA Respiratory Protection Program, October 26, 2006
[4]NIOSH 42 CFR Ch. 1 Part 84
[5]Respirator Selection Logic for particulate respirators 2004: http://www.cdc.gov/niosh/docs/2005-100/
[6]NIOSH Guide to the Selection and Use of Particulate Respirators - Certified Under 42 CFR 84, January 1996
[7]MMWR, Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005
[8]Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submissions, March 5, 2004
[9]FDA - About Personal Protective Equipment: www.fda.gov/cdrh/ppe/about.html
[10]www.aiha.org/Content/InsideAIHA/Standards/z88.htm
[11]www.iso.org
[12]www.astm.org

†FDA regulations apply to surgical masks and surgical N95 masks.
FDA has purview over respirators about which medical claims are made.

Agency / Feature/ Characteristic	CDC/NIOSH/ NPPTL	†FDA	OSHA	VA	ASTM	ISO
Blood & Body Fluids	[7]Combination product surgical mask/N95 disposable respirators (respirator portion certified by CDC/NIOSH and surgical mask portion listed by FDA) are available that provide both respiratory protection and bloodborne pathogen protection.	[8]Recommend that fluid resistance of device be evaluated using the following standard: ASTM F 1862: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood.	X	X	[12]**ASTM F2100-07** - Standard specification for performance of materials used in medical face masks; **ASTM F-1862-07** - Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Protection of Fixed Volume at a Known Velocity).	[11]**ISO 22609: 2004** Clothing for protection against infectious agents - medical face masks - test method for resistance against penetration by synthetic blood.
Reuse	[6]All filters should be replaced whenever they are damaged, soiled, or causing noticeably increased breathing resistance (e.g., causing discomfort to the wearer). N-series filters would also be subject only to considerations of hygiene, damage, and increased breathing resistance. [7]Respirators with replaceable filters are reusable, and a respirator classified as disposable can be reused by the same HCW as long as it remains functional and is used in accordance with local infection-control procedures.	[9]Do not reuse personal protective equipment. Almost all personal protective equipment used in patient care is disposable and is designed to be used one time for contact with one patient.	X	[2]Disposable respirators may be reused for up to two weeks or until the mask is soiled, or no longer maintains its structural or functional integrity as evidenced by inspection or failure of the fit check. Disposable N-95 masks should be discarded at the end of the work shift or when soiled or no longer maintains its structural or functional integrity.	X	X
Repeated Disinfection Durability	[7]Disposable respirators should be discarded according to local regulations.	[9]There is no proper way to wash or disinfect disposable personal protective equipment. Dispose of the equipment carefully after each patient use or if the equipment becomes soiled.	29 CFR Ch. XVII 1910.134 (h) (1) & Appendix B-2: Employer shall ensure that respirators are cleaned and disinfected using the procedures in Appendix B-2; the importance of thorough rinsing cannot be overemphasized. Detergents or disinfectants that dry on facepieces may result in dermatitis. In addition, some disinfectants may cause deterioration of rubber or corrosion of metal parts if not completely removed.	[3]Reusable respirators are to be regularly cleaned and disinfected at the designated respirator cleaning station located in each workspace. Respirators issued for the exclusive use of an employee shall be cleaned as often as necessary; however, specific cleaning frequencies may be developed by the Program Administrator. Disposable respirators have no user serviceable parts and a new one must be obtained when the old one is discarded. No components will be replaced or repairs made for reusable devices beyond those recommended by the manufacturer.	X	X

Abbreviations

AIHA - American Industrial Hygiene Association
ANSI - American National Standards Institute
ASTM - American Society for Testing andMaterials
CDC - Centers for Disease Control and Prevention
FDA - Food and Drug Administration
ISO - International Organization for Standardization
NIOSH - National Institute for Occupational Safety and Health
NIST - National Institute of Standards andTechnology
NPPTL - National Personal Protective Technology Laboratory
OSHA - Occupational Safety and Health Administration
VA - Department of Veterans Affairs

References

[1]OSHA Standard 29 CFR Ch. XVII 1910.134
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[3]VA Respiratory Protection Program, October 26, 2006
[4]NIOSH 42 CFR Ch. 1 Part 84
[5]Respirator Selection Logic for particulate respirators 2004: http://www.cdc.gov/niosh/docs/2005-100/
[6]NIOSH Guide to the Selection and Use of Particulate Respirators - Certified Under 42 CFR 84, January 1996
[7]MMWR, Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005
[8]Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submissions, March 5, 2004
[9]FDA - About Personal Protective Equipment: www.fda.gov/cdrh/ppe/about.html
[10]www.aiha.org/Content/InsideAIHA/Standards/z88.htm
[11]www.iso.org
[12]www.astm.org
†FDA regulations apply to surgical masks and surgical N95 masks.
FDA has purview over respirators about which medical claims are made.

Agency / Feature/ Characteristic	CDC/NIOSH/ NPPTL	†FDA	OSHA	VA	ASTM	ISO
Shelf-life Durability	X	X	X	X	X	X
Gauging Fit						
Elastomeric	[6]In addition to fit-testing, your respirator manufacturer has recommended fit-checking procedures that should be followed by the user each time the respirator is worn. For elastomeric respirators that have a chemical cartridge capability in addition to particullate filers 84.205 Facepiece test; minimum requirements requires an isoamyl acetate fit test on "persons having a varying facial of shapes and sizes	X	29 CFR Ch. XVII 1910.134 (g) (B) (iii) - For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 of this section..	[3]All employees shall conduct user seal checks each time they wear their respirator. Employees shall use either positive or negative pressure check (depending on which test works best for them) specified in OSHA's Respiratory Protection Standard.	X	X
Filtering Facepiece	[6]In addition to fit-testing, your respirator manufacturer has recommended fit-checking procedures that should be followed by the user each time the respirator is worn.	X	29 CFR Ch. XVII 1910.134 (g) (B) (iii) - For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 of this section.	[3]All employees shall conduct user seal checks each time they wear their respirator. Employees shall use either positive or negative pressure check (depending on which test works best for them) specified in OSHA's Respiratory Protection Standard.	X	X
Occupational Interference						
Hearing Integrity	X	X	X	X	X	X
Speech Intelligibility	X	X	X	X	X	X
Visual Field	[4]42 CFR Ch. 1 84.176 Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces.	X	X	X	X	X

Abbreviations

AIHA - American Industrial Hygiene Association
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ASTM - American Society for Testing andMaterials
CDC - Centers for Disease Control and Prevention
FDA - Food and Drug Administration
ISO - International Organization for Standardization
NIOSH - National Institute for Occupational Safety and Health
NIST - National Institute of Standards andTechnology
NPPTL - National Personal Protective Technology Laboratory
OSHA - Occupational Safety and Health Administration
VA - Department of Veterans Affairs

References

[1]OSHA Standard 29 CFR Ch. XVII 1910.134
[2]VA Tuberculosis Exposure Control Plan, August 14, 2008
[3]VA Respiratory Protection Program, October 26, 2006
[4]NIOSH 42 CFR Ch. 1 Part 84
[5]Respirator Selection Logic for particulate respirators 2004: http://www.cdc.gov/niosh/docs/2005-100/
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Feature/Characteristic \ Agency	CDC/NIOSH/ NPPTL	†FDA	OSHA	VA	ASTM	ISO
Facial Visualization	X	X	X	X	X	X
Equipment Compatibility	[4]42 CFR Ch. 1 84.175 (e) & (f) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging. (f) Half-mask facepieces shall not interfere with the fit of common industrial safety corrective spectacles.	X	29 CFR Ch. XVII 1910.134 (g) (1) (B) (ii) If an employee wears corrective glasses or goggles or other personal protective equipment, the employer shall ensure that such equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user.	X	X	X
Comfort & Tolerability						
Breathing Resistance	[4]42 CFR Ch. 1 84.180 (b) The resistances for particulate respirators upon initial inhalation shall not exceed 35 mm water column height pressure and upon initial exhalation shall not exceed 25 mm water column height pressure.	[8]Recommend differential pressure be evaluated for surgical masks that are not NIOSH certified N95 Respirators; surgical masks that are NIOSH certified N95 Respirators must meet NIOSH N95 requirements for differential pressure.	X	X	[12]**ASTM F2100-07** - Standard specification for performance of materials used in medical face masks.	[11]**ISO/TS 16976-1: 2007** Human factors Part 1: Metabolic rates and respiratory flow rates.
Facial Irritation	[4]42 CFR Ch. 1 84.61 (b) Respirator components which come in to contact with the wearer's skin shall be made of nonirritating materials.	[8]Recommended that biocompatibility of materials be evaluated as described in the standard ISO 10993, "Biological Evaluation of Medical Devices Part I: Evaluation and Testing."	X	X	X	[11]**ISO 10993-1:2003** Biological evaluation of medical devices --Part 1: Evaluation and testing; **ISO 10993-10:2002** Biological evaluation of medical devices --Part 10: Tests for irritation and delayed-type hypersensitivity; **ISO 10993-12:2007** Biological evaluation of medical devices--Part 12: Sample preparation and reference materials; **ISO 10993-18:2005** Biological evaluation of medical devices--Part 18: Chemical characterization of materials.

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FDA has purview over respirators about which medical claims are made.

Agency / Feature/ Characteristic	CDC/NIOSH/ NPPTL	†FDA	OSHA	VA	ASTM	ISO
Allergenicity	42 CFR 84.62 (a0 The component parts of each respirator shall be: (1) designed, constructed and fitted to insure against creation of any hazard to the wearer.	[8]Recommended that biocompatibility of materials be evaluated as described in the standard ISO 10993, "Biological Evaluation of Medical Devices Part I: Evaluation and Testing."	X	X	X	[11]**ISO 10993-1:2003** Biological evaluation of medical devices --Part 1: Evaluation and testing; **ISO 10993-10:2002** Biological evaluation of medical devices --Part 10: Tests for irritation and delayed-type hypersensitivity; **ISO 10993-12:2007** Biological evaluation of medical devices--Part 12: Sample preparation and reference materials; **ISO 10993-18:2005** Biological evaluation of medical devices--Part 18: Chemical characterization of materials.
Facial Pressure	[4]42 CFR Ch. 1 84.178 (a) All facepieces shall be equipped with head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face; [4]42 CFR Ch. 1 84.178 (b) Facepiece head harnesses, except those employed on single-use respirators, shall be adjustable and replaceable. Head harness is an undefined term in the regulation. NIOSH current policy is to accept applications with non-traditional facepiece mounting ofr "single-use respirators " using a quantitative particulate fit test to evaluate the effectiveness of the facepiece attachment. March 10 2009 Letter to All Manufacturers http://www.cdc.gov/niosh/npptl/usernotices/pdfs/Novel.pdf	X	[1]29 CFR Ch. XVII 1910.134 Appendix A Part I (A) (6) Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator: (a) position of the mask on the nose & (d) position of mask on face and cheeks; [1]29 CFR Ch. XVII 1910.134 Appendix A Part I (A) (7) The following criteria shall be used to help determine the adequacy of the respirator fit: (b) adequate strap tension, not overly tightened.	X	X	X

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Feature/ Characteristic \ Agency	CDC/NIOSH/ NPPTL	†FDA	OSHA	VA	ASTM	ISO
Facial Heat	X	[8]Recommend differential pressure be evaluated for surgical masks that are not NIOSH certified N95 Respirators; surgical masks that are NIOSH certified N95 respirators must meet NIOSH N95 requirements for differential pressure.	X	X	X	[11]**ISO/TS 16976-1: 2007** Human factors Part 1: Metabolic rates and respiratory flow rates.
Air Exchange	X	[8]Recommend differential pressure be evaluated for surgical masks that are not NIOSH certified N95 Respirators; surgical masks that are NIOSH certified N95 respirators must meet NIOSH N95 requirements for differential pressure.	X	X	X	[11]**ISO/TS 16976-1: 2007** Human factors Part 1: Metabolic rates and respiratory flow rates.
Moisture Management	42 CFR 84.175 (e) facepieces, hoods and helmets shall be designed to prevent eyepiece fogging	[8]Recommend differential pressure be evaluated for surgical masks that are not NIOSH certified N95 respirators; surgical masks that are NIOSH certified N95 respirators must meet NIOSH N95 requirements for differential pressure.	X	X	X	X
Mass Features	X	X	X	X	X	X
Odor	X	X	X	X	X	X
Prolonged Tolerability	X	X	X	X	X	X
Healthcare System Policies & Practices						
Employer Desirability	X	X	X	X	X	X
Employee Desirability	X	X	X	X	X	X
Patient Desirability	X	X	X	X	X	X
Cost Effective for Employers	X	X	X	X	X	X

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Table 2: Comparison of Current U.S. Governmental Agencies' and Oversight Organizations' Respirator Performance Characteristics with BREATHE Recommendations

	Current Agency Respirator Characteristics	BREATHE "B95" Recommendations	BWG Priority Value
Feature/ Characteristic			
Safety and Effectiveness			
Safety and Effectiveness	[1]29 CFR Ch. XVII 1910.134 (d) (3) (i) The employer shall provide a respirator that is adequate to protect the health of the employee and ensure compliance with all other OSHA statutory and regulatory requirements, under routine and reasonably foreseeable emergency situations; [3]All respirators used will be certified by (NIOSH) and be used in accordance with the terms of that certification; [9]Meets FDA recommendations & NIOSH certified N95 Respirator certification standards.	Respirators should meet current standards.	1
Self-Contamination	X	(a) A means should be developed to practically don and doff approved respirators without self-contamination and (b) A test should be developed, validated & standardized, that assesses respirator contamination in a clinical environment.	1
Fomite Transmission	X	(a) Designs should be utilized that prevent respirator-dependent transmission of infectious pathogens and (b) A test should be developed, validated & standardized that assesses respirator-dependent pathogen transmission in a clinical environment.	1
Protection/ Respirator Fit	[1]29 CFR Ch. XVII 1910.134 (d) (A) Table 1: APF = 10 for Air-Purifying Respirator, including filtering facepieces, and half masks with elastomeric facepieces; [5]Respirator Selection Logic 2004 (Table 1): Assigned Protection Factor > 10; can only be achieved if the respirator is qualitatively or quantitatively fit tested on individual workers. [4]42 CFR Ch. 1 84.175 (a) Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either: (1) By providing more than one facepiece size; or (2) By providing one facepiece size which will fit varying facial shapes and sizes.	Respirators (available in one or few sizes) used in the healthcare workplace should be capable of providing a Simulated Workplace Protection Factor of 100 that is assessed using a standardized and validated measure (*e.g.*, the NIOSH total inward leakage test) for a majority (90%) of healthcare workers.	1
Blood & Body Fluids	[8]Recommend that fluid resistance of device be evaluated using the following standard: ASTM F 1862: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood; [7]Combination product surgical mask/N95 disposable respirators (respirator portion certified by CDC/ NIOSH and surgical mask portion listed by FDA) are available that provide both respiratory protection and bloodborne pathogen protection.	Blood and body fluid penetration should be assessed with ASTM F 1862-07: Standard Test Method for Resistance of Surgical Mask to Penetration by Synthetic Blood.	3

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[13]BWG: BREATHE Working Group

	Current Agency Respirator Characteristics	BREATHE "B95" Recommendations	BWG Priority Value
Feature/ Characteristic			
Reuse	[7]Respirators with replaceable filters are reusable, and a respirator classified as disposable can be reused by the same HCW as long as it remains functional and is used in accordance with local infection-control procedures; [9]Do not reuse personal protective equipment. Almost all personal protective equipment used in patient care is disposable and is designed to be used one time for contact with one patient.	Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of >100 after 50 brief worker-patient encounters, if necessary, during a crisis.	1
Repeated Disinfection Durability	[1]29 CFR Ch. XVII 1910.134 (h) (1) & Appendix B-2: Employer shall ensure that respirators are cleaned and disinfected using the procedures in Appendix B-2; the importance of thorough rinsing cannot be overemphasized. Detergents or disinfectants that dry on facepieces may result in dermatitis. In addition, some disinfectants may cause deterioration of rubber or corrosion of metal parts if not completely removed. [4]42 CFR 84.61 (d) Mouthpieces, hoods and facepieces, except those employed in single use respirators, shall be constructed of materials which will withstand disinfection as recommended by the applicant in his instructions for use of the device. [4]42 CFR 84.62 (3) assembled to permit easy access to parts which require periodic cleaning and disinfecting	Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after 50 disinfections, each taking 60 seconds or less to complete.	1
Shelf-life Durability	X	Respirators should be durable enough for the respirator to provide a Simulated Workplace Protection Factor of > 100 after being stored in air-conditioned space for 10 years at 21-23°C (69-73°F) and 45-55% relative humidity.	2
Gauging Fit			
Elastomeric	[1]29 CFR Ch. XVII 1910.134 (g) (B) (iii) - For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 of this section.	Respirators should have a manufacturer-specified fit assessment technique (*e.g.*, a user seal check) that is capable of detecting inadequate fit (Simulated Workplace Protection Factor < 100) with at least 75% accuracy during work activities.	2
Filtering facepiece	[1]29 CFR Ch. XVII 1910.134 (g) (B) (iii) - For all tight-fitting respirators, the employer shall ensure that employees perform a user seal check each time they put on the respirator using the procedures in Appendix B-1 or procedures recommended by the respirator manufacturer that the employer demonstrates are as effective as those in Appendix B-1 of this section.	Respirators should have a manufacturer-specified fit assessment technique (*e.g.*, a user seal check) that is capable of detecting inadequate fit (Simulated Workplace Protection Factor < 100) with at least 75% accuracy during work activities.	5
Occupational Interference			
Hearing Integrity	X	(a) Specific word intelligibility tests should be developed, standardized and validated to more precisely measure the hearing accuracy of words in the healthcare setting and (b) Respirator wearers should achieve equivalent or higher scores on hearing acuity tests, on average, when wearing a respirator compared to no respirator.	1

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	Current Agency Respirator Characteristics	BREATHE "B95" Recommendations	BWG Priority Value
Feature/ Characteristic			
Speech Intelligibility	X	Respirator wearers should achieve equivalent or higher scores on speaking intelligibility tests, on average, when wearing a respirator compared to no respirator.	1
Visual Field	[4]42 CFR Ch. 1 84.176 Facepieces, hoods, and helmets shall be designed and constructed to provide adequate vision which is not distorted by the eyepieces.	(a) Visual fields should be assessed with a standardized and validated tool developed for use in the healthcare environment and (b) Healthcare visual field performance criteria should be developed for respirator wearers.	2
Facial Visualization	X	(a) Transparent respirator facepieces should be developed and, if possible, implemented and (b) Transparency should be assessed with an optical clearance test that is standardized and validated.	5
Equipment Compatibility	[4]42 CFR Ch. 1 84.175 (e) Facepieces, hoods, and helmets shall be designed to prevent eyepiece fogging and (f) Half-mask facepieces shall not interfere with the fit of common industrial safety corrective spectacles; [1]29 CFR Ch. XVII 1910.134 (g) (1) (B) (ii) If an employee wears corrective glasses or goggles or other personal protective equipment, the employer shall ensure that such equipment is worn in a manner that does not interfere with the seal of the facepiece to the face of the user.	(a) Respiratory protective equipment should be assessed for inter-equipment compatibility using a practical clinical test that should be developed, standardized, and validated and (b) Healthcare performance criteria for protective equipment compatibility should be developed.	2
Comfort & Tolerability			
Breathing Resistance	[4]42 CFR Ch. 1 84.180 (b) Resistance for particulate respirators upon initial inhalation shall not exceed 35 mm water column height pressure and upon initial exhalation shall not exceed 25 mm water column height pressure; [8]Recommend differential pressure be evaluated for surgical masks that are not NIOSH certified N95 Respirators; surgical masks that are NIOSH certified N95 Respirators must meet NIOSH N95 requirements for differential pressure.	(a) Respirators should have a level of breathing resistance that is low enough to be comfortable & tolerable for (1) > 2 hours of uninterrupted wear and (2) > 8 hours with 15 minute break periods every 2 hours and (b) Breathing resistance should be < 10 mm water pressure drop on average at 85 lpm.	1
Facial Irritation	[4]42 CFR Ch. 1 84.61 (b) Respirator components which come in to contact with the wearer's skin shall be made of nonirritating materials; 8Recommended that biocompatibility of materials be evaluated as described in the standard ISO 10993, "Biological Evaluation of Medical Devices Part I: Evaluation and Testing."	Facial irritation should be assessed using two standardized and validated tests: (a) A clinical assessment utilizing a pain or discomfort scale and (b) A lab-based sensitivity test, such as a transdermal water loss test or an animal skin sensitivity test.	1
Allergenicity	[9]Recommended that biocompatibility of materials be evaluated as described in the standard ISO 10993, "Biological Evaluation of Medical Devices Part I: Evaluation and Testing." [4]42 CFR 84.62 (a) The component parts of each respirator shall be: (1) designed, constructed and fitted to insure against creation of any hazard to the wearer.	(a) Immune system stimulation should be assessed with a standardized and validated test and (b) Performance characteristics for allergenicity should be developed.	1

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	Current Agency Respirator Characteristics	BREATHE "B95" Recommendations	BWG Priority Value
Feature/ Characteristic			
Facial Pressure	[1]29 CFR Ch. XVII 1910.134 Appendix A Part I (A) (6) Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator: (a) position of the mask on the nose & (d) position of mask on face and cheeks; [1]29 CFR Ch. XVII 1910.134 Appendix A Part I (A) (7) The following criteria shall be used to help determine the adequacy of the respirator fit: (b) adequate strap tension, not overly tightened; [4]42 CFR Ch. 1 84.178 (a) - All facepieces shall be equipped with head harnesses designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face; [4]42 CFR Ch. 1 84.178 (b) Facepiece head harnesses, except those employed on single-use respirators, shall be adjustable and replaceable.	(a) Respirator facial pressure should be low enough to be comfortable and tolerable for (1) > 2 hours of uninterrupted wear and (2) > 8 hours with 15 minute break periods every 2 hours and (b) Facial pressure should be assessed using two standardized & validated tests: a clinical assessment & a lab-based test.	2
Facial Heat	X	(a) Respirators should cause a level of facial heat rise that is low enough to be comfortable for (1) > 2 hours of uninterrupted wear and (2) > 8 hours with 15 minute break periods every 2 hours and (b) Facial heat should not exceed a 7° (F) rise from baseline, on average, when the wearer is under low level exertion at 21-23°C (69-73°F) ambient temperature and 45-55% relative humidity.	2
Air Exchange	[8]Recommend differential pressure be evaluated for surgical masks that are not NIOSH certified N95 Respirators; surgical masks that are NIOSH certified N95 Respirators must meet NIOSH N95 requirements for differential pressure.	(a) Respirator CO_2 dead space retention should be low enough to be comfortable for (1) > 2 hours of uninterrupted wear and (2) > 8 hours with 15 minute break periods every 2 hours and (b) Respirator chamber CO_2 levels at end-inhalation should be < 2% on average.	2
Moisture Management	X	(a) Respirator humidity should be maintained at levels perceived as comfortable for (1) > 2 hours of uninterrupted wear and (2) > 8 hours with 15 minute break periods every 2 hours and (b) Respirator relative humidity levels should be maintained at < 20% above baseline, on average, under low levels of exertion.	3
Mass Features	X	(a) Respirator weight should be low enough, and distribution of weight sufficiently symmetrical, to be comfortable and tolerable for (1) > 2 hours of uninterrupted wear and (2) > 8 hours with 15 minute break periods every 2 hours and (b) Respirator weight and mass distribution should be evaluated with a standardized and validated practical performance test for which performance criteria are developed.	3
Odor	X	(a) Odor should be assessed with a standardized and validated clinical tool and (b) Performance criteria should be developed.	3

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[4]NIOSH 42 CFR Ch. 1 Part 84
[5]Respirator Selection Logic for particulate respirators 2004: http://www.cdc.gov/niosh/docs/2005-100/
[6]NIOSH Guide to the Selection and Use of Particulate Respirators - Certified Under 42 CFR 84, January 1996
[7]MMWR, Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005
[8]Guidance for Industry and FDA Staff: Surgical Masks - Premarket Notification [510(k)] Submissions, March 5, 2004
[9]FDA - About Personal Protective Equipment: www.fda.gov/cdrh/ppe/about.html
[10]www.aiha.org/Content/InsideAIHA/Standards/z88.htm
[11]www.iso.org
[12]www.astm.org
[13]BWG: BREATHE Working Group

	Current Agency Respirator Characteristics	BREATHE "B95" Recommendations	BWG Priority Value
Feature/ Characteristic			
Prolonged Tolerability	X	Respirators should be comfortable enough to be worn for 10 consecutive days under the following circumstances: (1) > 2 hours of uninterrupted wear and (2) > 8 hours with 15 minute break periods every 2 hours and (b) Perceived respirator discomfort during prolonged wear should be assessed clinically using a validated and standardized test, such as a visual analogue scale.	1
Healthcare Systems Policies & Practices			
Employer Desirability	X	Employer interviews, surveys and clinical trials should be conducted to determine respirator features that would lead employers to purchase one respirator over another.	1
Employee Desirability	X	Employee interviews, surveys and clinical trials should be conducted to determine respirator features that would lead employees to choose one respirator over another.	1
Patient Desirability	X	Patient & healthcare visitor interviews and surveys should be conducted to determine respirator features that would lead them to prefer one respirator over another.	2
Cost Effective for Employers	X	(a) Studies that estimate the costs and benefits of respirators across diverse settings should be completed and (b) Health economists and other fiscal experts should be recruited for participation in cost-effectiveness assessments.	2

References & Abbreviations

[1]OSHA Standard 29 CFR Ch. XVII 1910.134
[2]VA Tuberculosis Exposure Control Plan, August 14, 2008
[3]VA Respiratory Protection Program, October 26, 2006
[4]NIOSH 42 CFR Ch. 1 Part 84
[5]Respirator Selection Logic for particulate respirators 2004: http://www.cdc.gov/niosh/docs/2005-100/
[6]NIOSH Guide to the Selection and Use of Particulate Respirators - Certified Under 42 CFR 84, January 1996
[7]MMWR, Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005
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[10]www.aiha.org/Content/InsideAIHA/Standards/z88.htm
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Table 3: Forthcoming Respirator Performance Requirements issued by Pertinent U.S. Governmental Agencies and Oversight Organizations

AGENCY	ANSI/AIHA[1]	ISO[2]	ASTM[3]
Feature/ Characteristic			
Safety and Effectiveness			
Safety and Effectiveness	**Z88.2 1992** Practices for Respiratory Protection; **Z88.12** Respiratory Protection for Infectious Aerosols.	**ISO/CD 16975** Respiratory Protective Devices - Selection, use, & maintenance.	X
Self-Contamination	X	X	X
Fomite Transmission	X	X	X
Protection/ Respirator Fit	X	**ISO/DIS 16900-1** Respiratory Protective Devices - Methods of Test & test equipment - Part 1: Determination of inward leakage; **ISO/DIS 16900-3** Methods of Test & Test equipment - Part 3: Determination of particle filter penetration. **ISO/CD TS 16976-2** Respiratory Protective Devices - Human factors Part 2: Anthropometrics.	X
Blood & Body Fluids	X	X	**ASTM WK17678** Revision of F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks; **ASTM WK14697** Revision of F1862-07 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood.
Reuse	**Z88.2 1992** Practices for Respiratory Protection; **Z88.12** Respiratory Protection for Infectious Aerosols.	**ISO/CD 16975** Respiratory Protective Devices - Selection, use, & maintenance.	X
Repeated Disinfection Durability	**Z88.2 1992** Practices for Respiratory Protection; **Z88.12** Respiratory Protection for Infectious Aerosols.	**ISO/CD 16975** Respiratory Protective Devices - Selection, use, & maintenance.	**ASTM WK19887** - New test method for evaluation of the effectivenss of biological decontamination procedures for air permeable materials when challenged by a viral aerosol; **ASTM WK14697** Revision of F1862-07 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood; **ASTM WK19888** - New Test Method for Evaluation of the Effectiveness of Biological Decontamination Procedures for Surfaces when Challenged with Viral Droplets.
Shelf-life Durability	X	X	X
Gauging Fit			
Elastomeric	X	**ISO/DIS 16900-1** Respiratory Protective Devices - Methods of Test & test equipment - Part 1: Determination of inward leakage.	X
Filtering facepiece	X	**ISO/DIS 16900-1** Respiratory Protective Devices - Methods of Test & test equipment - Part 1: Determination of inward leakage.	X

Abbreviations

AIHA - American Industrial Hygiene Association
ANSI - American National Standards Institute
ASTM - American Society for Testing and Materials
CDC - Centers for Disease and Control
FDA - Food and Drug Administration
ISO - International Organization for Standardization

References

[1]www.aiha.org/Content/InsideAIHA/Standards/z88.htm
[2]www.iso.org. Accessed March 2009.
[3]www.astm.org. Accessed March 2009

AGENCY	ANSI/AIHA[1]	ISO[2]	ASTM[3]
Feature/ Characteristic			
Occupational Interference			
Hearing Integrity	X	X	X
Speech Intelligibility	X	X	X
Visual Field	X	X	X
Facial Visualization	X	X	X
Equipment Compatability	X	X	X
Comfort & Tolerability			
Breathing Resistance	X	**ISO/DIS 16900-2** Respiratory Protective Devices - Methods of Test & test equipment - Part 2: Determination of breathing resistance.	**ASTM WK17678** - Revision of F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks.
Facial Irritation	X	X	X
Allergenicity	X	X	X
Facial Pressure	X	X	X
Facial Heat	X	**ISO/DIS 16900-2** Respiratory Protective Devices - Methods of Test & test equipment - Part 2: Determination of breathing resistance.	X
Air Exchange	X	**ISO/CD TS 16976-3** Respiratory Protective Devices - Human factors Part 3: Physiological responses and limitations of oxygen and carbon dioxide in the breathing environment; **ISO/NP 16900-9** Respiratory Protective Devices - Methods of Test & test equipment - Part 9: Carbon dioxide content of the inhaled air (dead space); **ISO/CD TS 16976-2** Respiratory Protective Devices - Human factors Part 2: Anthropometrics.	**ASTM WK17678** - Revision of F2100-07 Standard Specification for Performance of Materials Used in Medical Face Masks.
Moisture Management	X	X	X
Mass Features	X	X	X
Odor	X	X	X
Prolonged Tolerability	X	X	X
Healthcare System Policies and Practices			
Desired by employers	X	X	X
Desired by healthcare workers	X	X	X
Desired by patients	X	X	X
Cost effective for employers	X	X	X

Abbreviations

AIHA - American Industrial Hygiene Association
ANSI - American National Standards Institute
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References

[1]www.aiha.org/Content/InsideAIHA/Standards/z88.htm
[2]www.iso.org. Accessed March 2009.
[3]www.astm.org. Accessed March 2009

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