Recommended Requirements, Test Methods, and Pass/Fail Criteria for a "B95" Respirator for Healthcare Workers

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ABSTRACT

Project BREATHE (Better Respiratory Equipment using Advanced Technology for Healthcare Employees) seeks to improve respirator compliance for healthcare workers by promoting the development of more acceptable respirators. Previous work identified 28 idealized characteristics and suggested the need for development of a new voluntary standard ("B95" respirator). The goals of this manuscript are (1) to identify criteria for successful adoption of a voluntary B95 standard, (2) use these criteria to update Project BREATHE characteristics, and (3) to make preliminary recommendations for B95 requirements, test methods, and pass/fail criteria.

Criteria necessary for widespread adoption of a voluntary consensus standard were identified and used to provide recommendations for how the standards development process should proceed. After a reassessment process, only seven (25%) of the Project BREATHE characteristics remained a high priority and had a suitable test method available to reliably quantify performance. In the area of Safety & Effectiveness, one human subject test and one machine test were identified that address Project BREATHE characteristics related to respirator fit, reuse, and gauging fit. For Comfort & Tolerability, eight test methods – three machine and five involving human test subjects - were identified to address Project BREATHE characteristics related to breathing resistance, facial heat, air exchange, and moisture management. Pass/fail criteria were mostly identified using published data (where possible) from existing respirator models as the baseline. Overall, we feel that the proposed B95 respirator requirements, criteria, and test methods will provide a good starting point for deliberation and advancement through the consensus standards development process.

Keywords: respiratory protection, healthcare, infection control, comfort, fit, standards

INTRODUCTION

Background

In 2008, a working group led by the Department of Veterans Affairs (VA), in collaboration with the National Institute for Occupational Safety and Health (NIOSH), was formed to initiate Project BREATHE (**B**etter **R**espiratory **E**quipment using **A**dvanced **T**echnology for **H**ealthcare **E**mployees), with the goal of developing strategies to improve respirator compliance for healthcare workers (HCWs). The Project BREATHE working group developed a final report (Radonovich et al., 2009a) which outlined a list of 28 idealized HCW respirator characteristics and suggested the development of a new voluntary standard with performance requirements for a different type of respirator, termed initially as the "B95" respirator. The working group recommended the name "B95" to serve as a reminder of its historical origins in Project BREATHE, to educate users that this respirator was designed for use in healthcare to reduce exposure to infectious biological hazards such as influenza and TB, and to correspond with the well-known N-P-R classification scheme used for NIOSH respirator certification. A previous manuscript (Gosch et al., 2013) outlined the rationale for encouraging the development of a B95 respirator for HCWs, reviewed the 28 Project BREATHE "desirable" requirements, and described a national strategy to develop clinically-validated test methods, promulgate a voluntary B95 respirator standard, and to invent novel design features to improve respirator comfort and usability.

The goals of this manuscript are (1) to identify criteria for successful adoption of a voluntary B95 standard; (2) use these criteria to update and revise the original priorities assigned to the 28 "desirable" Project BREATHE characteristics; and (3) to make preliminary recommendations for proposed B95 requirements, criteria, and test methods, suitable for starting the consensus standards development process.

Use of Voluntary Consensus Standards for B95 Respirator Standards Development

There are a number of salient reasons why the Project BREATHE working group advocated for development of a voluntary consensus standards approach to transitioning new technologies (e.g., filters with lower levels of airflow resistance, face seals promoting enhanced fit, antimicrobial components, etc.) resulting from Project BREATHE to commercially available products. Standards encourage competition and innovation (Hemenway, 1980) and as noted in a report by the National Institute of Standards and Technology, "Standards promote understanding between buyer and seller and facilitate mutually beneficial commercial transactions"(Breitenberg, 1997). For many types of products, the buyer cannot determine by visual inspection or prior experience whether a given product will be particularly well-suited for his/her situation. Demonstration of product conformance to a standard provides the buyer with information regarding the suitability of the product for the intended application.

As discussed in the previous manuscript (Gosch et al., 2013), the current NIOSH and Food and Drug Administration (FDA) performance requirements for Surgical N95 respirators commonly used in healthcare, results in products commercially available today that are safe and effective at reducing occupational exposures to infectious aerosols, but are considered by HCWs to be insufficient to address some of their concerns related to comfort and overall usability. Due to the length of time required to implement changes to United States federal regulations (42 CFR Part 84) (CDC, 1995) governing the testing and certification of respirators, the Project BREATHE working group felt that the fastest pathway to commercialization of a respirator with enhanced features desirable to HCWs would be through a voluntary consensus standard.

A significant challenge faced by standards development organizations (SDOs) is that voluntary standards have little or no significance until they are adopted and used. According to new institutional

economics (NIE) theory, there are two barriers that must be overcome for successful adoption of a voluntary standard (Rosen et al., 2003). First, voluntary standards must have "remediable-ness" (i.e., offer more expected economic gains than alternatives) and legitimacy. Legitimacy refers to the belief by a critical mass of early adopters (e.g., end-users, product purchasers, etc.) that the standard has been developed through appropriate consensus processes that benefit the larger community. Others have noted that problems can occur when standards are not based upon sound science (Breitenberg, 2009).

The process outlined by the Project BREATHE working group strives to meet the two requirements outlined in NIE theory to increase the chances for widespread adoption of the voluntary B95 respirator requirements, criteria, and test methods. First, consensus standards development organizations (e.g., National Fire Protection Association (NFPA), International Safety Equipment Association (ISEA), American Society of Safety Engineers (ASSE), American Society for Testing and Materials (ASTM), International Organization for Standardization (ISO), etc.) familiar with the issues of respiratory protection, infection control, and/or worker safety and health will be engaged early in the process. At least one of these organizations will need to agree to create a work item and be the collaborative process for developing the standard. As envisioned by the Project BREATHE working group, the voluntary B95 respirator standard and conformity assessment process would require, as the starting point, successfully obtaining NIOSH certification via 42 CFR Part 84 as a powered or non-powered particulate respirator and clearance by the FDA, via the 510(k) process for marketing, as a class II medical device. Other industries (e.g., fire service) have successfully developed voluntary respirator standards unique for their workplace requirements using a similar model, where the consensus SDO sets additional requirements that exceed the general NIOSH respirator certification requirements. Under this model, respirator manufacturers are not required to seek certification of their products to the new voluntary standard, but instead are driven by market forces. Today, respirators certified to both NIOSH and NFPA requirements are considered the "de facto" standard for respirators used by the fire service during firefighting activities.

To further assist in meeting the NIE legitimacy test, having a solid scientific basis is critical. NIOSH has decades of experience in developing respirator performance requirements, tests, and criteria, and in the execution of a respirator certification program in the U.S. (Goldfrank and Liverman, 2008). For non-powered particulate respirators (e.g., TC-84A-xxxx), these requirements focus on filter performance and having a solid quality assurance program in place. Since 1996, the FDA has been clearing certain types of respirators for sale as medical devices. A respirator that is both NIOSH approved as a non-powered particulate respirator and cleared for sale by the FDA as a surgical mask is generally referred to as a "Surgical N95 Respirator". The FDA's 510(k) clearance process for Surgical N95 respirators uses several ASTM standards (Bailar et al., 2006) in addition to requiring prior NIOSH certification. Thus, the development of a voluntary B95 respirator standard for HCWs has precedence.

METHODS

Criteria for Prioritization of B95 Requirements

Performance standards are typically composed of three essential parts: (1) requirements, (2) criteria, and (3) tests (Hemenway, 1980). The basic format of the proposed voluntary B95 respirator standard follows this arrangement. The process of selecting requirements, criteria, and test methods began with reviewing the 28 desirable user requirements from the Project BREATHE report identified in Table I, keeping in mind the NIE criteria discussed above. Useful performance standards differentiate products according to end-user expectations. User input is critical for successful adoption of many commercial products. Available data suggest that compliance/adherence to recommended respirator use practices would increase with more comfortable equipment (Mitchell et al., 2012), availability (Green-McKenzie et al., 2001), and when the users believed that the device is more effective than alternatives

(Hu et al., 2012; Mitchell et al., 2012). All of these attributes were factored into the Project BREATHE requirements. Thus, initial considerations for requirements, criteria, and test methods were based (to the extent possible) on the 2009 Project BREATHE report (Radonovich et al., 2009a).

Table I. Original Project BREATHE Recommendations and Revised Priority Ratings

Feature/ Characteristic	Original B95 Recommendations	Revised Priority Rating
Safety & Effectiveness		
1. Safety and Effectiveness	Meets all current NIOSH (e.g., 42 CFR Part 84) and FDA standards (e.g., 510(k) process for class II medical devices) and be used within an OSHA respiratory protection program, including fit testing.	n/a
2. Self-Contamination	Users need to be able to easily and reproducibly don and doff respirators without self-contamination in a clinical environment.	3*
3. Fomite Transmission	Not be a conduit for fomite transmission of pathogens between persons	3*
4. Respirator Fit	Well-fitting (in one or few sizes) and capable of passing an OSHA accepted fit test on a majority (~90%) of U.S. healthcare workers	1
5. Blood and Body Fluids	Serve as a barrier to protect the wearer from blood and body fluids.	n/a
6. Reuse	Durable enough for the respirator to provide expected levels of protection (e.g., protection factor of 10 or greater for a half-mask respirator) after multiple brief worker-patient encounters.	1
7. Repeated Disinfection Durability	Durable enough to provide expected levels of protection after 50 disinfections, each taking < 60 seconds to complete.	3*
8. Shelf-life Durability	Durable enough to provide expected levels of protection after being stored in an air-conditioned space for 10 years at 21-23ºC (69-73ºF) and 45-55% relative humidity.	2†
9. Gauging Fit	Have a manufacturer-specified fit assessment technique (e.g., a user seal check) that is capable of detecting inadequate fit (which would result in less than expected protection) with at least 75% accuracy during work activities.	2
Occupational Interference		
10. Hearing Integrity	Not impede, and preferably improve, the wearer's ability to hear in a hospital environment.	1†
11. Speech Intelligibility	Not impede, and preferably improve, the ability of others to hear the wearer's spoken words.	1†
12. Visual Field	Cause minimal obstruction of the wearer's visual field.	2†

13. Facial Visualization	Transparent, to the extent feasible, allowing visualization of the wearer's face.	5†
14. Equipment Compatibility	Non-interfering with other equipment (e.g., stethoscope) used in healthcare	2†
Comfort & Tolerability		
15. Breathing Resistance	Have a breathing resistance (e.g., filter air flow resistance) low enough that it does not impact tolerance (e.g., should be <10 mm water pressure drop on average at 85 lpm continuous flow).	1
16. Facial Irritation	No facial irritation.	n/a
17. Allergenicity	No allergic reactions.	n/a
18. Facial Pressure	Constructed such that they cause minimal discomfort from pressure on the face (e.g., 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).	2†
19. Facial Heat	Constructed such the level of facial heat rise 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.	2
20. Air Exchange	Constructed such that they have adequate air exchange from the environment and do not cause unnecessary build-up of respiratory gases (e.g., 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.	2
21. Moisture Management	Constructed such that they have adequate air exchange from the environment and do not cause unnecessary build-up of humidity in the deadspace (e.g., respirator dead space humidity levels 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.	1*
22. Mass Features	Positioned on the face in a fashion that is comfortable and tolerable for (1) >2 hours of uninterrupted wear and (2) >8 hours with 15 minute break periods every 2 hours.	3
23. Odor	Non-malodorous.	3
24. Prolonged Tolerability	Comfortable enough to be worn for a prolonged period of time during a crisis (e.g., 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).	1†
Healthcare Systems Policies and Practices		
25. Employer Desirability*	Viewed by employers as an important and desirable component of their worker safety and infection control programs.	1†
26. Employee Desirability*	Viewed by employees as an important and desirable component of their workplace safety and infection control programs.	1†

27. Patient Desirability*	Viewed by patients/visitors as an important and desirable component of workplace safety and infection control programs.	2†
28. Cost Effective for Employers*	Usage should be cost-effective.	2†

* indicates that a change was made in the priority. † indicates a priority that was deemed as being unable to be reliably tested at this time. n/a refers to requirements that were deemed as not applicable to a proposed B95 standard because they are already adequately covered in the existing NIOSH and FDA respirator requirements.

However, some of the 28 desirable requirements in the Project BREATHE report are redundant, mutually exclusive, or not testable in their current form. Finally, cost needs to factor into the prioritization process as excessive testing to redundant or unrealistic requirements would add unnecessary burdens to both the test laboratories and the manufacturers. Ultimately, certification costs are usually passed onto the buyers of the product (Breitenberg, 1997). Thus, on behalf of the Project BREATHE working group, the authors performed a reassessment process to review the 28 Project BREATHE requirements and to reprioritize them based upon the latest science and with the goal to use only the minimum number of requirements necessary to close gaps in meeting key end-user expectations. During the reassessment process, all 28 Project BREATHE requirements were assigned a revised priority rating on a scale of 1 to 5, with 1 being given the highest priority. Characteristics with the highest priority ratings were considered more likely to contribute to future HCW respirator compliance.

Criteria for Selection of B95 Test Methods

Test methods should be capable of (1) evaluating the conformity of a product to the specified requirements in a manner that produces test results that are within an acceptable accuracy range; (2) producing consistent results when the same laboratory repeats the test; and (3) being duplicated by other testing bodies using the same or similar test methods (i.e., reproducible) (Breitenberg, 1997). To apply these general criteria to selecting B95 test methods, the authors identified possible B95 respirator test methods that would measure the property of interest. Other consensus respirator standards were also evaluated for possible B95 respirator test methods. Because many of the characteristics of an ideal respirator for HCWs involve test methods that are unique or at the cutting-edge, few data are available on reproducibility or repeatability. Thus, it was decided to focus on methods reported in peer-reviewed journal publications if there was no other validated test method available with sufficient data on performance of respirators commonly found in healthcare. In some cases, minor modifications (e.g., number of replicates or samples) were done to help transition research methodologies into something amenable to testing via a third-party. Peer-reviewed publications were further scrutinized to determine, via subject matter expert opinion, whether application of the standard would likely discriminate among products consistent with end-user expectations. Test methods involving human subjects were considered preferred, but because of the limitations of some of these methods, machine tests were also considered. As a practical matter, another consideration was whether the test equipment required was readily available at NIOSH or other test laboratories in the United States.

Criteria for Selection of B95 Pass/Fail Criteria

Once possible test methods were identified, the next step was to identify the most appropriate performance criteria. Pass/fail criteria should be set so that products that will not close gaps in meeting end-user expectations fail, but not so challenging that they create unnatural barriers to having products meet the standard. One method for achieving a good balance is to select an existing product that is likely to be acceptable as the baseline. The pass/fail level for a given test method is then set at the

performance level for this product, thus ensuring that at least one, and possibly others, would be able to pass. While this approach does not improve the performance of products likely performing at acceptable levels now, it does ensure that products unable to meet this level could not be marketed as meeting the requirement. Subsequent revisions of the standard can gradually increase the difficulty of passing the requirements (i.e., making them more stringent) to further improve end-user acceptance over time. Thus, at initial stages of adoption of this standard, improvements will be found at the macro scale improving the features of the pool of products available for selection; improvements at the micro-level (e.g., individual products) will result from future revisions with more stringent pass/fail criteria and/or better test methods.

There are hundreds of NIOSH-approved respirator models but little data related to comfort, fit, usability and psychophysiological responses to wear for the vast majority of them on which to base selection of an appropriate baseline. However, some data are available for a few of the more popular disposable N95 particulate filtering facepiece respirators (FFRs) such as the 15 models on the U.S. Strategic National Stockpile (Besser, 2009). For this manuscript, the authors reviewed the available literature to identify any specific data on these models. Data from three Surgical N95 respirator models (3M 1860, 3M 1870, and the Kimberly Clark PFR95) appeared most often in the peer-reviewed literature, although only two journal articles report side-by-side comparisons of the three models (Bryce et al., 2008; Viscusi et al., 2011). The data in one paper suggests the 3M 1870 as being the most comfortable among the models, although the data were not statistically significant and each model used a slightly different cohort of test subjects (Viscusi et al., 2011). Similarly, Bryce et al. (2008) reported that there were no significant differences among the three models in terms of comfort or compliance in a survey of 137 HCWs at an adult tertiary care hospital. In terms of fit, there were no head-to-head comparisons involving all three models, although several of these models have been used in various large scale fit test studies or exercises (Coffey et al., 2004; Duling et al., 2007; Lawrence et al., 2006; Lee et al., 2004; McMahon et al., 2008; Wilkinson et al., 2010). For example, 95.1% of users were able to pass a qualitative fit test in the 3M 1870 in one study of 1271 Canadian HCWs (McMahon et al., 2008). Because slightly more data was available on the 3M 1870, we selected this model as the baseline. For the test methods evaluated, published results from the 3M 1870 or a similar product such as the 3M 9210 were used (where available) to set proposed pass/fail levels. Where no such data were available, expert judgment was used.

RESULTS AND DISCUSSION

Prioritization of B95 Respirator Requirements

Table I contains the original 28 Project BREATHE characteristics for an ideal HCW respirator. The last column contains the revised priority rating derived from the reassessment process. Four of the requirements were found to already be part of an existing NIOSH or FDA respirator approval process. These were assigned a value of not applicable (n/a) because they were considered duplicative and did not need to be repeated as a new B95 respirator requirement. Of the remaining 24 Project BREATHE characteristics, 13 were kept unchanged. Many of these were already among the highest rating priorities, with 9 of them assigned a priority rating of 1 or 2. Not surprisingly, many of these characteristics relate to fit, comfort, and overall usability, themes common to studies that have surveyed end-users regarding desirability of various respirator features (Baig et al., 2010; Gershon et al., 2009).

Only one Project BREATHE characteristic, Moisture Management (requirement 21), was assigned a higher priority in the reassessment process. Since publication of the original Project BREATHE report in 2009, several publications have suggested that moisture build-up inside the respirator deadspace and on the respirator are important factors in respirator comfort/tolerability (Baig et al., 2010; Radonovich et al., 2009b; Roberge et al., 2012c). These issues may be related to sensations of heat due to the additive effect of humidity upon the “respirator deadspace apparent heat index“ (Roberge

et al., 2012c) and increased breathing resistance secondary to moisture blockage of respirator filter pores (Roberge et al., 2012a).

Three requirements (2, 3, and 7) were given reduced priorities (changed from a rating of 1 to a 3) because recent work at NIOSH (Fisher et al., 2014; Fisher and Shaffer, 2014) suggested that fomite transfer to the hands is unlikely in typical HCW environments. Another reason provided for the reduced rating was the general uncertainty (Heimbuch and Harnish, 2011) of obtaining NIOSH/FDA approval for decontamination and subsequent reuse of FFRs, although a recent manuscript suggests a path forward (Heimbuch et al., 2014). Furthermore, it is still not clear that HCWs desire a reusable product. In a survey of HCWs, researchers reported that 60% of respondents prefer disposable respirator models (Baig et al., 2010). However, some caution should be used in interpreting this survey response because the term "reusable" can mean to some users more than one donning and to other users wearing the same respirator for multiple patients without doffing. Methods of reducing fomite transmission via a contaminated respirator (e.g., disinfection) should remain as a long-term priority for HCW respirator research.

Analysis of Possible B95 Respirator Test Methods

Twelve of the 28 Project BREATHE characteristics in Table I require development or improvement of existing test methods before inclusion in a voluntary consensus standard. The limited number of available test methods were deemed by the authors to be not practical or validated for this application at this time. In some cases, methods to test for the desirable Project BREATHE requirement have not been published by an SDO or were unavailable in the peer-reviewed literature. The relatively large number (43%) of requirements without a suitable test method should be not surprising, as a 2011 report (IOM, 2011) from the Institute of Medicine emphasized the need for additional research on the human factors (field of view, visual acuity, communication) and operational performance aspects of respirator use among HCWs.

Only 3 of 12 Project BREATHE characteristics without a suitable test method are in the Safety & Effectiveness or Comfort & Tolerability areas. Shelf-life durability (requirement 8) is a desirable trait in a respirator (Viscusi et al., 2009), in particular for pandemic planning purposes. Many respirator manufacturers make claims of shelf-life, but we did not identify any test methods for quantifying this in the peer-reviewed literature. Future iterations of the standard can include a shelf-life requirement when manufacturers provide such methods to the public or if additional research is done to develop practical short-term test methods that can predict long-term (i.e., after 10 years of storage) performance. Several studies (Lim et al., 2006; Radonovich et al., 2009b; Snook et al., 1966) have shown that subjective increased facial pressure (requirement 18) is a factor in poor compliance. However, work in developing quantitative tools for measuring facial pressure resulting from a respirator is still evolving, although recent methods are promising (Niezgoda et al., 2013a; Niezgoda et al., 2013b; Roberge et al., 2012b). Additional research in this area is necessary. Prolonged tolerability (requirement 24) can be measured quantitatively using human test subjects (Radonovich et al., 2009b). However, such testing requires significant resources to perform and dedicated subjects willing to consent to wear a respirator for multiple consecutive hours. Research is needed to develop shorter, less intensive methods that predict long-term response. Recent research (Shenal et al., 2012) is encouraging, as devices reported to be associated with less discomfort after two hours tended to also have less relative discomfort after 6-8 hours.

Test methods for all 5 of the Project BREATHE requirements in the area of Occupational Interference were deemed as not practical or reliable at this time. The two highest priorities within this area (requirements 10 and 11) involve the ability to communicate in healthcare environments. Although the adverse effects of non-powered and powered elastomeric half-mask and full-facepiece respirators on speech communication (Coyne and Barker, 2010; Coyne et al., 2001; Johnson et al., 2000) and hearing integrity (Khoo et al., 2005) are well documented, fewer studies address disposable devices. Studies by

Radonovich et al. (2010) and Mendel (2008) were found to address speech interference effects of respirators and loose-fitting surgical masks in healthcare and dental offices. Other human subject studies have focused on non-healthcare situations such as air traffic control (Hah et al., 2009) or helicopter crews (Thomas et al., 2011), and among students taking oral exams (Coniam, 2005). Overall, these studies suggest that respirators similar to Surgical N95 respirators do not attenuate speech sufficiently to impair intelligibility and current test methods may not be sensitive enough to discern minor differences in voice transmission. No published references were found to quantify the other Project BREATHE requirements related to Occupational Interference (requirements 12-14) using the types of respirators commonly found today in healthcare, although adaptation of tests used for other types of respirators may be possible. Clearly, additional research in all aspects of Occupational Interference is needed to better discern the problems (if any) of current devices and to develop appropriate test methods to discriminate product according to user experience.

The last four requirements (25-28), all in the Healthcare System Policies and Practices area, are also very important, but are nearly impossible to evaluate and there are no established test methods. For example, there are no validated tools for assessing employer or patient desirability. Some limited research has been conducted to develop an employee respirator assessment tool using three major criteria – fit/comfort, aesthetics, and somatic impact (Gershon et al., 2009). Although promising, this approach has not been validated and requires employees at the local level to participate, thus not amenable to being conducted at a governmental or independent test laboratory necessary for implementing a voluntary standard. Similarly, cost effectiveness, while important, is difficult to develop into a criterion that can be measured as it depends upon many local cost factors and availability of raw materials.

Selection of B95 Respirator Test Methods and Pass/Fail Criteria

Consistent with the goal to optimize the number of test methods recommended for a voluntary B95 respirator standard, proposed B95 respirator test methods and performance requirements were identified only for the seven Project BREATHE characteristics in Table I that received a revised priority rating of 1 or 2 and for which there was a viable test method. For these seven Project BREATHE characteristics, the process identified in the Methods section was used to identify the best test methods and to select an appropriate pass/fail level. For brevity, only a synopsis of each proposed test method is discussed in this manuscript. Additional details, including environmental conditions, can be found in the citations. As these are just the proposed test methods or established research methodologies at this point, additional details will be developed by the SDO for each one as the proposed voluntary B95 respirator standard matriculates through the standards development process.

Safety & Effectiveness

Table II contains the two proposed B95 respirator test methods and performance requirements for Safety & Effectiveness, which cover three Project BREATHE characteristics (4, 6, and 9). Relationships between device effectiveness and safety and device compliance have been studied. For example, some studies have suggested that end-user perception of device effectiveness is a contributor to improved compliance (Hu et al., 2012; Mitchell et al., 2012). Fit is the largest determinant of half-mask respirator effectiveness (Grinshpun et al., 2009); thus, increasing user confidence in the fit of their device could contribute to compliance. Furthermore, as noted by Baig et al (2010), only a minority of HCWs in their survey reported that they wanted a “socially acceptable” respirator, suggesting that safety was more important than aesthetics. The following sections summarize the test methods and performance requirements for each Project BREATHE characteristic pertaining to Safety & Effectiveness.

Table II. Proposed B95 Safety & Effectiveness Test Methods and Requirements

Feature(s)	Test Procedure	Passing Level
Respirator Fit	• A panel of 35 human test subjects, designed to match the NIOSH bivariate fit test panel, will be recruited. Each subject will be shown how to don the respirator properly and asked to wear a sample of each prototype design. • If the prototype comes in multiple sizes, the researcher will select a sample of the size that will most likely provide a good fit. • Respirator fit tests will be conducted using the TSI PortaCount® with N95 companion, with a pass/fail criterion of 100 for the individual fit test. • If the subject fails the fit test after 2 attempts, another size will be provided until all of the sizes of that prototype are tested. Once a subject passes the fit test with that prototype, no other sizes of that prototype will be tested. • Calculate the % of subjects that were able to pass the individual fit test in at least one of the sizes tested	≥ 74% (26/35)
Reuse / Gauging Fit	• Prototype respirators will be probed and placed by the technician on the medium-sized static advanced headform with breathing machine. If the prototype comes in multiple sizes, the researcher will select a medium-size sample. • Five samples will be tested. 10 replicate fit tests will be performed on each one. • Fit testing will be done using TSI PortaCount with N95 Companion. The breathing machine will be programmed to perform normal breathing (11.2 lpm) and deep breathing (20.4 lpm) exercises. • After each abbreviated fit test, a fit factor will be calculated and the sample removed from the headform. • For each sample, calculate the geometric mean fit factor from the 10 replicate donnings. • Calculate the % of samples with a Geometric mean fit factor ≥ 100	= 100% (5/5)

Respirator Fit

Finding respirators that fit a diverse population will save hospitals and other employers money and time by reducing re-testing costs and easing logistics (e.g., only need to stock one or two models) (Lee et al., 2004). Decades of research have gone into developing respirator fit test methods (Lofgren, 2012). To address Respirator Fit (characteristic 4 in Table I), we started with the respirator fit procedures adopted by NIOSH in its Health Hazard Evaluation (HHE) study to address concerns raised by the California Department of Public Health about the fitting characteristics of a particular model in their pandemic stockpile (BerryAnn, 2010). This study used the TSI PortaCount with N95 companion (also known as the PortaCount Respirator Fit Tester 8038), which is commonly used for both fit testing research and within workplaces to implement a respirator fit test program (Duling et al., 2007; Wilkinson et al., 2010). Studies using the TSI PortaCount with N95 companion have demonstrated that it measures predominantly face seal leakage (Rengasamy et al., 2012). Furthermore, subjects obtaining fit factors greater than 100 with this method, were able to achieve geometric mean workplace protection factors ranging from 18-154 for various biological contaminants (Cho et al., 2011), demonstrating the validity of using the TSI PortaCount with N95 companion for respirator fit testing. The number of human test subjects chosen for the proposed B95 standard were modified slightly from the HHE report (from 40 subjects to 35 subjects) based upon recent work by NIOSH, which uses a binomial model to quantify alpha and beta errors for various panel sizes (Landsittel et al., 2014). Similar to the NIOSH HHE report,

the NIOSH bivariate panel (Zhuang et al., 2007) was chosen to select the appropriate balance of facial sizes and shapes for the 35 human test subjects. No data is available for some of the commonly used respirators in healthcare for this specific proposed test method, but data from the peer-reviewed literature suggest that a few of the better fitting Surgical N95 respirator models will likely be able to meet this criterion (Coffey et al., 2004; Duling et al., 2007; Lawrence et al., 2006; Lee et al., 2004; McMahon et al., 2008).

Reuse / Gauging Fit

For Reuse (characteristic 6) and Gauging Fit (characteristic 9), it was decided to use a machine test based on quantitative fit testing with a TSI PortaCount with N95 companion and a recently developed, improved headform, with a human-like skin surface (Bergman et al., 2014). As discussed previously, other than in the case of a crisis scenario resulting from a respirator shortage, the need for a reusable respirator *per se* is unclear. However, extended use (e.g., wearing the same respirator to treat multiple patients in the same hospital ward) is commonly practiced in tuberculosis (TB) control and thus remains a desirable trait for a B95 respirator for HCWs. For implementation as a test method, repeated donning/doffing can be tiresome for a human test subject, but has been shown to be effective at demonstrating the impact of multiple donnings on respirator fit in one study (Bergman et al., 2012). Demonstrating the ability to maintain an acceptable level of fit across multiple donnings on a headform is a cost effective substitute for human subject testing.

The ultimate purpose of the Gauging Fit (characteristic 9) requirement is to reduce the chances of a user donning their respirator poorly, causing unnecessary reduction in device effectiveness. Reducing the chances for a poor donning is currently done via a user seal check (USC) (Viscusi et al., 2012). Rather than replace the required USC step, we propose to encourage the development of respirators that put less burden on the user. We feel that demonstrating reproducible donnings on the advanced headform (without using a USC) is the most promising approach for achieving this goal. Respirator prototypes that are less sensitive to minor changes in placement on the headform would be more likely to pass this requirement and presumably place less (but not eliminate) burden on the user to detect a poor donning. Data obtained from tests with the improved headform suggest that the 3M1860, 3M1860S, and the 3M 1870 would likely pass this proposed criterion (Bergman et al., 2014).

Comfort & Tolerability

Table III contains the eight proposed B95 respirator test methods and performance requirements for the four highest priority Project BREATHE characteristics (15, 19, 20, and 21) related to Comfort & Tolerability. Numerous studies have identified improved respirator comfort as essential for increasing compliance (Guo et al., 2009; Radonovich et al., 2009b). The following sections summarize the test methods and performance requirements for each Project BREATHE characteristic pertaining to Comfort & Tolerability.

Breathing Resistance

Increased filter airflow resistance from respirators has been shown to adversely affect physical performance of humans, particularly at high work rate conditions (Caretti et al., 2012). These effects are mainly observed for the types of respirators used by the military for protection against chemical warfare agents which have higher levels of airflow resistance compared to the types of respirators typically used in healthcare. Although most FFRs marketed for healthcare applications already feature low pressure drop (i.e., resistance across the respirator filter) compared to other types of respirators (Roberge et al., 2013), there is a benefit to codifying a more stringent pass/fail criterion as part of the proposed B95 standard to ensure continued performance for future products. In-line pressure transducers offer the possibility of pressure drop measurements of subjects wearing FFRs (Jones, 1991) and recent research

utilizing a modified full face mask rhinomanometry and spirometry methods may be promising (Lee and Wang de, 2011) for determination of airway pressures while wearing FFRs. However, the field of filter testing has developed numerous robust laboratory machine-test based methods for measuring filter air flow resistance (ISO/CD-16900, 2012; Shykoff and Warkander, 2011). In general, machine-based methods have been validated against military end-user experience for full facepiece air purifying respirators (Caretti et al., 2001; Johnson et al., 1999), but scant data is available for the types of respirators used in healthcare.

Among these methods, a common piece of equipment in respirator test laboratories is the TSI 8130 automated filter tester (TSI, Shoreview, MN). Publications exist which demonstrate the performance of existing products used in healthcare against this test method (Viscusi et al., 2009). Many Surgical N95 respirators on the market today can meet the proposed pass/fail requirement of < 10 mm H_2O of inhalation pressure drop at 85 LPM, while some barely exceed this threshold (Jones, 1991; Roberge et al., 2010a). Prior investigations have demonstrated that the threshold for perception of an increase in airway resistance is 6.5 mm $H_2O/L \cdot sec^{-1}$ pressure (Aitken, 1969; Bennett et al., 1962), which happens to be the lowest level of the normal airway resistance of man (Lerman et al., 1983) so that attempts to develop respirators with inhalation pressure drops below this level may be useless as they will be imperceptible to the wearer (Roberge et al., 2013). There is a need for further research in this area.

Table III. Proposed B95 Comfort & Tolerability Test Methods and Requirements

Feature(s)	Test Procedure	Passing Level
Breathing Resistance	• Measure filter air flow resistance (pressure drop) of a sealed FFR at 85 l/min constant flow	≤ 10 mm H_2O
Facial Heat	• On 20 human test subjects, measure air temperature inside the prototype respirator during one hour of continuous wear during treadmill exercise at 3.5 mph. • For each subject, calculate change in air temperature by subtracting the air temperature during the first 5 minutes (baseline) from the last 5 minutes. • Calculate average increase in air temperature	≤ 2.5°C increase over baseline
	• On 20 human test subjects, measure skin (cheek) temperature inside the prototype respirator during one hour of continuous wear during treadmill exercise at 3.5 mph. • For each subject, calculate change in skin temperature by subtracting the skin temperature during the first 5 minutes (baseline) from the last 5 minutes. • Calculate average increase in skin temperature	≤ 2.5°C increase over baseline
Air Exchange (machine tests)	• Seal prototype respirator to a headform and mount on an automated breathing and metabolic simulator (ABMS) • Operate the ABMS at an O_2 consumption rate of 0.5 l/min for 5 min and measure volume-weighted average inhaled CO_2 • Calculate the average volume-weighted average inhaled CO_2 for the last minute of simulated exercise • Repeat test 2 more times with a different sample and report the average of the 3 tests	≤ 3.0%.
	• ABMS average inhaled O_2 concentration at 0.5 L/min • Seal prototype respirator to a headform and mount on an automated breathing and metabolic simulator (ABMS) • Operate the ABMS at an O_2 consumption rate of 0.5 l/min for 5 min and measure inhaled O_2 concentration	≥ 16.5%

	• Calculate the average inhaled O_2 concentration for the last minute of simulated exercise • Repeat test 2 more times with a different sample and report the average of the 3 tests	
Air Exchange (human subject tests)	• On 20 human test subjects, measure transcutaneous CO_2 at the earlobe during one hour of continuous wear during treadmill exercise at 3.5 mph. • For each subject, calculate change in transcutaneous CO_2 by subtracting the transcutaneous CO_2 during the first minute (baseline) from the last minute. • Calculate average increase in transcutaneous CO_2	≤ 4 mm Hg increase over baseline
	• On 20 human test subjects, measure O_2 saturation during one hour of continuous wear during treadmill exercise at 3.5 mph. • For each subject, calculate change in O_2 saturation by subtracting the O_2 saturation during the first minute (baseline) from the last minute. • Calculate average decrease in O_2 saturation	≤ 1% decrease over baseline
Moisture Management	• For 20 human test subjects, measure weight (grams) of respirator before and after one hour of continuous wear during treadmill exercise at 3.5 mph. • For each subject, calculate % change in weight per hour. • Calculate average % change	≤ 4%

Facial Heat

Several studies have noted that respirator use impacts thermoregulation (Roberge et al., 2012e). In one survey, a majority (56.4%) of HCWs self-reported that they felt that respirator use increased the temperature around their face (Baig et al., 2010). Even for loose-fitting surgical masks, facial warmth is one of the most common complaints (Roberge et al., 2012d). Human subject studies have quantified this effect and found that, although temperature and humidity in the breathing zone increase during use, little impact on core body temperature was observed (Roberge et al., 2012a). In reviewing the literature, it became apparent that there was no appropriate machine test to reliably quantify this characteristic. During use, the user's skin under the respirator contributes significantly to the respirator microenvironment temperature increase, which cannot be readily simulated by a machine test at this time. The methodology developed by NIOSH (Kim et al., 2013; Roberge et al., 2012a; Roberge et al., 2012c; Roberge et al., 2012d) for studying the comfort/tolerability of respirators was considered the most appropriate. To date, only a few respirator models and one surgical mask model have been evaluated using this test methodology (Roberge et al., 2012a; Roberge et al., 2012d). All of the models tested to date would pass at the identified performance requirement. Further testing is needed before a more stringent criterion could be identified.

Air Exchange

A well designed respirator allows for easy exchange of air from inside the respirator (often called the "deadspace") to the area outside the respirator. During the normal breathing cycle, exhalation into the respirator (effective) deadspace can cause increases in carbon dioxide (CO_2) and decreases in oxygen (O_2). Depending upon a number of human factors (e.g., work rate, minute volume, lung disorders, etc.) and respirator design characteristics (e.g., size of the deadspace, presence/absence of an exhalation valve, etc.), over time, composition of the respirator gases in the deadspace will not be in equilibrium with the outside environment, which can contribute to the user inhaling elevated levels of CO_2 and decreased levels of O_2. Incomplete flushing of the deadspace leading to increasing levels of residual CO_2 and

decreasing levels of O_2 are most pronounced for respirators with larger deadspaces and at the lowest levels of energy expenditure (Roberge et al., 2013). Previous research using human volunteers breathing 0.06 – 4% inhaled CO_2 resulted in changes in visual performance, modified exercise endurance, headaches and dyspnea, psychological effects (e.g., decreased reasoning and alertness), and increased irritability (Satish et al., 2012; Vercruyssen et al., 2007). Other studies have found that breathing 17% O_2 produced higher levels of lactic acid and lower levels of peak exercise performance (Hogan et al., 1983). Although the subjects in those studies were not wearing respirators, the findings demonstrate the possible need for this requirement to ensure that future respirator design options do not adversely affect the air exchange such that these human responses are generated.

There are a variety of machine-based test methods to measure respiratory gases in the respirator deadspace space as an indicator of air exchange. The NIOSH respirator certification program does not include any test procedures for CO_2 or O_2 for the types of respirators typically used by healthcare workers, although a CO_2 machine test method exists for self-contained breathing devices (CDC, 1995) and a Standard Test Procedure is used for evaluating inhaled CO_2 and O_2 concentrations with a human-test of escape-only CBRN-APR hoods (NIOSH, 2005). Another machine test method involves the use of an automated breathing and metabolic simulator (ABMS), which historically has been used in the testing and evaluation of respirators used for mine escape. Sinkule and coworkers reported the use of an ABMS to evaluate the effect of covering an N95 FFR with a surgical mask (Sinkule et al., 2013). This study evaluated 30 FFR models, including several that were approved as Surgical N95 respirators. Overall, at the lowest level of energy expenditure, three of the 30 models tested exhibited averaged inhaled CO_2 concentrations above 4%, including one model at 5.8%. Cup style FFRs – which tend to have the smallest effective deadspace areas – had, on average, less inhaled CO_2 concentrations than horizontal flat fold models (2.49% vs. 3.52% at the lowest level of energy expenditure).

It is also possible to use human subject testing to quantify CO_2 and O_2 in respirator deadspace. Methods for doing this exist as far as back as 1987 (Dahlback and Fallhagen, 1987), although never applied to Surgical N95 respirators. NIOSH researchers (Roberge et al., 2010b; Roberge et al., 2010c; Roberge et al., 2010d) conducted a series of studies in 2009 and 2010, in which they measured average mixed inhaled/exhaled CO_2 and O_2 in the respirator deadspace of N95 FFRs. They were also the first to publish results from simultaneously measured transcutaneous CO_2 and O_2 saturation via a sensor attached to the ear lobe. In general, despite observing elevated levels of mixed inhaled/exhaled CO_2 and decreased levels of mixed inhaled/exhaled O_2 in respirator deadspace, transcutaneous CO_2 levels and O_2 saturation levels were not statistically different from the controls (no respirator). Similar measurements of O_2 saturation and transcutaneous CO_2 were made in a subsequent study (Kim et al., 2013) using a slightly higher work rate, a different cohort of test subjects, and different set of FFR models. They observed transcutaneous CO_2 increases of 1.7 to 3.0 mm Hg over 1 hour of respirator use and decreases in O_2 saturation levels of less than 1%.

Rather than choose either a machine test or a human subject test for Air Exchange characteristic, we chose to recommend both. The ABMS-based method of Sinkule (2013) is the only machine method containing data on Surgical N95 respirators. For facial heat measurements (discussed above), we have already included a human subject based test method. Thus, asking the subjects to don an extra sensor while they are walking on the treadmill during the facial heat test to also measure O_2 saturation and transcutaneous CO_2 is highly cost effective. Future research is needed to see if the machine test alone will be sufficient.

Moisture Management

Moisture retention in respirators can have multiple effects upon the wearer. There is the possibility of increased breathing resistance secondary to moisture accumulation blocking filter pores (Roberge et al., 2010a). Increased moisture also results in an increase in the “respirator deadspace apparent heat index”, a combined effect of temperature and humidity that the wearer senses as the

respirator microenvironment temperature (Roberge et al., 2012a). Moisture can also impact the seal of the respirator to the face (Gardner, 2003). Moisture on protective facemasks that are not rigid in structure (e.g., flat fold shaped masks, etc.) can result in collapse of the respirator (and subsequent impaired breathing) during heavy breathing (Roberge et al., 2012d). Lastly, a moist respirator upon facial skin can be unpleasant subjectively to the wearer; at thermo-neutral (comfortable) environmental conditions, similar to a hospital environment, one study reported that 22% of the complaints offered by surgical mask wearing human test subjects related to the mask sticking to their face or moisture buildup (Roberge et al., 2012d).

However, there are a number of different ways of measuring moisture management. These measurements are complicated because moisture retention within a respirator can be greatly affected by environmental conditions (e.g., humidity). Similar to the procedures described above to measure facial heat, human subject tests can be performed, with relative humidity measured inside the respirator during exercise. However, deadspace temperature and humidity are highly correlated (0.988, $p < 0.01$) (Roberge et al., 2012d), suggesting that including a respirator deadspace humidity measurement would be redundant in this standard. Another option would involve machine testing. Using an ABMS, (Roberge et al., 2010a) determined that moisture retention in current N95 FFRs is generally <1.0 gram at upwards of 4 hours of continuous usage. During their human subject experiments, they also performed the same pre- and post-use weighing method to determine moisture retention. We decided to use this latter approach as it involves a very simple measurement method (weighing respirators pre- and post-test) and can be performed easily during the human subject tests already planned to assess air exchange and facial heat. All of the surgical N95 respirator models tested thus far using this procedure would meet the suggested moisture retention limit of < 4% by weight (or <0.3 gm/hr) at low-to-moderate work rates as measured under temperate ambient conditions (i.e., 20-22°C, 30-50% humidity). It is likely that future work can be done to improve this test method or make the pass/fail criteria more stringent.

Other Issues

It is important to note that, although not the focus of this manuscript, any B95 standard would need to be part of the larger conformity assessment (CA) process, which includes additional challenges such as user instructions for the device, product labeling, post-market testing, and who is certified to declare conformance to the standard (e.g., first-party testing vs. third-party testing) (IOM, 2010). Experience working with SDOs for other types of products suggests that the entire CA process involves both “art” and “science” and the ability to satisfy multiple stakeholders with competing priorities. Going forward, any SDO that initiates development of the B95 standard should consider incorporating a strong CA program at the start of the process. Without an established CA process, the potential exists for a loss in legitimacy, possibly affecting acceptance of the standard among certain HCWs.

Clearly the naming of a new type of respirator is not a scientific discussion, but more one of marketing and education to devise a naming convention that resonates with end users and differentiates products meeting this standard from others on the market. Thus, we anticipate that one of the many important issues facing the SDO that decides to matriculate the standard will need to reconcile is the best name for this new type of respirator. Although B95 is the name we continued to use in this manuscript, we are not recommending, at this time, that B95 is the final best name for this new type of respirator. Some concerns have been raised that the B95 terminology implies that the product will be tested with a biological agent and that the term reinforces the need for special protection from biological aerosols. Other designations such as “healthcare worker respirator”, “M95”, “Medical-95”, or “HC95”, to name a few, are recommended for consideration by the SDO.

Although the primary focus of the B95 standard has been on HCWs, it should be recognized that many of the desirable attributes (e.g., better fit, comfort) are applicable to other types of workers that also use respirators (Fukakusa et al., 2011; Gutierrez et al., 2014; Harris and DeSieghardt, 1974; Popendorf et

al., 1995). Thus, it is possible that aspects of a successful B95 standard may find application in those settings as well.

CONCLUSIONS AND SUMMARY

Project BREATHE seeks to stimulate the development of a more acceptable respirator for HCWs, with the ultimate goal of increasing compliance with recommended respirator policies and procedures. This manuscript expanded upon the previous work of (Gosch et al., 2013) in three specific areas:

- A key component of Project BREATHE is the development and eventual promulgation of a voluntary B95 respirator consensus standard. Data from the literature were provided to describe criteria necessary for widespread adoption of a voluntary consensus standard. NIE theory suggests that successful voluntary standards have "remediable-ness" and legitimacy. The manuscript describes several steps necessary for Project BREATHE to meet these criteria.
- Next, keeping the NIE criteria in mind, a reassessment was conducted to evaluate the original 28 Project BREATHE requirement and to reprioritize them if necessary. Publications completed since the original Project BREATHE report was written provided sufficient evidence to increase the priority rating for the moisture management and to decrease the priority rating for three requirements in the area of fomite transmission / respirator reuse. To optimize the number of performance requirements and test methods in the draft voluntary standard, each of the 28 Project BREATHE requirements was evaluated to remove redundant or low priority requirements and to identify requirements in which current methods are either not available or practical. During this process, four requirements were identified as redundant because they were already covered by an existing NIOSH or FDA standard, while five requirements were given a low priority rating (>3). Twelve requirements involve test methods that need to be improved or validated before they can be considered acceptable for use in the standards development process. Almost half of these were in the area of Occupational Interference, suggesting that this area should be considered a priority area for future research.
- Finally, proposed respirator test methods and pass/fail criteria were identified to address the remaining seven Project BREATHE characteristics. In the area of Safety & Effectiveness, one human subject test and one machine test were identified that address three Project BREATHE characteristics. The final set of proposed B95 requirements focus on Comfort & Tolerability. In this area, eight test methods – three machine and five involving human test subjects - were identified to address four Project BREATHE characteristics.

Overall, we feel that the proposed B95 respirator requirements, criteria, and test methods described in this manuscript will provide a solid foundation for deliberation and advancement through the consensus standards development process. We hope that publishing this starting point will expedite the consensus standards development process, which can take 5 years or longer before products meeting the standard are commercially available.

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