Impact of Three Cycles of Decontamination Treatments on Filtering Facepiece Respirator Fit

Michael S. Bergman[1], Dennis J. Viscusi[1], Andrew J. Palmiero[2], Jeffrey B. Powell[1], Ronald E. Shaffer[1]*

[1]National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochrans Mill Road, Pittsburgh, PA 15236

[2]URS Corp., 626 Cochrans Mill Road, P.O. Box 18070, Pittsburgh, PA 15236

*Corresponding author: RShaffer@cdc.gov

ABSTRACT

Decontamination and reuse of N95 filtering facepiece respirators (FFRs) may be a strategy for mitigating a supply shortage during an influenza pandemic. The objective was to determine if multiple decontamination treatments affect respirator fit. Quantitative fit tests were performed on three different surgical N95 FFR models before and after multiple applications of ultraviolet germicidal irradiation (UVGI), moist heat incubation (MHI), or microwave-generated steam (MGS). Ten test subjects initially qualified for each FFR model by passing (fit factor (FF) ≥ 100) a standard OSHA-accepted quantitative fit test. Fit was then evaluated over multiple consecutive donnings using an abbreviated fit test protocol: first on an untreated FFR and then on the same sample following one, two, and three decontaminations. FFRs were visually examined for physical degradation following each decontamination cycle. MGS and MHI treatments caused one FFR model to experience a slight separation of the inner foam nose cushion. MGS caused a melted headstrap in one FFR sample. UVGI did not cause any physical degradation. Fit test passing rate ranged from 90 % to 100 % and varied by respirator model/decontamination method combination and donning trial. Mean faceseal leakage (FSL) for each donning for all FFR models was < 1 % (i.e., corresponding to FF > 100). Tests were non-significant ($p > 0.05$) comparing the mean FSL of each of the four donning trials for all FFR model / decontamination method combinations. Three applications of the decontamination methods studied did not cause significant changes in respirator fit. Further research is needed before specific recommendations employing these methods can be made.

Keywords: filtering facepiece respirator, fit test, healthcare workers, N95, decontamination, N95 fit, pandemic influenza, respirator reuse

INTRODUCTION

National Institute for Occupational Safety and Health (NIOSH) N95 filtering facepiece respirators (FFRs) are used by healthcare workers as part of a respiratory protection program to reduce exposure to airborne infectious biological aerosols (NIOSH, 2010). In general, NIOSH guidance states that FFR service time is limited by considerations of hygiene, physical damage, and excessive breathing

resistance (NIOSH, 2010; NIOSH, 1997). FFRs are generally considered limited-use devices and during infectious disease outbreaks are normally discarded after each patient encounter because of concerns that the FFR could serve as a fomite. Concerns remain that shortages of FFRs during an influenza pandemic may occur due to increased demand (IOM, 2006). Evidence of this concern was reported in a study of three Vancouver, Canada hospitals during the 2009 H1N1 influenza pandemic where N95 FFRs were used at double the weekly rate compared to the previous season (Murray *et al.*, 2010).

Decontamination of FFRs utilizing various methods has been investigated as a possible strategy for extending service time. Ultraviolet germicidal irradiation (UVGI), microwave-generated steam (MGS), and moist heat incubation (MHI) are promising because they are relatively simple to perform, have been shown not to degrade filtration efficiency, and demonstrate biocidal efficacy (Bergman *et al.*, 2010; Heimbuch *et al.*, 2010; Fisher *et al.*, 2009, 2010; Fisher and Shaffer, 2010; Fisher *et al.*, 2011; Viscusi *et al.*, 2009; Vo *et al.*, 2009). UVGI, MGS, and MHI have been reported to reduce viable H1N1 influenza on FFRs by > 4 logs for virus deposited as aerosols and droplets (Heimbuch *et al.*, 2010). MGS has been reported to reduce bacteriophage MS2-containing droplet nuclei by > 4 logs on FFR coupons (5 cm^2 circular filter media samples cut from the FFR) (Fisher *et al.*, 2009). Additionally, MGS generated in sealed microwave steam bags yielded a reduction of ≥ 3 logs of MS2 applied as droplets (Fisher *et al.*, 2011). Fisher *et al.* (2010) also demonstrated biocidal efficacy using MGS and UVGI on FFR coupons over three cycles of MS2 aerosol contamination and decontamination.

The goal of FFR decontamination is to remove biological contamination so that the FFR can safely be reused by the same wearer; however, FFR decontamination for purposes of reuse is not recommended primarily because of concerns that decontamination could degrade a respirator's filtering or fitting characteristics. Additionally, using FFRs in this manner would currently void their NIOSH approval because NIOSH respirator certification regulations do not include provisions for these practices (CFR, 1995). Consensus standards have recently been developed by ASTM International for evaluating decontamination efficacy of air-permeable materials and a wide variety of environmental surfaces (ASTM 2010a-b) and these standards have been applied for research on FFR decontamination (Heimbuch et al, 2010; Fisher *et al.*, 2009; Vo *et al.*, 2009; Woo *et al.*, 2010).

The degradation of FFR materials (including straps, strap attachments, and nose clips, etc.) following any type of decontamination method must be considered because of the potential to affect facepiece fit. Physical degradation of FFRs has been observed previously following various decontamination methods (e.g., melting of filtration material during microwaving (dry method 'no steam') and separation of foam nose pads from the FFR body during microwaving (utilizing steam) and moist heat incubation) (Bergman *et al.*, 2010; Viscusi *et al.*, 2009, 2011). Melting of FFR components has also been observed when exposed to dry oven heat > 100 °C and shrinkage has resulted from autoclaving (Viscusi *et al.*, 2007, 2009).

For tight-fitting respirators such as N95 FFRs, the U.S. Occupational Safety and Health Administration (OSHA) requires annual fit testing as part of a respiratory protection program (CFR, 1998). Several studies have demonstrated the importance of fit testing (Coffey *et al.*, 1999; Zhuang *et al.*, 2003). Most of the aerosol contaminants that enter an N95 FFR worn by a person are the result of faceseal leakage (FSL) and not filtration performance (Grinshpun *et al.*, 2009). Viscusi *et al.* (2011) assessed facepiece fit and test subject perceptions of smell, donning ease, and comfort for N95 FFRs which had undergone one cycle of decontamination processing using either UVGI, MGS, or MHI. That study found that only MHI caused a slight reduction in fit compared to the controls for two of the six models tested; however, the mean fit factors of the MHI treated FFR models were still > 100. The authors concluded that five consecutive donnings following one cycle of decontamination for these three methods did not negatively impact fit.

Because situations arise in which multiple uses of the same FFR would be desirable (e.g., during an FFR shortage resulting from an influenza pandemic), this study evaluated three applications of decontamination treatments on FFR fit. Unlike the previously mentioned study (Viscusi *et al.*, 2011), this study evaluated both multiple decontamination and donnings to better understand actual use practices.

Additionally, this current research is complementary to a recent evaluation of N95 FFR filtration performance following three cycles of decontamination which found that UVGI, MHI, and MGS did not adversely affect filtration efficiency (Bergman *et al.*, 2010).

This study tested the experimental hypothesis: *Facepiece fit is expected to remain good (i.e., face seal leakage (FSL) will be < 1 %) over multiple consecutive donnings using FFRs treated with a decontamination process between donnings.* This hypothesis was tested by evaluating the facepiece fit of three models of surgical N95 FFRs over four donnings which included a decontamination cycle after the first, second, and third donnings. Surgical N95 respirators are NIOSH-certified respirators that are also cleared by the U.S. Food and Drug Administration (FDA) for sale as medical devices (FDA, 2010).

MATERIALS AND METHODS

Respirator Selection

Three models of surgical N95 respirators (3M 1860, 3M 1870, and Kimberly Clark PFR95-270 (46767)) were evaluated. These same models were previously evaluated in our earlier one-cycle decontamination fit test study (Viscusi *et al.*, 2011). All FFRs were purchased and verified to be from the same respective manufacturing lot at the beginning of the study to minimize lot-to-lot variation.

Decontamination Methods

The three decontamination methods used are summarized in Table I. The methods are similar to those used in our previous decontamination fit test study (Viscusi *et al.*, 2011), although the UVGI and MHI treatments were shortened from 30 min to 15 min each to reduce the overall duration of the test subject visit.

Using a 15 min UVGI treatment ((254 nm) 1.6-2.0 mW/cm^2) Heimbuch *et al.* (2010) demonstrated > 4-log reduction of viable H1N1 influenza virus on FFRs against both droplet and aerosol challenges. The same group also demonstrated > 4-log reduction of viable H1N1 on FFRs using MHI for 30 min (Heimbuch *et al.*, 2010); however, we are not aware of MHI efficacy data for FFRs for a 15 min treatment.

Fit Test Apparatus

Fit testing was conducted in a laboratory environment (21 °C ± 2 °C, 50 % ± 10 % RH). Fit tests were conducted using a PORTACOUNT® Plus Model 8020A Respirator Fit Tester with an N95 Companion™ Model 8095 accessory (TSI, Inc., Shoreview, MN). The maximum achievable fit factor (FF) is 200 when the N95 Companion™ is utilized. FitPlus™ (computer software developed by TSI, Inc.) automated the fit test data collection.

Phase 1 - Respirator Qualification

This study was approved by the NIOSH Institutional Review Board and subjects gave their written consent to participate. Similar to our previous study (Viscusi *et al.*, 2011), test subjects first participated in a qualifying phase for a given FFR model which required achieving a passing result (FF ≥ 100) on a standard OSHA-accepted 8-exercise quantitative fit test (CFR, 1998). Subjects were given two trials to achieve a passing result. Prior to beginning the fit test, subjects were trained using the manufacturer's user instructions on the proper donning and user seal check (USC) procedures for each model. Subjects donned the FFR, performed the USC, and made any necessary adjustments to the FFR until they felt they had achieved a good seal. Next, subjects wore the FFR for a 3 min acclimatization period. Following

acclimatization, the fit test was started. Once qualified for a given FFR model, subjects tested a new sample of that FFR model in the decontamination fit testing phase of the study (Phase 2). A total of 13 test subjects (7 men and 6 women) participated in the Phase 1 testing in order to obtain 10 qualifying subjects for each of the three FFR models to later be tested in Phase 2. The distribution of the number of test subjects to the number of qualified FFR models is shown in Table II.

Table I. Filtering Facepiece Respirator (FFR) Decontamination Treatments

Treatment	Parameters
Ultraviolet Germicidal Irradiation (UVGI)	15 min exposure to outer side of FFR. FFRs were placed on a laboratory stand inside a Sterilgard III laminar flow cabinet (The Baker Company, Sanford, ME) fitted with a 40 W UV-C bulb. Intensity 1.8 mW/cm^2 measured with a UVX Digital Radiometer with model UVX-25 sensor (254 nm filter) (VWR Lab Shop, Batavia, IL).
Moist Heat Incubation (MHI)	15 min incubation at 60 °C (upper temp. limit), 80 % RH in a Caron model 6010 laboratory incubator (Marietta, OH).
Microwave-generated Steam (MGS)	2 min exposure at power setting 10 (maximum power). Commercially available 2450 MHz, Sharp Model R-305KS (Sharp Electronics, Mahwah, NJ) microwave oven with revolving glass carousel, 1100 W (manufacturer rated); 750 W/ft^3 experimentally measured. FFR placed outer-side down and centered on top of two side-by-side pipette tip boxes (each box 11.7 cm x 8.0 cm x 5.0 cm). Each box contained 50 ml room temperature tap water (~20 °C).

Table II. FFR Qualification

No. Test subjects	No. Qualified FFR Models
6	3
5	2
2	1
Total 13	

Phase 2 - Decontamination Fit Testing

A shortened 121 sec PORTACOUNT protocol was used for the multiple donning fit testing. A similar protocol was used in previous studies (Bergman *et al.*, 2011; Roberge *et al.*, 2011; Viscusi *et al.*, 2011) to minimize subject test time when performing multiple donning fit tests; details of the test procedure can be found in these studies, but will be described here briefly. Only six test exercises were performed as compared to the standard OSHA-accepted test which specifies eight exercises. Test subjects performed the same exercises described in the standard OSHA-accepted protocol but for only 10 sec each instead of the normal 60 sec duration for each exercise; however, the first exercise (normal breathing) was 70 sec due to an additional amount of time required by the test system to clear internal pathways of particles and measure the ambient particle concentration. The 121 sec protocol is comprised of a sequence of four actions by the PORTACOUNT: ambient purge (6 sec), ambient sample (15 sec), mask purge (19 sec), and mask sample (81 sec). Previous studies (Campbell *et al.*, 2005; Sreenath *et al.*, 2001) using different methods have shown a strong correlation between fit test sampling data for the first ten seconds of an exercise when compared with the full 60 sec sampling data, although further analysis of our data would be needed to determine such a correlation.

The modified protocol calculates an integrated FF for the six test exercises. This calculation method differs from the standard OSHA-accepted 8-exercise fit test method where the PORTACOUNT calculates the overall FF as the harmonic mean of FFs obtained from seven of the eight individual fit test exercises (a FF for the 'grimace' exercise is not included in the calculation). The FF for the modified protocol was calculated as the ratio of the ambient particle concentration (sampled for 15 sec) divided by the mask concentration (sampled for 81 sec). Even though the modified protocol used was not designed to be equivalent to the standard OSHA-accepted protocol, similar pass/fail criteria were used. A decision was made prior to beginning data collection to perform retesting if a FF < 100 occurred on the first donning or if a head strap break occurred on any of the four donnings. These occurrences were recorded but the FF data were not used for statistical analysis. Instead, a new FFR sample was retested by the same subject as a replacement (i.e., all cycles of donning and decontamination were repeated). A FF < 100 on the first donning was repeated because this study was interested in determining how fit was affected by successive decontamination cycles; thus, a FF ≥ 100 was necessary for the first donning as a basis of comparison. Retesting in the case of broken head strap occurrences was necessary to collect a complete data set comprised of all four donnings.

For Phase 2, the test sequence was randomized for each qualifying subject on the basis of decontamination treatment type, FFR model, and FFR sample number (2 replicate FFR samples were tested per test subject). The decontamination fit testing procedure included four sequential fit test trials for each FFR sample. In all, a total of 720 fit test trials were performed in Phase 2. The USC procedure and 3 min acclimatization period were performed prior to each fit test trial. The first fit test trial was performed on a new untreated FFR sample. Following this first trial, the FFR sample was then taken from the subject and then treated with the first cycle of pre-selected decontamination treatment. The FFR sample was then

returned to the subject for the second fit test trial. This sequence was repeated two more times resulting in a total of four fit test trials with the second, third and fourth trials being preceded by one cycle of decontamination treatment; the same type of decontamination treatment (e.g., UVGI, MHI, or MGS) was used for each of the three separate treatment cycles. The UVGI and MHI fit test sequence durations each lasted approximately 1.5 hr and the MGS test sequence lasted approximately 40 min. A test subject visit lasted between 2 and 3 hr depending on the randomly selected combination of tests for that visit.

Observations of Physical Degradation

FFR samples were inspected by test technicians following each decontamination cycle for any visible signs of degradation or deterioration.

Data Analysis and Statistics

For each of the nine FFR model/decontamination method combinations (3 FFR models x 3 decontamination methods), the arithmetic mean FSL (FSL = 1/FF when utilizing the N95 Companion accessory) for each of the four donning trials was calculated from 20 fit test results (10 subjects x 2 replicate FFR samples). Since FFs and their corresponding FSL values were not normally distributed, Kruskal-Wallis tests using Wilcoxon scores (i.e., the non-parametric ANOVA equivalent test) were performed for each of the nine FFR model / decontamination method combinations to compare the mean FSL values of each of the four donning trials. Results were considered statistically significant for p-values < 0.05. The fit test passing rate (% of fit tests with FF ≥ 100) was calculated for each of the four donnings for each FFR model/decontamination method combination. All statistical analyses and calculations were performed using SAS Version 9.2 (© 2002-2008, SAS Institute Inc., Cary, NC).

RESULTS

Fit Test Data Analysis

Overall, 96.9 % (698/720) of all donnings in the study (i.e., across all models, test subjects, donning trials and decontamination methods) resulted in FSL values < 1 % (i.e., FFs > 100). The fit test passing rate ranged from 90 % to 100 % and varied by the FFR model/decontamination method combination and donning trial (Table III). All Kruskal-Wallis tests were non-significant ($p > 0.05$) indicating that fit was not significantly affected over the four fit test trials. Kruskal-Wallis tests of log transformed FF data also resulted in non-significant results. Table IV shows the mean percent FSL (n = 20 fit tests) and standard deviation for each FFR model / decontamination treatment combination. All mean FSL values were < 1 % and ranged from 0.50 % ± 0.00 % (for the 3M 1870, MGS treatment, donning #1) to 0.67 % ± 0.55 % (for the Kimberly Clark PFR95-270, MGS treatment, donning #2).

Observation of Physical Degradation

Observations of FFR component degradation were similar to those observed in previous FFR decontamination studies (Bergman *et al.*, 2010; Viscusi *et al.*, 2011). MGS and MHI treatments caused the 3M 1870 samples to experience a slight separation of the inner foam nose cushion (some to a lesser or greater degree) from the FFR body; however, multiple treatments were not noticed to cause a more pronounced separation as compared to a single treatment. MGS treatment caused one head strap melting in a Kimberly Clark PFR95-270 sample during the third treatment and the FFR subsequently could not be donned for the final fit test trial. To obtain replacement data for this sample, a new FFR sample was provided to the test subject and then the entire sequence of four donnings (including the

three interspersed decontaminations) was repeated. While all three FFR models included in this study had metallic nosepieces, no sparking occurred during the MGS processing which was a similar observation in previous studies (Bergman *et al.*, 2010; Viscusi *et al.*, 2011). UVGI did not cause degradation in any FFR models.

Table III. Fit Test Passing Rates for Multiple Cycles of Donnings and Decontaminations

FFR Model[A]	Fit Test Trial	UVGI[B]	MHI[C]	MGS[D]
		Passing Rate (%)	Passing Rate (%)	Passing Rate (%)
3M 1860	1 (new FFR sample)	100	100	100
	2 (after 1st decon)	95	90	100
	3 (after 2nd decon)	100	95	100
	4 (after 3rd decon)	100	95	95
3M 1870	1 (new FFR sample)	100	100	100
	2 (after 1st decon)	100	90	100
	3 (after 2nd decon)	100	95	100
	4 (after 3rd decon)	100	95	95
KC PFR95-270 (46767)	1 (new FFR sample)	100	100	100
	2 (after 1st decon)	95	95	90
	3 (after 2nd decon)	95	90	100
	4 (after 3rd decon)	90	95	95

[A] FFR= Filtering Facepiece Respirator.

[B] UVGI= Ultraviolet Germicidal Irradiation.

[C] MHI= Moist Heat Incubation.

[D] MGS= Microwave-generated Steam.

Table IV. Arithmetic Mean Faceseal Leakage (FSL) and Standard Deviation for Multiple Cycles of Donnings and Decontaminations

FFR Model[A]	Fit Test Trial	UVGI[B]	MHI[C]	MGS[D]
		Mean FSL (%) (n=20 fit tests)	Mean FSL (%) (n=20 fit tests)	Mean FSL (%) (n=20 fit tests)
3M 1860	1 (new FFR sample)	0.52 ± 0.05	0.56 ± 0.15	0.53 ± 0.07
	2 (after 1st decon)	0.62 ± 0.45	0.59 ± 0.19	0.55 ± 0.13
	3 (after 2nd decon)	0.51 ± 0.04	0.55 ± 0.14	0.54 ± 0.10
	4 (after 3rd decon)	0.51 ± 0.04	0.59 ± 0.20	0.57 ± 0.14
3M 1870	1 (new FFR sample)	0.51 ± 0.02	0.57 ± 0.14	0.50 ± 0.00
	2 (after 1st decon)	0.52 ± 0.06	0.60 ± 0.24	0.52 ± 0.07
	3 (after 2nd decon)	0.53 ± 0.09	0.53 ± 0.13	0.52 ± 0.09
	4 (after 3rd decon)	0.56 ± 0.11	0.58 ± 0.21	0.63 ± 0.55
KC PFR95-270 (46767)	1 (new FFR sample)	0.51 ± 0.04	0.53 ± 0.07	0.52 ± 0.05
	2 (after 1st decon)	0.60 ± 0.16	0.59 ± 0.27	0.67 ± 0.55
	3 (after 2nd decon)	0.59 ± 0.35	0.61 ± 0.30	0.55 ± 0.11
	4 (after 3rd decon)	0.62 ± 0.25	0.59 ± 0.29	0.56 ± 0.14

[A] FFR= Filtering Facepiece Respirator.

[B] UVGI= Ultraviolet Germicidal Irradiation.

[C] MHI= Moist Heat Incubation.

[D] MGS= Microwave-generated Steam.

DISCUSSION

The Institute of Medicine (IOM) has suggested that decontamination methods for FFRs should remove biological contamination, not affect the health of the user, and should not compromise the FFR's protective qualities (e.g., fit and filtration) (IOM, 2006). The results of this study supported our hypothesis that good levels of FFR fit would be retained over multiple decontamination cycles using UVGI, MHI, or MGS processing. In fact, all mean FSL values were < 1 % (corresponding to our criteria of a passing FF of ≥ 100) over four consecutive donnings. Additionally, no statistical significance was found in the comparison of mean FSL values of donning trials for each of the nine FFR model/decontamination method combinations. This result should not be completely surprising given that Viscusi *et al.* (2011) had similar observations related to FF over five consecutive donnings of one-cycle decontaminated FFRs; Bergman *et al.* (2010) also found no degrading effects on filtration performance after applying three cycles of these decontamination methods (albeit that these studies used slightly different treatment conditions for UVGI and MHI than this current study).

The results are supportive of FFR decontamination and reuse as a possible option to alleviate depleted FFR supplies; however, several limitations must be considered. This study utilized an abbreviated fit test protocol, only three FFR models and a small group (n = 10) of respirator test subjects per FFR model. Results may have differed using a larger group of test subjects, different FFR models, or a longer test protocol. Given that the maximum FF output using the Companion is 200, results may have been different if other instrumentation capable of recording higher fit factors had been used. Subjects wore their FFRs for a shorter total test time of ~5 min (which includes the 3 min acclimatization period) using the modified protocol compared to the standard OSHA-accepted protocol (~12 min), thus results may have differed using the OSHA-accepted protocol. In the healthcare setting, the continuous length of time an FFR is worn is likely to vary under different circumstances (e.g., type of procedure being performed) and so our results may not directly correlate to FFR use in the workplace. An additional limitation is that a different cohort of subjects was used for each model. Also, two of the methods (UVGI and MHI) were made shorter in duration (reduced from 30 min to 15 min) than those in our previous one-cycle decontamination fit test study (Viscusi *et al.*, 2011) in order to reduce the duration of the visit; thus, results may have been different if the full 30 min decontamination times had been used.

The Centers for Disease Control and Prevention (CDC), NIOSH, and FDA currently do not recommend FFR decontamination and reuse because the practice is inconsistent with established regulations. NIOSH respirator certification regulations do not include provisions for FFR decontamination (CFR, 1995). The FDA 510(k) clearance designates that all FDA-cleared surgical N95 respirators are labeled as "single use", disposable devices (FDA, 2010). The FDA has established regulatory requirements for many types of medical devices to be reprocessed (i.e., sterilized and reused) (FDA, 2006; GAO, 2008); however, FDA has not yet established clearance requirements for reprocessing medical masks (i.e., surgical mask or procedure mask) or surgical N95 respirators. Although FFR decontamination cannot currently be implemented, guidelines developed by the CDC discuss respirator extended use (i.e., wearing the FFR for serial patient encounters without removing or re-donning) and reuse (i.e., removing and re-donning between patient encounters) for situations where FFRs could be in short supply during an emergency such as an influenza pandemic. When practiced under an administered infection control program, these guidelines could be part of a hierarchy of infection control measures which include administrative and engineering controls and the use of gloves, gowns, and eye protection (CDC, 2009).

Before FFR decontamination and reuse could be safely implemented in workplaces, more research is needed to develop standardized procedures and corresponding user guidelines. In the meantime, governmental occupational health entities such as NIOSH, FDA, and OSHA should review the body of FFR decontamination research published in recent years in an effort to develop policies for how such programs could be safely developed and implemented in the workplace.

CONCLUSIONS

The three cycles of the decontamination methods studied here (UVGI, MGS, and MHI) did not cause significant changes in respirator fit on a small group of test subjects. These results and those of Viscusi *et al.* (2011) show that a good level of fit can be maintained with certain N95 FFR models following treatment by these decontamination methods; however, it should be noted that the impact on fit due to shortening the duration of the UVGI and MHI methods has not been assessed. Further research is needed before specific recommendations for FFR decontamination and reuse can be made.

Disclaimer

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REFERENCES

American Society for Testing and Materials International (ASTM). (2010a) ASTM E2720-2010: Standard Test Method for Effectiveness of Decontamination of Air-Permeable Materials Challenged with Biological Aerosols Containing Human Pathogenic Viruses. ASTM. West Conshohocken (PA).

American Society for Testing and Materials International (ASTM). (2010b) ASTM E2721-2010: Standard Test Method of Evaluating of the Effectiveness of Decontamination Procedures for Surfaces when Challenged with Droplets Containing Human Pathogenic Viruses. ASTM. West Conshohocken (PA).

Bergman MS, Viscusi DJ, Heimbuch BK, Wander JD, Sambol AR, and Shaffer RE. (2010) Evaluation of Multiple (3-Cycle) Decontamination Processing for Filtering Facepiece Respirators. *J. Eng. Fibers and Fabrics*. 5(4):33-41.

Bergman MS, Viscusi DJ, Zhuang Z, Palmiero A, Powell J, and Shaffer RE. (2011) Impact of Multiple Consecutive Donnings on Filtering Facepiece Respirator Fit. *Am J. Infect. Control.* 2011. In Press.

Campbell DL, Coffey CC, Jensen PA, and Zhuang Z. (2005) Reducing Respirator Fit Test Errors: A Multi-Donning Approach. *J. Occup. Environ. Hyg.* 2(8):391-399.

Centers for Disease Control and Prevention (CDC). (2009) Questions & Answers Regarding Respiratory Protection for Infection Control Measures for 2009 H1N1 Influenza Among Healthcare Personnel. http://www.cdc.gov/h1n1flu/guidance/ill-hcp_qa.htm#reuse. Accessed July 27, 2011.

Code of Federal Regulations (CFR). (1995) *Approval of Respiratory Protective Devices*, U.S. Government Printing Office, Office of the Federal Register, Washington, DC. Title 42, CFR, Part 84.

Code of Federal Regulations (CFR). (1998) *Respiratory Protection*, U.S. Government Printing Office, Office of the Federal Register, Washington, DC. Title 29, CFR, Part 1910.134.

Coffey CC, Campbell DL, and Zhuang Z. (1999) Simulated Workplace Performance of N95 Respirators. *Am. Ind. Hyg. Assoc. J.* 60:618-624.

Fisher E, Rengasamy S, Viscusi D, Vo E, and Shaffer RE. (2009) Development of a Test System to Apply Virus Containing Particles to Air Permeable Materials for the Evaluation of Decontamination Procedures for Filtering Facepiece Respirators. *Appl. Environ. Microbiol*. 75(6):1500-1507.

Fisher E, and Shaffer RE. (2010) A Method to Determine the Available UV-C Dose for the Decontamination of Filtering Facepiece Respirators. *J. Appl. Microbiol*. 110:287-295.

Fisher E, Williams J, and Shaffer RE. (2010) The Effect of Soil Accumulation on Multiple Decontamination Processing on N95 filtering Facepiece Respirator Coupons using Physical Methods. *J. Int. Soc. Respir. Prot*. 27(1):16-26.

Fisher EM, Williams JL, and Shaffer RE. (2011) Evaluation of Microwave Steam Bags for the Decontamination of Filtering Facepiece Respirators. *PLoS ONE*. 6(4)e18585:1-7.

Food and Drug Administration (FDA). (2010) Masks and N95 respirators. Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/PersonalProtectiveEquipment/ucm055977.htm. Accessed July 27, 2011.

Grinshpun SA, Haruta H, and Eninger RM. (2009) Performance of an N95 Filtering Facepiece Particulate Respirator and a Surgical Mask During Human Breathing: Two Pathways for Particle Penetration. *J. Occup. Environ. Hyg.* 6:593-603.

Heimbuch BK, Wallace WH, Kinney K, Lumley A, Wu CY, Woo MH, and Wander JD. (2010) A Pandemic Influenza Preparedness Study: Use of Energetic Methods to Decontaminate Filtering Facepiece Respirators Contaminated with H1N1 Aerosols and Droplets. *Amer. J. Infect. Control*. 39:e1-9.

Institute of Medicine of the National Academies (IOM). (2006) Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic. Reusability of Facemasks During an Influenza Pandemic: Facing the Flu. Washington, D.C.: National Academies Press.; 92 p. Contract No. 200-2005-10881.

Murray M, Grant J, Bryce E, Chilton P, and Forrester L. (2010) Facial Protective Equipment, Personnel, and Pandemics: Impact of the Pandemic (H1N1) 2009 Virus on Personnel and Use of Facial Protective Equipment. *Infect. Control Hosp. Epidemiol.* 31(10):1011-1016.

National Institute for Occupational Safety and Health (NIOSH). (1997) May 2, 1997 Letter to All Users of P-Series Particulate Respirators - NIOSH Service Time Recommendations for P-Series Particulate Respirators. http://www.cdc.gov/niosh/npptl/usernotices/run-050297.html. Accessed July 27, 2011.

National Institute for Occupational Safety and Health (NIOSH). (2010) Respirator Trusted-Source Information Page. National Personal Protective Technology Laboratory. http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html. Accessed July 27, 2011.

Roberge RJ, Monaghan WD, Palmiero AJ, Shaffer RE, and Bergman MS. (2011) Infrared Imaging For Leak Detection of N95 Filtering Facepiece Respirators: A Pilot Study. *Am. J. Ind. Med.* 54:628-636.

Sreenath A, Weed J, and Church T. (2001) A Modified Protocol for Quantitative Fit Testing Using the PortaCount®. *Appl. Occup. Environ. Hyg.* 16:979-988.

Food and Drug Administration (FDA). (2006) Medical Device User Fee and Modernization Act of 2002, validation data in premarket notification submissions (510(k)s) for reprocessed single use medical devices. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm. Accessed July 27, 2011.

United States Government Accountability Office (GAO). (2008) Reprocessed single-use medical devices. GAO-08-147. http://www.gao.gov/products/GAO-08-147. Accessed July 27, 2011.

Viscusi DJ, King WP, and Shaffer RE. (2007) Effect of Decontamination on the Filtration Efficiency of Two Filtering Facepiece Respirator Models. *J. Int. Soc. Respir. Prot.* 24:93-107.

Viscusi DJ, Bergman MS, Eimer BC, and Shaffer RE. (2009) Evaluation of Five Decontamination Methods for Filtering Facepiece Respirators. *Ann. Occup. Hyg*. 53(8):815-827.

Viscusi DJ, Bergman MS, Novak DA, Faulkner KA, Powell J, Palmiero A, and Shaffer RE. (2011) Impact of Three Biological Decontamination Methods on Filtering Facepiece Respirator Fit, Smell, Comfort, and Donning Ease. *J. Occup. Environ. Hyg*. 8:426-436.

Vo E, Rengasamy S, and Shaffer RE. (2009) Development of a Test System to Evaluate the Effectiveness of Decontamination Procedures for Respirator Surfaces when Challenged by Viral Droplets. *J. Appl. Environ. Microbiol*. 75:7303-7309.

Woo MH, Hsu YM, Wu CY, Heimbuch B, and Wander J. (2010) Method for Contamination of Filtering Facepiece Respirators by Deposition of MS2 Viral Aerosols. *J. Aerosol Sci*. 41:944-952.

Zhuang Z, Coffey CC, Jensen PA, Campbell DL, Lawrence RB, and Myers WR. (2003) Correlation Between Quantitative Fit Factors and Workplace Protection Factors Measured in Actual Workplace Environments at a Steel Foundry. *Am. Ind. Hyg. Assoc. J.* 64:730-738.