



Effectiveness of N95 Facepiece Respirators in Filtering Aerosol Following Storage and Sterilization

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ABSTRACT

The use of electret N95 filtering facepiece respirators (N95FFRs) after prolonged storage or treatment can reduce the expense of buying non-expired N95 and thus enable developing and developed countries to optimize their use of limited resources to against airborne particles and diseases, such as coronavirus disease 2019 (COVID-19). The filtration performance of five N95FFR models following long-term storage, removal of charge using isopropanol alcohol (IPA), autoclaving, or treatment with gamma-radiation was assessed using a TSI 8130 automated filter tester. Statistically significant differences were found in the penetration (P), pressure drop (Δp) and quality factor (q_f) between non-expired and expired N95 models 3M-8210 and 3M-8511. A statistically significant linear correlation was also obtained between the N95 penetration ratio (PR) and the difference between year of manufacture and time of test (DYM). The PR of N95 was more strongly influenced by eliminating the charge (for extremely out-of-date respirators) on the electret filter than by the DYM . Sterilization by gamma irradiation increased the P into non-expired and expired N95FFR models ($p < 0.05$), reducing their q_f . The q_f of all N95FFR models, except UVEX-3200, was strongly affected by gamma irradiation, the removal of charge using IPA, autoclaving, and storage in that order. All expired models maintained acceptable filtration performance and still could be used to collect aerosol effectively, even though models 3M-8511 and 3M-1860 had been manufactured up to 13 years previously. As the COVID-19 outbreaks in 2019 and is getting worse in 2020, these data are useful in developing a global stockpiling strategy to maximize the longevity of N95FFRs for public health and healthcare workers. However, the aging of the straps and seal materials (rubbers, plastics) of the N95FFRs may affect their fit factor and effectiveness.

Keywords: N95; Storage; COVID-19; Autoclave; Gamma irradiation; Filtration performance.

INTRODUCTION

To protect environmental health, occupational hygiene, and the health of healthcare workers (HCWs) and home healthcare workers (HHWs) (Ollier *et al.*, 2019), certified respiratory protection devices are used to prevent respiratory infections. Research reveals that patients can release airborne transmission-available pathogen particles and may be possible

spread to a distance > 3 m from a patient with a respiratory disease (Lee *et al.*, 2019). Respiratory protection devices are the last line of defense against such infections. Wearing respiratory protection devices is the most effective way to reduce exposure to aerosol, and a properly fitting N95 filtering facepiece respirator (N95FFR) is approximately 20 times more efficient than a surgical mask (Ollier *et al.*, 2019).

During a severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS) or coronavirus disease 2019 (COVID-19) outbreak that became a national emergency, N95FFRs were in short supply (Leung *et al.*, 2020). Health authorities in Taiwan began stockpiling N95FFRs for their HCWs after SARS event (Roberge, 2008; Chen *et al.*, 2017). When many unused N95FFRs have reached

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their expiration dates, they were destroyed (Chen *et al.*, 2017). In 2011, the Australian government developed a range of strategies to improve the efficiency of stockpile management (ANAO, 2014). One of them was the development of a fully costed model for extending the shelf-life of P2 respirators, involving an acceptable level of risk, to deliver significant savings, given that the items dominate the total capital cost of such a stockpile (ANAO, 2014).

The filtration efficiency of N95FFRs, including aerosol penetration (P), pressure drop (Δp) and filter quality (q_f), is important in determining whether the risk of their use is acceptable (Lin *et al.*, 2017a, b). Viscusi *et al.* (2009) investigated 21 types of NIOSH-certified N95FFR for use during flu pandemics. These respirators were manufactured from 1999 to 2001 and were stored for at least six years at temperatures between 15°C and 32°C and a relative humidity (RH) between 20% and 80%. NaCl particles, certified by NIOSH, were used to measure P at a test gas flow rate of 85 L min⁻¹. The results thus obtained revealed that two of the 21 types of respirator had mean values of P of greater than 5%, and initial mean values from 0.39% to 5.83%. Upon loading, the mean maximum values fell to between 0.95% and 5.83%, revealing that the duration of storage was not directly related to whether the respirators met standards of filter performance (Viscusi *et al.*, 2009). The relationship between the penetration and the year of manufacture of non-expired/expired N95FFRs has not yet been accurately determined.

The contamination of N95FFRs during manufacture, transportation and prolonged storage is a concern. Common methods for decontaminating medical products involve an autoclave (steam sterilization) or gamma irradiation for large-scale sterilization (World Health Organization, 2004). The latter method has been approved by the WHO. The decontamination efficiency depends on the gamma irradiation dosage (da Silva Aquino, 2012). Exposure to gamma irradiation doses of less than 10 kGy effectively deactivates pathogenic microorganisms such as *Salmonella* and *Campylobacter*. Irradiation doses of between 20 and 30 kGy are most frequently used to treat food that is intended for consumption by pathogen-free animals (da Silva Aquino, 2012). The ISO (2013) recommends a sterilizing dose of 25 kGy for single-use medical devices. Therefore, an autoclave under general operating conditions with 10, 25, and 30 kGy gamma irradiation is used for decontamination treatment herein.

The Taiwan CDC requires that for the storage of a stockpile of N95FFRs, the room temperature must not exceed 35°C and the relative humidity (RH) is less than 80%, or the storage conditions must be as recommended by the suppliers (Chen *et al.*, 2017). Items must be placed on shelves, cabinets or pallets. All items must be stored by category and clearly labeled. Records of requisition, receipt and any damage, including wear and tear, must be maintained. All stockpiled N95FFRs must be dry, clean, undamaged, odorless and without exposed threads. The non-expired/expired N95FFR samples that were tested in this work had been stored under these conditions.

In accordance with US 42 CFR 84, this work compares

the P and Δp values of disposable N95FFRs with various life expectancies to evaluate their q_f . To evaluate the effect of this factor on the filtering characteristics of electret N95FFRs, the q_f of N95FFRs was also obtained before and after autoclave sterilization or gamma irradiation.

MATERIAL AND METHODS

Collecting and Testing N95FFRs (Non-expired/Expired/Extremely Out-of-date)

This work involved five NIOSH-certified N95FFR models (Table 1), and they are 3M-8210, 3M-1860, SH-2950, 3M-8511 and UVEX-3200 models. All these five N95FFR models are Taiwan stockpiling respirators after SARS event. 3M-8210 model is a cup style mask with welded dual point attachment and has cushioning nose foam. 3M-1860 model is a cup shape mask with fluid resistant, braided headbands, and has cushioning nose foam. SH-2950 model is a flat-fold type mask with embossed fringe seal, and has an adjustable nose pad. 3M-8511 model is also a cup shape mask with braided headbands two-strap design, and has dual point attachment. UVEX-3200 model is a folding and cup-shaped mask with seamless headband and has an adjustable nose clip. The non-expired N95FFRs were purchased during the test and the out-of-date (expired) ones had been stored as part of Taiwan's stockpile program (Chen *et al.*, 2017), enabling 'before-and-after' comparisons to be made (Viscusi *et al.*, 2009) (Fig. 1). To compare the effectiveness of charged electret N95FFRs with that of uncharged ones, randomly selected new 3M-8210 N95FFRs were sprayed with isopropanol alcohol (IPA) to eliminate the electret filter charge (Lehtimäki and Heinonen, 1994; Huang *et al.*, 2013).

A TSI 8130 automated filter tester (TSI Inc., St. Paul, MN) was used to measure the filtering percentage P and Δp , consistent with the US 42 CFR 84 particulate respirator certification protocol (NIOSH, 2016). Accordingly, the test aerosol was sodium chloride whose particle size distribution was a count median diameter of $0.075 \pm 0.020 \mu\text{m}$ (most penetrating particle size) with a geometric standard deviation (GSD) of not more than 1.86. The test aerosols were passed through a bipolar aerosol neutralizer (Model 8113, TSI Inc., St. Paul, MN), which neutralized test aerosols to the Boltzmann charge equilibrium (Chang *et al.*, 2018; Lin *et al.*, 2019; Jung *et al.*, 2020). The 99% test aerosol size range was from 0.007 to 0.882 μm . Before a filter was tested, it was placed in an environment of $85 \pm 5\%$ RH at $38 \pm 2.5^\circ\text{C}$ for 25 ± 1 hours (NIOSH, 2016). Consistent with the testing standard US 42 CFR 84, the test was conducted in the next three minutes and the results were compared to those of an initial penetration test that were taken from another work (Viscusi *et al.*, 2009). The initial penetration test can be used to determine the status of stored N95FFRs in preference to the more complex and longer maximum penetration test, which requires the respirator to be loaded with 200 mg of sodium chloride aerosol (Viscusi *et al.*, 2009). In this work, each respirator underwent an initial penetration test and six samples of each non-expired and expired model, for a total of 192 samples, were tested.

Table 1. Tested N95FFR models.

Model	Non-expired model			Expired model			g. Difference between year of manufacture and time of test (DYM) of non-expired and expired N95FFR models (a-d)
	a. Year manufactured ¹	b. Years of storage ² (2016-a)	c. Years of expiration ³	d. Year manufactured ¹	e. Years of storage ² (2016-d)	f. Years of expiration ³	
3M-8210	2013	3	5	2009	7	5	4
3M-1860	2015	1	5	2003	13	5	12
SH-2950	2013	3	5	2012	4	3	1
3M-8511	2015	1	5	2003	13	5	12
UVEX-3200	2014	2	3	2011	5	3	3

^{1,3} from the declaration by the manufacturer on the label of each respirator.

² from manufactured year to test year 2016 (this study).

Sterilization of N95FFRs

The N95FFRs were sterilized using an autoclave (six respirators of each non-expired and expired model) or gamma irradiation (three respirators at each irradiation dose). They were heated for 15 min at 121°C under 1.06 kg cm⁻² (15 pounds per square inch, psi) of pressure in an autoclave (Lin et al., 2018). In the irradiation test, the N95FFRs were subjected to integral irradiation doses (hEγi = 1.17 and 1.33 MeV, ⁶⁰Co source) of 10, 25 or 30 kGy accumulated in air at a dose rate of 1.3 kGy h⁻¹ (Viraneva et al., 2015). Then, they were tested using a TSI 8130 automated filter tester following the US 42 CFR 84 protocol (NIOSH, 2016).

Calculation of Filter Quality and Penetration Ratio

The q_f of a filter incorporates P and Δp , and is an index of filter performance (Huang et al., 2013). It is defined as follows.

$$q_f = \frac{\ln\left(\frac{1}{P}\right)}{\Delta p} \tag{1}$$

Both P and Δp should be considered in ranking N95FFRs. A lower P and Δp yield a higher q_f , indicating better filter performance (Lin et al., 2017a, b). When the penetration limit is 5%, (q_f is 0.084 and 0.120 mm H₂O⁻¹ when the inhalation and exhalation resistance limit is 35 and 25 mm H₂O, respectively (NIOSH, 2016). Since the test performance index of a single filter of US 42 CFR 84 has two values and uses two different limits (inhalation and exhalation resistance). In this study, these values will be used as standard references of P , Δp and q_f .

To evaluate the amplitude of the P of N95FFRs that were out of date and to standardize the measured performance of N95FFR models, the penetration ratio (PR) is calculated as follows (Fig. 1).

$$PR = \frac{P_{expired}}{P_{non-expired}} \tag{2}$$

where $P_{expired}$ = particle penetration through an expired N95FFR, and $P_{non-expired}$ = particle penetration through a non-expired N95FFR.

$PR = 1$ means that particle penetration through an expired N95FFR that equals that through a non-expired one of the same model. $PR > 1$ or < 1 indicates that particle penetration through the expired N95FFR is higher or lower, respectively, than that through the non-expired one.

Statistical Analysis

For each of the five tested N95FFR models (six or three samples of each model under each test condition), the mean and standard deviation of PR were calculated in Microsoft Excel (Microsoft Corp, Redmond, WA). Each mean P was categorized as either passing or failing with respect to the maximum allowable penetration level of 5% for NIOSH certification (Viscusi et al., 2009). The ‘before-and-after’ comparisons were made using non-parametric statistical tools

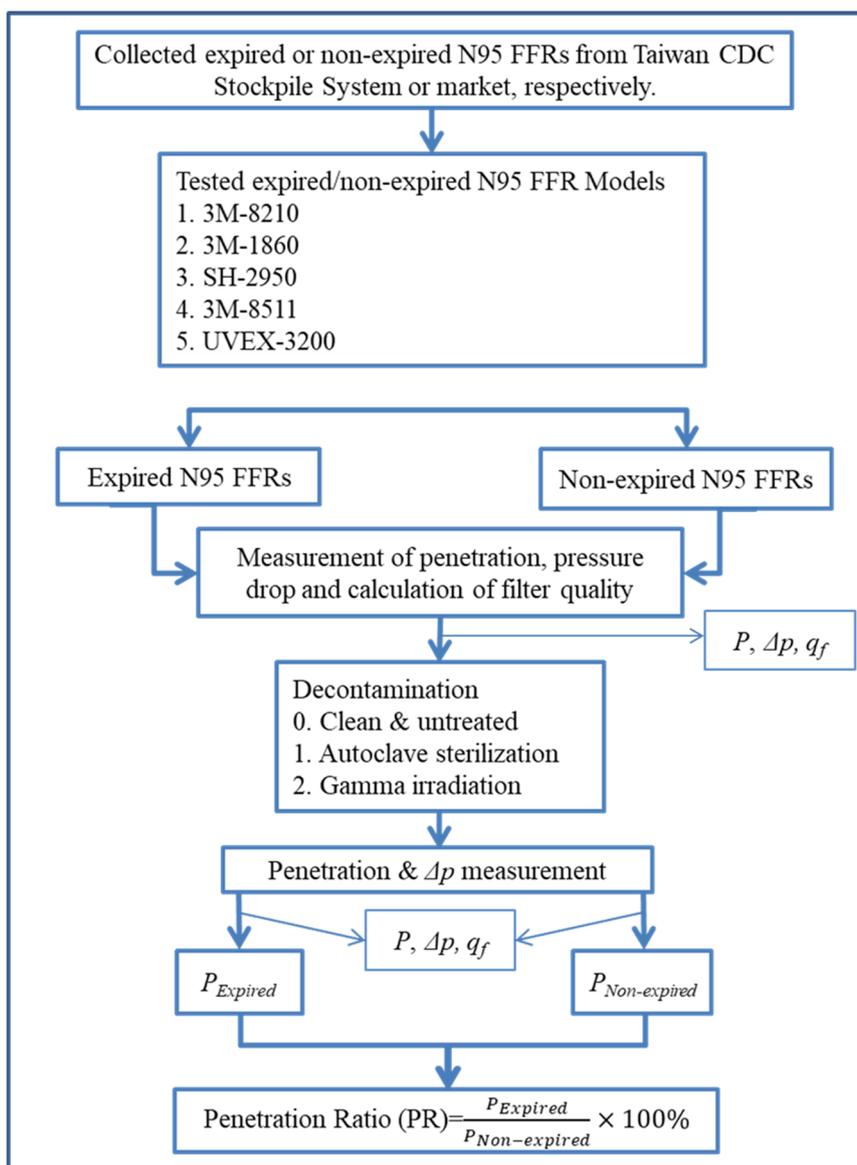


Fig. 1. Experimental flow-chart.

in SPSS software, version 17.0 (SPSS Inc., Chicago, IL). Two regression models, linear and logarithmic, were used to determine the relationship between PR and the difference between year of manufacture and time of test (DYM) of the non-expired and expired N95FFRs. Statistical differences were considered to be significant at $p < 0.05$.

RESULTS

Effect of Storage Duration on Performance of N95FFRs

The P and Δp of all expired and non-expired N95FFRs met the US 42 CFR 84 standards ($P < 5\%$ in Fig. 2 and $\Delta p < 25$ mm H₂O in Fig. 3). All expired N95FFRs had a higher P and a lower Δp than the non-expired ones of the same model. In Fig. 2, the P of the expired 3M-8210 is 0.399% (± 0.218) and the non-expired one is 0.212% ($\pm 0.087\%$). The P of the expired 3M-1860, SH-2950, 3M-8511 and UVEX-3200 is 0.924 (± 0.558), 0.617 (± 0.265), 1.586 (± 0.302), and 4.772

($\pm 3.737\%$), respectively. Moreover, the P of the non-expired 3M-1860, SH-2950, 3M-8511 and UVEX-3200 is 0.383 (± 0.122), 0.549 (± 0.042), 0.568 (± 0.099), and 2.490 ($\pm 1.194\%$), individually. All these five N95FFR models had passed the US 42 CFR 84 N95 penetration criteria. However, expired and non-expired UVEX-3200 revealed higher standard error on P than the other four N95FFR models.

Fig. 3 indicated that all the expired N95FFR models had lower Δp than the non-expired models. Besides, all the expired or non-expired N95FFR models approved the US 42 CFR 84 criteria on exhalation or inhalation resistance. The Δp of expired 3M-8210, 3M-1860, SH-2950, 3M-8511 and UVEX-3200 is 7.794 (± 0.439), 9.056 (± 1.126), 10.161 (± 1.933), 8.511 (± 0.143) and 11.133 (± 1.048) mmH₂O, respectively. Additionally, the Δp of non-expired 3M-8210, 3M-1860, SH-2950, 3M-8511 and UVEX-3200 is 8.778 (± 0.435), 9.639 (± 0.607), 10.994 (± 0.362), 9.333 (± 0.392) and 11.550 (± 0.650) mmH₂O, respectively.

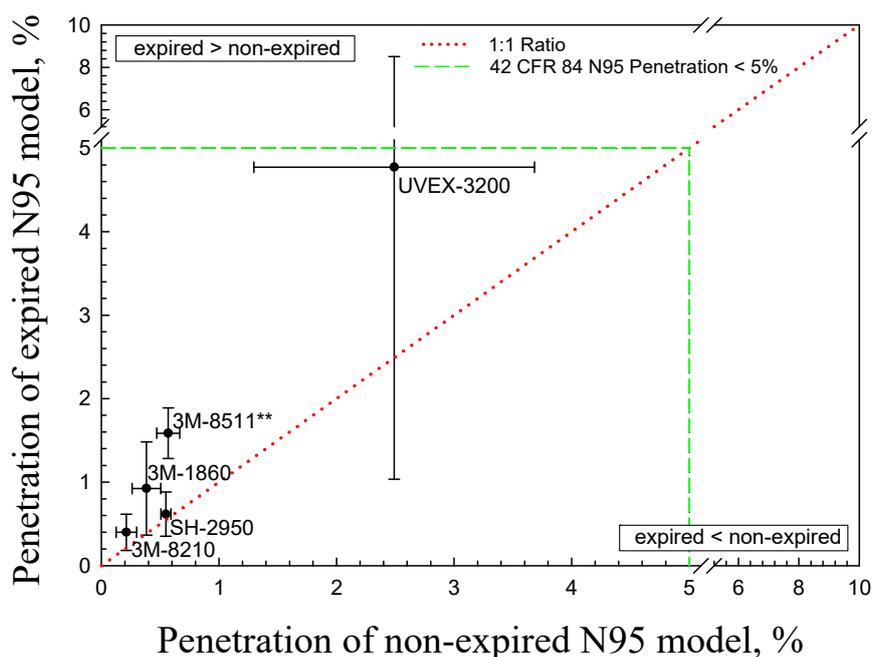


Fig. 2. Penetration of particles through non-expired and expired N95FFR models. Error bars represent one standard deviation.

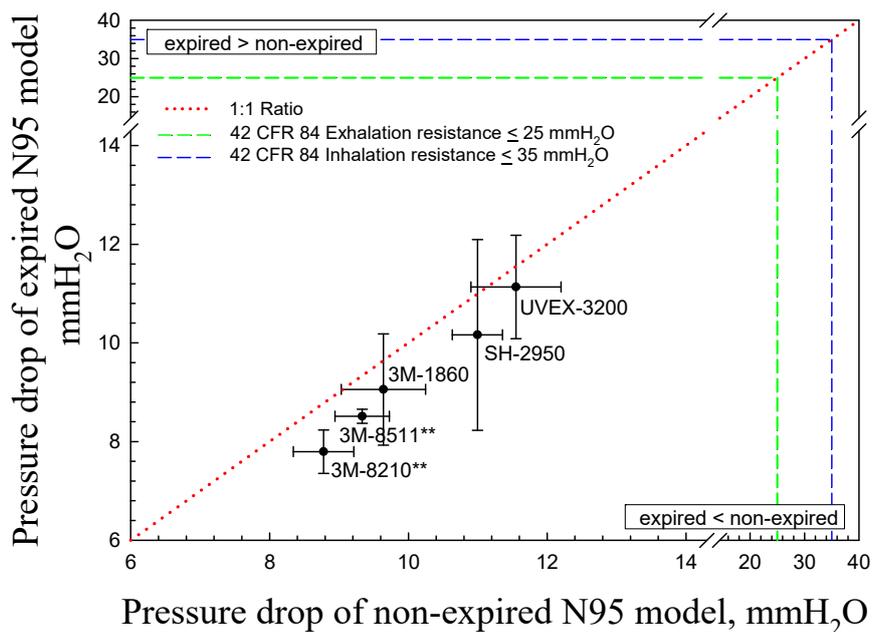


Fig. 3. Pressure drop across non-expired and expired N95FFR models. Error bars represent one standard deviation.

All five N95FFR models had better q_f than US 42 CFR 84 breathing and penetration criteria with reference to Eq. 1, as shown in Fig. 4. The q_f of expired 3M-8210, 3M-1860, SH-2950, 3M-8511 and UVEX-3200 is $0.728 (\pm 0.102)$, $0.551 (\pm 0.147)$, $0.524 (\pm 0.107)$, $0.489 (\pm 0.019)$ and $0.300 (\pm 0.077)$, respectively. Also, the q_f of non-expired 3M-8210, 3M-1860, SH-2950, 3M-8511 and UVEX-3200 is $0.711 (\pm 0.067)$, $0.585 (\pm 0.058)$, $0.474 (\pm 0.018)$, $0.556 (\pm 0.027)$ and $0.330 (\pm 0.053)$, correspondingly. No statistically significant difference in P , Δp or q_f existed between the expired and non-expired N95FFR models, except for the Δp of model 3M-8210 (Fig. 3) and

the P , Δp and q_f of model 3M-8511 (Figs. 2, 3, and 4).

Fig. 5 plots the relationship between PR and DYM for the non-expired and expired N95FFR models. As DYM increased from one to 12 years, PR increased from 1.1 to as high as 2.8 (model 3M-8511), as calculated using Eq. (2). The values of R^2 that were obtained using both the linear and the logarithmic regression models exceeded 0.8. When randomly selected new model 3M-8210 N95FFRs were sprayed with IPA, their PR was 69 (Eq. (2), 14.49 divided by 0.21 , 3M-8210' in Fig. 5) when the DYM was assumed to be infinite (∞). Calculations made using the linear regression or logarithmic

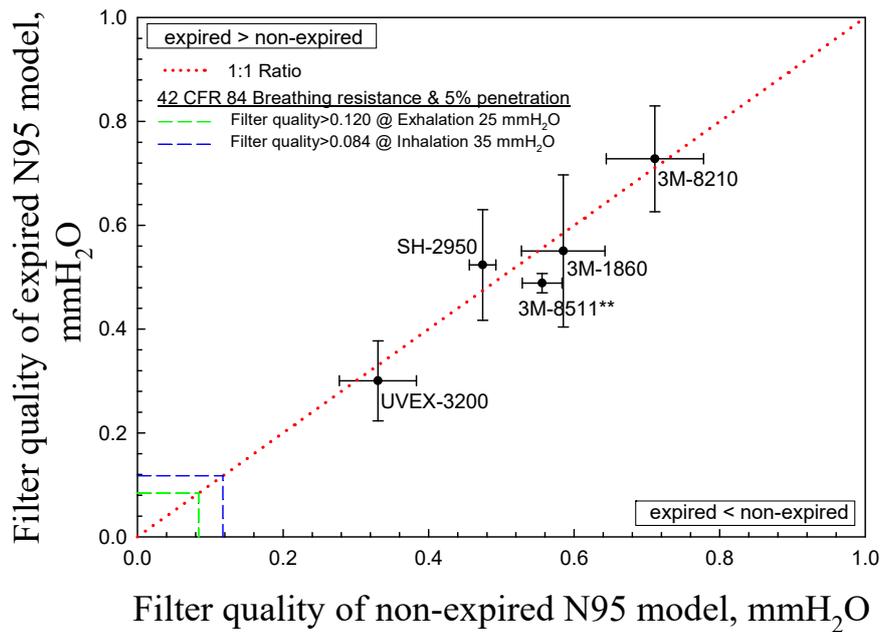


Fig. 4. Filter quality of non-expired and expired N95FFR models. Error bars represent one standard deviation.

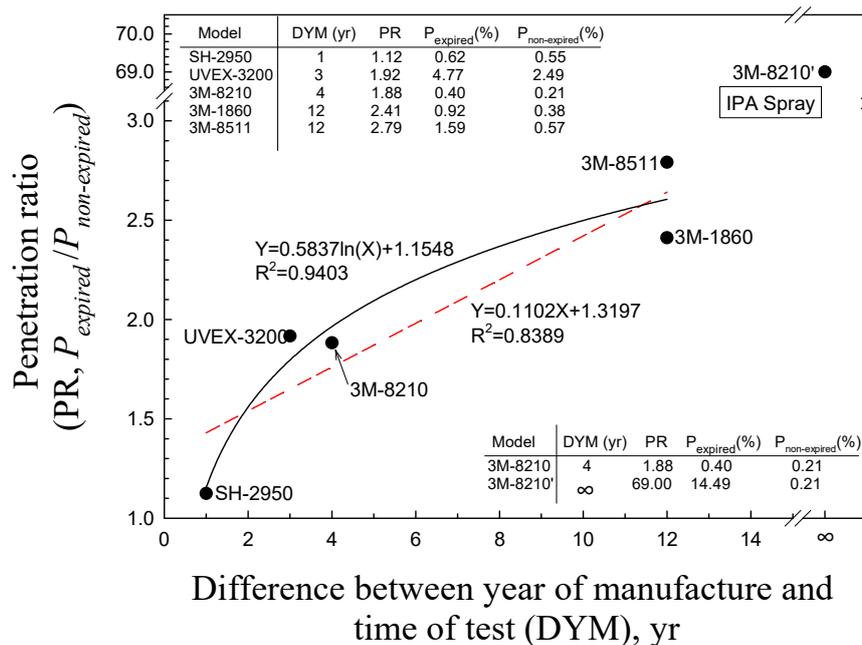


Fig. 5. Penetration ratio of non-expired and expired N95FFR models vs. difference between year of manufacture and time of test (DYM).

regression model yielded $PR = 69$ at $DYM = 614$ or $3E50$ years, respectively. Eq. (1) yielded a q_f of 0.18 for 3M-8210'.

Effect of Sterilization on Performance of N95FFR Models

Treatment using an autoclave significantly increased the P ($p < 0.05$) only of model 3M-8511 (Fig. 6). Sterilization by gamma irradiation increased the P of both non-expired and expired N95FFR models ($p < 0.05$). Sterilization using an autoclave caused the P of two of the five expired N95FFR

models to exceed the 5% certification penetration limit (Lehtimäki and Heinonen, 1994). Sterilization by gamma irradiation yielded P values of the five N95FFR models of 23 to 56%. Treatment using an autoclave or gamma irradiation caused all N95FFR models, non-expired and expired, to satisfy the 25 mm H₂O certification breathing resistance requirement of US 42 CFR 84 (NIOSH, 2016) (Fig. 7). Sterilization using an autoclave or gamma irradiation reduced the q_f values of both non-expired and expired N95FFR models ($p < 0.05$) (Fig. 8). The q_f values of models 3M-8210,

3M-1860 and 3M-8511 following gamma irradiation, as calculated using Eq. (1), did not satisfy the $0.084 \text{ mm H}_2\text{O}^{-1}$ certification criterion. No statistically significant variation in P , Δp or q_f with gamma dose was observed.

DISCUSSION

Consistent with US 42 CFR 84 (NIOSH, 2016), variation of the q_f , including P and Δp , of the N95FFR models with

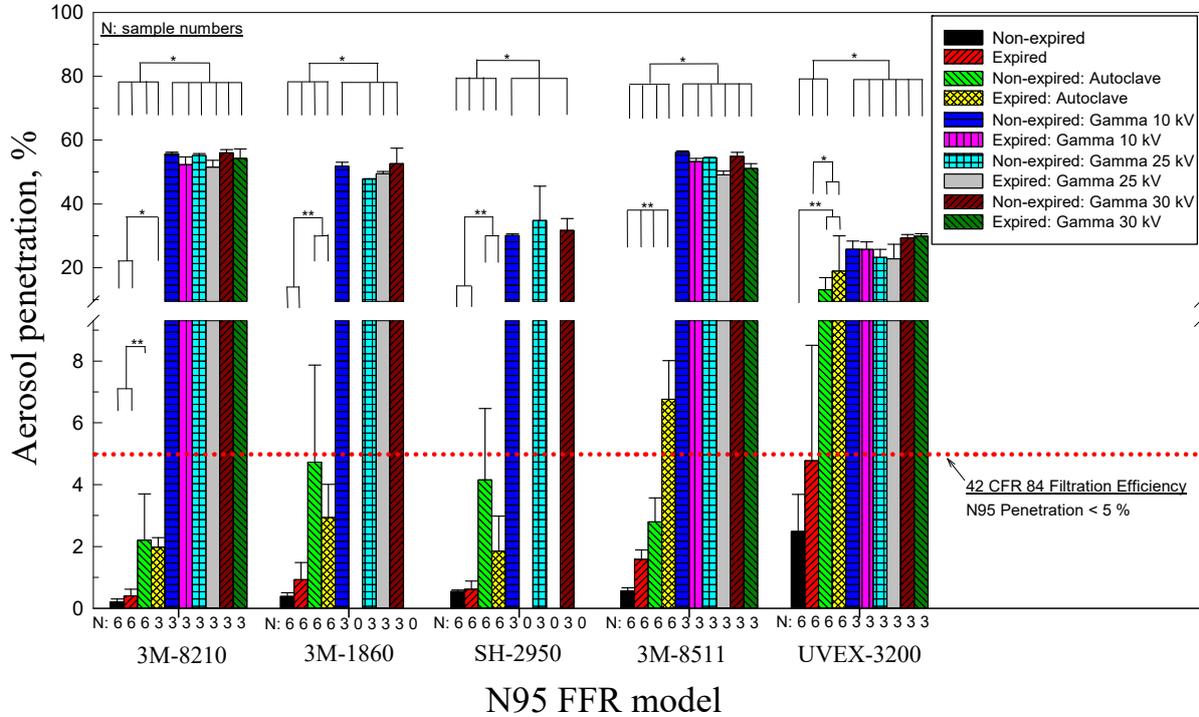


Fig. 6. Penetration of particles through non-expired and expired N95FFR models following sterilization. Error bars represent one standard deviation. “N” is number of samples.

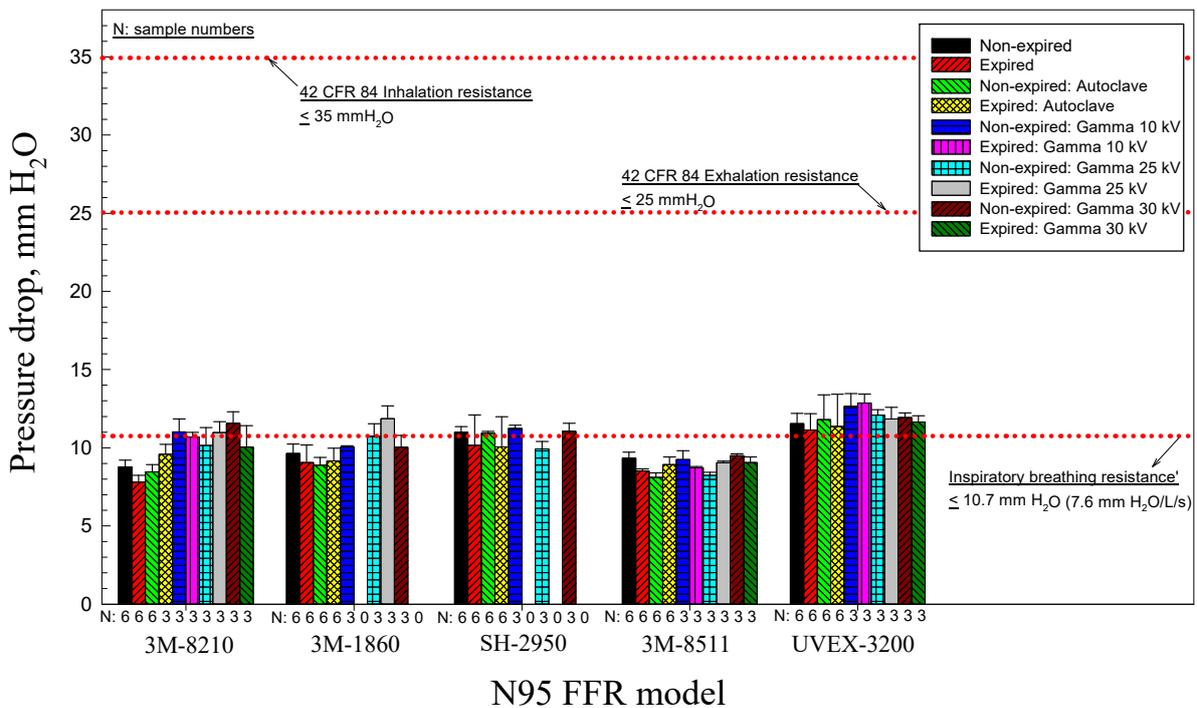


Fig. 7. Pressure drop across non-expired and expired N95FFR models following sterilization. Error bars represent one standard deviation. “N” is number of samples.

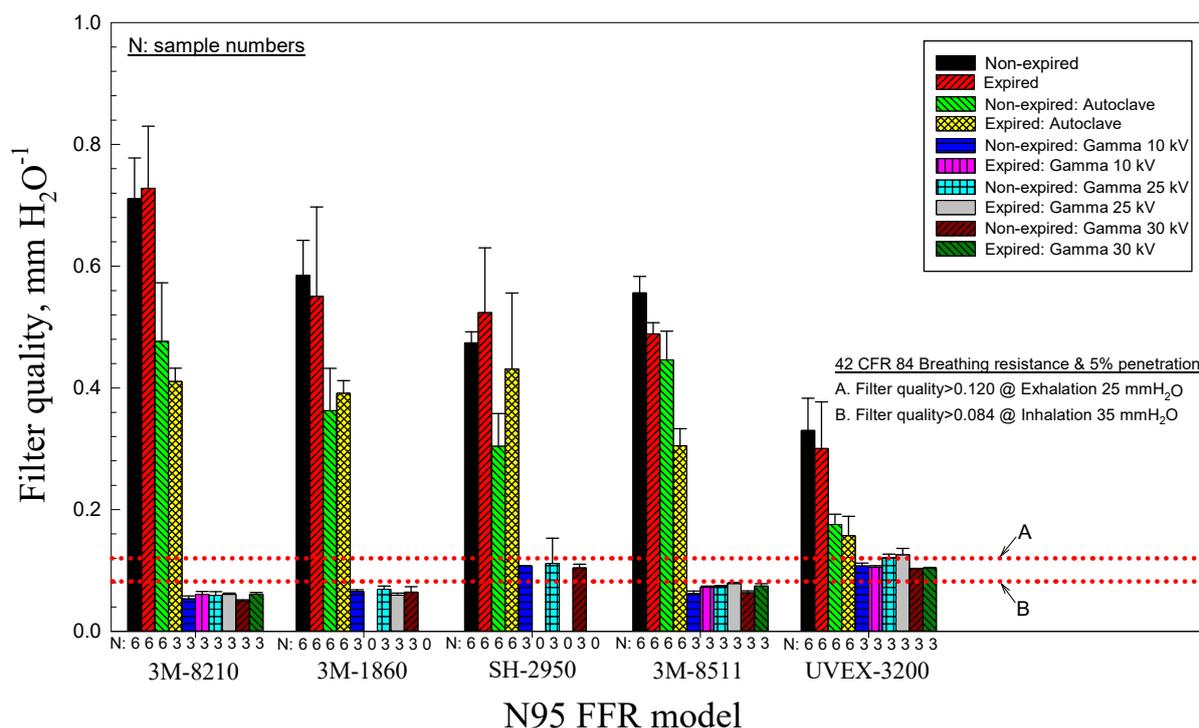


Fig. 8. Filter quality of non-expired and expired N95FFR models following sterilization. Error bars represent one standard deviation. “N” is number of samples.

the duration of validity is considered. Although all mean P values of the expired N95FFR models exceeded those of the non-expired N95FFR models, the difference was only significant ($p < 0.01$) for model 3M-8511 (Fig. 2). Most of the expired N95FFR models maintained an acceptable P even 13 years after their manufacture (Table 1). The Δp values of the expired N95FFR models were lower than those of non-expired models (Fig. 3). The Δp values of non-expired and expired N95FFR of models 3M-8210 also differed significantly, as did those of 3M-8511 ($p < 0.01$). All expired N95FFR models had Δp values that satisfied the requirement of US 42 CFR 84 and were better than those of non-expired N95FFR models. Only the q_f values of the non-expired and expired 3M-8511 N95FFR differed significantly ($p < 0.01$), and the mean q_f values of the expired N95FFR models (were close to the 1:1 ratio line, or $x = y$ line) (Fig. 4). All of the expired N95FFR models had acceptable q_f values.

An earlier study found no relationship between the duration of storage and failure to pass the initial penetration test and it found that the degree of degradation of filtration efficiency was probably model-specific (Viscusi et al., 2009). These discrepancies could have arisen from a lack of dates on the original packaging of 15 of the 21 models in that earlier work. In this work, no relationship between P and the duration of storage between one and 13 years was found. Since the degree of filtration efficiency degradation depended on the model, two novel parameters, PR and DYM , were developed and used herein, and two statistically significant regressions of these parameters were obtained (Fig. 5).

For the linear regression, R^2 was 0.839, while for the logarithmic regression, it was slightly higher at 0.940 (Fig. 5).

Both regression analyses revealed that the PR approached 2.6 at a DYM of 12, which was the upper limit of each regression. Both regression models provided a positive correlation between PR and DYM . To predict the highest possible PR value, non-expired model 3M-8210 N95FFRs were sprayed with IPA to eliminate the charge on the electret filter (Lehtimäki and Heinonen, 1994; Huang, et al., 2013). The PR of both the sprayed and unsprayed model 3M-8210 N95FFRs was 69 (as shown in Fig. 5), revealing that the linear regression may be more effective than the logarithmic regression in providing the relationship between PR and DYM . However, this suggestion warrants further study.

The reference model herein was the non-expired and pre-decontaminated N95FFR model. Decontamination using either an autoclave or gamma irradiation statistically significantly increased the P of all non-expired and expired N95FFR models (Fig. 6). The autoclaved expired models 3M-8210, 3M-1860 and SH-2950 still met the 5% penetration criterion for certification. However, gamma irradiation caused all N95FFR models to violate the 5% penetration criterion. Lin et al. (2017) used five decontamination methods to retrieve N95FFRs, and revealed decontamination increased the sizes of the most penetrating particles, changing the q_f values of all of the N95FFRs. Moreover, chemical decontamination methods (bleach, IPA and ethanol) reduced the overall filter quality values for the three electret N95FFRs. On the other hand, physical decontamination methods (Taiwan traditional rice cooker and autoclave) are less destructive to the N95FFRs than chemical methods, and recommended that when buying new or reclaiming N95FFRs, penetration efficiency should be considered as the priority.

The inhalation resistance of none of the tested N95FFR models came close to the US 42 CFR 84 specification (Fig. 7). However, the previously reported range of normal threshold for the detection of inspiratory breathing resistance (IBR) was 6–7.6 mm H₂O (L s⁻¹)⁻¹ (Roberge *et al.*, 2013). The calculated IBR at 85 L min⁻¹ was 10.7 mm H₂O (Fig. 7). Two of the five pre-decontaminated N95FFR models (SH-2950 and UVEX-3200) did not meet the IBR threshold. Similar results were obtained following use of an autoclave. Gamma irradiation caused four of the five models to exceed the IBR threshold but not model 3M-8511. The IBR was probably related to the normal breathing resistance threshold for HCWs (Roberge *et al.*, 2013; Lin *et al.*, 2017b).

Two of the five expired N95FFR models (3M-8210 and SH-2950) had better q_f values than the corresponding non-expired ones (Fig. 8) because they had better Δp (Fig. 7). However, no significant statistical difference existed between either the Δp values or the q_f values of the non-expired and expired models. No significant difference in the P , Δp or q_f values between the non-expired and expired N95FFR models existed following the use of the autoclave or sterilization by gamma irradiation. Significant differences in the P , Δp or q_f values were observed as a result of decontamination of the five N95FFR models, and gamma irradiation yielded a statistically significantly higher P and lower q_f than the autoclave. Since all of the Δp values were around the IBR threshold, filter penetration dominated q_f .

No statistically significant variation of P , Δp or q_f with the amount of gamma irradiation (10, 25, and 30 kGy) was observed when the N95FFR models were decontaminated therewith, probably because the accumulated dose rates were all about 1.3 kGy h⁻¹. Exposure to gamma irradiation might have had an effect similar to that of IPA, which eliminated the charge on the electret filter (Lehtimäki and Heinonen, 1994; Huang *et al.*, 2013). In 1962, research from Gross and Moraes revealed that the electret charge can be released by reheating of the sample or accompanied by a depolarization current. The depolarization might be brought about by x-ray or gamma irradiation. Gamma irradiation is a recognized method of sterilization (Rutala and Weber, 2008) but greatly increases P of the N95FFRs.

The above results show that the filter performance of the N95FFRs that were stored for a long time (such as the expired N95FFR models) generally met the US 42 CFR 84 standards for P and Δp . Therefore, the storage duration of 13 years, considered herein, was not an important factor in determining the charge characteristics or q_f of the N95FFRs. The q_f values of the four N95FFR models other than UVEX-3200 were strongly influenced by gamma radiation, the removal of charge by IPA (q_f of 3M-8210' = 0.18), autoclaving, and storage in that order (Fig. 8). Since enough expired N95FFR models could not be obtained and the test variables were many, the number of test samples (three or six) was lower than ($n = 20$) required by US 42 CFR 84 (NIOSH, 2016).

All five N95FFR models, either non-expired or expired, had penetration levels of below 5%. The filtration test that was used in this study was comparable to the NIOSH certification test and was performed under a set of “worst-case” conditions (high flow rate, charge-neutralized particles,

and 85% RH). As stated above, 19 of the 21 models that were stored for up to ten years also had initial penetration levels of less than 5% (Viscusi *et al.*, 2009).

All five N95FFR models in this work met the standards for P and Δp . Although one model (3M-8511) exhibited a significant increase in P after the expiration date, the P values of the other four models increased after expiration but not significantly. The Δp values of all five expired N95FFR models were lower after the expiration date than before it; however, the change was significant for only two models (3M-8511 and 3M-8210). One model (3M-8511) had a significantly reduced q_f while the other four models exhibited no significant change in q_f . The change in filter performance upon prolonged storage and sterilization was therefore model-specific (Mueller *et al.*, 2018).

A related study by Viscusi *et al.* (2009) was not a typical aging study, and so did not offer true “before-and-after” comparisons. In contrast, the present study compares the filter performances of non-expired and expired N95FFR models. It is a more formal aging study that provides useful information on the potential longevity of stored N95FFRs for stockpile authorities. In this study, a true “before-and-after” analysis was performed by performing a non-parametric paired t test to determine statistically significant changes in P , Δp and q_f .

This study is limited by the fact that only five N95FFR models and 192 samples were analyzed, because other expired N95FFR models had been discontinued, consequently, non-expired ones could not be purchased during the study. The other non-expired N95FFR models in the current Taiwan stockpile program do not have any expired counterparts. Notably, US 42 CFR 84 requires that all changes and modifications to N95FFRs are examined by NIOSH to determine whether testing is required (NIOSH, 2016). In this work, all results of tests of non-expired and expired N95FFR models met the NIOSH test standards. However, N95FFR manufacturers are continually modifying, refining, and restructuring their products to continue to satisfy NIOSH certification performance standards without always changing the model numbers (Viscusi *et al.*, 2009). Therefore, the N95FFR models that were considered herein may or may not be representative of commercially available today.

The results in this investigation show that all five expired models (without sterilization) maintained a P of below 5% and met the US 42 CFR 84 requirement. Therefore, this investigation is the first study to prove that these five expired models can still be used against aerosol even though two of them (3M-8511, 3M-1860) had been manufactured 13 years ago. Research study has suggested that respirator stockpile administrators should consider contacting respirator manufacturers to determine whether their products have recommended storage duration limits (Viscusi *et al.*, 2009). Another study has recommended that stockpile authorities should consider periodic (perhaps annual) evaluations of representative samples from their stockpile to ensure that their N95FFRs maintain the required P , Δp and q_f after several years of storage (Viscusi *et al.*, 2009; Lin *et al.*, 2017a, b).

Shakya *et al.* (2017) showed that inexpensive cloth masks were extensively used in developing countries to protect against particulate pollution. However, inexpensive cloth

masks are only marginally beneficial in protecting individuals from particles of size $< 2.5 \mu\text{m}$ while N95FFRs were found to be more effective in removing most tested particles (Shakya *et al.*, 2017). If expired but usable N95FFRs must be worn by HCWs or other users, then stockpile authorities or users must consider that the aging of N95FFRs and the conditions thereof may affect their straps and seal materials (rubbers, plastics) and, therefore, their wearing fit factor and effectiveness (Viscusi *et al.*, 2009; Lam *et al.*, 2011; Spies *et al.*, 2011; Lin *et al.*, 2017a, b; Meadwell *et al.*, 2019).

CONCLUSIONS

Following the stockpile program, prolonged storage duration did not strongly affect the q_f of the NIOSH-certified N95FFR models in this study, although all five expired N95FFR models had a higher P and a lower Δp than the non-expired ones of the same model. The mean aerosol P and Δp of all models remain met US 42 CFR 84 respirator test standards within and outside the period of validity. Without decontamination by gamma irradiation or the use of an autoclave, all expired N95FFR models maintained acceptable filtration performance and still could be used to collect aerosol effectively, even though models 3M-8511 and 3M-1860 had been manufactured up to 13 years formerly.

Ideally, N95FFRs should not be used after the manufacturer's stated expiration date. However, if a pandemic should strike and diseases control materials are in short supply, then authorities should consider extending the use of stockpiled and expired N95FFRs. Therefore, expired N95FFRs that nevertheless met the US 42 CFR 84 standards for filter performance can still be used in some situations. For example, extending their service lives following proper inspection and testing effectively reduces the cost of buying non-expired devices for protecting against airborne particles and accordingly enables countries to optimize their use of limited resources for training related to protection against airborne particles and disease prevention, especially when the world is suffering COVID-19 outbreak and N95FFRs are in short supplies. Before expired N95FFRs are used, testing data that are obtained by reliable testing institutions should be analyzed to ensure their effectiveness. Fit factor is still another important issue and should be tested before one needs to use the expired N95FFRs.

DECLARATION

Availability of Data and Materials

All data generated or analyzed in this study are included in the published article.

COMPETING INTERESTS

The authors declare no competing interests.

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