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The Respirator Fit Capability Test: Enhancing the Efficacy of Filtering Facepiece Respirators

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Abstract

When NIOSH promulgated its Respiratory Protective Devices rule in 1995 (Title 42 code of Federal Regulations, Part 84), which specified approval standards for respirators, no test for evaluating the fitting characteristics of filtering facepiece respirators was included. The consequences of the lack of a fit test in 42 CFR 84 included the approval of devices that did not fit the general respirator-wearing population very well, higher costs for conducting the OSHA-required fit test, and the potential for wearing to pass a fit test in error. Today, the need still exists for a fit test for use by manufacturers of filtering facepiece respirators and conformity assessment organizations.

Abstract

Editor's note: In 1919, the United states Department of Mines initiated the nation's first respirator certification program. In observance of this anniversary, The Synergist and NIOSH present this digital supplement to the September issue, which discusses the development of a new voluntary standard for ensuring the proper fitting of respirators.

BACKGROUND

Since 1937, the United States respirator approval program has recognized the need to assess the fitting characteristics of half-facepiece particulate air-purifying respirators. That year, in an article published in the Journal of Industrial Hygiene and Toxicology, the United States Bureau of Mines stated, "the difficulty of properly fitting the halfmask facepieces of mechanical-filter respirators to all types of faces has been brought out by the approval program, the Direct Leakage and Man Test"[1], which was described in the agency's Schedule 21 publication.[2] The Direct Leakage and Man Test consisted of three men—the test subjects – with different facial features (full, average, and lean) exercising for thirty minutes in a room containing visible coal dust. At the end of the test, the men's nose and the part of the face covered by the respirator could not show amounts of coal dust appreciably greater than what was present before the test (see Figure 1). In 1965, when USMB revised requirements in Schedule 21, it added a qualitative isoamyl acetate test and a quantitative dioctyl phthalate test (for respirators having high-efficiency filters).[3]

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Starting in 1972, under the coal Mine Health and Safety Act, USBM and NIOSH jointly conducted the respirator approval program.[5] The agencies consolidated the separate USBM schedules into Title 30, Code of Federal Regulations, Part 11.[6] Schedule 21 was incorporated as Subpart K of 30 CFR 11. The two isoamyl acetate tests (one for dust, fume, and mist respirators have an air contamination level not less than 0.05 mg/m^3 and one for dust, fume, and mist respirators having an air contamination level less than 0.05 mg/m^3 and radionuclides) were the only fit tests to be transferred to the new regulation. The tests required the use of a surrogate respirator designed to remove organic vapors but did not stipulate the number of subjects needed.

In July 1995, NIOSH promulgated an updated standard for the approval of respiratory protective devices. Changes to the technical requirements for particulate filtering respirator types were incorporated into what formerly had been codified as 30 CFR 11 and published as an updated Respiratory Protective Devices rule (42 CFR 84).[7] One of the changes to Subpart K was the elimination of the two fit tests for the following reasons:

1. The surrogate filtering facepiece respirator may have had different fitting characteristics than the actual submitted respirator. Most elastomeric half-masks and most full-facepieces used as a base for particulate-filtering respirators have organic vapor cartridges available and can undergo isoamyl acetate testing with no modifications.
2. The isoamyl acetate tests were not validated.
3. A lack of consensus over a replacement fit test since there was no quantitative method for filters with an efficiency rating of 95 percent.
4. The marketplace would force filtering facepiece respirators to have good fitting characteristics.
5. A significant relationship had never been shown between any facepiece fit test and the performance of a respirator in the workplace.

NIOSH stated in the preamble to the updated 42 CFR 84 that it would “address issues associated with face-fit efficacy in a separate module (regulatory revision) upon completion of the necessary research.”[7] But studies showed that a high percentage of filtering facepiece respirators did not have good fitting characteristics even eight years after the updated 42 CFR 84 was promulgated.[8–13] Without a certification requirement to assess fitting characteristics, additional responsibility was placed on respirator program administrators to find respirators that fit their workers, as described in a 2001 paper published in the AIHA Journal.[14] Some filtering facepiece respirator models that had been approved under 42 CFR 84 fit very few faces well enough to pass the OSHA-required workplace test. As a result, additional models needed to be offered to individuals undergoing fit testing so that everyone could find a model that fit adequately. Having more models resulted in more fit trials per individual, which increased costs and the probability of passing a fit test in error.

To resolve this situation, starting in 2008 NIOSH collected and evaluated total inward leakage (TIL) data for 101 half-facepiece air-purifying particulate respirator models then commercially available.[15] Concurrently NIOSH was supporting development of the

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International Organization for Standardization's respirator standard and participated in discussions about the ISOL TIL test method and performance requirement concept. Thus, the NIOSH data collection effort was referred to as TIL.

At that time approximately 30 percent of the models NIOSH tested did not have good fitting characteristics, so in 2009 NIOSH published a notice of proposed rulemaking and hosted public meetings to discuss incorporating the TIL method into 4 CFR 84 as the particulate filtering respirator fit test. After much public input, NIOSH failed to build adequate consensus among its stakeholders. Stakeholders' concerns included the number of test subjects required and the need to collect particulate concentrations inside the facepiece, which would include (as implied by the TIL concept and name) some particulate that passed through the filter media. NIOSH considered a second approach, named simply "inward leakage" (IL), in an attempt to avoid dealing with the particulates that penetrated through the filter media. This approach also failed because stakeholders were concerned about the numbers of subjects that were required to be tested and the statistical analysis of the fit test results. NIOSH stopped pursuing incorporating the TIL/IL method into 42 CFR 84 in 2012 and officially withdrew the notice of proposed rulemaking in 2017.[16]

Based on the difficulties encountered with the promulgation of the TIL and IL methods, NIOSH decided to work with a standards development organization to develop a voluntary consensus standard. Since 2015, NIOSH's National Personal Protective Technology Laboratory has been collaborating with ASTM International to develop a consensus standard establishing a new test method for respirator fit capability (RFC) conformance for half-mask air-purifying particulate respirators to assess respirator face-sealing characteristics. The purpose of the RFC standard is to increase the probability that the available respirators fit a general worker population. The standard provides greater assurance to respirator purchasers and users that respirators that meet the requirement of this standard can be expected to effectively protect properly trained and fitted persons with various facial shapes and sizes against particulate contaminants. This standard will not eliminate the need for every wearer to undergo a personal respirator fit test, nor will it guarantee that every respirator wearer will be able to achieve the required fit factor on a particular manufacturer's single-size or multi-size respirator model.

METHODOLOGY

The current draft of the RFC standard consists of testing a respirator model with a 25-member NIOSH bivariate panel. This proves involves 25 test subjects with faces whose dimensions fall in one or more of the cells shown in Figure 2. (For information about the bivariate panel, refer to "New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force" in September 2007 Journal of Occupational and Environmental Hygiene.)

When testing respirators with filters whose efficiencies are greater than or equal to 99 percent, each panel member will wear the respirator in the chamber containing between 2,000 and 8,000 particles/cm^3 of sodium chloride. For testing respirators whose filter efficiency is less than 99 percent, the concentration in the chamber will be between 100

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and 800 cm^3. The particles in the chamber should be between 0.02 and 1 micrometer. The chamber and in-facepiece concentrations will be measured using a condensation nuclei counter with particle classifier technology (for example, a differential mobility analyzer). The test administrator will familiarize the test subjects on the donning procedures, completing the appropriate seal checks, and doffing procedures as specified by the manufacturer's user instructions. To reduce the inter-and intra-wearer variability, each test wearer will don the respirator under the supervision of the test administrator. The test wearer and test administrator will be permitted to adjust the facepiece until both are satisfied that the respirator is being worn in compliance with the manufacturer's user instructions including passing the appropriate seal checks. For multiple-size models, a subject who fails the seal check will be allowed to don different sizes of the respirator and perform the seal check again until either the seal check is passed, or all sizes are tried. Subjects who cannot pass the seal check with any of the sizes will not be allowed to perform the RFC test. Another test subject in the same test panel cell will be recruited and the procedure repeated.

After entering the test chambers for the RFC test, the subject will perform the following exercises: normal breathing, deep breathing, turning head side to side, moving head up and down, talking, grimacing, bending over, and normal breathing. The length of each exercise is one minute except for the grimace exercise, which the subject will perform for 15 seconds.

The calculation of the overall fit factor involves converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{7}{\frac{1}{FF_1}+\frac{1}{FF_2}+\frac{1}{FF_3}+\frac{1}{FF_4}+\frac{1}{FF_5}+\frac{1}{FF_6}+\frac{1}{FF_7}+\frac{1}{FF_8}}$$

Where FF1, FF2, FFC, and so on are the individual fit factors for the various exercises. The grimace exercise (number 6) is not included in the calculation.

For one-size models, test subjects who do not obtain an overall passing result (that is, a fit factor of at least 100) will repeat the seal check and RFC test procedure after doffing and redonning the same respirator (or a different respirator of the same size and model). If an overall passing result is not obtained after the additional donning, the test subject will be recorded as failing the RFC test. At least 13 to 25 test subjects mush obtain an overall fit factor of 100 or greater for the model to pass the RFC test.

For multiple-size models, test subjects who do not obtain an overall passing fit factor result will doff the respirator, don another respirator of the same size, and repeat the test procedure. Subjects who still do not achieve an overall passing result will select another size (from the same respirator model) and repeat the RFC test procedure. Subjects who do not achieve an overall passing fit factor result on any of the facepiece sizes after wearing all the available sizes for that respirator model will be recorded as failing the RFC test. At least 13 of 25 test subjects must obtain an overall fit factor of 100 or greater for the model. Of the test subjects passing the RFC test, one must be from each of the following groups: Group A consisting of NIOSH bivariate panel cells 1, 2 and 3 with two subjects per cell; Group Be consists of

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NIOSH panel cell 4 with five subjects, cell 5 with two subjects, cell 6 with two subjects, and cell 7 with four subjects; and Group C consisting of NIOSH bivariate panel cells 8, 9 and 10, with two subjects per cell (see Figure 2). The number of subjects in each is based on population distribution of the NIOSH bivariate panel, as explained in a 2007 paper published in the Journal of Occupational and Environmental Hygiene.[17] It is the respirator model and not the individual sizes that pass or fail the RFC test.

CURRENT STATUS AND FUTURE ACTIVITIES

ASTM Subcommittee F23.65 voted on the RFC standard during April 2019. Our of 35 ballots sent, 23 were returned. There were 12 affirmative votes, 3 negative votes, and 8 abstentions. At its meeting in June 2019, the subcommittee addressed comments from the negative ballots. One comment questioned whether the grimace exercise is necessary, and another asked about the effect of cell distribution on the method's precision and bias. The other comments were editorial. The standard was revised to incorporate all the editorial comments. NIOSH is working to design and conduct a study to validate the method, including measuring the precision and bias and determining the necessity of the grimace exercise. NIOSH plans to complete the study within three to five years. The revised standard will be included on the next F23 ballot.

NIOSH is also considering how to implement the RFC standard following its publication by ASTM. One option would be for manufacturers to test their particulate respirators to the standard (first-party testing with a supplier declaration of conformity) and inform users that the product was tested and meets the standard. NIOSH would not have a role in this option. A second option would be for manufacturers to test their products to the standard and submit that data and information to NIOSH, which would evaluate it and determine conformance. Manufacturers whose respirators are in conformance to the standard could include statements on their respirator approved labels and in user instructions and other documents that the respirators meet the standard and has been reviewed and approved by NIOSH. A third option would be an accredited third-party certification, similar to the testing conducted by the Safety Equipment Institution of self-contained breathing apparatus to National Fire Protection Association standards. The final option would be for NIOSH to promulgate the RFC standard either in its entirety or to add parts to the 42 CFR 84.

In conclusion, the RFC standard defines performance requirements that could be used as part of a conformity assessment program to ensure certified respirators (and families of respirators) are capable of fitting a specified percentage of their intended user population.

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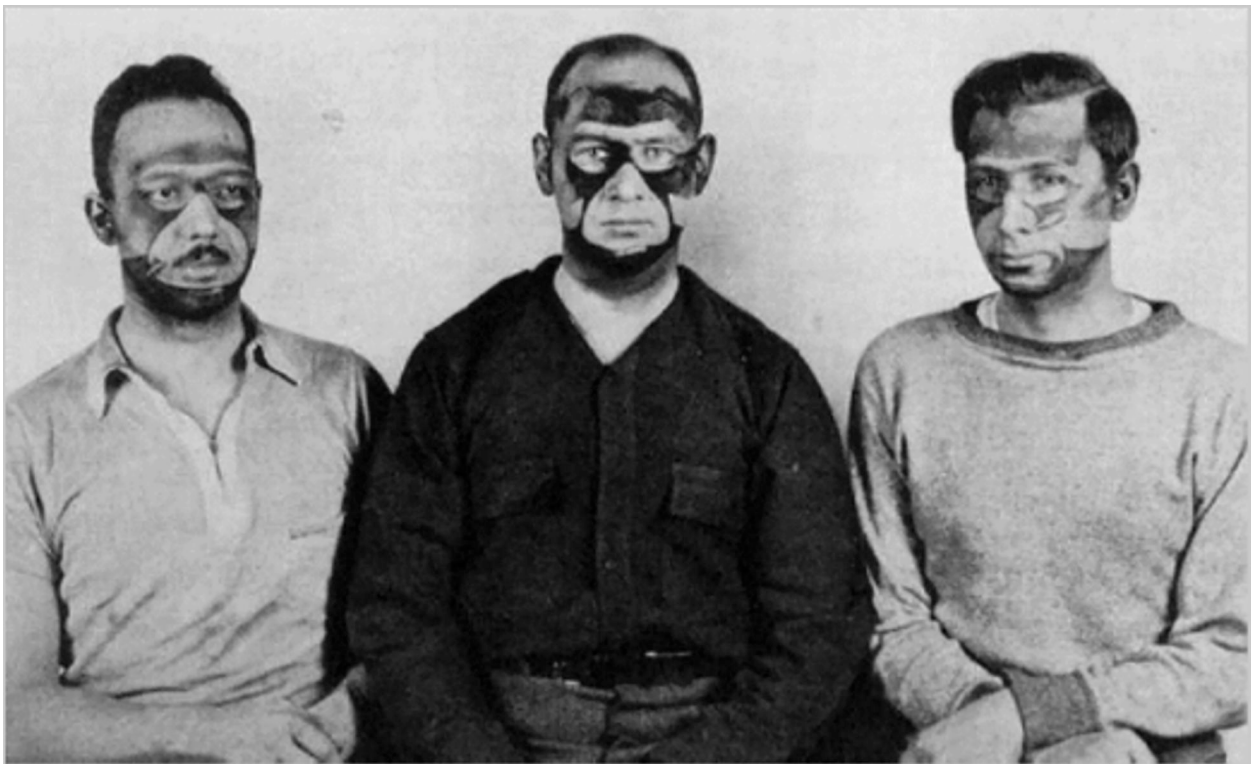

Figure 1.
The effects of face seal leakage by intentionally producing mask leaks by inserting toothpicks under the facepiece.[4]

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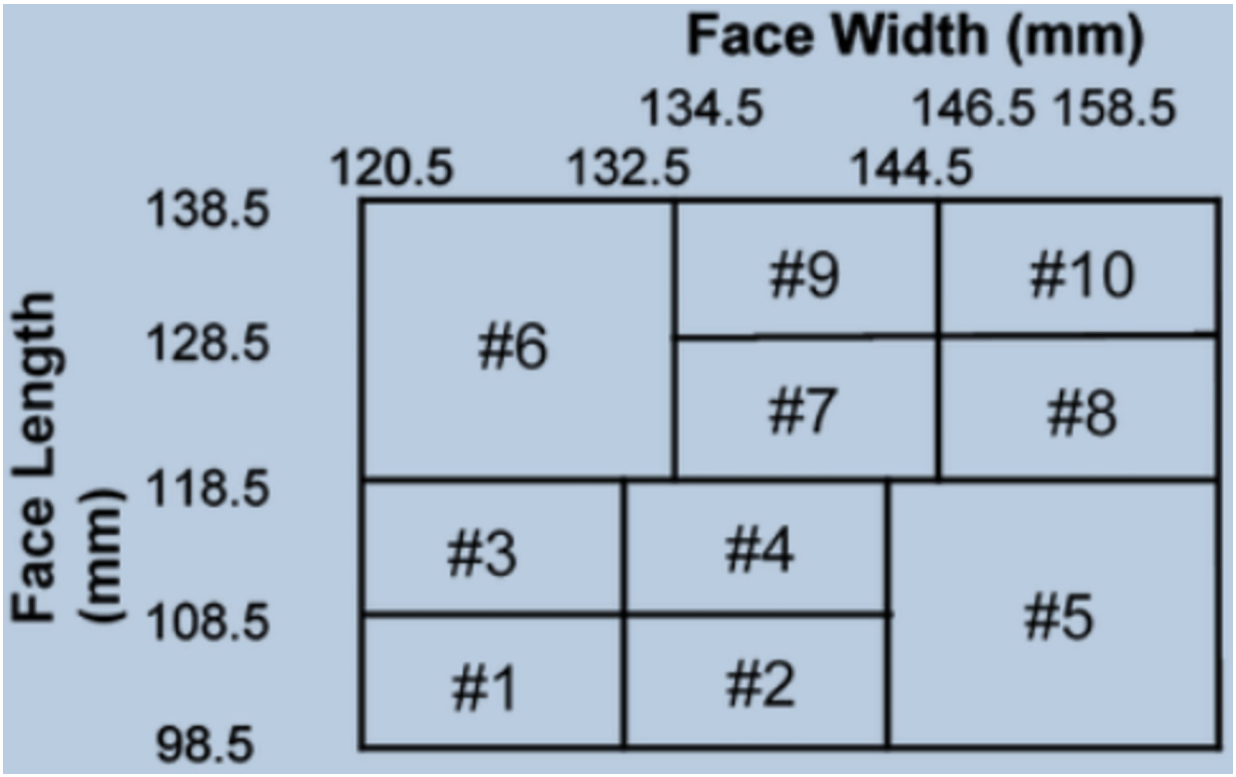

Figure 2.
NIOSH bivariate panel based on face length and face width. The panel cells are number 1 through 10. When the test subject's face length or face width falls on the cell boundaries, the test subject is classified into the higher numbers designated by larger facial dimensions.