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# The history of the evaluation of particulate respirator fitting characteristics in U.S. approval requirements

**Christopher Coffey**[a], **Colleen Miller**[b], **Jonathan Szalajda**[b]

[a]Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, NIOSH, Morgantown, West Virginia (Current affiliation: Advanced Technologies and Laboratories (ATL) International, Inc., consultant to NIOSH's National Persona Protective Technology Laboratory)

[b]National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Pittsburgh, Pennsylvania

## Background

To be effective, a negative-pressure, air-purifying, particulate-removing, half-facepiece respirator (particulate respirator) must form a good seal against the wearer's face. This fact has long been recognized by those in the respiratory protection n community. As one historical example, in 1911, German investigators conducted studies on fit (Brown 1937). However, the current National Institute for Occupational Health and Safety (NIOSH) respirator approval program does not evaluate particulate respirator fit characteristics. Therefore, it is difficult to predict which particulate respirator model will be the best fit in a particular population. Having particulate respirators with good fit characteristics is extremely important today. With the resurgence of tuberculosis (TB) in the United States in the 1990s, the use of particulate respirators in healthcare has increased due to surgical masks only providing barrier protection against droplets that include large respiratory particles. Most surgical masks lack an adequate face seal and do not effectively filter small particles from the air or aerosols, allowing for leakage around the mask and subsequent exposure (Umer et al. 2020). Therefore, surgical masks do not provide adequate protection against infectious respiratory diseases since they are transmitted via droplets and aerosols. With this increased use of particulate respirators in healthcare, supplies of particulate respirators, including N95 filtering facepiece respirators (FFRs), can become depleted during a pandemic or widespread outbreak of infectious respiratory illnesses (Institute of Medicine 2006). However, previous shortages pale in comparison to those caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection. The resulting respirator shortage left doctors, nurses, and other frontline workers dangerously ill-equipped to care for COVID-19 patients while protecting themselves from being infected with SARS-CoV-2. The shortages were so severe that even with the availability of hundreds of NIOSH-approved particulate respirator models, under an emergency use authorization, the U.S. Food and Drug Administration (FDA) allowed certain non-NIOSH approved particulate respirators to be used in healthcare for protection against COVID-19 (FDA 2020). Many employers had to buy whatever respirators they could find, resulting in healthcare workers having to wear particulate respirators with which they were unfamiliar. With the need to

wear these respirators immediately to care for COVID-19 patients, some healthcare workers may have increased their risk of exposure and infection by wearing respirators with poor fit characteristics. In addition to healthcare workers, particulate respirator wearers in other industries may be at risk from overexposure to various contaminants. A 2001 survey of over 40,000 establishments designed to represent all private-sector establishments revealed that only about 57% of those requiring the use of tight-fitting facepiece respirators performed fit testing (BLS/ NIOSH 2003). Having particulate respirators that meet a standard such as the new ASTM F3407-20 Standard Test Method for Respirator Fit Capability (RFC) for Negative-Pressure Half-Facepiece Particulate Respirators would reduce the number of employees who may be overexposed due to wearing a particulate respirator with poor fit characteristics.

In pursuit of such an RFC standard, this paper provides a historical overview of related efforts by the U.S. Bureau of Mines (BOM), NIOSH, and ASTM International to evaluate fit characteristics in particulate respirators. The goal is to enable particulate respirator manufacturers to improve their designs in relation to fit characteristics with the potential to serve a much greater percentage of the worker population.

## Bureau of Mines efforts

In the United States, the first respirator conformity assessment program owner, the U.S. Bureau of Mines, issued schedules (approval requirements) for respirator testing starting in 1919 with the first being Schedule 13 for self-contained breathing apparatus. Schedule 21 for particulate respirators was issued in 1934 as part of Title 30 Code of Federal Regulations, Part 14 (30 CFR 14, USDOI 1934). In a 1939 report, the BOM noted “the difficulty of properly fitting the half mask facepieces of mechanical-filter respirators to all types of faces has been brought out by the approval work on such respirators” (Schrenk 1939). To ensure approved particulate respirators had adequate fit characteristics, the BOM added the first facepiece fit test to Schedule 21, the Direct Leakage and Man Test (USDOI 1934). The test was also known as “the coal dust tightness test.” Three men, each with different facial features (described as full, average, and lean), exercised for 30 min in a room containing visible coal dust while wearing particulate respirators. After removing the respirator, at the end of the test, each man’s nose and the parts of the face covered by the particulate respirator could not show appreciable amounts of coal dust when compared to similar observations made before testing (Figure 1).

The BOM revised Schedule 21 to Schedule 21A in 1955 (USDOI 1955). A pressure tightness test was among several requirements added in the revision. This test consisted of “15 to 20 persons having a wide variety of facial shapes and sizes.” The wearer sealed off the particulate respirator facepiece inhalation ports and exhaled. The respirator passed if the wearer felt a positive pressure in the facepiece during exhalation. A third revision to Schedule 21 (Schedule 21B) occurred in 1965 (USDOI 1965) to include the addition of a qualitative isoamyl acetate and quantitative dioctyl phthalate fit tests. The quantitative dioctyl phthalate fit tests were only used for those particulate respirators with high-efficiency filters. Next, the U.S. Congress passed the Federal Coal Mine Health and Safety Act in 1969 (USDOL 1977), also known as the Coal Act. Under the authority of the Coal Act, the BOM

and NIOSH began to jointly conduct the particulate respirator approval program in 1972. Around the same time, the BOM and NIOSH consolidated the separate BOM schedules into Title 30, Code of Federal Regulations, Part 11 (30 CFR 11) as separate subparts, replacing 30 CFR 14 (Respiratory Protective Devices 1972). Schedule 21 was incorporated as Subpart K of 30 CFR 11 (Figure 2). The two isoamyl acetate tests were the only BOM fit tests included in Subpart K—one for particulate respirators approved for dusts, fumes, and mists having an air contamination level not less than 0.05 milligram per cubic meter, and one for those particulate respirators approved for dusts, fumes, and mists having an air contamination level less than 0.05 milligram per cubic meter and radionuclides. To conduct these tests, in order to receive approval, the applicant had to provide NIOSH with a surrogate particulate respirator designed to remove organic vapors. Subpart K did not contain the number of subjects required to perform the tests. NIOSH efforts In July 1995, as shown in Figure 2, NIOSH transferred and updated the standard for the approval of respiratory protective devices from 30 CFR 11 to Title 42, Code of Federal Regulations, Part 84 (42 CFR 84) (Respiratory Protective Devices 1995). Subpart K for particulate respirators underwent several modifications as part of the transfer. The two isoamyl acetate fit and pressure tightness tests were removed for the following reasons.

1. The fit characteristics of the surrogate filtering facepiece respirators could have been different from those of the approved particulate respirator.
2. The isoamyl acetate test was not validated.
3. There was no agreement on a replacement test since at the time there was no quantitative method available for the new 95% efficient filters.
4. NIOSH was concerned that purchasers would stop buying filtering facepiece particulate respirators that did not have good fit characteristics due to the time and cost of repeat fit testing.
5. A correlation was not shown between fit factor (quantitative measures of the fit of a specific particulate respirator facepiece to a particular individual) and workplace protection factors (measures of the protection provided in the workplace by properly functioning particulate respirators when correctly worn and used) (Respiratory Protective Devices 1995).

It should be noted that NIOSH currently uses the qualitative isoamyl acetate method and standard test procedure RCT-APR-STP-005-05a-06 to assess both half-facepiece and full-facepiece fit before approving chemical cartridge respirators and gas masks (NIOSH 2018). NIOSH planned to address the above issues on fit characteristics of particulate respirators in a separate module (regulatory revision) after the necessary research was completed (Respiratory Protective Devices 1995).

Following the promulgation of 42 CFR 84, NIOSH and others conducted studies to determine if purchasers stopped buying particulate respirators, especially FFRs with poor fit characteristics, as NIOSH had postulated (Coffey et al. 1999, 2004; Zhuang et al. 2004; Lawrence et al. 2006; Duling et al. 2007; Reponen et al. 2011). These studies indicated that a high number of FFRs with poor fit characteristics were still on the market up to eight years after the promulgation of 42 CFR 84.

During a 2009 outbreak of pandemic influenza, which resulted in shortages of N95 FFRs, the California Department of Public Health made stockpiled 3M Model 8000 N95 particulate respirators available to healthcare workers. However, one large healthcare organization did not have anyone pass a Bitrex qualitative fit test with these particulate respirators. The Bitrex test is a pass/fail method used on half-facepiece particulate respirators that relies on the wearer's taste to detect air with a harmless, bitter-tasting chemical leaking into facepiece. 3M and NIOSH were notified and conducted independent investigations which found pass rates of only 40% to 65%, respectively (Berry Ann 2010). These results help to confirm that market forces alone were not enough to prevent particulate respirators with poor fit characteristics from being sold.

Having NIOSH-approved particulate respirators with poor fit-characteristics being used puts an additional burden on particulate respirator program administrators. Managers must ensure their programs provide a sufficient variety of particulate respirator models so that every user requiring the protection offered by a particulate respirator can achieve an acceptable level of fit. The use of inherently poor-fitting particulate respirators causes fit testing to be repeated multiple times per individual, which increases costs to the program. More importantly, as an individual undergoes more fit tests, the probability of erroneous passing test results increases the possibility of the wearer passing in error (Campbell et al. 2001).

Based on the above information, NIOSH pursued the development of a fit-characteristic test to be incorporated into Subpart K of 42 CFR 84. Starting in 2002, and continuing to the present, NIOSH supported harmonized particulate respirator performance standard development by the International Organization for Standardization (ISO) by participating in the development of performance standards under development by the ISO Technical Committee 94 (TC94) Personal Safety–Protective Clothing and Equipment Subcommittee 15 (SC15) Particulate respiratory Protective Devices (RPD). As part of this effort, NIOSH participated in discussions about the ISO total inward leakage (TIL) test method Standard, ISO 16900-1, first published in 2014 (ISO 2014) and revised in 2019 (ISO 2019). The TIL method determines the amount of leakage into the facepiece regardless of the source (i.e., filter penetration, any exhalation valve leakage, or facepiece seal leakage). The method uses a minimum of ten subjects with at least one from each of the eight cells of the Principal Component Analysis Panel which is based on ten facial dimensions (Figure 3). For particulate respirators, the test subjects perform a series of exercises in a chamber containing either sodium chloride (solid aerosol) or corn oil (liquid aerosol). Based on the ISO discussions, NIOSH began to investigate adding the TIL method as the 42 CFR 84 fit characteristic evaluation method in Subpart K.

NIOSH first developed a peer-reviewed research protocol to collect and assess benchmark TIL data for 101 NIOSH-approved half-facepiece air-purifying particulate respirator models then commercially available (Total Inward Leakage Requirements for Respirators 2009). TIL data was collected on 101 particulate filter models (57 filtering facepiece particulate respirators, 43 elastomeric half-mask particulate respirators, and 1 quarter-mask particulate respirator). A panel of 25 subjects completed three donnings with each particulate respirator. TSI PortaCount® with N95 Companion technology (TSI Inc., Shoreview, MN) was used for testing particulate respirators with N95 filters.

Approximately 30% of the models tested did not have good fit characteristics, evidenced by not achieving a quantitative fit factor of at least 100. Based on these results, in 2009 NIOSH began the federal rulemaking process of incorporating a TIL test into 42 CFR 84 as the assessment of facepiece fit test for particulate respirators only by publishing a notice of proposed rulemaking (NPRM) (Total Inward Leakage Requirements for Respirators 2009). The NPRM was followed by public meetings to discuss incorporating the TIL method. The public input identified several issues with the proposed TIL method including the number of test subjects needed, sample variability, and the fact that, as implied by the TIL name, some of the particle concentration sampled inside the facepiece would necessarily include those particles that passed through the filter media. Since the TIL naming convention implied the proposed test methodology was not solely a test of the performance of the face seal, NIOSH and the stakeholders involved failed to reach consensus.

Next, NIOSH considered a second method, named simply Inward Leakage (IL). NIOSH thought that this method would avoid the issue of those particles that passed through the filter media. In 2013, NIOSH hosted two webinars to discuss studies done to address the concerns of stakeholders (NIOSH 2013a, 2013b). NIOSH also opened Docket 250, published a Federal Register Notice, and held a public meeting to reengage stakeholders on conceptual development of inward leakage standards for half-mask air-purifying particulate respirators currently certified under the provisions of 42 CFR Part 84 Subpart K (Development of Inward Leakage Standards for Half-Mask Air-Purifying Particulate Respirators 2013).

The stakeholders involved and NIOSH still could not reach agreement on some of the same issues raised about the TIL method, including the numbers of subjects and the statistical analysis. In the ISO RPD classification scheme, TIL is used to determine the protection class and level of an RPD. In the ISO scheme, the RPD protection level is used for selection and use. There was general concern that using an IL performance requirement was still too close to the ISO TIL performance requirement and would ultimately be used to select and use RPDs. Therefore, stakeholders indicated that the IL method needed further validation. Consequently, NIOSH stopped pursuing the incorporation of the TIL/IL method into 42 CFR 84 in 2012 and officially withdrew the notice of proposed rulemaking in 2017 (Total Inward Leakage Requirements for Respirators 2017).

NIOSH then contacted ASTM International to explore its potential interest in facilitating the development of a voluntary consensus standard. ASTM International accepted this challenge and requested that NIOSH, as leaders in conducting personal protective equipment research for the nation, chair the committee. This approach to standards development is consistent with the National Technology Transfer and Advancement Act, which directs federal agencies to use consensus standards to address policy objectives and activities where practical (NTAA 1995). ASTM efforts ASTM International developed the ASTM F3407-20 Standard Test Method for Respirator Fit Capability (RFC) for Negative-Pressure Half-Facepiece Particulate Respirators, published on October 13, 2020 (ASTM International 2020). The purpose of the RFC standard is to increase the probability that available half-facepiece particulate respirators fit a general worker population. The standard provides increased assurance to purchasers and users that both single-size and multiple-size

particulate respirators can be expected to effectively protect a majority of properly trained and fitted wearers with various facial shapes and sizes. Importantly, this standard does not eliminate the need for every wearer to undergo a personal particulate respirator fit test. Particulate respirators meeting this standard will still have to be fit tested in the workplace on each wearer as required by the Occupational Safety and Health Administration (OSHA) (OSHA 2021). It also does not guarantee that every particulate respirator wearer will be able to achieve the required fit factor on a manufacturer's single-size or multi-size particulate respirator model. The ASTM RFC standard uses 25 subjects forming a bivariate fit test panel based on the anthropometric facial survey of U.S. civilian respirator wearers conducted in 2003 (Figure 4) (Zhuang et al. 2007). The 25-member panel defines 3 size ranges and distributes six subjects into the small size range, 13 subjects into the medium range, and six subjects into the large range. The RFC test is performed in a chamber containing a sodium chloride (salt) aerosol. Specialized equipment counts the salt particles present in the environment of the chamber and those that leaked into the facepiece. The number of particles that have leaked into the particulate respirator is divided into the number of particles outside the particulate respirator in the chamber to achieve an RFC result.

The subject enters the chamber and performs eight exercises, each of which represents an individual exercise result. The subject's RFC result is calculated by dividing the number of exercises by the sum of one over each of the individual exercise results. To pass, a subject must achieve an RFC result of at least 100. An RFC result of 100 means that the number of particles outside the particulate respirator is 100 times greater than inside. At least 13 of 25 (>50%) test subjects must obtain an RFC result of 100 or greater for the particulate respirator model to pass the RFC test.

For particulate respirators having multiple sizes, test subjects select the size they believe will be most likely to fit. If the subject does not receive a passing RFC result, a different size is then tested. If the subject does not achieve an RFC result of at least 100 with any of the available sizes submitted, the subject fails the RFC test. Additionally, at least one subject in each of the three size groups (small, medium, and large) must pass.

The standard's precision values are based on studies that used procedures similar to those used by the RFC. NIOSH is in the process of designing a multilaboratory study to (1) determine the ease of performing the testing, (2) provide a more accurate precision value, and (3) determine the necessity of performing all eight of the exercises. NIOSH plans to complete the study within the next three to four years.

## Discussion

The protection provided by a particulate respirator depends on both the number of particles penetrating through the filter and leaking around the face seal. Face seal leakage is usually the larger contributor to the number of particles coming into the facepiece, which compromises protection. When there is face seal leakage, filter penetration is assumed to be negligible. For this reason, in the U.S. from 1934 to 1995, conformity assessment organizations evaluated the fit characteristics of particulate respirators prior to approving them. It was believed that approving particulate respirators with good fit characteristics

would enable wearers to achieve a higher level of protection in the workplace. A variety of evaluation tests were used during this time: the coal dust tightness test, pressure tightness test, and qualitative isoamyl acetate and quantitative dioctyl phthalate fit tests.

In 1995, when NIOSH revised the approval requirements for particulate respirators, the fit characteristic evaluations were deleted under the premise that the OSHA-required facepiece fit testing would ensure particulate respirators that provided the expected level of protection in the workplace. However, studies conducted after 1995 showed that the fit characteristics of particulate respirators, especially FFRs, were not improving. Even after fit testing, some FFRs did not provide the expected level of protection. In addition, there was evidence that the OSHA-required fit testing was not being performed in every particulate respiratory protection program. Therefore, in 2009, NIOSH attempted to re-instate a fit characteristic for particulate respirators back into its approval regulations, beginning the federal rulemaking process to incorporate an inward leakage test. After two failed attempts, NIOSH stopped the federal rulemaking process, deciding to work with a standards development organization in 2017 to develop a voluntary consensus standard that particulate respirator manufacturers could use. The result of this effort is the ASTM F3407 Standard Test Method for the RFC for Negative-Pressure Half-Facepiece Particulate Respirators. Table 1 is a summary of the major requirements of the ASTM RFC and the ISO TIL standards.

## Conclusions

There are several important health and safety, financial, and practical benefits that would emerge from the RFC standard being published, as detailed below.

1. The ASTM RFC standard will enable particulate respirator manufacturers to improve the design of particulate respirators models to have better fit characteristics with the potential to fit a much greater percentage of the worker population. Having particulate respirators with good fit characteristics improves the health and safety of workers relying on those respirators. Since fit tests are not 100% accurate, having particulate respirators that meet the RFC standard will reduce the chance of a wearer of being assigned a respirator with poor fit after passing a fit test (Coffey et al. 2006). Wearing a particulate respirator with an undetected high level of face seal leakage could cause an overexposure, compromising the health and safety of the wearer.

2. The standard will lower costs to particulate respiratory protection programs by reducing the number of different models needed in the program. Purchasers of particulate-only respirators could reference ASTM F3407 Standard in procurement packages to maximize the potential for receiving those with good fit characteristics. When particulate respirators do not necessarily have good fit characteristics, particulate respirator program administrators should exercise increased care in the selection of particulate respirator models and increased care in fit testing. This also increases the burden on the program.

3. Conformity assessment program owners such as NIOSH will be able to use the RFC standard in their programs to evaluate conventional and novel particulate respirator designs requiring particulate filtration—for example, those not having traditional head harnesses (i.e., two straps to provide adequate tension during use and even distribution of pressure). If published, the RFC standard will help maximize the potential for providing workers with better protection. This is critical in all industries where workers are exposed to a variety of agents requiring particulate filtration, particularly during times of high demand when new designers and manufacturers are entering the market to provide particulate respirators.

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**Figure 1.**
An example of the results of the Direct Leakage and Man Test (the coal dust tightness test) (USDOI 1934).

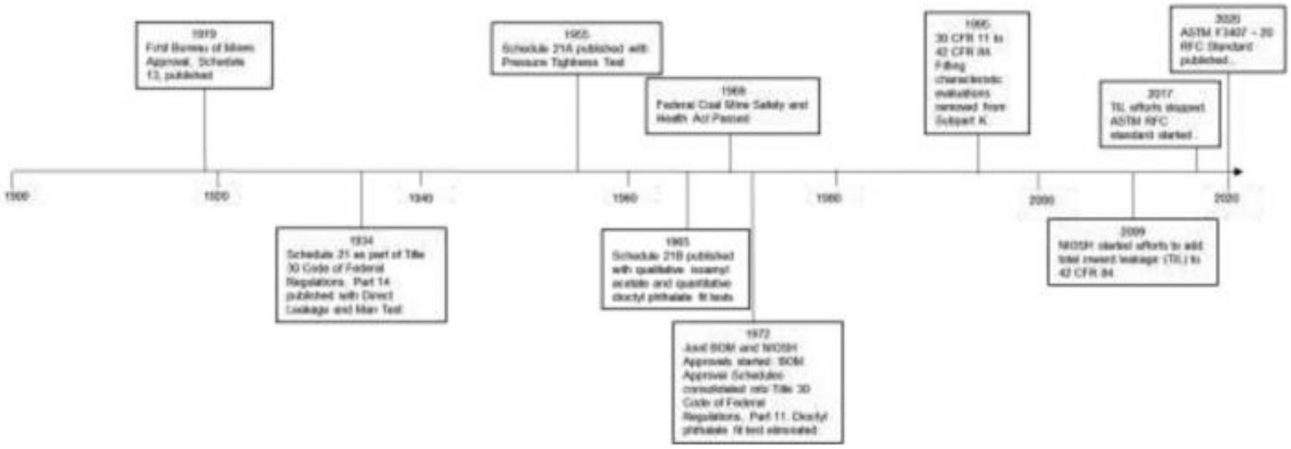


**Figure 2.**
Timeline of approval requirements and fit tests related to particulate respirators.

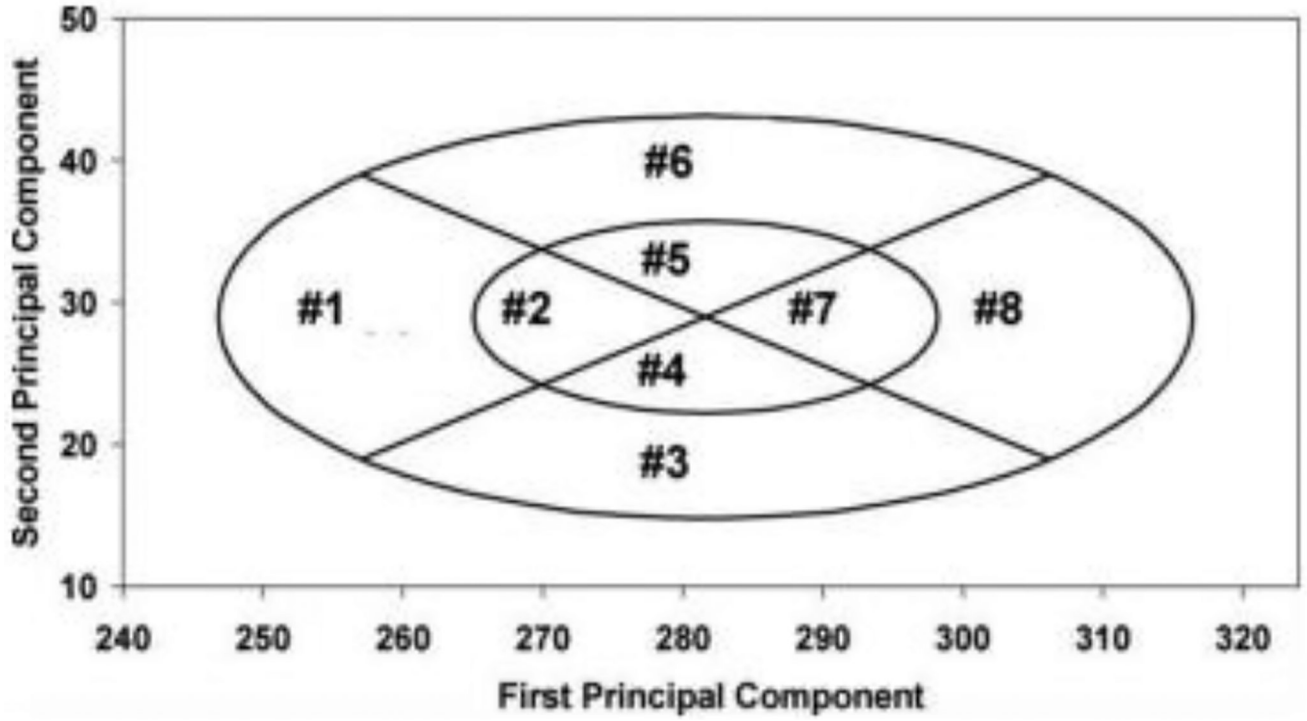


**Figure 3.**
The PCA Panel based on two principal components with cells number from 1 to 8.

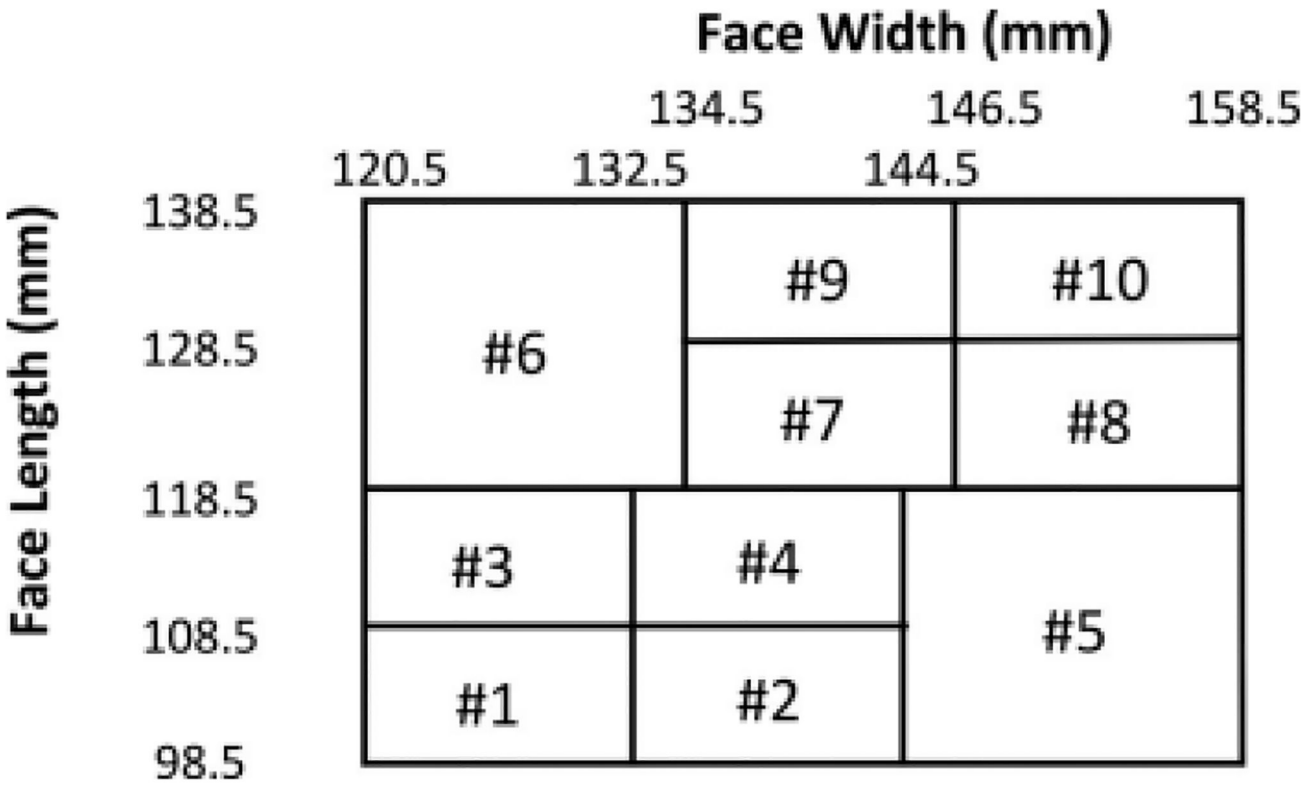


**Figure 4.**

NIOSH Bivariate Panel based on face length and face width. The panel cells are numbered 1 –10. When the test subject's face length or face width falls on the cell boundaries, the test subject is classified into the higher-number cells, designated by larger facial dimensions.

**Table 1.**

Comparison of requirements between ASTM and ISO standards.

| Requirement | ASTM RFC | ISO TIL 16900-1 |
|---|---|---|
| Number of subjects | 25 | Minimum of 10 |
| Panel type | NIOSH Bivariate Panel uses face length and width only (Figure 4) | Principal Component Analysis (PCA) uses 10 of 18 possible facial dimensions (Figure 3) |
| Requires chamber | Yes | Yes |
| Test agent | Sodium chloride (NaCl) | NaCl or corn oil |
| Test agent aerosol size | 0.02 μm and 1 μm with a geometric standard deviation ≤2 | NaCl – polydisperse with range of 0.2 μm to 2 μm aerodynamic diameter with a mass median aerodynamic diameter (MMAD) of 0.6 ± 1 μm<br>Corn oil – MMAD of 0.4 μm to 0.7 μm |
| Test agent concentration | 2,000 to 8,000 particles/$cm^3$ | NaCl – 8 ± 4 $mg/m^3$<br>Corn oil – 20 $mg/m^3$ to 26 $mg/m^3$ |
| Test agent detection method | Condensation nuclei counter with particle classifier technology | NaCl – flame photometer or condensation particle counter<br>Corn oil – rear light scattering laser photometer |
| Number of test exercises | 8 | 9 or 10 |
| Procedure for testing of multiple size models | Yes | No |
| Pass/fail criteria | 13 of 25 subjects must have a fit factor 100 | None – results are used to determine degree of protection allocated to a particulate respirator for selection and use purposes (protection level) |