

# **NIOSH Conformity Assessment Interpretation Notice**

**NIOSH CA 2019-1011  
January 2019**

**NIOSH Respirator Approval Program's use of the NIOSH Bivariate Panel  
during Isoamyl Acetate Fit Testing beginning February 1, 2019**

**Supersedes**

**May 18, 2005 Letter to All Respirator Manufacturers**



**Centers for Disease Control  
and Prevention**  
National Institute for Occupational  
Safety and Health

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**Supersedes the May 18, 2005 Letter to All Respirator Manufacturers**

### 1 SUMMARY

NIOSH is phasing out the use of the Los Alamos National Laboratory (LANL) Panels and updated [Standard Testing Procedure \(STP\) TEB-APR-STP-0005-05a-06, Determination of Qualitative Isoamyl Acetate \(IAA\) Facepiece Fit, Air-Purifying Respirators](#), to include use of the NIOSH Bivariate Panel (NIOSH Panel). The NIOSH Panel's anthropometric limits and individual panel cells (1-10) are shown in Figure 1. The population cell distribution of the NIOSH Panel is given in Table 1, based on an 18-member panel.

Beginning February 1, 2019, NIOSH will implement use of the NIOSH Panel during evaluation of all new approvals of air-purifying respirators (half mask and full-facepiece, excluding non-powered, particulate only air-purifying respirators). These types of approval projects, accepted in the NIOSH Division Electronic Information Management System (DEIMS) on or after February 1, 2019, will be evaluated using the NIOSH Panel and the updated STP. A new approval may include a respirator facepiece configuration previously approved as part of a different respirator approval configuration. Applicants may continue to use the LANL panels to generate pre-submission test data however, NIOSH recommends using the procedure outlined in the updated STP.

Respirators previously approved following testing with LANL Panels continue to be NIOSH-approved respirators. When these approvals are submitted for an extension of approval, and the application requires human subject testing, the respirator will be evaluated using the NIOSH Panel and if a pass is not achieved, the testing will be repeated using the relevant LANL Panel.

After December 31, 2019, when respirators previously approved following testing with LANL Panels are submitted for an extension of approval requiring human subject testing and do not pass the NIOSH Panel, they will **not** be reevaluated using the LANL Panel.

Certified product audit testing including the use of the anthropometric panels will allow the use of the panel used during the original testing for the approval until December 31, 2019. For example, if the half-facepiece LANL panel was used during the original testing, the half-facepiece LANL panel will be used for certified product audit testing until December 31, 2019.

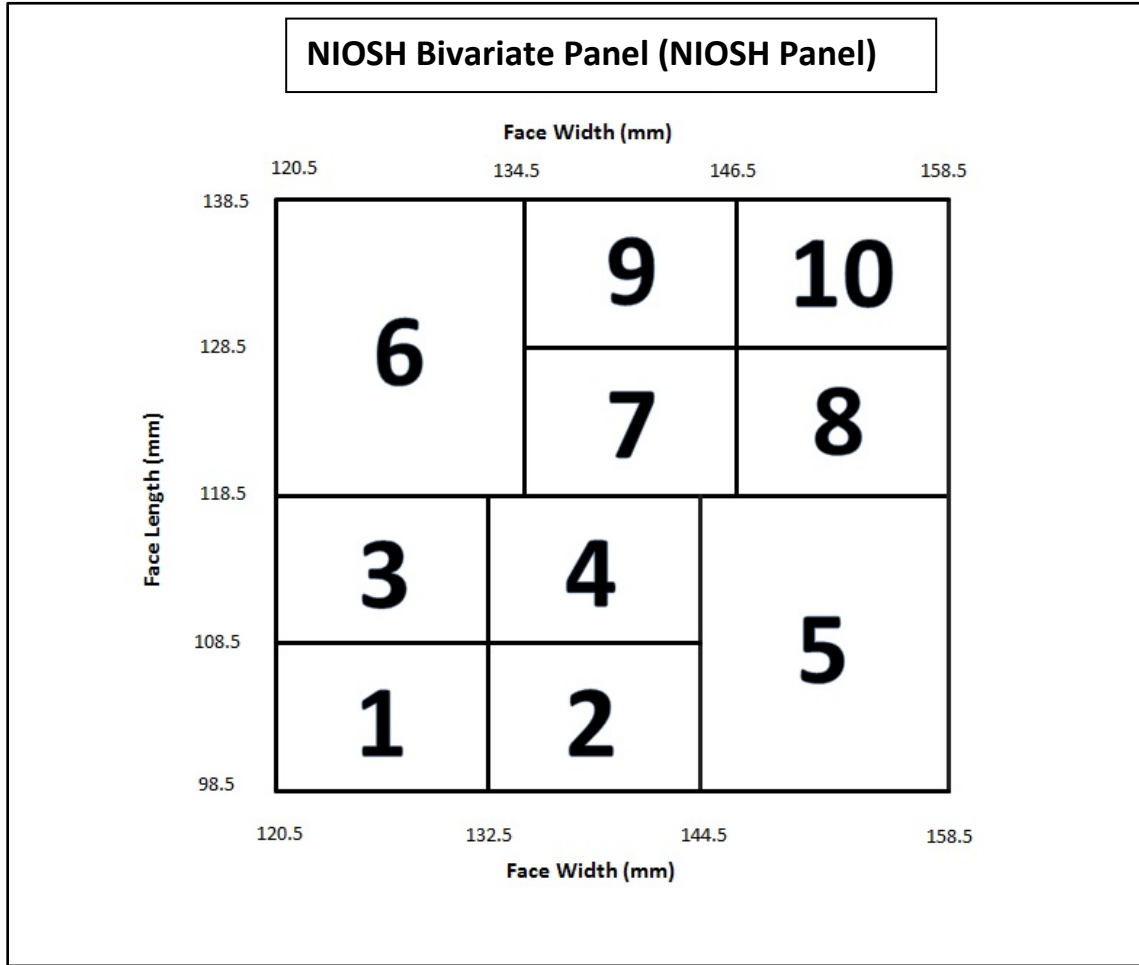


Figure 1. The NIOSH Bivariate Panel (NIOSH Panel) includes ten individual member cells defined by face width and face length (mm)

NIOSH Panel – cell number	Population distribution (%)	Number of test subjects based on the population distribution
1	5.5	1
2	5.3	1
3	10.5	2
4	25.0	4
5	7.1	1
6	5.7	1
7	21.3	4
8	8.7	2
9	5.2	1
10	3.5	1
Total number of subjects		18

Table 1: NIOSH Panel cell designations, population distribution, and number of test subjects per cell, based on an 18-member panel

2 AUTHORITY

[42 CFR Part 84, Respiratory Protective Devices](#)

TEB-APR-STP-0005-05a-06, Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit, Air-Purifying Respirators

3 REFERENCES

[Approval of Respiratory Protective Devices, 42 CFR, Part 84](#)

NIOSH [May 18, 2005](#) Letter to All Respirator Manufacturers, Air-Purifying Fit Test Subject Selection

[Revised TEB-APR-STP-0005-5a-06](#)

Zhuang, Z., Bradmiller, B., Shaffer, R.: New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. J. Occup. Environ. Hyg. 4: 647-659 (2007).

## Appendix A – Background and Supplemental Information

Prior to February 1, 2019, the NIOSH Respirator Approval Program used human test subjects, identified by the LANL Panels (Figures A1 and A2) to assess fit in accordance with 42 Code of Federal Regulations Part 84. Use of the LANL Panels to assess fit of air-purifying respirators was included in the May 18, 2005 NIOSH Letter to All Respirator Manufacturers, and NIOSH TEB-APR-STP-0005-5a-06. Revision 2.0 (20 March 2008), Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit, Air-Purifying Respirators.

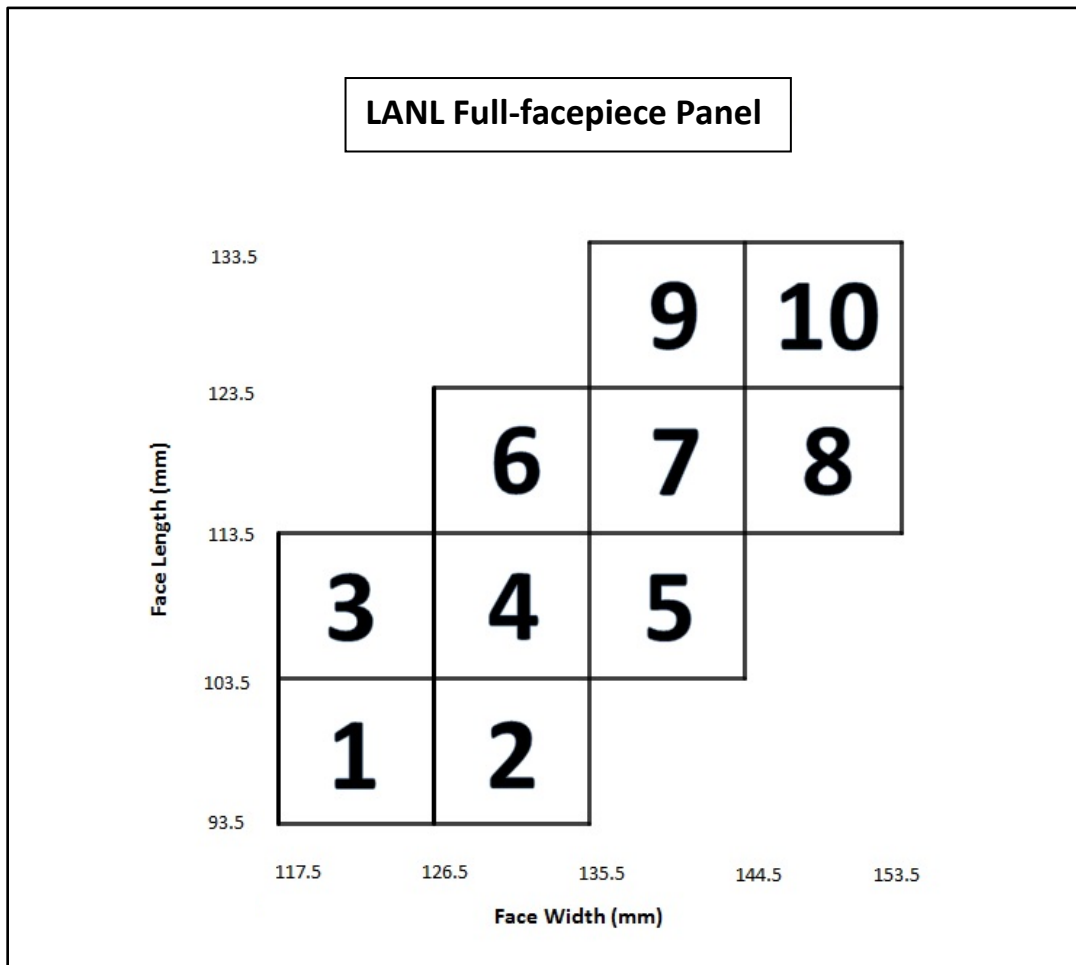


Figure A1. Los Alamos National Laboratory Full-facepiece Panel, with 10 cell boxes identified

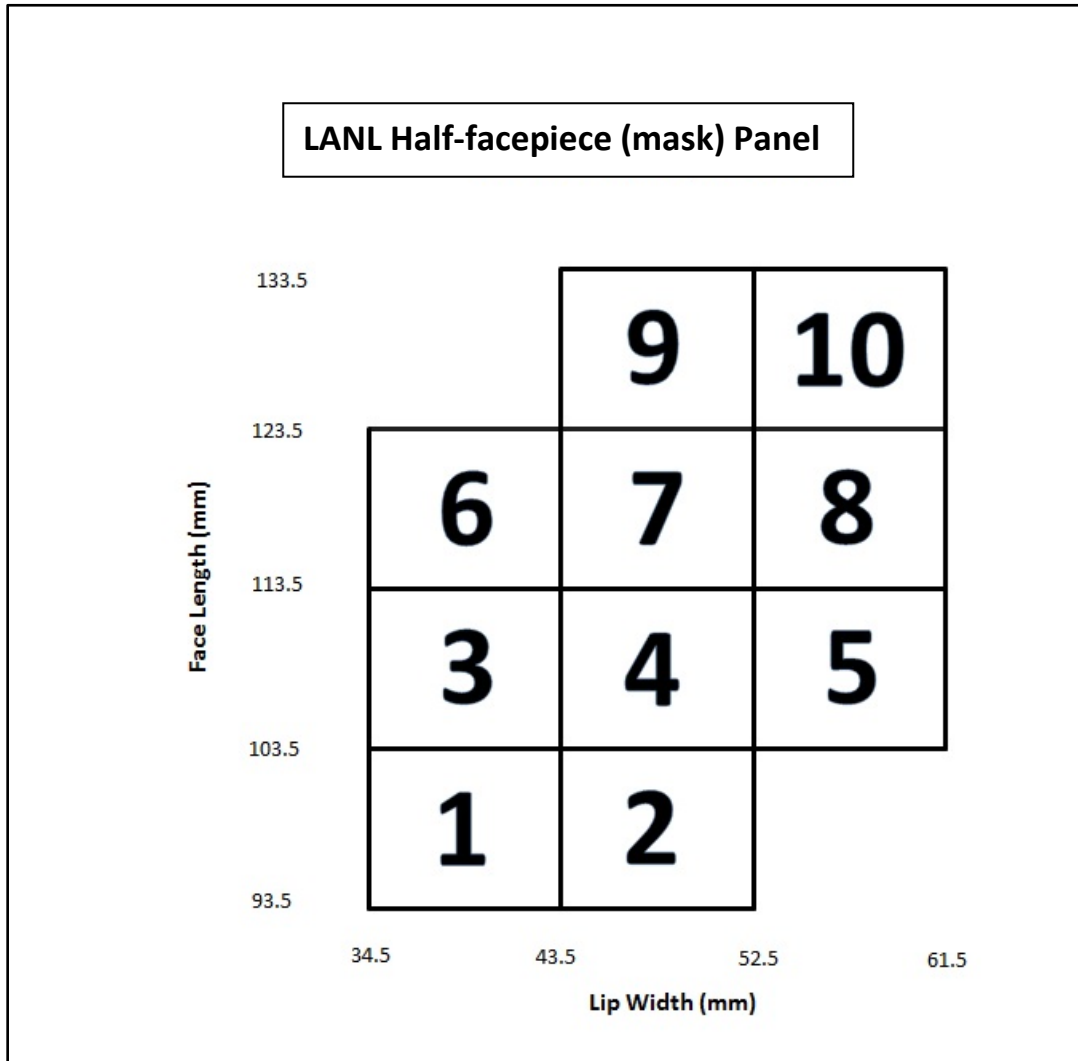


Figure A2. Los Alamos National Laboratory Half-facepiece (mask) Panel, with 10 cell boxes identified

A.1 (Withdrawn) Proposed rulemaking and public comments

[The October 30, 2009 NIOSH notice of proposed rulemaking](#) – Total Inward Leakage Requirements for Respirators (NIOSH Dockets 36 and 137, RIN 0920-AA33) included a reference to the [National Academies of Sciences, Engineering, and Medicine study Assessment of the NIOSH Head-and-Face Anthropometric Survey of U.S. Respiratory Users](#). The notice summarized; *It is documented in testing and agreed by reviewers that the proposed panel represents a substantial improvement over its predecessor panel and should be implemented (p 56144, Federal Register, Vol. 74, No. 209)*. The use of the panel in the 2012 NIOSH inter-panel variability study and implementation of the panel in the NIOSH Respirator Approval Program was discussed during two webinars completed in July and August of 2013 (webinar slides and recordings are available in [NIOSH Docket 250](#) – Development of Inward Leakage Standards for Half-Mask Air-Purifying Particulate Respirators).

Additionally, NIOSH received comments to CDC-2013-0017 [NIOSH Docket 250 \(p 54432 Federal Register, Vol. 78, No. 171, September 4, 2013\)](#). Stakeholders responded to questions asked about development of an inward leakage standard for half-mask air-purifying particulate respirators and the use of anthropometric panels to assess respirator fit. The commenters generally supported using a single bivariate panel for performance testing as part of the NIOSH Respirator Approval Program. While some responders indicated concerns about the differences between the LANL Panels and the NIOSH Panel, they tended to support the use of the more recently developed NIOSH Panel.

A.2 LANL Panel content TEB-APR-STP-0005-5a-06: Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit Test, Air-Purifying Respirators

*Respirator manufactured in one unique size*

According to the NIOSH May 18, 2005 [Letter to All Manufacturers, Air-Purifying Fit Test Subject Selection](#) ten subjects, one from each cell, were tested and one failure permitted (Table A1). NIOSH considered retaining this procedure and modifying the STP to include the use of the NIOSH Panel and remove the use of the LANL Panels. However, after several discussions about the multiple panel distributions and panel sizes used (as given in Tables A1 and A2) NIOSH decided to consider a more streamlined approach, and completed a statistical analysis to help identify a better panel size to be used when testing any model of respirator.

Table A1. Number of subjects selected using LANL panels during isoamyl acetate testing of a respirator designed and manufactured in one unique size to fit persons with various facial shapes and sizes.

LANL Panel – Cell number	Number of Test Subjects	
1	1 subject	One subject per cell tested, one failure allowed. The manufacturer may accept an unpopulated cell as a failure and pass the other 9 cells or the program could substitute an additional subject from a neighboring cell to test if needed.
2	1 subject	
3	1 subject	
4	1 subject	
5	1 subject	
6	1 subject	
7	1 subject	
8	1 subject	
9	1 subject	
10	1 subject	

Table A2. Number of subjects selected using LANL panels during isoamyl acetate testing of a respirator manufactured in one unique size as designated by the manufacturer. No failures were allowed.

NIOSH Panel – Cell number	Number of Test subjects		
1	6 subjects total from cells 1-4 (1 or 2 from each cell to total 6)	6 subjects total from cells 3-8 (1 from each cell to total 6)	6 subjects total from cells 7-10 (1 or 2 from each cell to total 6)
2			
3			
4			
5			
6			
7			
8			
9			
10			

Table A3. Number of subjects selected using LANL panels during isoamyl acetate testing of a respirator designed and manufactured in two unique sizes to fit persons with various facial shapes and sizes.

NIOSH Panel – Cell number	Number of Test Subjects		
1	Small/medium 6 subjects total from cells 1-6 (1 from each cell to total 6)	Medium/large 6 subjects total from cells 5-10 (1 from each cell to total 6)	
2			
3			
4			
5			
6			
7			
8			
9			
10			

NIOSH NPPTL considered the identification and use of overlapping subject cell designations during the implementation of the NIOSH Panel. Using the anthropometric data collected [Zhuang 2007], as illustrated in Figure A3, the “overlapping cells” identified where a subject may be considered a small/medium subject or a medium/large subject. Discussions considered how the new panel “fits” over the LANL full-facepiece panel and determined the overlaps may occur in NIOSH Cell 2 (small and medium), Cell 5 (medium and large), Cell 6 (small and medium) and Cell 9 (medium and large).



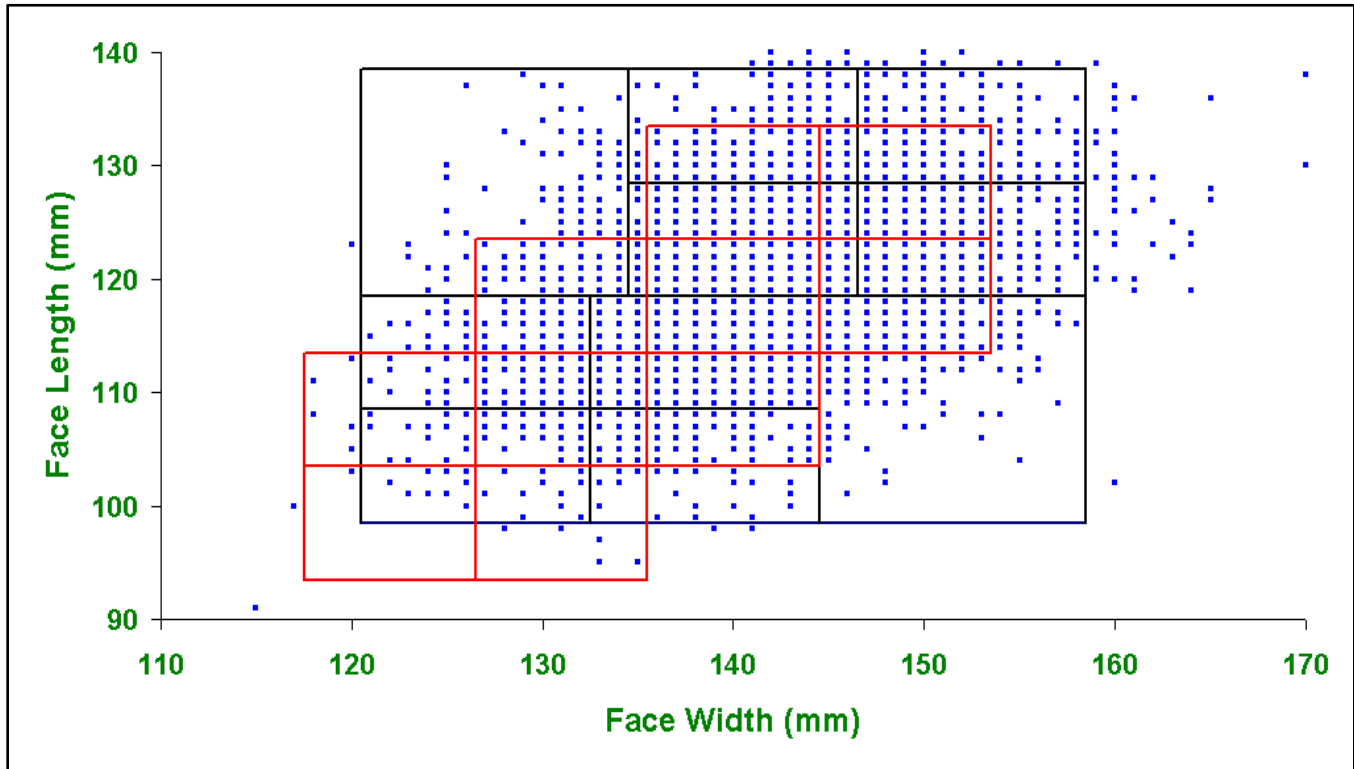


Figure A3. NIOSH Panel (outlined in black) and the LANL Panel Full-facepiece (outlined in red) with individual subject anthropometric data (given in blue).

### A.3 Statistical analysis and determination of consistent sample size and pass/fail criteria.

NIOSH NPPTL completed a statistical analysis to test different sample sizes representative of 5, 10, 12, 18, and 24-member panels. The simulation study defined the true population fit test fail rate, took 75 random samples of each distinct sample size, and compared the sample observed average fail rate and variance between the sample sizes.

The true fail rate was varied between 1%, 5%, 15% and the population was set to be 100,000 “people.” The true population fail rate means the percentage of the population that would not fit this “sample” or “respirator.” For example, in the case of the 15% rate, using 100,000 samples, 15% or 15,000 are designated as a “1” or “failure” in the Bernoulli distribution and 85% are designated as a “0” or a non-failure. Seventy-five distinct random samples were taken for each member panel size studied. Member panel sizes varied between 5, 10, 12, 18, and 24. Table 4, column C reports the average observed fail rate for each of the sample sizes and each of the true population fail rates over 75 random samples with replacement.

Replacement was used so that the underlying true population fail rate was not effected from sample to sample. The analysis observed the means and compared them to the true population fail rate to determine how well the sample size estimates the truth over 75 random samples. The data indicated each of the sample sizes estimated the true population fail rate across 75 random samples. The information in Table A4, column E shows the p values for the comparisons between each of the mean fail rates by sample size compared to a sample size of 18. None of the observed fail rates were statistically different compared to sample size of 18.

Table A4 column D shows the standard deviation of the observed fail rates across the 75 samples for each sample size. This statistic shows the sampling variability and lower variability in the sampling distribution is better. As variability decreases there is more confidence that each individual sample comes as close as possible to estimating the true population fail rate.

Using median and mean based homogeneity of variance tests Table A4, column F suggests that the variance within sample sizes of 5, 10, and 12 differ significantly from a sample size of 18. A sample size of 18 does not differ significantly from a sample size of 24. NIOSH NPPTL concluded there appears to be benefits to using a sample size of 18 over a sample size of 5, 10, and 12 and noted no added benefit of using a sample size of 24 over 18.

Table A4. Statistical analysis data used to determine the panel sample size.

A	B	C	D	E			F	
				Difference between observed fail rates among sample sizes: P value			Difference between observed variances among sample sizes: P value	
True Population Fail Rate	Sample Size	Observed Mean Fail Rate Across 75 Samples	Standard Deviation of Sampling Distribution Across 75 Samples	Parametric Maximum Likelihood Estimate	Parametric Ordinary Least Squares	Non-Parametric	Brown Forsythe-Median based homogeneity of variance test	Levene-mean based homogeneity of variance test
1%	5	1.87%	5.86%	0.66	0.36	0.18	0.36	0.01
	10	1.07%	3.11%	0.94	0.80	0.26	0.80	0.95
	12	0.89%	2.59%	0.85	0.49	0.26	0.49	0.28
	18	1.19%	2.63%	Reference Group				
	24	1.00%	2.15%	0.90	0.64	0.90	0.64	0.18
5%	5	6.67%	10.57%	0.41	0.36	0.14	0.17	<0.01
	10	5.33%	6.44%	0.96	0.94	0.41	0.06	<0.01
	12	6.11%	7.03%	0.65	0.50	0.74	<0.01	<0.01
	18	5.41%	5.55%	Reference Group				
	24	6.22%	4.86%	0.60	0.34	0.37	0.73	0.99
15%	5	15.20%	17.35%	0.62	0.73	0.31	<0.01	<0.01
	10	15.07%	12.56%	0.69	0.72	0.38	<0.01	<0.01
	12	14.78%	11.18%	0.83	0.84	0.99	0.02	0.01
	18	14.44%	8.22%	Reference Group				
	24	14.67%	7.48%	0.89	0.86	0.63	0.70	0.45

NIOSH considered pass-fail criteria for the proposed 18-member panel. A mathematical model developed by NIOSH Researchers estimated the probability of getting a number of failures in a single panel test. The model varied the true population fail rate (1, 5, 10, and 15%), the sample size (5, 10, 12, 18, and 24-member panels) and the number of failures (0, 1, 2, 3, 4, and 5).

Based on the analysis, NIOSH NPPTL will allow four failures when testing an 18-member panel during evaluations of respirators manufactured in one, two, or three unique sizes, since approximately 100% of the individual samples will result in four or fewer failures. Similarly, four failures will be allowed when testing a 21 or 24-member panel used during evaluations of respirator designed and manufactured in four or five unique sizes, respectively.

REFERENCES – Appendix A

Hack, A., McConville, J.: Respirator Protection Factors: Part 1 - Development of an Anthropometric Test Panel. Am. Ind. Hyg. Assoc. J (39): 970-975 (1978).

Zhuang, Z., Bradmiller, B., Shaffer, R.: New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. J. Occup. Environ. Hyg. 4: 647-659 (2007).

[NIOSH Docket 036 https://www.cdc.gov/niosh/docket/archive/docket036.html](https://www.cdc.gov/niosh/docket/archive/docket036.html)

[NIOSH Docket 137 https://www.cdc.gov/niosh/docket/archive/docket137.html](https://www.cdc.gov/niosh/docket/archive/docket137.html)

[NIOSH DOCKET 250 https://www.cdc.gov/niosh/docket/archive/docket250.html](https://www.cdc.gov/niosh/docket/archive/docket250.html)