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Statistical Performance of Proposed Panel Fit Test

Final Report

Prepared for

National Institute for Occupational Safety and Health

Prepared by

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The *Statistical Performance of Proposed Panel Fit Test Draft Report* is the report documenting the findings of review of a statistical test of panel fit. This work was funded by the National Institutes for Occupational Safety and Health (NIOSH) under Contract No. 200-2009-31310, Task Order No. 5. The NIOSH Project Officer is Edward Fries in the NIOSH Personal Protective Technology Program. Jonathan Szalajda and Bill Newcomb of the National Personal Protective Technology Laboratory provided technical direction. The fit test review was conducted by staff at RTI International, Research Triangle Park, NC under the direction of Dr. David Wilson.

Table of Contents

List of Tables

1. INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH) proposes to establish total inward leakage (TIL) requirements under 42 CFR Part 84 for half-mask air-purifying particulate respirators, including both elastomeric face piece and filtering face piece types. The proposed new requirements specify TIL minimum performance requirements and testing to be conducted by NIOSH and respirator manufacturers.

NIOSH published a proposed rule on total inward leakage requirements for respirators on October 30, 2009 and established and extended a public-comment period that ended September 30th, 2010. Public comments were collected into a regulatory docket accessible online.[1] NIOSH received public comments that suggested that limitations of the proposed statistical test made the test undesirable and proposed alternatives.

RTI reviewed the statistical properties of the proposed NIOSH statistical test and reviewed the public comments in the docket. This report presents the findings of these reviews.

[1] **http://www.cdc.gov/niosh/docket/archive/docket137.html**

2. METHODS

This section summarizes the methods used in the review of the statistical performance of the NIOSH proposed statistical test described in Landsittel et al. Two variations of the NIOSH proposed test were also reviewed. Section 2.1 describes the NIOSH proposed test and the two variants of that test that were reviewed. Section 2.2 discusses the panel sizes used to assess the performance of the three tests described in Section 2.1. Section 2.3 synthesizes the three tests described in Section 2.1 and panels sizes described in Section 2.2 and shows how all tests may be represented as variations of three rules. Section 2.4 describes the statistical methods used to assesses performance of the tests.

2.1 Description of Three Tests

2.1.1 Landsittel Test

The statistical test described in Landsittel et al. is a simple threshold test. For a given panel of N individuals, a respirator is said to fit the population represented by the panel members if the number of individuals for whom the given respirator fits meets or exceeds some predetermined threshold n. In order to determine the threshold n, for a given panel size N, Landsittel et al. identified four criteria that must be satisfied:

1) If a given respirator fits 90% of the population, then any test must have a probability of failing that is less than or equal to 10%.
2) If a given respirator fits 80% of the population, then any test must have a probability of failing that is less than or equal to 20%.
3) If a given respirator fits 60% of the population, then any test must have a probability of failing that is more than or equal to 95%.
4) If a given respirator fits 50% of the population, then any test must have a probability of failing that is more than or equal to 99%.

As noted in Landsittel et al., if one assumes that fits of panel members are independent and assumes that the probability of a respirator fitting is the same for each panel member, then the total number of panel members for whom a respirator fits is a binomial variable.

Landsittel et al. identified threshold requirements under different panel sizes by utilizing the binomial formula to calculate probabilities of failure. Based on the results given in their paper, the original NIOSH proposed test specified a panel size of 35 and a threshold size of 26.

2.1.2 First Variant Test

The statistical test described in the NIOSH proposed inward leakage testing differed from the Landisttel et al. test. Following the requirements of this test, a second statistical test was created from the Landsittel test by modifying the test as follows:

1) The 35 panel members must be allocated to 10 cells defined by the bivariate distribution of face width and length[2].
2) At least one panel member must pass the respirator fit test in each of the 10 cells.

The requirement for 26 or more panel members to pass the respirator fit test remains the same as in the Landsittel test.

2.1.3 Second Variant Test

Following discussions with NIOSH, a third statistical test was created from the Lansittel test by modifying the test as follows:

1) The 35 panel members must be allocated to 10 cells defined by the bivariate distribution of face width and length.
2) At least one panel member must pass the respirator fit test in each pair of adjacent cells. Adjacent cells are identified in NIOSH procedure RCT-APR-STP-0068.

The requirement for 26 or more panel members to pass the respirator fit test remains the same as in the Landsittel test.

2.2 Discussion of Panel Sizes

A review of the statistical performance of all three tests described above, where the panel size was 35, suggested that increasing cell sizes would result in tests with improved statistical properties. In consideration of the cost increase associated with increasing the number of panel members, the performance of the three tests under panels of size 40 and 50 was examined. For each of these additional panel sizes, three tests were constructed in the following fashion:

Test 1

Calculate the threshold required under the requirements given in Landsittel et al. using the increased panel size.

Test 2

[2] http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-137/0137-081209-DraftTIL.pdf

Modify Test 1 by allocating the panel members equally to the 10 cells defined in NIOSH procedure RCT-APR-STP-0068. Require at least one panel member pass a respirator fit test in each cell in addition to meeting the threshold requirement derived for Test 1.

Test 3

Modify Test 1 by allocating the panel members equally to the 10 cells defined in NIOSH procedure RCT-APR-STP-0068. Require at least one panel member pass a respirator fit test in pair of adjacent cells in addition to meeting the threshold requirement derived for Test 1. Adjacent cells are described in NIOSH procedure RCT-APR-STP-0068.

2.3 Representing Tests as Rules

While a total of nine statistical tests were reviewed, comparison of the results of that review is aided by codifying the statistical tests as three rules applied to different panel sizes. Given a panel of size N, the rules are as follows:

1) A threshold Rule (Rule 1)
   n or more of the N panel members must pass the respirator fit test in order for the respirator to fit the panel.
2) A threshold and a single pass per cell Rule (Rule 2)
   Allocate panel members to ten cells. n or more of the N panel members must pass the respirator fit test AND at least one person in each of 10 cells must pass the respirator fit test in order for the respirator to fit the panel.
3) A threshold and a single pass per adjacent cell Rule (Rule 3)
   Allocate panel members to ten cells. n or more of the N panel members must pass the respirator fit test AND at least one person in each pair of adjacent cells, among the 10 cells, must pass the respirator fit test in order for the respirator to fit the panel.

The statistical performances of these rules using three panel sizes were examined, leading to review of nine statistical tests. Note that allocation of panel members to cells was not identical. Members in Panels of size 35 were allocated to ten cells according to the bivariate distribution described in NIOSH procedure RCT-APR-STP-0068. Members in Panels of size 40 and 50 were allocated equally to the ten cells described in NIOSH procedure RCT-APR-STP-0068. The reason for the equal allocation for larger panel sizes was to account for small cell sizes when using panels of size 35 while trying to constrain the total number of panel members in acknowledgement of the associated cost increase to carry out the panel fit tests.

The remainder of this report refers to the performance of specific tests by identifying the Rule, as described in this section, and panel size associated with the test.

2.4 Assessing Statistical Performance

Unlike the derivation of the statistical test given in Landsittel, the statistical distributions of test statistics described in Rules 2 and 3 do not have simple closed-form expressions. Consequently, analyses of the statistical properties of all tests were carried out using simulation.

Conceptually, for any given rule and panel size, panel members are allocated to one of ten cells. Simulation of the distribution of the test statistic appropriate for the given rule was carried out by:

1 Generating a binomial variable for each cell, where the cell size was used as the number of trials.

2) Summing the binomial values across all ten cells.

3) Applying the overall threshold requirement to the value generated in two and, if required, applying the cell requirements of the specific Rule.

4) Steps 1 through 3 were repeated 500,000 times in order to approximate the distribution of the test statistic.

All simulations were implemented using R software.

Statistical performances of the three rules with three different panel sizes were examined by investigating the two questions:

1) How does each test perform under the four requirements specified in Landsittel and described in Section 2.1?

2) How does each test perform if one of the ten cells represents a population that has a much lower probability of respirator fit than those population represented by the other nine cells?

The answers to these questions are given in the following section.

3. FINDINGS: STATISTICAL PERFORMANCE OF RULES

This section presents the results of the review of the statistical performance of the three proposed tests under three different panel sizes.

3.1 35 Member Panels

3.1.1 Rule 1

The test described in Landsittel et al. specifies a minimum number of panel members that must pass a respirator fit test in order for the respirator to be classified as fitting the population represented by the panel. This test is of the form covered by Rule 1, as described in Section 2.3.

Following the criteria given in Landsittel et al., and summarized in Section 2.1, the probability that a threshold test fails was calculated under different threshold requirements and for different underlying probabilities of respirator fit. Table A1 in Appendix A shows these probabilities for panels of size 35. A comparison of the values in this table with the values given in Table 3 of Landsittel et al. shows that the simulated values are in agreement, to one decimal place, with the exact values reported in Landsittel et al.

Consequently, the Landsittel et al. description of the statistical properties of the proposed NIOSH test that requires 26 of 35 panel members to pass a respirator fit test are confirmed by the simulation study.

3.1.2 Rule 2

Under rule 2, panel members are allocated to one of ten cells, based on their face width and length. For panels of size 35, this results in the following allocation of panel members to cells:

Table 1: Allocation of Panel of size 35 to Anthropomorphic-based Cells

Cell number	Number in each cell for n=35
1	2
2	2
3	4
4	9
5	2
6	2
7	7
8	3
9	2
10	2

The performance of a test derived from Rule 2 was examined by applying a threshold requirement for panels of size 35 and applying the one pass per cell requirement of Rule 2. For this test, a respirator was said to fit the population represented by the 35 member panel if:

1) The number of panel members passing the respirator fit test met a threshold and
2) At least one panel member passed the respirator fit test within each cell.

Table A2 in Appendix A shows the probabilities of this test failing under different threshold requirements and for different underlying probabilities of respirator fit. A comparison of TablesA1 and A2 of Appendix A show that the one pass per cell requirement increases the probability of the test failing. For example, if a threshold of 26 is used, this test will fail 30.1% of the time even when the underlying probability of fit is 80%. This test fails one of the Landsittel et al. test criteria, namely the second of the criteria listed Section 2.1. Practically speaking, a respirator that fits 80% of a population would fail this test 30% of the time when the threshold is set to 26. Any other threshold used for a test would result in a test that fails more than one of the four Landsittel et al. criteria.

An additional analysis of the performance of a test based on Rule 2 was carried out. The performance of the following test:

1) The number of panel members passing a respirator fit test is 26 or more and
2) At least one panel member passes the respirator fit test within each cell was examined under the following condition:
   The population represented by one cell of size two was assumed to have a lower probability of respirator fit than the population represented by the other nine cells.

Table A3 in Appendix A shows the probability that this Rule 2 based test would result in a pass for varying values of fit probabilities. The Rows in Table A3 show the assumed probability of fit in the cell of size 2 while the columns show the assumed probability of fit in the remaining cells. For example, if a respirator fits 10% of the population represented by the cell of size 2 and the respirator fits 80% of the population represented by the other cells, then the test will pass the respirator 13.2% of the time. The value of 13.2% comes from the first row and third column in Table A3. This analysis means that the test based on Rule 2, using a panel of size 35 with members allocated to ten cells as described, would lead to respirators passing the test a high percentage of the time even if one cell of size two had a much lower probability of fit than the other cells.

3.1.3 Rule 3

Rule 3 requires panel members to be allocated to ten cells in the same manner as that under Rule 2 (See Table 1 above).

The performance of a test derived from Rule 3 was examined by applying a threshold requirement for panels of size 35 and applying the one pass per two adjacent cells requirement of Rule 3. For this test, a respirator was said to fit the population represented by the 35 member panel if:

1) The number of panel members passing the respirator fit test exceeded a threshold and

2 At least one panel member passed the respirator fit test within each pair of adjacent cells

Adjacent cells are defined by the order of cells shown in Table 1. There are nine pairs of adjacent cells: (1,2), (2,3), (3,4), (4,5),(5,6),(6,7),(7,8),(8,9),(9,10).

Table A4 in Appendix A shows the probabilities of this test failing under different threshold requirements and for different underlying probabilities of respirator fit. A comparison of Tables A1, A2, and A4 of Appendix A show that the one pass per each pair of adjacent cells requirement produces test fail rates that are roughly within .3% of the fail rates for the Landsittel et al. test. The fail rates under Rule 3 are slightly higher than the fail rates under Rule 1 and much lower than under Rule 2.

Under this Rule 3 test, if a threshold of 26 is used, this test will fail 14.8% of the time when the underlying probability of fit is 80%. As with the Landsittel test, this test based on Rule 3 passes three of the four test criteria given in Section 2.1 and does not quite meet the 3rd test criterion listed in Section 3.1. No other threshold size comes closest to meeting the four test criteria outlined in Landsittel et al.

An additional analysis of the performance of a test based on Rule 3 was carried out. The performance of the following test:

1) The number of panel members passing a respirator fit test is 26 or more and

2) At least one panel member passes the respirator fit test within each pair of adjacent cells was examined under the following condition:
The population represented by one cell of size two was assumed to have a lower probability of respirator fit than the population represented by the other nine cells.

Table A5 in Appendix A shows the probability that this Rule 3 based test would result in a pass for varying values of fit probabilities. The Rows in Table A5 show the assumed probability of fit in the cell of size 2 while the columns show the assumed probability of fit in the remaining cells. For example, if a respirator fits

10% of the population represented by the cell of size 2 and the respirator fits 80% of the population represented by the other cells, then the test will pass the respirator 68% of the time. The value of 68% comes from the first row and third column in Table 5. This analysis means that the test based on Rule 3, using a panel of size 35 with members allocated to ten cells as described, would lead to respirators passing the test an extremely high percentage of the time even if one cell of size two had a much lower probability of fit than the other cells.

3.1.4 Comparing Rules for Panels of Size 35

Tests based on Rules 1 and 3 using a threshold of size 26 meet three of the four test criteria given in Landsittel et al. and almost meet the other criterion. However, tests based on Rule 2 are less likely, though the rates are still high, to pass a respirator that poorly fits a population represented by one cell of size two and that fits the populations represented by the other cells well.

3.2 40 Member Panels

The tests described in Section 3.1 were based on panels of size 35 and sample members were allocated to one of ten cells based on their face width and length characteristics. Since this allocation resulted in some cells consisting of two panel members, the estimates of probability of fit within those cells are highly variable. In order to try and reduce the variability of cell estimates, an investigation of how tests based on the three Rules would perform if panel size was increased was carried out. In this section, the performance of the three Rules with panels of 40 members was examined.

3.2.1 Rule 1

Table B1 in Appendix B shows the probability that a threshold test fails under different threshold requirements and for different underlying probabilities of respirator fit. A review of the probabilities in this table show that a threshold test requiring 30 or more fits satisfies the four test criteria listed in Section 2.1.

3.2.2 Rule 2

Under rule 2, panel members are allocated to one of ten cells, based on their face width and length. While the allocation of 35 panel members was based on proportional representation derived from estimates of the population distribution of face width and length, the allocation of 40 panel members followed an equal allocation across cells. For panels of size 40, this results in the following allocation of panel members to cells:

Table 2: Allocation of Panel of Size 40

Cell number	Number in each cell for n=40
1	4
2	4
3	4
4	4
5	4
6	4
7	4
8	4
9	4
10	4

The rationale for this allocation is based on the notion that any respirator that fits a population should also fit the subpopulations defined by various face width and length characteristics. In this situation, it is important to have enough data within each cell to make precise estimates within each cell.

The performance of a test derived from Rule 2 was examined by applying a threshold requirement for panels of size 40 and applying the one pass per cell requirement of Rule 2. For this test, a respirator was said to fit the population represented by the 40 member panel if:

1) The number of panel members passing the respirator fit test met a threshold and
2) At least one panel member passed the respirator fit test within each cell.

Table B2 in Appendix B shows the probabilities of this test failing under different threshold requirements and for different underlying probabilities of respirator fit. As with Rule 1, a threshold requirement of 30 results in a test that satisfies all four Landsittel et al. test criteria listed in Section 2.1. A comparison of Tables B1 and B2 of Appendix B show that the fail rates are essentially identical.

An additional analysis of the performance of a test based on Rule 2 was carried out. The performance of the following test:

1) The number of panel members passing a respirator fit test is 30 or more and
2) At least one panel member passes the respirator fit test within each cell was examined under the following condition:
   The population represented by one cell of size four was assumed to have a lower probability of respirator fit than the population represented by the other nine cells.

Table B3 in Appendix B shows the probability that this Rule 2 based test would result in a pass for varying values of fit probabilities. The Rows in Table B3 show

the assumed probability of fit in the cell of size four while the columns show the assumed probability of fit in the remaining cells. For example, if a respirator fits 10% of the population represented by the cell of size four and the respirator fits 80% of the population represented by the other cells, then the test will pass the respirator 14.7% of the time. The value of 14.7% comes from the first row and third column in Table B3. This analysis means that the test based on Rule 2, using a panel of size 40 with members allocated to ten cells as described, would lead to respirators passing the test a high percentage of the time even if one cell of size four had a much lower probability of fit than the other cells.

3.2.3 Rule 3

Rule 3 requires panel members to be allocated to ten cells in the same manner as that under Rule 2 (See Table 2 above).

The performance of a test derived from Rule 3 was examined by applying a threshold requirement for panels of size 40 and applying the one pass per two adjacent cells requirement of Rule 3. For this test, a respirator was said to fit the population represented by the 40 member panel if:

1) The number of panel members passing the respirator fit test exceeded a threshold and
2) At least one panel member passed the respirator fit test within each pair of adjacent cells

Adjacent cells are defined by the order of cells shown in Table 2. There are nine pairs of adjacent cells: (1,2), (2,3), (3,4), (4,5),(5,6),(6,7),(7,8),(8,9),(9,10).

Table B4 in Appendix B shows the probabilities of this test failing under different threshold requirements and for different underlying probabilities of respirator fit. A comparison of Tables B1, B2, and B4 of Appendix B show that a threshold of 30 results in a test that satisfies all four of the Landsittel et al. criteria. Furthermore, with a threshold of 30, the probabilities of failing under different probabilities are almost identical across the three Rules.

An additional analysis of the performance of a test based on Rule 3 was carried out. The performance of the following test:

1) The number of panel members passing a respirator fit test is 30 or more and
2) At least one panel member passes the respirator fit test within each pair of adjacent cells was examined under the following condition:
   The population represented by one cell of size four was assumed to have a lower probability of respirator fit than the population represented by the other nine cells.

Table B5 in Appendix B shows the probability that this Rule 3 based test would result in a pass for varying values of fit probabilities. The Rows in Table B5 show the assumed probability of fit in the cell of size four while the columns show the assumed probability of fit in the remaining cells. For example, if a respirator fits 10% of the population represented by the cell of size four and the respirator fits 80% of the population represented by the other cells, then the test will pass the respirator 31% of the time. The value of 31% comes from the first row and third column in Table B5. This analysis means that the test based on Rule 3, using a panel of size 40 with members allocated to ten cells as described, would lead to respirators passing the test a high percentage of the time even if one cell of size four had a much lower probability of fit than the other cells.

3.2.4 Comparing Rules for Panels of Size 40

Tests based on Rules 1, 2 and 3 using a threshold of size 30 meet all criteria given in Landsittel et al. Tests based on Rule 2 are less likely, though the rates are still high, to pass a respirator that fits a small percentage of a population represented by one cell of size four and that fits a high percentage of the population represented by the other cells.

3.3 50 Member Panels

Following on the examination of how the Rules-based tests perform with panels of size 40, the performance of such tests was examined using panels of size 50.

3.3.1 Rule 1

Table C1 in Appendix C shows the probability that a threshold test fails under different threshold requirements and for different underlying probabilities of respirator fit. A review of the probabilities in this table show that both a threshold test requiring 38 and a threshold test requiring 37 or more fits satisfies the four test criteria listed in Section 2.1. For subsequent examination of the performance of tests derived under Rules 2 and 3, we used a threshold of 38 though a threshold of 37 could have been used.

3.3.2 Rule 2

Under Rule 2, panel members are allocated to one of ten cells, based on their face width and length. While the allocation of 35 panel members was based on proportional representation derived from estimates of the population distribution of face width and length, the allocation of 50 panel members followed an equal allocation across cells. For panels of size 50, this results in the following allocation of panel members to cells:

Table 3: Allocation of Panel of Size 50

Cell number	Number in each cell for n=50
1	5
2	5
3	5
4	5
5	5
6	5
7	5
8	5
9	5
10	5

The rationale for this allocation is based on the notion that any respirator that fits a population should also fit the subpopulations defined by various face width and length characteristics. In this situation, it is important to have enough data within each cell to make precise estimates within each cell.

The performance of a test derived from Rule 2 was examined by applying a threshold requirement for panels of size 50 and applying the one pass per cell requirement of Rule 2. For this test, a respirator was said to fit the population represented by the 50 member panel if:

1) The number of panel members passing the respirator fit test met a threshold and
2) At least one panel member passed the respirator fit test within each cell

Table C2 in Appendix C shows the probabilities of this test failing under different threshold requirements and for different underlying probabilities of respirator fit. As with Rule 1, a threshold requirement of 38 results in a test that satisfies all four Landsittel et al. test criteria listed in Section 2.1. A comparison of Tables C1 and C2 of Appendix C show that the fail rates are essentially identical.

An additional analysis of the performance of a test based on Rule 2 was carried out. The performance of the following test:

1) The number of panel members passing a respirator fit test is 30 or more and
2) At least one panel member passes the respirator fit test within each cell was examined under the following condition:
   The population represented by one cell of size five was assumed to have a lower probability of respirator fit than the population represented by the other nine cells.

Table C3 in Appendix C shows the probability that this Rule 2 based test would result in a pass for varying values of fit probabilities. The Rows in Table C3 show

the assumed probability of fit in the cell of size five while the columns show the assumed probability of fit in the remaining cells. For example, if a respirator fits 10% of the population represented by the cell of size five and the respirator fits 80% of the population represented by the other cells, then the respirator would pass the test 13% of the time. The value of 13% comes from the first row and third column in Table C3. This analysis means that the test based on Rule 2, using a panel of size 50 with members allocated to ten cells as described, would lead to respirators passing the test a high percentage of the time even if one cell of size five had a much lower probability of fit than the other cells.

3.3.3 Rule 3

Rule 3 requires panel members to be allocated to ten cells in the same manner as that under Rule 2 (See Table 3 above).

The performance of a test derived from Rule 3 was examined by applying a threshold requirement for panels of size 50 and applying the one pass per two adjacent cells requirement of Rule 3. For this test, a respirator was said to fit the population represented by the 50 member panel if:

1) The number of panel members passing the respirator fit test exceeded a threshold and
2) At least one panel member passed the respirator fit test within each pair of adjacent cells.

Adjacent cells are defined by the order of cells shown in Table 3. There are nine pairs of adjacent cells: (1,2), (2,3), (3,4), (4,5),(5,6),(6,7),(7,8),(8,9),(9,10).

Table C4 in Appendix C shows the probabilities of this test failing under different threshold requirements and for different underlying probabilities of respirator fit. A comparison of Tables C1, C2, and C4 of Appendix C show that a threshold of 38 results in a test that satisfies all four of the Landsittel et al. criteria. Furthermore, with a threshold of 38, the probabilities of failing under different probabilities are almost identical across the three Rules.

An additional analysis of the performance of a test based on Rule 3 was carried out. The performance of the following test:

1) The number of panel members passing a respirator fit test is 38 or more and
2) At least one panel member passes the respirator fit test within each pair of adjacent cells was examined under the following condition:
   The population represented by one cell of size five was assumed to have a lower probability of respirator fit than the population represented by the other nine cells.

Table C5 in Appendix C shows the probability that this Rule 3 based test would result in a pass for varying values of fit probabilities. The Rows in Table C5 show the assumed probability of fit in the cell of size five while the columns show the assumed probability of fit in the remaining cells. For example, if a respirator fits 10% of the population represented by the cell of size five and the respirator fits 80% of the population represented by the other cells, then the test will pass the respirator 24% of the time. The value of 24% comes from the first row and third column in Table C5. This analysis means that the test based on Rule 3, using a panel of size 50 with members allocated to ten cells as described, would lead to respirators passing the test a high percentage of the time even if one cell of size five had a much lower probability of fit than the other cells.

3.3.4 Comparing Rules for Panels of Size 50

Tests based on Rules 1, 2 and 3 using a threshold of size 38 meet all criteria given in Landsittel et al. Tests based on Rule 2 are less likely, though the rates are still high, to pass a respirator that fits a small percentage of a population represented by one cell of size four and that fits a high percentage of the population represented by the other cells.

3.4 Comparison of Rules and Panel Sizes

Table 4 shows the threshold required, for a given panel size, for a test based on the Landsittel et al. approach to best satisfy their four test criteria:

Table 4: Thresholds for a Given Panel Size and the Associated Failure Rates

Threshold	Panel Size	Fail Rate at 80	Fail Rate at 60
26	35	15% (30%)[3]	94% (96%)[4]
30	40	17%	97%
38[5]	50	19%	99%

*Unless otherwise noted, reported rates are identical for all three Rules.

Reviewing the information given in Table 4, there is no clear Rule and panel size that maximizes the failure rate when the underlying probability of success is 60 and minimizes the failure rate when the underlying probability of success is 80. However, any rule under a panel of size 40 using a threshold of 30 results in a test

[3] The first value in the cell is the rate for Rules 1 and 3 while the value in parentheses is the rate for Rule 2.
[4] The first value in the cell is the rate for Rules 1 and 3 while the value in parentheses is the rate for Rule 2.
[5] A threshold of 37 also meets the criteria.

that satisfies all four Landsittel et al. test criteria and results in a lower failure rate at 80 than occurs if the panel size is increased to 50.

Under the scenario where cell represents a population with a lower probability of fit than the population represented by the other cells, Rule 2 has a lower pass rate than Rule 3. However, panels of size 35 have the lowest pass rates under Rule 2, followed by panels of size 50 under Rule 2, and then by panels of size 40 under Rule 2.

From a statistical perspective, a test based on Rule 2 using a panel of size 50 and a threshold of 38 (or 37) would result in a test that satisfies the Landsittel et al. criteria while limiting the rate at which respirators pass a panel fit test when one cell represents a population with a low fit rate and the remaining cells represent a population with a high fit rate.

4. REVIEW OF PUBLIC DOCKET

All public submissions in the docket 137[6] were reviewed for comments related to statistical issues regarding the performance of the proposed NIOSH statistical test and statistical means to improve the testing of respirators.

Many of the issues raised in the public submissions have to do with differences of opinion on topics that, while important to the development of a test of respirator fit, are not topics that can be independently assessed and reviewed using information provided in the public comments. In particular, many comments state the positions:

1) That face width and length do not predict respirator fit
2) Related to 1), that other facial characteristics are related to respirator fit
3) A fit-factor of 100 is too high a threshold to be used for determining that a respirator fits
4) That current "well-fitting" respirators do not meet fit-factors of 100

These four positions are not ones that can be substantiated by an independent review of the public comments so subsequent discussion of the public comments will not address these topics.

Each subsection first summarizes the public comments and then provides RTI commentary about the comments and ramifications for the proposed NIOSH test.

4.1 One pass per cell

On the one hand, some comments stated that one pass per cell is not sufficient to indicate that a respirator fits the population represented by a cell but, on the other hand, other comments stated that one pass per cell is too stringent and should be removed.

RTI Commentary

Ideally, if a respirator is supposed to fit the population represented by panel members in each cell, then a test should estimate the proportion of individuals in each cell that pass the fit test. For small cell sizes, say of size 2, estimates of the proportion of individuals in the population for whom a given respirator fits would be highly variable. This means that even if one pass occurs in every cell of a 35 member panel, there can be significant uncertainty about whether or not a respirator fits the population represented in each at the target rate (e.g. 80%).

Requiring at least one pass per cell is statistically better than not requiring one pass per cell if the goal is to try and ensure that a respirator fits the population represented by each cell. However, a single pass within a cell, especially a cell

[6] http://www.cdc.gov/niosh/docket/archive/docket137.html

based on few members, is not necessarily indicative of a respirator fitting the population a large percentage (say 80%) of the time.

4.2 Panel to Panel Variability and Within Cell Variability

One often mentioned concern with the proposed NIOSH test is related to the requirement to have 35 panel members. 3M and ISEA provided the most in-depth discussion of this concern. Their concern was that panel to panel variability among panel members would result in situations where assessment of respirator fit would vary quite wildly from panel to panel.

Both 3M and ISEA stated that the proposed NIOSH test would be improved if the number of panel members was increased (they proposed using 105 panel members instead of 35). The rationale for increasing the panel size was to try and reduce the possible variation in fit measurements between panels.

While most comments suggested NIOSH remove the one pass per cell requirement, both 3M and ISEA suggested and small cell sizes associated with the 35 member panels would result in inaccurate estimates of respirator fit within a given cell; this could lead to high rates of erroneously accepting or erroneously rejecting respirators.

RTI Commentary

The performance of the proposed NIOSH test relies on two assumptions:

1) That panel members represent the target population of users for a given respirator (e.g. there is no panel selection bias that would prevent the panel members from being representative)
2) That, for a given respirator, the probability of respirator fit is the same for all ten populations represented by the cells.

Selection bias can result in panel to panel variability. One method of ensuring that the process of selecting panel members is unbiased is to randomly sample panel members from some larger set of individuals that is thought to be representative of the target population(s). When requiring respirators to fit population across cells, sampling would have to be performed separately for each cell.

The process of random selection helps removed unintended biases, which could lead to panel to panel variability, but another source of variability is driven by the panel size and the number of panel members per cell. Under assumption two, given above, eight of the nine tests examined in this report pass the statistical

requirements listed in Section 2.1. The one test that does not meet those requirements is the 35 panel test requiring one pass per cell.

However, as also noted in this report, and as noted in the public comments, if the probability of respirator fit varies by cell population then the probability of a respirator passing any one of the tests examined in this report can be quite high even if the probability of respirator fit is quite low for one or more of the ten cell populations.

The performance of the proposed NIOSH statistical test to distinguish between well-fitting and poor-fitting respirators would be improved if both the panel size was increased and the cell sizes were increased. While this report examines increasing panel size to 50 and cell size to 5, the panel size and cell size that would result in precise estimates of fit would necessarily vary by respirator and population(s) from which the panel members were selected.

4.3 Bootstrap Analyses

Both 3M and ISEA reported on using Bootstrap Analyses to estimate the variability of fit factor measurements and probabilities of respirator fit. Their analyses illustrate how estimates of population variability may be derived from using observed fit factor measurements on panel members.

RTI Commentary

The Bootstrap Analyses were used to illustrate the variability of fit factor measurements, and pass rates, of some existing respirators when using panels of size 35 and applying the proposed NIOSH testing procedure. No suggestion was provided that described how Bootstrap estimation may be applied to the proposed NIOSH test. Rather, the comments implied that an alternative test should be used; one based on estimating the population variability of fit factor measures. No specifics of such a test were provided.

Conceptually, one could calculate the mean fit factor for a panel, use Bootstrap analysis to estimate the variance of the mean, and then carry out a statistical test to see if the mean fit factor for the population exceeded some value. While the NIOSH proposed fit factor of 100 was used to say that a respirator fit an individual, public comments suggested using a fit factor of around 50.

It should be noted that if a respirator is supposed to fit each cell's population equally, Bootstrap analysis does not help given the very small cell sizes that arise

when using panels of Size 35. Using a Bootstrap analysis with a panel size of 50 and 5 members per cell is an improvement but still has limited utility.

An alternative to the proposed NIOSH test would be for manufacturers to use Bootstrap analysis within each cell, estimate the population variability of the mean fit factor within each cell, and then test to see if the mean fit factors were statistically greater than a fit factor of 100 or not. This would require a larger panel size and cell size than currently envisioned.

5. CONCLUSION

While the Landsittel test meets all of the test criteria outlined in Landsittel et al., the proposed additional requirement of one fit per cell results in a test that does not meet the Landsittel criteria. If the panel size is increased to 40 or 50 and an equal number of individuals is allocated to each cell, then under the assumptions in the Landsittel et al. paper, the one fit per cell requirement results in a test that meets the Landsittel criteria.

The public comments may be summarized as stating that panel to panel variability arising from small panel sizes and small cell sizes may cause real world fit of respirators to differ from the assumption behind the NIOSH test; namely, that the probability of a respirator fitting each cell's population is constant across cells. If that assumption is violated, then a respirator may pass the fit test a high percentage of the time even when the probability of fit in one cell is low. Increasing cell sizes would help reduce the likelihood of such a scenario occurring.

Bootstrap analysis does not appear to be helpful in modifying the proposed NIOSH test to improve its statistical performance. Rather, Bootstrap analysis could be used as part of an alternative test, though the exact way in which manufacturers would apply Bootstrap analysis to determine respirator fit is unclear from their public comments.

6. REFERENCES

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APPENDIX A

Table A1: Fail Rates for Rule 1 under Panels of Size 35

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0	0.002	0.628	11.316	50.204
19	0	0.022	1.596	19.472	63.15
20	0	0.052	3.602	30.34	74.758
21	0	0.162	7.272	42.514	84.638
22	0	0.482	13.492	56.356	91.212
23	0.006	1.478	22.466	69.788	95.524
24	0.012	3.538	34.766	80.816	97.888
25	0.024	7.556	49.146	88.734	99.188
26	0.158	14.65	63.65	94.164	99.754
27	0.648	25.618	76.522	97.436	99.886
28	1.938	40.024	86.59	98.92	99.984
29	5.69	57.056	93.478	99.648	99.998
30	13.348	72.886	97.322	99.882	99.996
31	26.922	85.478	99.076	99.982	100
32	46.792	93.884	99.756	99.998	100
33	69.334	98.11	99.952	100	100
34	88.136	99.61	99.988	100	100
35	97.542	99.976	100	100	100

Table A2: Fail Rates for Rule 2 under Panels of Size 35

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	6.034	22.02	45.31	68.826	88.326
19	5.97	22.624	45.284	69.994	89.698
20	5.948	22.434	46.012	72.126	91.826
21	5.942	22.452	46.51	74.798	94.276
22	5.998	22.648	48.174	78.87	96.224
23	5.938	22.692	51.9	84.07	97.872
24	5.98	23.826	57.358	88.66	98.842
25	6.124	26.192	64.508	92.612	99.5
26	5.902	30.122	72.832	95.902	99.824
27	6.478	37.33	81.29	98.032	99.908
28	7.262	47.556	88.91	99.13	99.992
29	10.154	61.464	94.27	99.684	99.998
30	16.866	74.752	97.548	99.89	99.998
31	28.986	86.072	99.154	99.982	100
32	47.644	94.026	99.762	99.998	100
33	69.536	98.132	99.952	100	100
34	88.136	99.61	99.988	100	100
35	97.542	99.976	100	100	100

Table A3: Pass Rates for Rule 2 under Panels of Size 35 When One Cell Has a Low Probability of Fit

	Underlying Probability of Fit For All but One Cell				
Probability of Fit for One Cell of Size 2	60	70	80	90	100
10	0.679	4.7272	13.1728	17.9742	18.9654
20	1.3608	9.2378	24.9278	34.1718	36.0236
30	2.0358	13.3786	35.5976	48.338	50.9366
40	2.7394	17.1874	44.9216	60.607	63.9314
50	3.4202	20.7786	52.9978	70.9574	74.9644
60	4.0792	24.0966	59.9844	79.5272	83.986

Table A4: Fail Rates for Rule 3 under Panels of Size 35

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0.03	0.508	3.126	17.01	55.206
19	0.036	0.508	4.074	23.938	66.208
20	0.03	0.526	5.846	33.462	76.326
21	0.032	0.672	9.1	44.514	85.378
22	0.03	0.966	14.862	57.542	91.552
23	0.034	1.91	23.446	70.434	95.63
24	0.04	3.92	35.44	81.088	97.92
25	0.048	7.842	49.504	88.83	99.194
26	0.184	14.844	63.818	94.184	99.756
27	0.672	25.732	76.576	97.45	99.886
28	1.952	40.08	86.602	98.922	99.984
29	5.702	57.078	93.482	99.648	99.998
30	13.352	72.888	97.322	99.882	99.996
31	26.922	85.478	99.076	99.982	100
32	46.792	93.884	99.756	99.998	100
33	69.334	98.11	99.952	100	100
34	88.136	99.61	99.988	100	100
35	97.542	99.976	100	100	100

Table A5: Pass Rates for Rule 3 under Panels of Size 35 When One Cell Has a Low Probability of Fit

	Underlying Probability of Fit For All but One Cell				
Probability of Fit for One Cell of Size 2	60	70	80	90	100
10	2.337	20.1518	67.8562	98.0432	100
20	2.9472	22.8776	70.6342	98.3552	100
30	3.5864	25.5092	73.2886	98.6632	100
40	4.2856	28.0392	75.9956	98.9192	100
50	4.9812	30.774	78.486	99.1856	100
60	5.7538	33.5986	80.8104	99.3306	100

APPENDIX B

Table B1: Fail Rates for Rule 1 under Panels of Size 40

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0	0	0.034	1.972	21.3
19	0	0	0.08	4.116	31.76
20	0	0	0.238	7.5	43.9
21	0	0	0.65	12.77	56.43
22	0	0.006	1.436	20.92	67.97
23	0	0.024	3.202	31	78.58
24	0	0.108	6.43	42.99	86.77
25	0	0.314	11.24	55.91	92.28
26	0	0.79	19.19	68.22	95.93
27	0	1.828	29.58	78.96	98.19
28	0.006	4.35	42.08	87.21	99.21
29	0.028	8.888	55.79	93.04	99.7
30	0.112	16.14	69.17	96.42	99.89
31	0.49	26.71	80.17	98.45	99.98
32	1.482	40.49	89.04	99.39	99.99
33	4.234	55.78	94.61	99.8	100
34	10.31	71.18	97.56	99.94	100
35	20.22	84.02	99.17	99.99	100
36	37.11	92.32	99.76	100	100
37	57.43	97.14	99.92	100	100
38	77.97	99.28	99.99	100	100
39	91.92	99.85	100	100	100
40	98.54	99.99	100	100	100

Table B2: Fail Rates for Rule 2 under Panels of Size 40

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0.102	1.524	7.788	23.524	51.68
19	0.104	1.514	7.93	24.474	55.59
20	0.112	1.614	7.876	25.812	61.352
21	0.106	1.574	8.192	28.364	68.156
22	0.12	1.618	8.508	33.56	75.094
23	0.086	1.65	10.004	40.538	82.568
24	0.078	1.56	12.378	49.272	88.734
25	0.064	1.874	16.036	59.896	93.144
26	0.072	2.286	23.012	70.482	96.266
27	0.104	3.222	32.28	80.048	98.312
28	0.124	5.308	43.704	87.694	99.248
29	0.122	9.744	56.758	93.25	99.706
30	0.21	16.812	69.614	96.486	99.888
31	0.59	27.094	80.33	98.464	99.976
32	1.546	40.692	89.096	99.388	99.992
33	4.29	55.882	94.62	99.804	99.996
34	10.324	71.202	97.564	99.94	100
35	20.234	84.026	99.166	99.99	100
36	37.116	92.324	99.76	99.998	100
37	57.434	97.144	99.918	99.998	100
38	77.974	99.28	99.988	100	100
39	91.924	99.846	100	100	100
40	98.536	99.988	99.998	100	100

Table B3: Pass Rates for Rule 2 under Panels of Size 40 When One Cell Has a Low Probability of Fit

	Underlying Probability of Fit For All but One Cell				
Probability of Fit for One Cell of Size 4	60	70	80	90	100
10	0.072	2.14	14.69	32.31	34.724
20	0.276	4.428	26.984	56.08	58.99
30	0.482	6.988	37.528	72.83	76.072
40	0.678	9.732	46.286	83.79	87.086
50	1.182	12.636	54.074	90.914	93.648
60	1.538	15.66	60.762	95.452	97.404

Table B4: Fail Rates for Rule 3 under Panels of Size 40

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0	0.002	0.094	2.364	22.348
19	0	0	0.138	4.476	32.404
20	0	0.002	0.302	7.75	44.264
21	0	0.006	0.686	13.02	56.63
22	0	0.01	1.48	21.034	68.044
23	0	0.026	3.23	31.08	78.628
24	0	0.108	6.442	43.024	86.782
25	0	0.316	11.262	55.926	92.282
26	0	0.792	19.204	68.226	95.926
27	0	1.828	29.59	78.962	98.192
28	0.006	4.35	42.08	87.214	99.208
29	0.028	8.888	55.79	93.042	99.698
30	0.112	16.142	69.166	96.42	99.886
31	0.49	26.71	80.168	98.446	99.976
32	1.482	40.494	89.04	99.388	99.992
33	4.234	55.782	94.606	99.804	99.996
34	10.306	71.176	97.56	99.94	100
35	20.222	84.018	99.166	99.99	100
36	37.112	92.322	99.76	99.998	100
37	57.434	97.144	99.918	99.998	100
38	77.974	99.28	99.988	100	100
39	91.924	99.846	100	100	100
40	98.536	99.988	99.998	100	100

Table B5: Pass Rates for Rule 3 under Panels of Size 40 When One Cell Has a Low Probability of Fit

	Underlying Probability of Fit For All but One Cell				
Probability of Fit for One Cell of Size 4	60	70	80	90	100
10	0.106	3.596	30.754	88.214	100
20	0.316	5.34	37.25	91.072	100
30	0.506	7.512	43.412	93.342	100
40	0.69	10.086	49.498	94.96	100
50	1.196	12.844	55.774	96.184	100
60	1.55	15.848	61.6	97.582	100

APPENDIX C

Table C1: Fail Rates for Rule 1 under Panels of Size 50

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0	0	0	0.02	1.636
19	0	0	0	0.044	3.228
20	0	0	0	0.138	6.024
21	0	0	0.002	0.308	10.19
22	0	0	0.002	0.782	16.02
23	0	0	0.01	1.62	24.42
24	0	0	0.054	3.176	33.74
25	0	0	0.098	5.782	44.64
26	0	0	0.234	9.65	55.46
27	0	0.002	0.592	15.56	65.82
28	0	0.008	1.238	23.34	75.8
29	0	0.01	2.626	33.25	83.8
30	0	0.034	4.842	43.86	89.8
31	0	0.088	8.374	55.69	94.22
32	0	0.234	13.95	66.4	96.83
33	0	0.644	21.79	76.59	98.33
34	0	1.458	31.54	84.21	99.19
35	0.006	2.964	43.2	90.51	99.62
36	0.002	6.064	55.48	94.71	99.88
37	0.03	11.206	67.07	97.27	99.96
38	0.09	18.472	77.37	98.59	99.98
39	0.314	28.862	86.07	99.45	99.99
40	1.022	41.868	92.02	99.81	100
41	2.372	55.816	96.03	99.93	100
42	5.66	69.356	98.15	99.97	100
43	12.34	81.162	99.15	99.99	100
44	22.94	89.41	99.81	100	100
45	38.45	95.114	99.93	100	100
46	56.99	98.132	99.98	100	100
47	75.11	99.436	100	100	100
48	88.74	99.844	100	100	100
49	96.78	99.976	100	100	100
50	99.44	99.998	100	100	100

Table C2: Fail Rates for Rule 2 under Panels of Size 50

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0.008	0.286	2.478	9.768	27.386
19	0.006	0.308	2.298	9.834	28
20	0.016	0.326	2.458	9.944	28.926
21	0.002	0.322	2.44	9.896	30.722
22	0.012	0.322	2.414	10.074	34.186
23	0.01	0.334	2.408	10.636	39.028
24	0.012	0.31	2.458	11.728	45.08
25	0.004	0.314	2.366	13.696	52.79
26	0.012	0.292	2.638	16.556	61.15
27	0.004	0.314	2.92	21.178	69.484
28	0.008	0.33	3.474	27.714	77.972
29	0.01	0.354	4.54	36.606	84.984
30	0.016	0.324	6.616	46.168	90.354
31	0.01	0.402	9.922	57.138	94.48
32	0.006	0.526	15.168	67.188	96.932
33	0.008	0.948	22.714	77.08	98.36
34	0.018	1.72	32.166	84.43	99.194
35	0.012	3.18	43.62	90.602	99.63
36	0.008	6.23	55.678	94.74	99.884
37	0.044	11.356	67.186	97.28	99.964
38	0.106	18.546	77.434	98.588	99.982
39	0.326	28.916	86.102	99.45	99.99
40	1.028	41.888	92.022	99.808	100
41	2.386	55.828	96.028	99.934	99.998
42	5.664	69.36	98.15	99.974	100
43	12.34	81.162	99.154	99.992	100
44	22.944	89.41	99.806	100	100
45	38.448	95.114	99.928	100	100
46	56.986	98.132	99.978	100	100
47	75.108	99.436	99.996	100	100
48	88.738	99.844	99.998	100	100
49	96.78	99.976	100	100	100
50	99.436	99.998	100	100	100

Table C3: Pass Rates for Rule 2 under Panels of Size 50 When One Cell Has a Low Probability of Fit

	Underlying Probability of Fit For All but One Cell				
Probability of Fit for One Cell of Size 5	60	70	80	90	100
10	0.026	1.124	13.412	38.49	41.31
20	0.058	2.444	24.232	63.534	67.12
30	0.158	3.932	33.838	79.612	83.312
40	0.234	5.832	43.018	88.928	92.212
50	0.39	7.994	50.948	94.402	96.904
60	0.556	10.77	57.858	97.026	98.992

Table C4: Fail Rates for Rule 3 under Panels of Size 50

	Underlying Probability of Fit				
Number of Required Success	90	80	70	60	50
18	0	0	0.008	0.12	2.33
19	0	0	0.006	0.124	3.812
20	0	0	0.008	0.214	6.516
21	0	0	0.002	0.396	10.558
22	0	0	0.008	0.876	16.282
23	0	0	0.016	1.672	24.652
24	0	0	0.06	3.222	33.864
25	0	0	0.1	5.832	44.718
26	0	0	0.238	9.692	55.488
27	0	0.002	0.596	15.582	65.834
28	0	0.008	1.238	23.358	75.806
29	0	0.01	2.626	33.262	83.806
30	0	0.034	4.842	43.864	89.804
31	0	0.088	8.376	55.688	94.22
32	0	0.234	13.946	66.406	96.828
33	0	0.644	21.794	76.596	98.326
34	0	1.458	31.542	84.214	99.188
35	0.006	2.964	43.202	90.512	99.622
36	0.002	6.064	55.484	94.714	99.884
37	0.03	11.206	67.07	97.268	99.964
38	0.09	18.472	77.368	98.586	99.982
39	0.314	28.862	86.072	99.45	99.99
40	1.022	41.868	92.016	99.808	100
41	2.372	55.816	96.028	99.934	99.998
42	5.66	69.356	98.148	99.974	100
43	12.34	81.162	99.154	99.992	100
44	22.944	89.41	99.806	100	100
45	38.448	95.114	99.928	100	100
46	56.986	98.132	99.978	100	100
47	75.108	99.436	99.996	100	100
48	88.738	99.844	99.998	100	100
49	96.78	99.976	100	100	100
50	99.436	99.998	100	100	100

Table C5: Pass Rates for Rule 3 under Panels of Size 50 When One Cell Has a Low Probability of Fit

	Underlying Probability of Fit For All but One Cell				
Probability of Fit for One Cell of Size 5	60	70	80	90	100
10	0.026	1.574	23.822	87.844	100
20	0.058	2.69	30.2	90.964	100
30	0.164	4.044	36.734	93.67	100
40	0.234	5.884	44.444	95.428	100
50	0.392	8.024	51.518	97.042	100
60	0.56	10.784	58.056	97.842	100