

Testimony - NIOSH TIL Public Hearing
ISEA Respirator Fit Test Study

Prepared by Environmental Health & Safety, Inc.



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 - ▶ Ron Pearson, Principal Consultant, M.S., CIH
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Study Goals

- ▶ Evaluate variability in subject pass rates for half-facepiece air purifying respirators following the proposed NIOSH test protocol
 - ▶ Determine probability that subjects will attain fit factors ranging from 20-100
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Key Findings

- ▶ Proposed test criteria are very stringent and will exclude almost all filtering facepiece (FFR) and 50% of elastomeric respirators (ER) from the marketplace.
- ▶ 25% of FFR and 80% ER would be certified if FF criterion = 20
- ▶ 55% of FFR and 90% ER would be certified if FF criterion = 10
- ▶ Requiring that at least one subject in each cell receive a passing fit factor is very stringent and handicaps cells with small numbers of subjects.
- ▶ 50% chance of failure in cells 1, 2, 5, 6, 9 and 10 (2 subjects/cell)
- ▶ 25-33% chance of failure in cells 3 and 8 (4 and 3 subjects/cell)
- ▶ 11-14% chance of failure in cells 4 and 7 (9 and 7 subjects/cell)

Key Findings

- ▶ The proposed NIOSH protocol would be more rigorous with:
 - ▶ More than 35 subjects in a single panel
 - ▶ More than one panel of 35 subjects
 - ▶ Similar and larger number of subjects in each cell (≥ 5 per cell)
 - ▶ Multiple donnings of a respirator on each subject
- ▶ Bootstrap analyses would lead to more informed decisions about the probability that a respirator will fit a population of users. These would require:
 - ▶ Multiple panels or
 - ▶ Multiple donnings of a respirator on each subject
- ▶ A consistent approach for testing multi-size respirators is needed:
 - ▶ Recommend using the approach developed in this study, which included a preliminary qualitative evaluation of each size through assisted donning prior to final size selection.

Key Findings

- ▶ NIOSH benchmark tests were not strictly relevant to the proposed certification protocol:
 - ▶ Too few subjects (25)
 - ▶ Different test panel (Los Alamos criteria)
 - ▶ Tested each size of a respirator with a separate panel (many subjects were likely to receive incorrect size)
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Methods

- ▶ Experiments with a filtering facepiece respirator [FFR] (cup shape, single size)
 - ▶ FFR tested with one panel of 35 subjects
 - ▶ Day 1 = first respirator donned 3 times
 - ▶ Day 2 = second (new) respirator donned 3 times
 - ▶ Day 3 = third (new) respirator donned 3 times
 - ▶ FFR tested with three different panels of 35 subjects
 - ▶ Panel 1 = each subject dons one respirator 3 times
 - ▶ Panel 2 = new set of subjects, each dons one respirator 3 times
 - ▶ Panel 3 = new set of subjects, each dons one respirator 3 times
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Methods

- ▶ Experiments with an Elastomeric Respirator [ER] (3 sizes)
 - ▶ ER tested with 1 panel of 35 subjects
 - ▶ Day 1 = first respirator donned 3 times (after size selection process)
 - ▶ Day 2 = second (new-same size) respirator donned 3 times
 - ▶ Day 3 = third (new-same size) respirator donned 3 times
 - ▶ NIOSH Benchmark Test Data [FFR and ER]
 - ▶ ISEA members requested benchmark test results for their respirators from NIOSH and shared data with ISEA, which conveyed data to study team
 - ▶ Obtained data for 17 FFR (2 multi-size) and 20 ER panels
 - NIOSH conducted a separate panel for each size of multi-size respirators
 - NIOSH used 25-member panels; cell distributions matched Los Alamos criteria
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Methods

- ▶ TSI PortaCount Plus Model 8020 with N95-Companion
 - ▶ Fit test software with no upper limit on fit factors
 - ▶ Test chamber with 2500 particles/cm³ average challenge conc.
 - ▶ NaCl generated aerosol (TSI 9306 6-Jet Atomizer)
 - ▶ Seven exercises using 60-second mask sample
 - ▶ Test subjects had previous respirator donning experience
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Data Analyses

- ▶ Descriptive statistics (GM*, GSD**, Analysis of Variance)
- ▶ Between-subject vs. within-subject variability in fit
- ▶ Pass rates for FFR and ER
- ▶ Predicting fit using bootstrap analyses
 - ▶ FFR experimental data (3 panels)
 - ▶ NIOSH benchmark data

* GM = geometric mean

** GSD = geometric standard deviation



Descriptive Statistics – FF Respirator

- ▶ FFR single panel, 3 days
 - ▶ All days combined: GM Fit Factor (FF) = 30 (GSD 2.5)
 - ▶ Day 1 (GM FF 37) > Day 2 (GM FF 30) = Day 3 (GM FF 27)
 - ▶ Donning 1 (GM FF 36) > Donning 2 (GM FF 30) = Donning 3 (GM FF 27)
 - ▶ FFR 3 panels, 1 day
 - ▶ GM FF = 37 (GSD 3)
 - ▶ Panel 1 (GM FF 30) = Panel 2 (GM FF 35) = Panel 3 (GM FF 40)
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Descriptive Statistics

- ▶ ER single panel, 3 days
 - ▶ All days combined: GM FF = 3641 (GSD 4)
 - ▶ Day 1 (GM FF 3641) = Day 2 (GM FF 4023) = Day 3 (GM FF 2981).
 - ▶ Donning 1 (GM FF 3294) = Donning 2 (GM FF 3641) = Donning 3 (GM FF 3641)
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Between- and Within-Subject Variability

- ▶ FFR single panel, 3 days
 - ▶ Between-subject variability (0.5) > within-subject variability (0.3)
 - ▶ FFR 3 panels, 1 day
 - ▶ Between-subject variability (0.8) > within-subject variability (0.2)
 - ▶ ER single panel, 3 days
 - ▶ Between-subject variability (0.5) < within-subject variability (1.2)
 - ▶ NIOSH Benchmark Studies (FFR and ER)
 - ▶ Between-subject variability > within-subject variability
 - ▶ Keep in mind that each size of a multi-size respirator was tested with a full panel.
 - ▶ Between-subject variability ranged from 0.3 to 8
 - ▶ Within-subject variability ranged from 0.1 to 2
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Pass Rates – FFR, 1 Panel, 3 Days

		Number of Subjects that Achieve Goal by Cell										Total
		Cell and Number of Subjects										
Fit Test	Goal	1	2	3	4	5	6	7	8	9	10	N (%)
		6	6	12	27	6	6	21	9	6	6	105 (100%)
10		4	6	12	27	6	6	21	9	6	6	103 (98%)
15		3	6	11	22	6	6	21	7	5	4	91 (87%)
20		2	6	10	22	5	6	21	6	4	3	85 (81%)
25		2	5	9	21	5	6	21	6	4	3	82 (78%)
30		2	3	9	19	5	6	20	3	4	3	74 (70%)
40		2	3	6	17	5	4	15	3	3	2	60 (57%)
50		2	3	6	14	4	4	13	2	2	2	52 (49%)
60		2	2	4	11	3	4	11	2	2	2	43 (41%)
75		1	1	4	6	2	4	10	2	1	2	33 (31%)
100		1	0	3	3	1	1	4	2	1	1	17 (16%)

Pass Rates – FFR, 1 Panel, Day 1

		Number of Subjects that Achieve Goal by Cell										Total
		Cell and Number of Subjects										
Fit Test		1	2	3	4	5	6	7	8	9	10	N (%)
Goal		2	2	4	9	2	2	7	3	2	2	35 (100%)
10	1	2	2	4	9	2	2	7	2	2	2	33 (94%)
15	1	2	2	3	9	2	2	7	2	2	1	31 (89%)
20	1	2	2	3	8	2	2	7	2	2	1	30 (86%)
25	1	2	2	3	6	2	2	7	1	2	1	27 (77%)
30	1	2	2	2	6	2	2	6	1	2	1	25 (71%)
40	1	2	2	2	5	2	2	5	1	2	1	23 (66%)
50	1	1	1	1	5	1	2	4	1	2	1	19 (54%)
60	0	1	1	1	2	1	2	4	1	1	1	14 (40%)
75	0	0	0	1	1	0	1	1	1	1	0	6 (17%)
100	2	2	4	9	2	2	2	7	3	2	2	35 (100%)

Pass Rates – FFR, 1 Panel, Day 2

		Number of Subjects that Achieve Goal by Cell										Total
		Cell and Number of Subjects										
Fit Test		1	2	3	4	5	6	7	8	9	10	N (%)
Goal	2	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	1	2	4	9	2	2	7	7	3	2	2	34 (97%)
15	1	2	4	6	2	2	7	7	3	1	1	29 (83%)
20	1	2	4	6	1	2	7	7	2	1	1	27 (77%)
25	1	1	4	6	1	2	7	7	2	1	1	26 (74%)
30	1	0	4	6	1	2	7	7	1	1	1	24 (69%)
40	1	0	2	5	1	2	4	4	1	0	1	17 (49%)
50	1	0	2	4	1	2	4	4	0	0	1	15 (43%)
60	1	0	1	3	1	2	4	4	0	0	1	13 (37%)
75	1	0	1	1	1	2	4	4	0	0	1	11 (31%)
100	1	0	1	1	1	0	2	2	0	0	1	7 (20%)

Pass Rates – FFR, 1 Panel, Day 3

		Number of Subjects that Achieve Goal by Cell										Total
		Cell and Number of Subjects										N (%)
Fit Test	Goal	1	2	3	4	5	6	7	8	9	10	N (%)
	10	2	2	4	9	2	2	7	3	2	2	35 (100%)
	15	1	2	3	7	2	2	7	2	2	1	29 (83%)
	20	0	2	3	7	2	2	7	2	1	1	27 (77%)
	25	0	2	2	7	2	2	7	2	1	1	26 (74%)
	30	0	1	2	7	2	2	6	1	1	1	23 (66%)
	40	0	1	2	6	2	0	5	1	1	0	18 (51%)
	50	0	1	2	5	1	0	4	1	0	0	14 (40%)
	60	0	1	2	3	1	0	3	1	0	0	11 (31%)
	75	0	0	2	3	0	0	2	1	0	0	8 (23%)
	100	0	0	1	1	0	0	1	1	0	0	4 (11%)

Pass Rates – FFR, 3 Panels Tested Once

Fit Test Goal	Number of Subjects that Achieve Goal by Cell										Total N (%)
	Cell and Number of Subjects										
	1	2	3	4	5	6	7	8	9	10	
10	4	5	11	27	6	6	21	9	6	6	101 (96%)
15	3	5	11	27	6	6	19	8	6	5	96 (91%)
20	2	5	9	26	5	6	19	7	6	4	89 (85%)
25	2	5	8	24	5	6	18	7	6	4	85 (81%)
30	2	5	8	22	4	6	17	6	6	4	80 (76%)
40	2	5	7	21	4	6	16	5	5	3	74 (70%)
50	1	3	6	18	4	5	12	5	3	3	60 (57%)
60	1	2	4	17	3	5	11	5	3	3	54 (51%)
75	0	2	4	11	3	4	10	4	2	3	43 (41%)
100	0	0	3	7	2	3	6	3	2	1	27 (26%)

Pass Rates – FFR, Panel 1

		Number of Subjects that Achieve Goal by Cell										Total
		Cell and Number of Subjects										N (%)
Fit Test	Goal	1	2	3	4	5	6	7	8	9	10	
	10	1	2	4	9	2	2	7	2	2	2	33 (94%)
	15	1	2	3	9	2	2	7	2	2	1	31 (89%)
	20	1	2	3	8	2	2	7	2	2	1	30 (86%)
	25	1	2	3	6	2	2	7	1	2	1	27 (77%)
	30	1	2	2	6	2	2	6	1	2	1	25 (71%)
	40	1	2	2	5	2	2	5	1	2	1	23 (66%)
	50	1	1	1	5	1	2	4	1	2	1	19 (54%)
	60	0	1	1	2	1	2	4	1	1	1	14 (40%)
	75	0	0	1	1	0	1	1	1	1	0	6 (17%)
	100	2	2	4	9	2	2	7	3	2	2	35 (100%)

Pass Rates – FFR, Panel 2

		Number of Subjects that Achieve Goal by Cell										Total
		Cell and Number of Subjects										
Fit Test		1	2	3	4	5	6	7	8	9	10	N (%)
Goal	2	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	2	2	2	3	9	2	2	7	3	2	2	34 (97%)
15	1	2	3	9	2	2	2	5	3	2	1	30 (86%)
20	0	2	3	8	2	2	2	5	3	2	1	28 (80%)
25	0	2	2	8	2	2	2	4	3	2	1	26 (74%)
30	0	2	2	8	1	1	2	4	3	2	1	25 (71%)
40	0	2	2	7	1	1	2	4	3	1	1	23 (66%)
50	0	0	1	6	1	1	2	3	3	0	1	17 (48%)
60	0	0	1	6	1	1	2	3	3	0	1	17 (48%)
75	0	0	1	4	1	1	1	3	2	0	1	13 (37%)
100	0	0	0	4	1	1	1	2	1	0	1	10 (28%)

Pass Rates – FFR, Panel 3

Fit Test	Number of Subjects that Achieve Goal by Cell										Total
	1	2	3	4	5	6	7	8	9	10	
Goal	2	2	4	9	2	2	7	3	2	2	35 (100%)
10	1	1	4	9	2	2	7	3	2	2	33 (94%)
15	1	1	4	9	2	2	7	3	2	2	33 (94%)
20	1	1	3	9	1	2	7	2	2	2	30 (86%)
25	1	1	3	8	1	2	7	2	2	2	29 (83%)
30	1	1	3	8	1	2	6	2	2	2	28 (80%)
40	1	1	3	8	1	2	6	1	2	1	26 (74%)
50	0	1	3	7	1	1	4	1	1	1	20 (57%)
60	0	1	2	6	1	1	4	1	1	1	18 (51%)
75	0	1	2	5	1	1	3	1	1	1	16 (46%)
100	0	0	2	2	1	1	3	1	1	0	11 (31%)

Pass Rates – ER, One Panel, 3 Days

		Number of Subjects that Achieve Goal by Cell										Total
		Cell and Number of Subjects										
Fit Test	Goal	1	2	3	4	5	6	7	8	9	10	N (%)
10		6	6	12	27	6	6	21	9	6	6	105 (100%)
15		6	6	12	27	6	6	21	9	6	6	105 (100%)
20		6	6	12	27	6	6	21	9	6	6	105 (100%)
25		6	6	12	27	6	6	21	9	6	6	105 (100%)
30		6	6	12	27	6	6	21	9	6	6	105 (100%)
40		6	6	12	27	6	6	21	9	6	6	105 (100%)
50		6	6	11	27	6	6	21	9	6	6	104 (99%)
60		6	6	11	26	6	6	21	8	6	6	102 (97%)
75		6	6	11	26	6	6	19	8	6	5	99 (94%)
100		6	6	11	26	6	6	19	8	6	5	99 (94%)

Bootstrap Analysis Experimental Data - FF Respirator, 3 Panels

Fit Factor	% of Times the Respirator is Donned	% Users	Lower 95% Confidence Limit	Upper 95% Confidence Limit
5	95	99.98	99.95	1.0002
10	95	98.15	97.71	98.60
15	95	61.47	59.36	63.57
20	95	15.69	14.18	17.20
25	95	2.53	1.95	3.10
30	95	0.14	0.14	0.41
40	95	0.05	-0.05	0.15
50	95	0.05	-0.05	0.15
60	95	0.05	-0.05	0.15
75	95	0.05	-0.05	0.15
100	95	0.05	-0.05	0.15

Bootstrap Analysis NIOSH Benchmark Data – Filtering Facepiece

Fit Factor	% of Times the Respirator is Donned	% Users	Lower 95% Confidence Limit	Upper 95% Confidence Limit
5	95	86.22	84.99	87.44
10	95	26.39	24.71	28.08
15	95	5.62	4.90	6.33
20	95	1.22	0.95	1.49
25	95	0.30	0.20	0.39
30	95	0.08	0.04	0.12
40	95	0.01	0	0.01
50	95	0	-0	0
60	95	0	-0	0
75	95	0	-0	0
100	95	0	-0	0

Bootstrap Analysis NIOSH Benchmark Data – Elastomeric

Fit Factor	% of Times Respirator is Donned	% Users	Lower 95% Confidence Limit	Upper 95% Confidence Limit
5	95	99.95	99.89	100
10	95	99.07	98.76	99.38
15	95	94.19	93.20	95.18
20	95	85.83	84.31	87.36
25	95	75.19	73.25	77.12
30	95	64.15	61.98	66.32
40	95	44.55	42.31	46.79
50	95	30.18	28.14	32.22
60	95	20.31	18.58	22.03
75	95	11.21	9.96	12.45
100	95	4.18	3.50	4.85

Recommendations

- ▶ Use a 75% pass criterion at or near a fit factor of 10 (the assigned protection factor)
- ▶ Drop the criteria for pass rates in every cell
- ▶ Increase the number of subjects in the panel, or use multiple panels
- ▶ Employ a single, consistent method for selecting an appropriate size when testing multi-size respirators
- ▶ Consider incorporating multiple tests of the same respirator on each subject
- ▶ Consider the use of multiple panels and/or multiple donnings per subject and a bootstrap analysis approach to assess the probability that a respirator will fit a population of wearers