

Evaluation of the NIOSH Proposed STP for Fit Testing Half Facepiece Respirators



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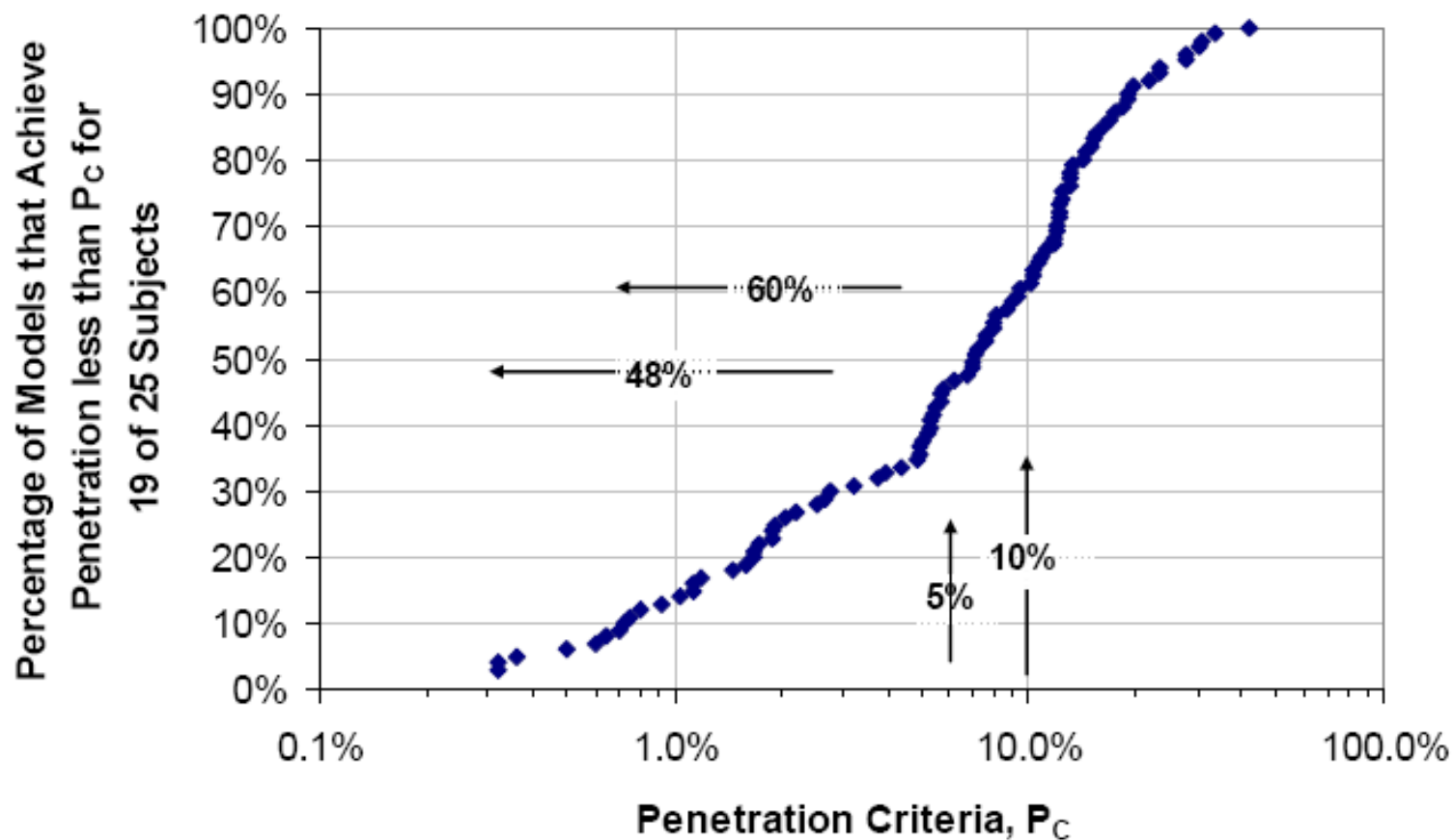
Background

- 42 CFR 84 (1995)
- Revised tests for particulate removing respirators
- New filters (N, R and P)
- Eliminated the IAA test
- Requirement to fit persons with various facial shapes and sizes stayed the same
 - STP proposal for determining compliance is new (2009)

NIOSH Proposal

- Based on Benchmark Testing performed by NIOSH
- ~30% of half mask, air-purifying particulate respirators had facepiece seals that did not achieve a fit factor of 100
 - “According to NIOSH benchmark testing and other research, ... with significant production capacity are likely to pass the proposed TIL testing and performance standards without modifications.”
- Not sure how this conclusion was reached because:

TIL Test Results: 101 Respirator Models



PF=1000

PF=100

PF=10

PF=1

Materials and Methods

- 3 Studies:
 - Evaluated several models of well-fitting FFR following the proposed STP
 - Evaluated a well –fitting and a poor-fitting FFR according to the proposed STP as well as different minimum FF and panel pass rates
 - 105 member panel (3 35-member panels)
 - Evaluated variability within a 35 member panel

Fit Testing

- Followed RCT-APR-STP-0068 (proposed TIL)
- TSI PortaCount Pro+
- Exercises
 - Normal Breathing (2 times)
 - Deep Breathing
 - Side to Side
 - Up and Down
 - Talking
 - Bending Over
 - Grimace (not included in the calculation)

Proposed Pass Criteria

- 35-member panel based bivariate NIOSH grid with exclusion of outliers through use of NIOSH PCA panel
- Quantitative fit test
- At least 26 subjects in the panel must pass at least one out of three fit tests (fit factor > 100) $\sim 74\%$
- At least one subject in each cell of the bivariate grid must pass a fit test

Exceptions

- PortaCount model 8020A Fit Tester w/ N95 companion (8095) TSI, St. Paul, MN
- Tests conducted in a fit test chamber (6'X8'X9')
 - Filtered air
 - NaCl aerosol generators
- 3M developed software to allow fit factors > 200 to be measured

Study One

- Tested 5 -well fitting 3M FFR following the STP
- Well-fitting = 80 – 100% pass ($FF \geq 100$) rate on workers
- 35 member panels, different panel for each FFR
 - Each subject tested 3 times
 - New respirator for each test

Site	Industry or application	Estimated # of workers in user pool	Estimated Fit Test Pass Rate for User Pool				
			3M Model E	3M Model G	3M Model A	3M Model D	3M Model C
1	Chemical, plastic, fiber manufacturing	2000	90%	80-85%			
2	Pharmaceutical	400					99.5%
3	Pharmaceutical	200	90%		90-95%		
4	Pharmaceutical	150	95%				
5	Ingot manufacturing	115				98%	
6	Flavor/food additive manufacturing	35				100%	

Study Two

- Purpose:
 - Evaluate the proposed STP for its ability to differentiate between poor- and well-fitting FFR
- Well-fitting respirator from Study one
 - Popular in the market and 90-95% pass rate
- Poor-fitting identified by Lawrence *et al.*
- 315 tests (3 panels X 35 subjects X 3 fit tests per person)

Study Two (cont)

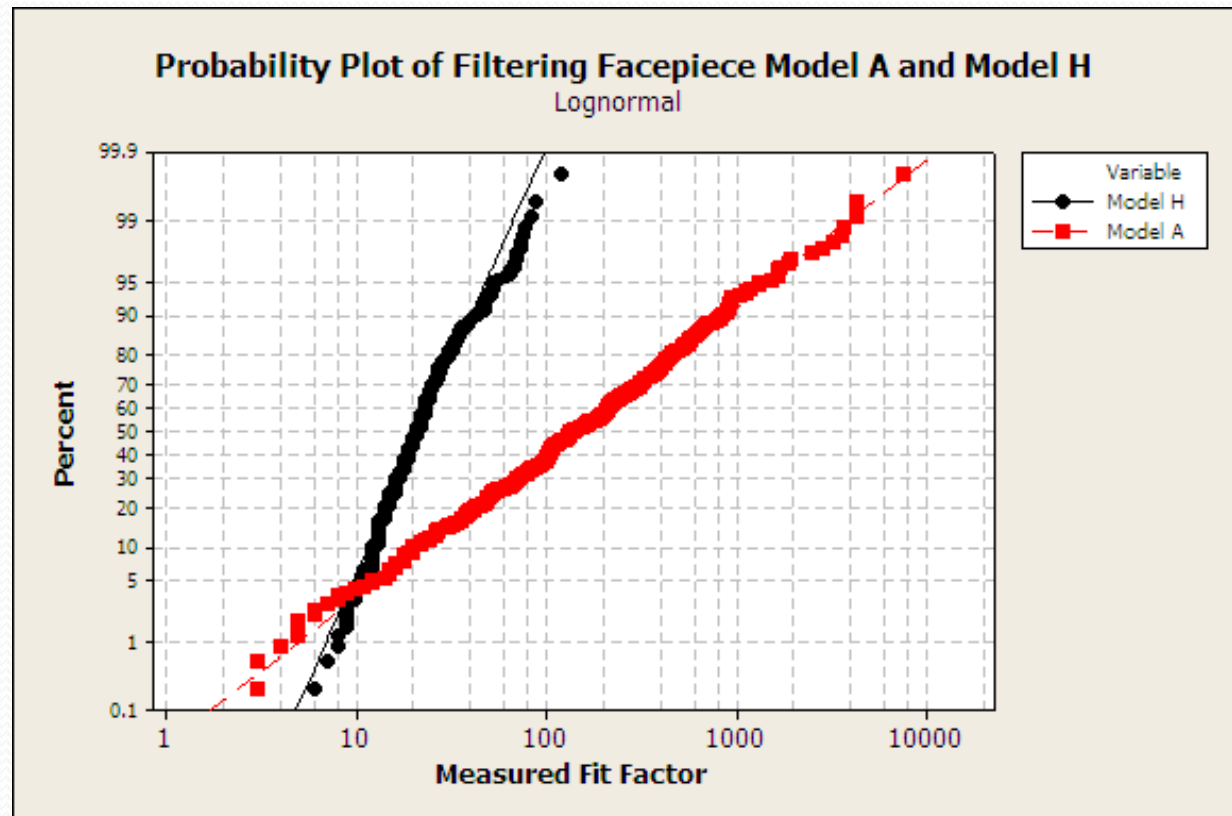
- Fit test used to generate 1000 simulated 35-subject panels via a bootstrap techniques
 - Each panel a random sample of 35 subjects meeting the panel requirements
 - Pass criterion: 25 out of 35 test subjects
 - Various passing fit factors of 10 -100 used in steps of 10

Laboratory Testing of Five FFR Based on the Proposed NIOSH TIL Criterion

Respirator	Pass Rate	1 Pass/Cell	Pass NIOSH Draft
A	77%	Yes	Yes
B	83%	Yes	Yes
C	86%	No	No
D	83%	Yes	Yes
E	71%	Yes	No

Fit Test Results of Model A and H

- Model A – 196 out of 315 fit tests with fit factor > 100
- Model H – 1 out of 315 fit tests with fit factor > 100



What criteria can be used to differentiate between models A and H?

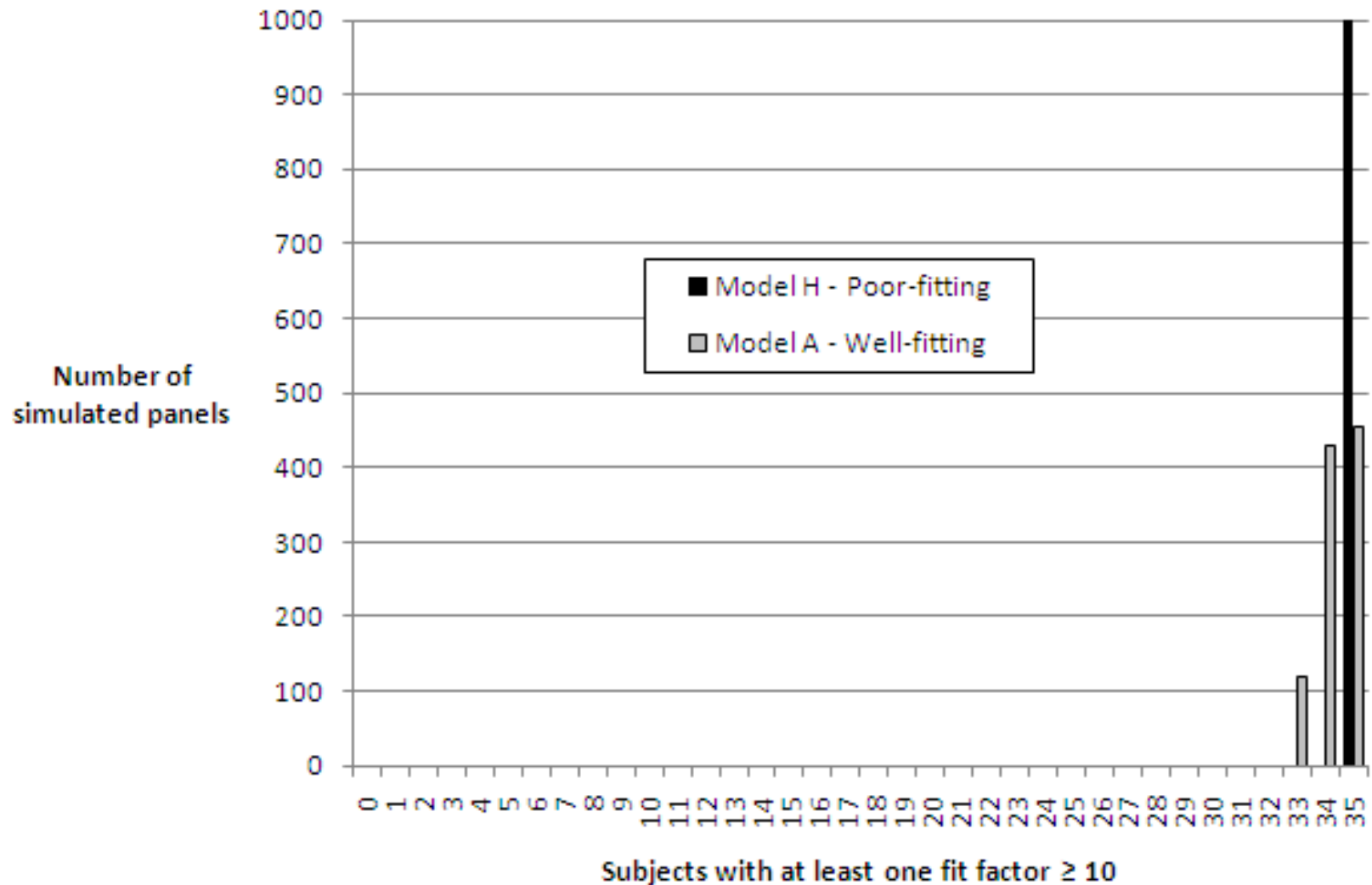
- Data sets for each model were used to create 1000 simulated 35-member panels
 - Each simulated 35-member panel was randomly selected (without replacement) from 105 subjects tested for each model
 - Each simulated panel complied with the requirements of NIOSH procedure RCT-APR-STP-0068
 - Over 10^{23} simulated panels could be created
- Simulation process shows predicted variation between different 35-member panels
- Each simulated panel was evaluated for a range of approval criteria

Possible approval criteria evaluated

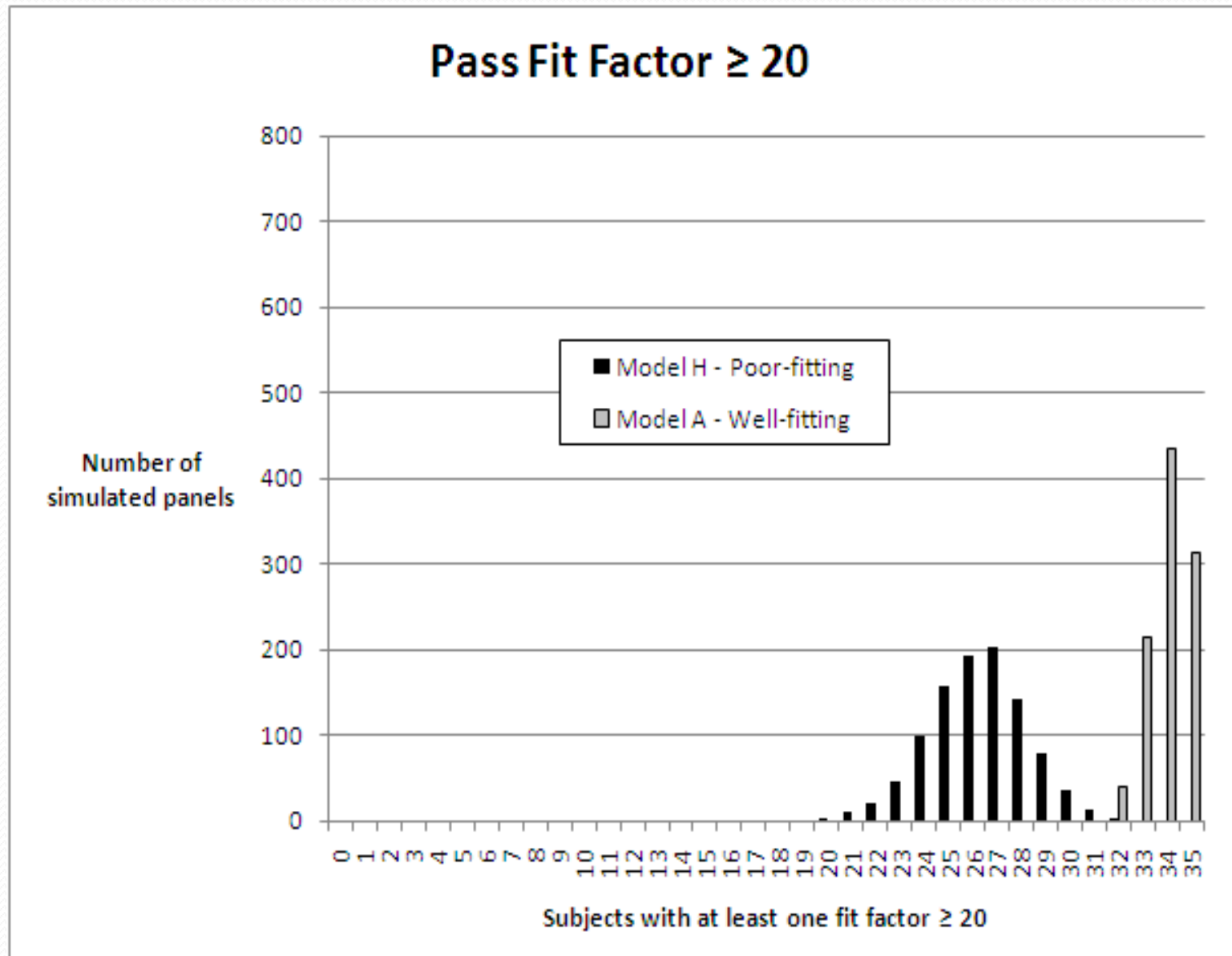
- Minimum fit factor from 10 to 100
- Subject pass rate from 0 to 35 out of 35
 - A pass for a subject is based on at least one out of three fit tests for the subject greater or equal to the minimum fit factor
- “One pass per cell” was evaluated as part of the written comments submitted previously
 - This presentation will not include that analysis

1000 Simulated Fit Test Panels

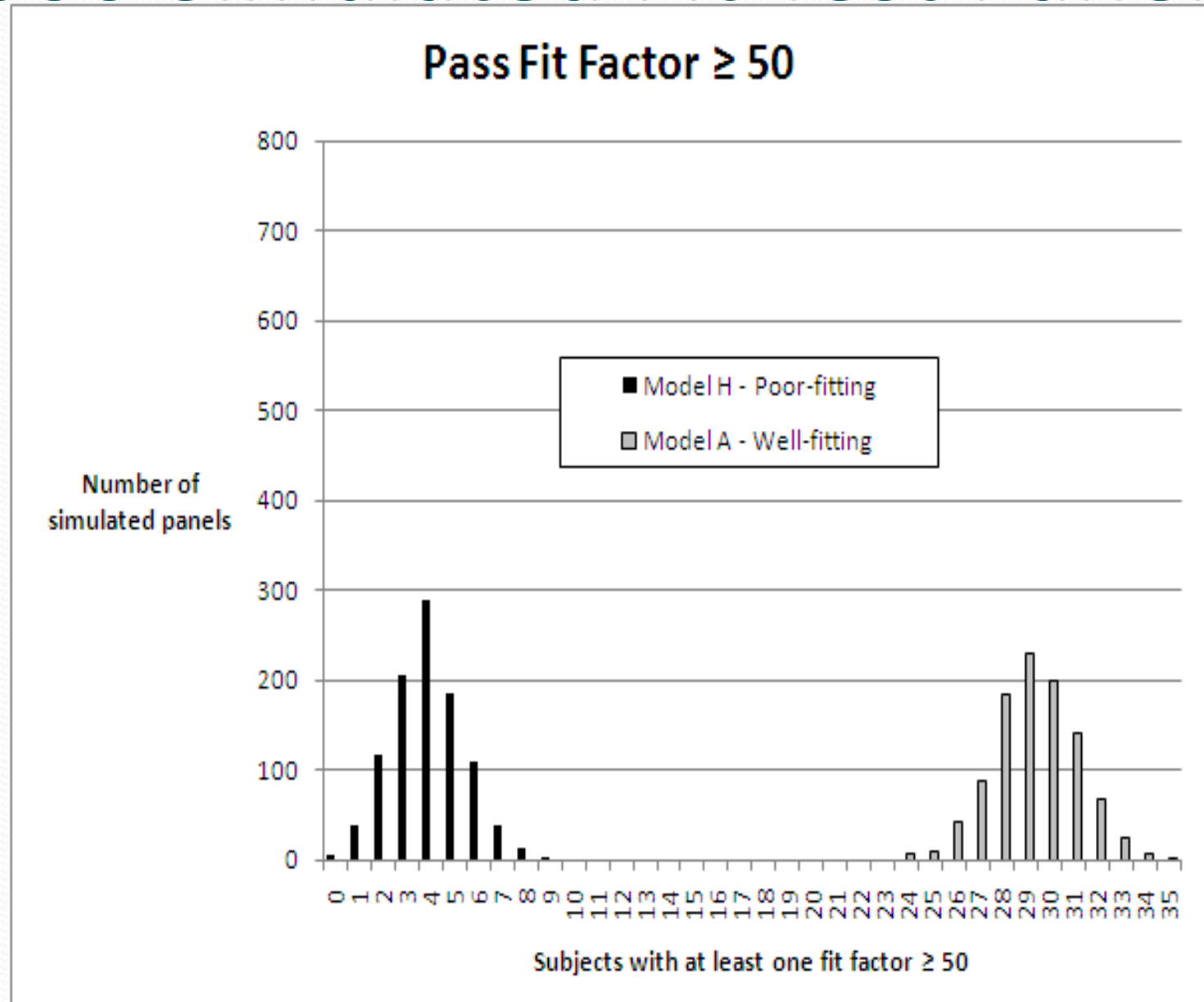
Pass Fit Factor ≥ 10



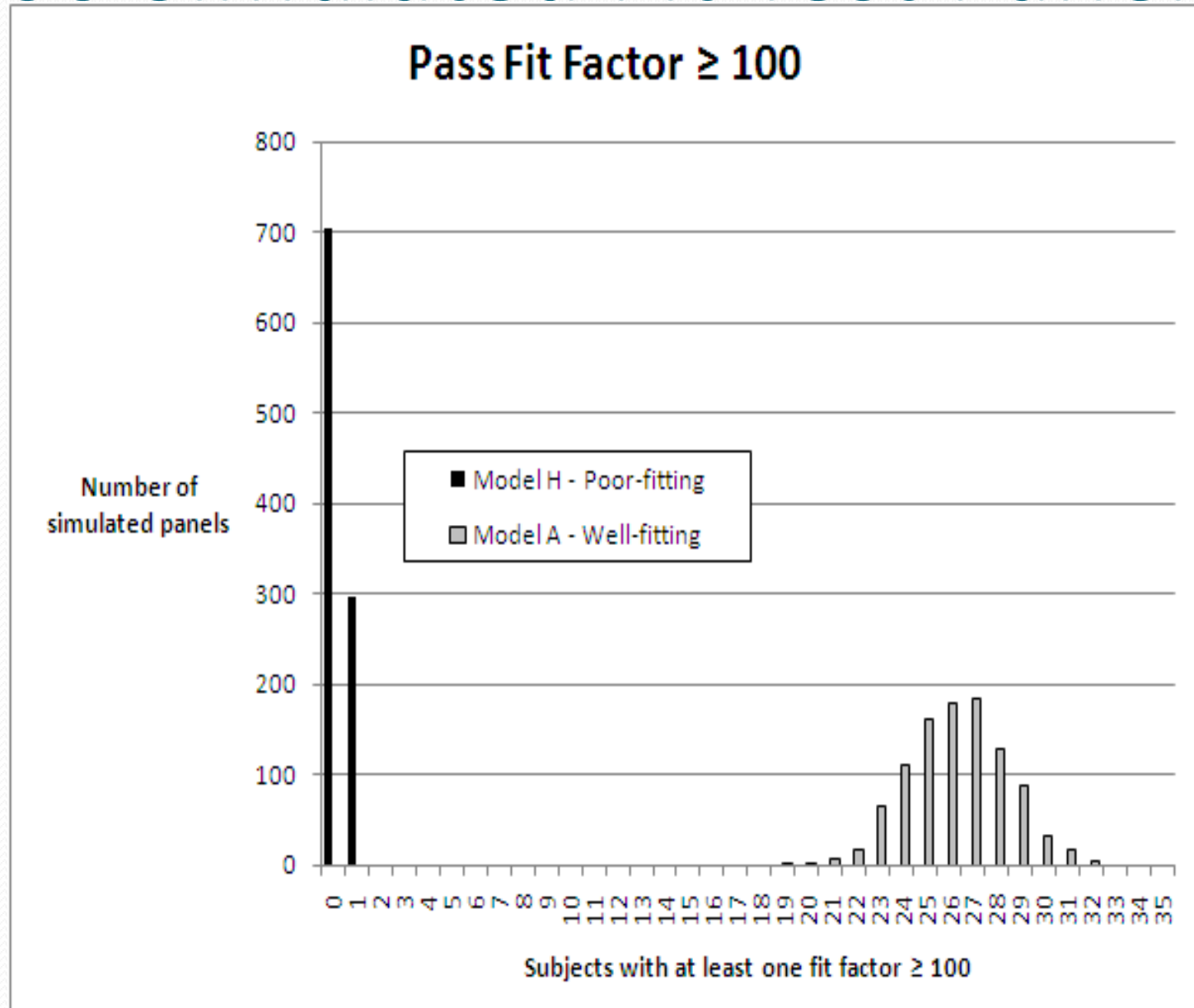
1000 Simulated Fit Test Panels



1000 Simulated Fit Test Panels



1000 Simulated Fit Test Panels



Conclusions from evaluation of possible approval criteria

- Fit factor 20 or lower does not differentiate between poor- and well-fitting respirators
- Fit factor of 50 provides good differentiation
- Subject pass rate of 50% (18 out of 35) is sufficient to reject poor-fitting respirator

FFR Model A – 105 Subject Bootstrap Analysis

NIOSH Pass Criteria	Fraction of Panels Meeting Criteria
26 out of 35 panel subjects $FF \geq 100$	655 out of 1000
One panel subject with $FF \geq 100$ per cell	463 out of 1000
26 out of 35 panel subjects $FF \geq 100$ and one panel subject with $FF \geq 100$ per cell	369 out of 1000

Recommendations to Proposed NIOSH Fit Requirement

- Use a test chamber and aerosol as used in this study and...
- Raise the panel size to 105 members

OR

- Change required subject pass rate to between 50% and 60% at a fit factor of 50 to 100
 - This will separate poor-fitting respirators from well-fitting respirators

Questions?

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