

**3M** Occupational Health &  
Environmental Safety Division

**Testimony on 42 CFR Part 84  
Total Inward Leakage  
Requirements for Respirators**

**July 29, 2010**

Notice of Proposed Rulemaking

RIN 0920-AA33

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This presentation is a summary of findings based on studies conducted following the last public meeting for the proposed TIL rule. Detailed written comments will be submitted to the docket.

# NIOSH Fit Test Proposal

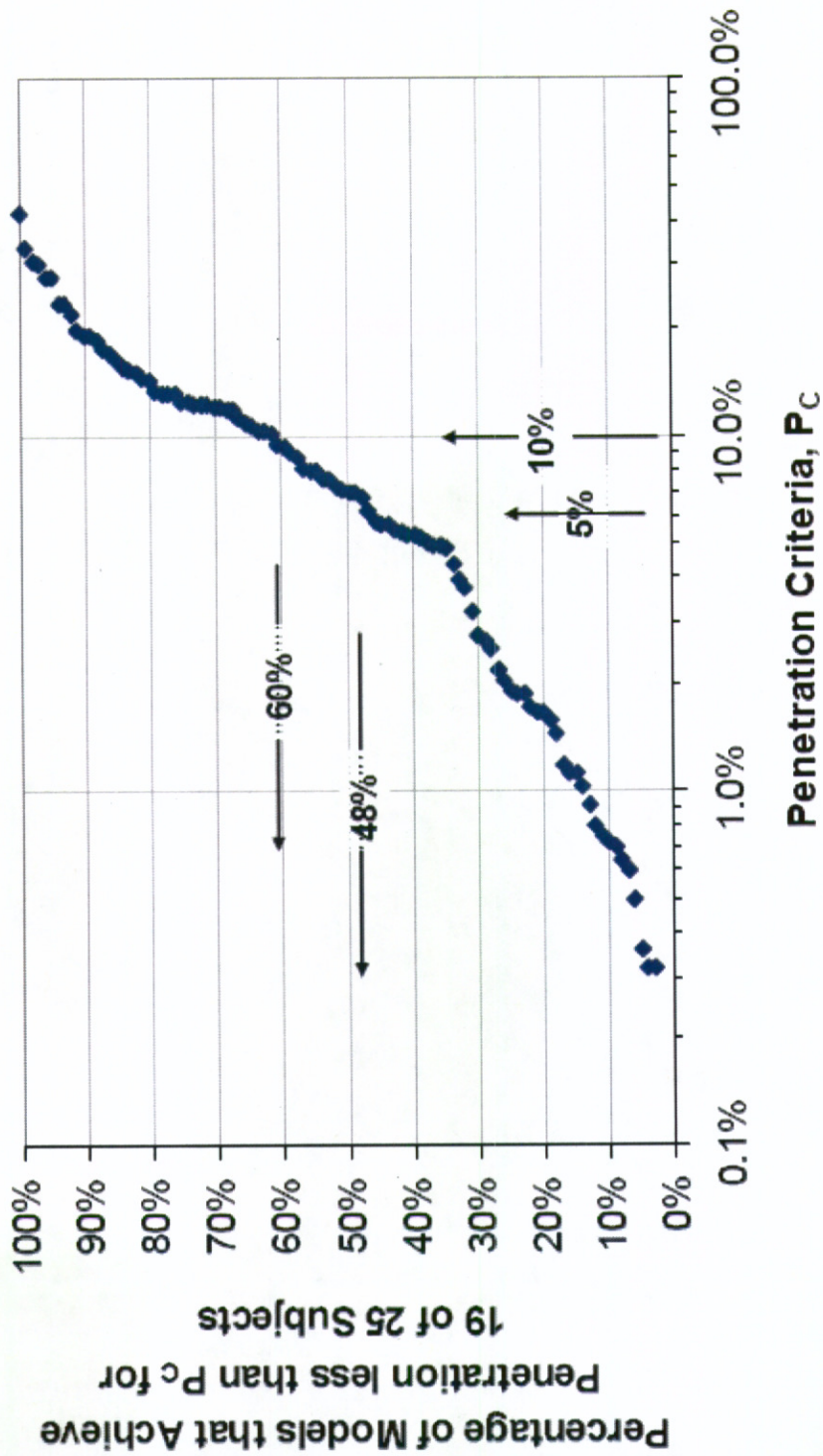
- Requirement to fit persons with various facial shapes and sizes stays the same
  - STP proposal for determining compliance is the issue
- “User instructions for half-mask respirators shall specify information necessary to identify the intended population of users:
  - The applicant shall specify in the user instructions the face sizes or sizes that the respirator is intended to fit...”

# Conclusions Stated by NIOSH from their Benchmark Data

- “Approximately 30 percent of this class of respirators have facepiece seals that did not perform adequately to 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.”
  - “NIOSH benchmark testing indicates ... that the new TIL requirements can be met by current products without additional development or manufacturing costs.”
- Not sure how this conclusion was reached because:

# NIOSH Benchmark Results

TIL Test Results: 101 Respirator Models



PF=1000

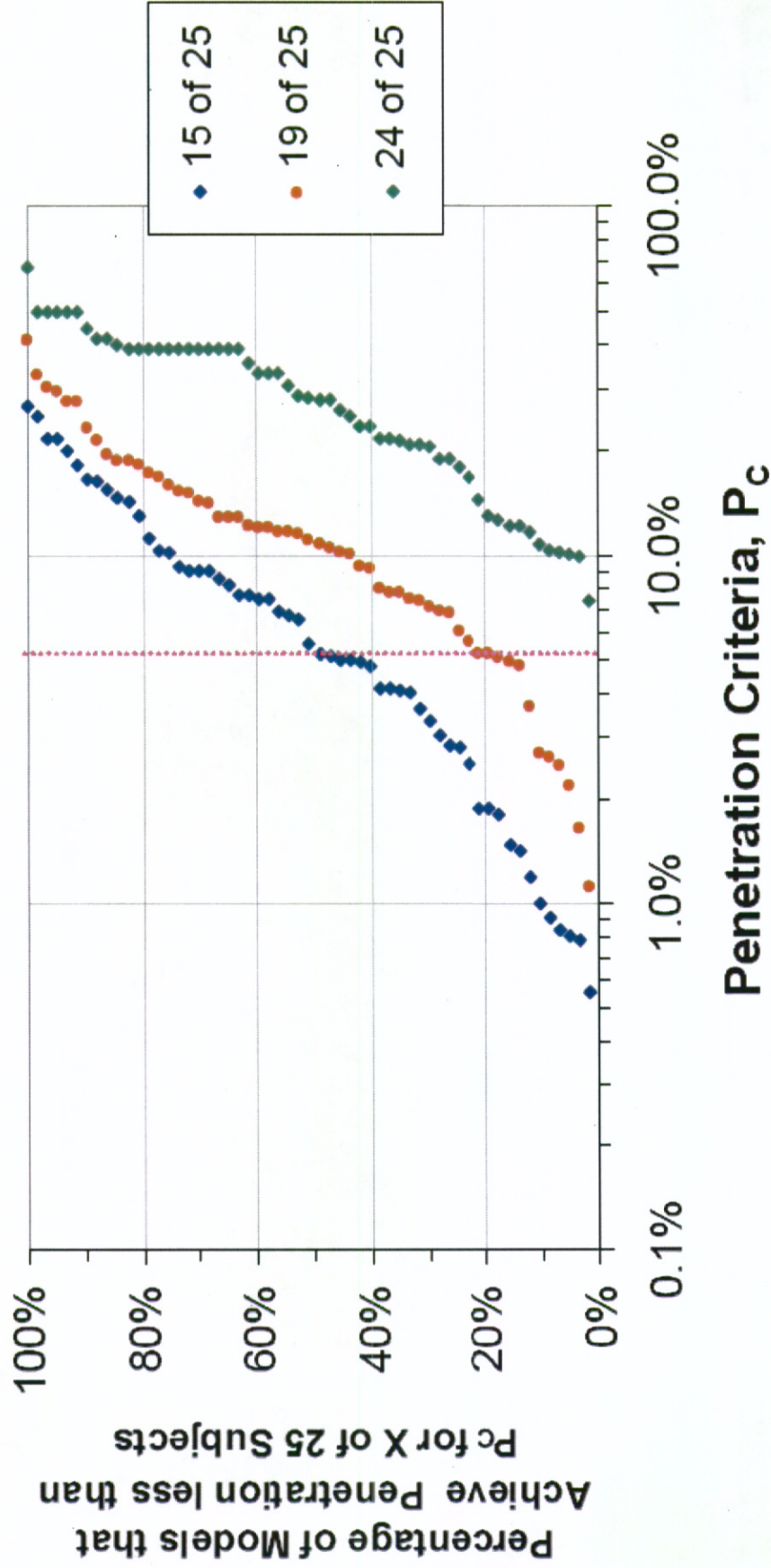
PF=100

PF=10

PF=1

# NIOSH Benchmark Results

TIL Test Results: Filtering-Facepiece Models



# Benchmark Data Appears Inconsistent with Conclusions

- These data do not support NIOSH's conclusions nor its intentions
- This discrepancy indicated a need for evaluation
  - 3M reviewed the NIOSH benchmark testing of its respirators
  - 3M conducted a study following the proposed fit test on several products
  - ISEA conducted a similar study
    - Evaluated respirators to the proposed fit test
    - Reviewed respirator manufacturers' NIOSH data

# *Federal Register* References

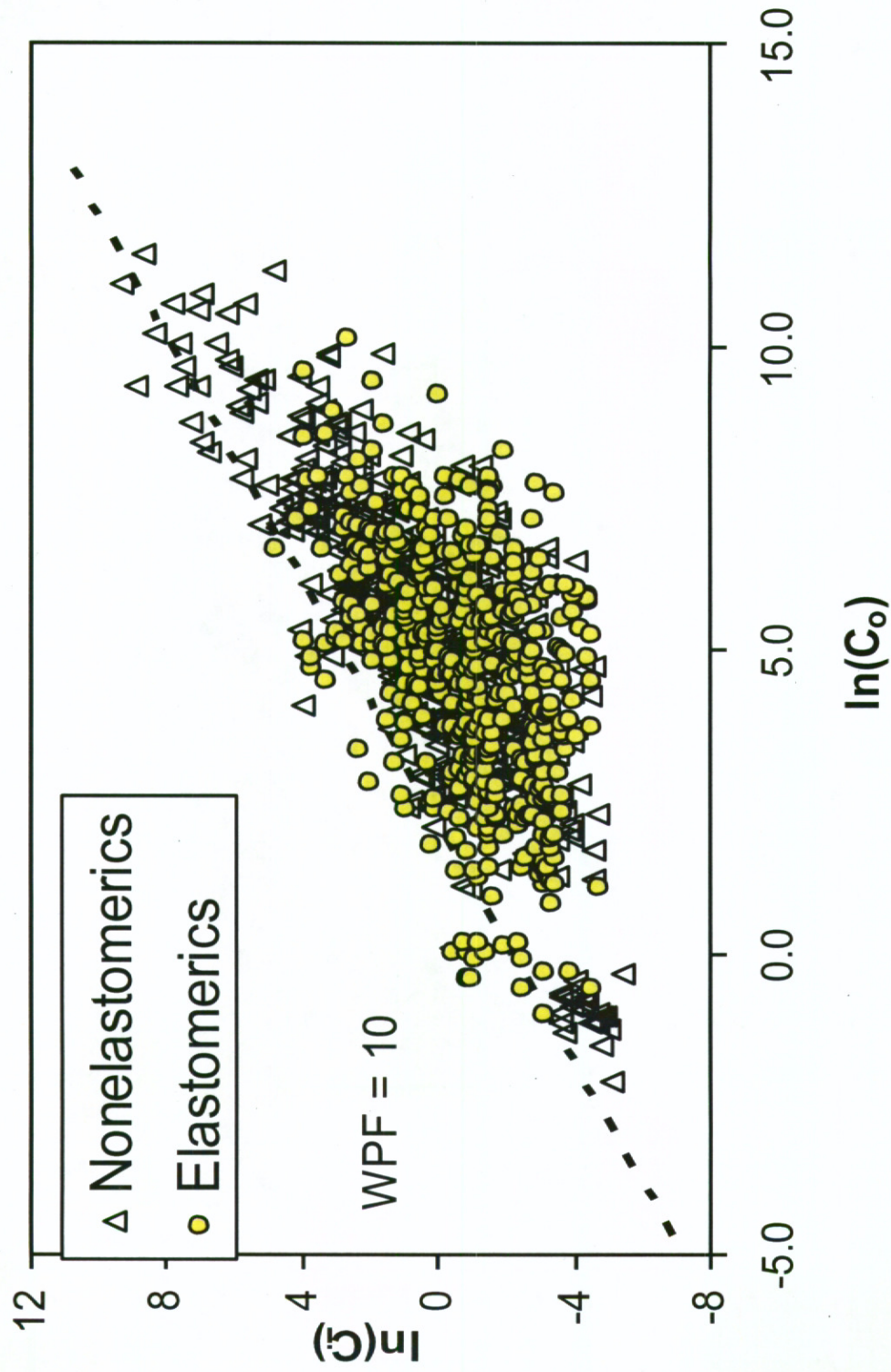
- NIOSH mentioned articles by Coffey *et al.* and Lawrence *et al.* that indicate there are well fitting and poor fitting filtering facepiece respirators on the market
  - Using these studies 3M tested well fitting respirators (6) and a poor fitting respirator identified in these articles
  - The proposed fit test is incapable of differentiating between them (eliminates everything)
  - Based on user feedback, there are well fitting respirators on the market
- Together with the NIOSH benchmark data, this demonstrates there will be no filtering facepiece respirators and very few elastomeric respirators approved
- **Therefore, this rule should not proceed in its present form**



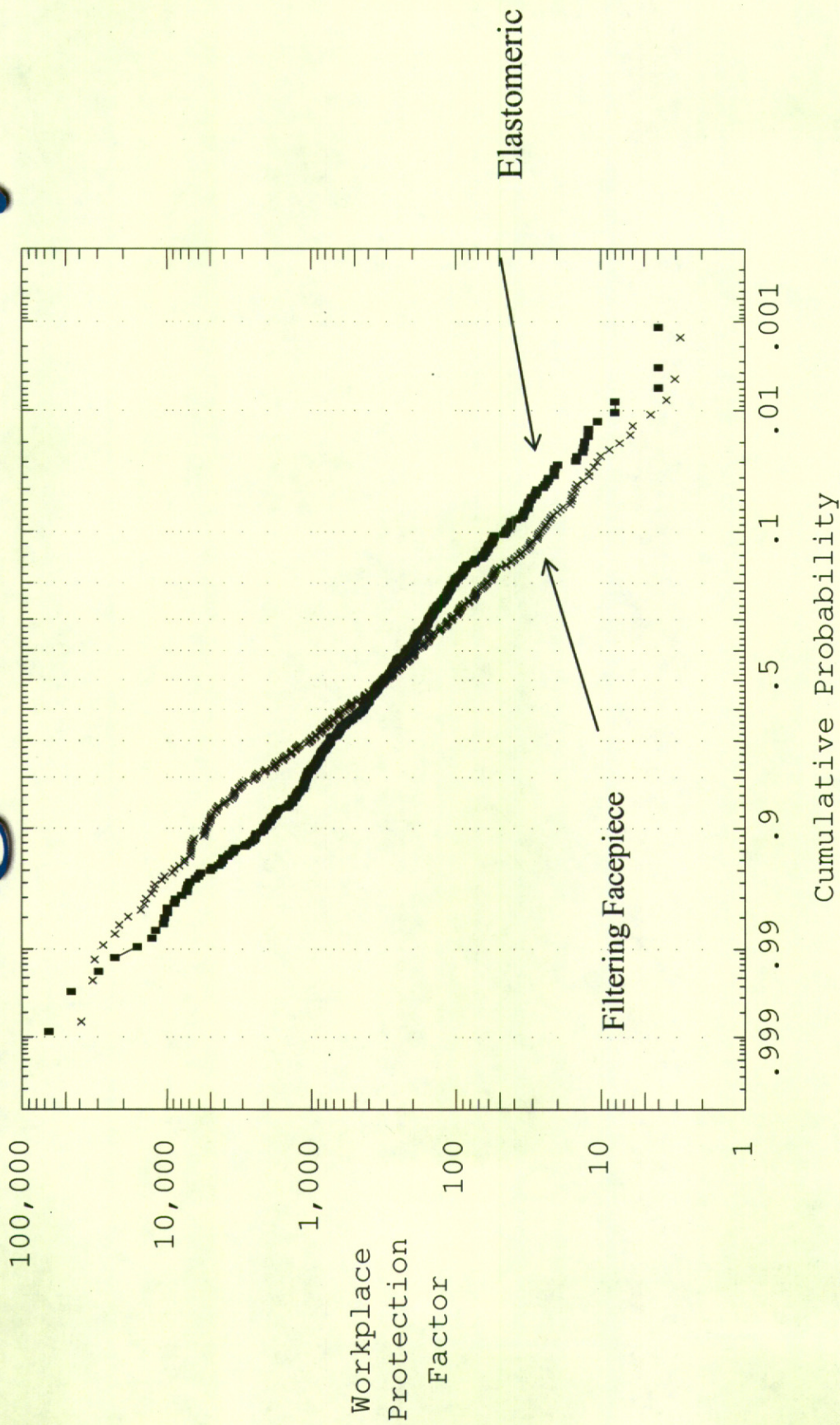
# Additional Experience

- AJIC 36(4):298-300 2008
  - QLFT on 1271 health care workers
  - All males fitted, all but 6 females fitted with FFP
  - First FFP choice fitted 95.1% of males, 85.4% females
  - NIOSH study indicated good fitting characteristics
    - Lawrence et al., *J. Occup. Environ Health & Hyg* 3:465-474 2006
  - WPF results indicate good performance in workplace
  - This respirator model did not pass the benchmark test.
  - When we tested according to the proposal, the model did not pass
- **The proposal does not reflect real world experience**

# WPF Results: FFP & Elastomeric Half-Facepiece



# WPF Log Probability



# Issues with Current Proposal: Individual Fit Testing

- Regardless of how products are designed and tested, it will not ensure respirators fit “out of the box”
  - No fit testing means they have no program
  - No training – donning, user seal checks
  - No supervision –facial hair and other issues that interfere with fit
- UK study on elastomeric respirators tested for TIL (EN140)
  - *Ann Occup. Hyg.* 43(8):513-517 (1999)
  - No fit testing performed
  - 69% of 211 subjects had respirators that did not fit
- To provide effective protection, individual fit testing will still need to be performed within the context of a complete respirator program

# Issues with Current Proposal: Panel-to-Panel Variability

- The panel make-up would become more important than the respirator fit characteristics
- Therefore the test method needs to overcome this issue
  - Dramatically increase panel size (minimum of 105 subjects)
  - Reduce variability in the panel cells
    - “Standardized” faces, test heads for each cell
  - Change the pass/fail criteria of the test
    - Passing fit factor, pass rate
- NIOSH audits would be another challenge
  - No change to product, no change from QA plan, but fails test

# Issues with Current Proposal: Implementation

- If no FFPs approved, everyone would need to move to the remaining elastomeric respirators
- According to NCEM, 413 FFPs approved
  - The time needed to redesign, test and certify with fit test results for 413 existing models will be ???
  - Assuming fit tests only
  - $413 \times 35 \times 1-3 = 14,455 - 43,365$  fit tests
  - $0.25$  hours/fit test =  $\sim 3614 - 10,841$  hrs ( $1355 \times 8$  hr days, max)

# Issues with Current Proposal:

## Financial Impacts

- Due to the huge variability in panel results, significant chance of failure with any given respirator model
- As respirators are designed to pass the proposed panels, the standard becomes design focused instead of performance
  - Re-design and improvements would be discouraged, so fewer models from one manufacturer
  - Less diversity between manufacturers, “hard to fit” person falls out (eg. small faces)

# Issues with Current Proposal: User Instructions

- The two dimension facial measurements from the panel do not predict fit
- Providing this guidance would not assure fit, but people would most likely think that it would
- The proposed rule requires respirator manufacturers to specify the face size or sizes the respirator is intended to fit in the user instructions.
  - For respirator selection, employers would need to:
    - acquire calipers,
    - receive training on their use,
    - measure facial dimensions of each wearer, and
    - acquire respirators for those face sizes.
    - fit test each wearer in those respirators.
  - Fit testing becomes cumbersome and time consuming



# 3M Technical Assessment

- 3M supports a fit performance requirement in certification evaluation
- NIOSH's proposed change to 42 CFR 84 with a "TIL" test for half-facepiece respirators has significant gaps and inconsistencies
- Based on 3M's experience and research, the proposed rule will not accomplish NIOSH's stated objectives
  - Remove poor-fitting respirators from the market while approving well-fitting respirators
  - Improve respiratory protection of workers not in complete respiratory protection programs

# 3M Recommended Modifications to NIOSH TIL Rule

- Replace the term “TIL” with “face fit factor” or “fit factor”
- Remove any language that implies that the fit of a respirator on an individual can be effectively predicted based on face length and width – the selection of respirators in the workplace must include fit testing
- Remove the “one pass per cell” requirement
  - Little or no predictive capability, especially for NIOSH grid cells with two subjects
- 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

## Well-fitting and poor-fitting respirators

- Stated objective of modified rule is to remove poor-fitting half-facepiece respirators from the market
- A NIOSH study (Lawrence *et al.*, JOEH, 2006) presented fit test results of surgical masks, filtering facepieces and half-face elastomeric facepieces
- In comments supplied to the docket 3M and ISEA have evaluated well-fitting respirators identified in Lawrence *et al* (high probability of passing workplace fit test)
- 3M has evaluated a poor-fitting respirator identified in Lawrence *et al* (low probability of passing workplace fit test)

# What is a well-fitting respirator?

- For an individual respirator user a well-fitting respirator is simply a respirator that fits them, i.e. they pass a fit test
- For an employer, a well-fitting respirator is a respirator that will fit some workers as determined with fit testing
  - In some cases a well-fitting respirator may not fit any workers at worksite, but this should be unlikely

# Some real-world experiences with well-fitting respirators

Company	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%	

# What is a poor-fitting respirator?

- For an employer, a poor-fitting respirator is a respirator that fits significantly fewer workers than expected
- Poor fitting respirators do exist
  - Lawrence *et al* identified a number of filtering facepiece respirators which had a “no pass” result for 25-member test panels

# How can well-fitting and poor-fitting respirators be identified?

- NIOSH's proposed TIL rule attempts to identify poor-fitting respirators that should not be approved
  - 35-member panel based on the 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  $\geq 100$ )
  - At least one subject in each cell of the bivariate grid must pass a fit test

# Additional 3M studies

- 3M is continuing to evaluate NIOSH's proposed TIL rule during the extended comment period
- The fit performance of a poor-fitting respirator was compared to a well-fitting respirator
  - One of the six filtering facepieces with a “no pass” result in Lawrence *et al* was evaluated with three 35-member panels per NIOSH's procedure RCT-APR-STP-0068
  - Poor-fitting respirator was designated model H
  - The well-fitting respirator was 3M filtering facepiece model A (see previous 3M comments to NIOSH docket 0137)



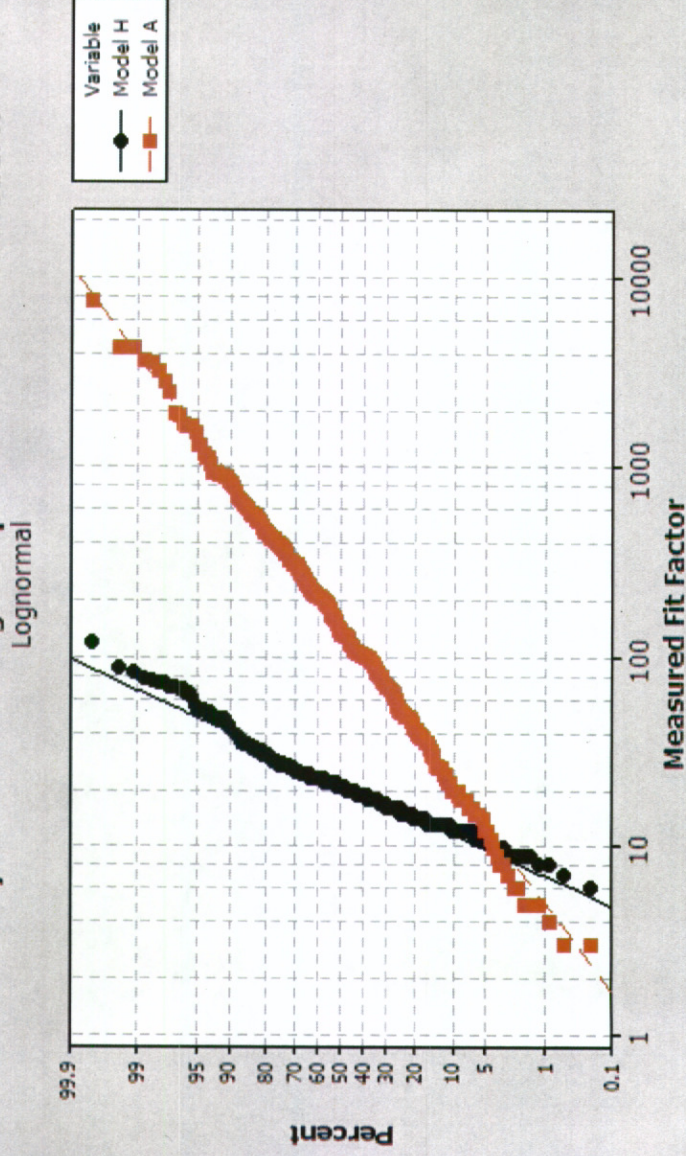
# **Analysis of Well-fitting and Poor-fitting Filtering Facepiece Respirators**

- Three 35-member panels of fit test subjects were assembled for each product to be tested
- Each 35-member panel complied with requirements in NIOSH Procedure RCT-APR-STP-0068
- Each subject was tested three times with each sample

# Fit Test Results of Model A and H

- Model A – 79 out of 105 test subjects (75%) had at least one fit test with fit factor  $\geq 100$
- Model H – 1 out of 105 test subjects (1%) had at least one fit test with a fit factor  $\geq 100$

Probability Plot of Filtering Facepiece Model A and Model H



# 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% (0 out of 35) to 100% (35 out of 35)
  - A subject passes if at least one of three fit tests has a fit factor  $\geq$  minimum fit factor
- “One pass per cell” was evaluated as part of the written comments submitted previously
  - This presentation will not include that analysis

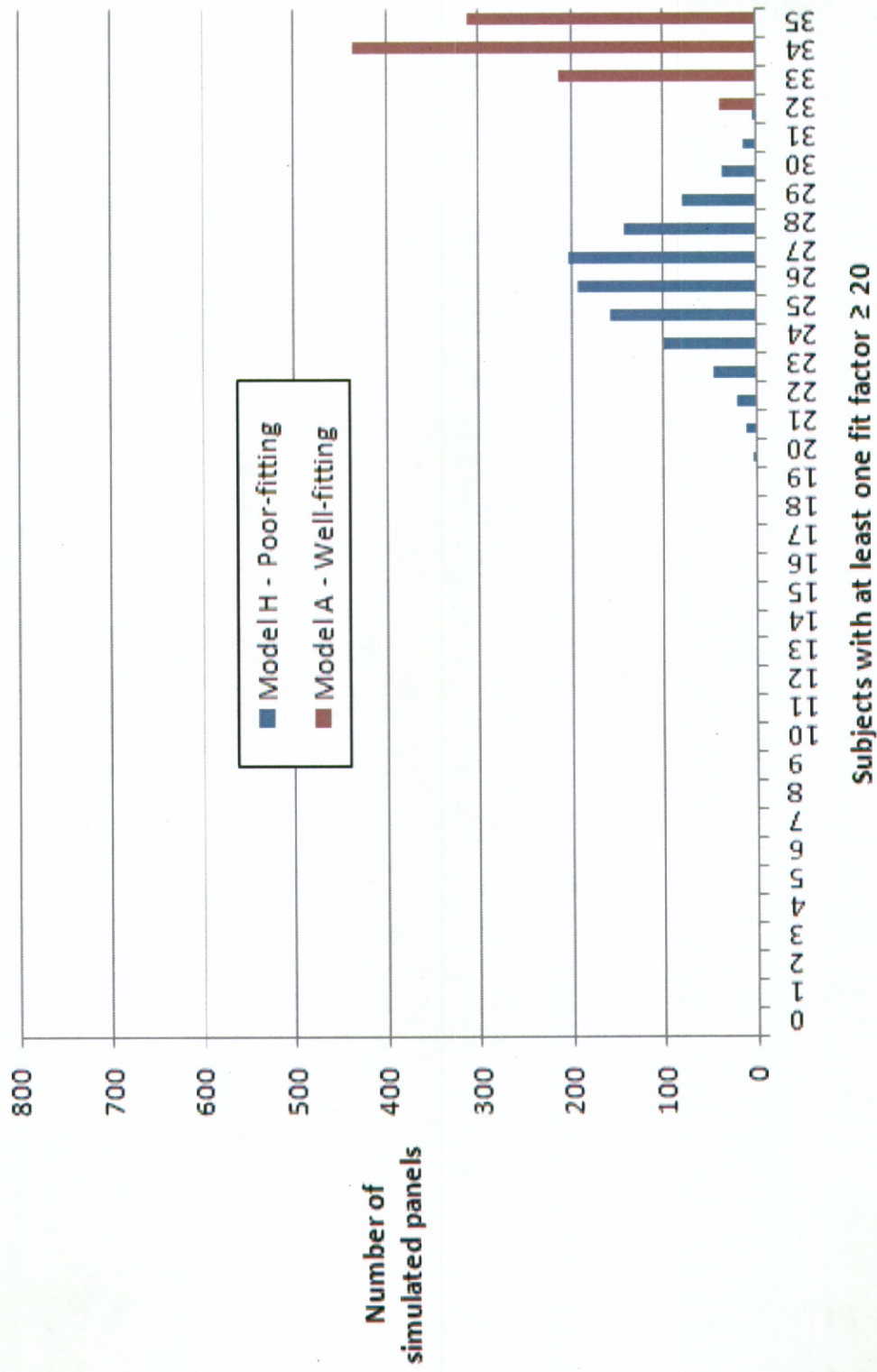
# Minimum fit factor of 10

Pass Fit Factor  $\geq 10$



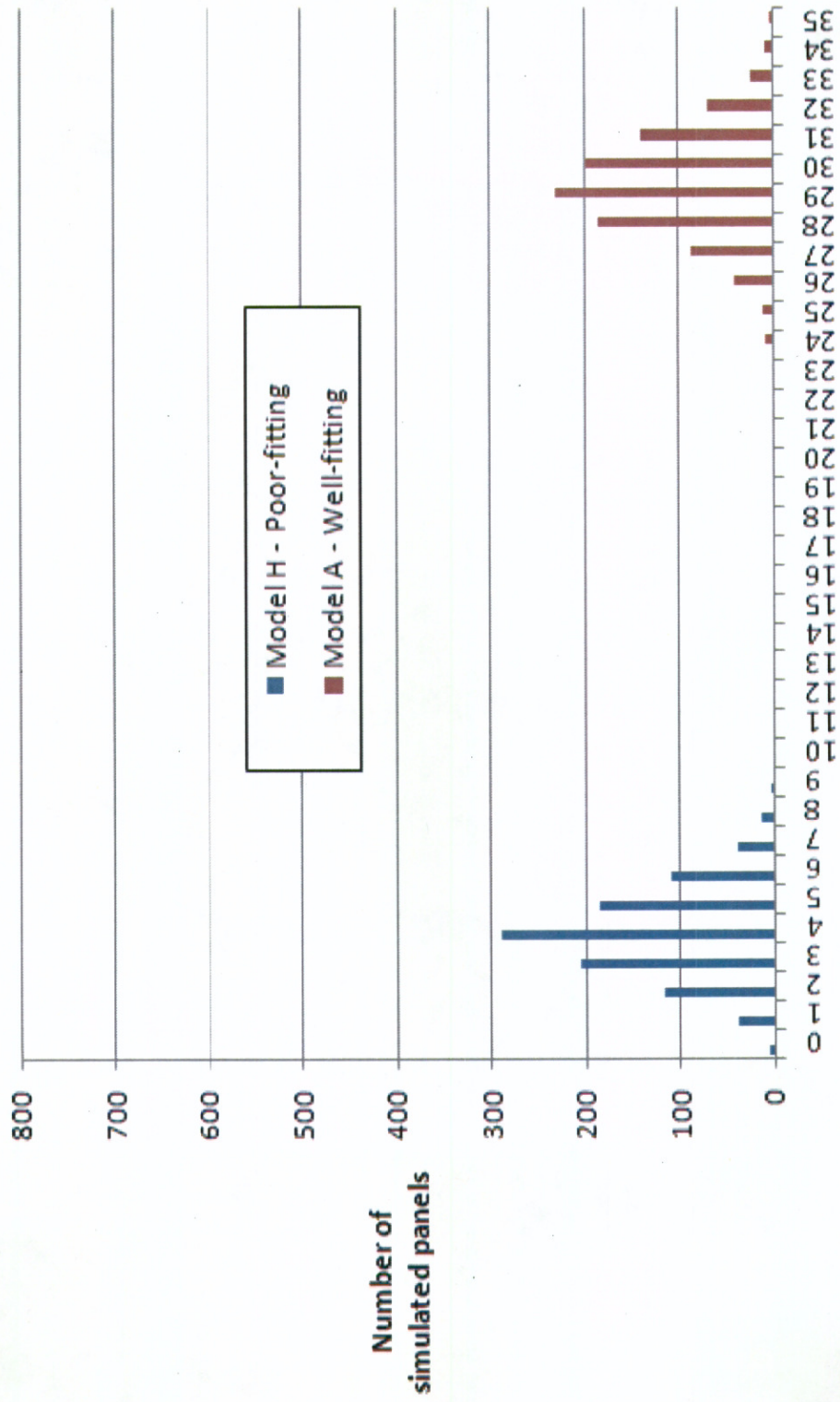
# Minimum fit factor of 20

Pass Fit Factor  $\geq 20$



# Minimum fit factor of 50

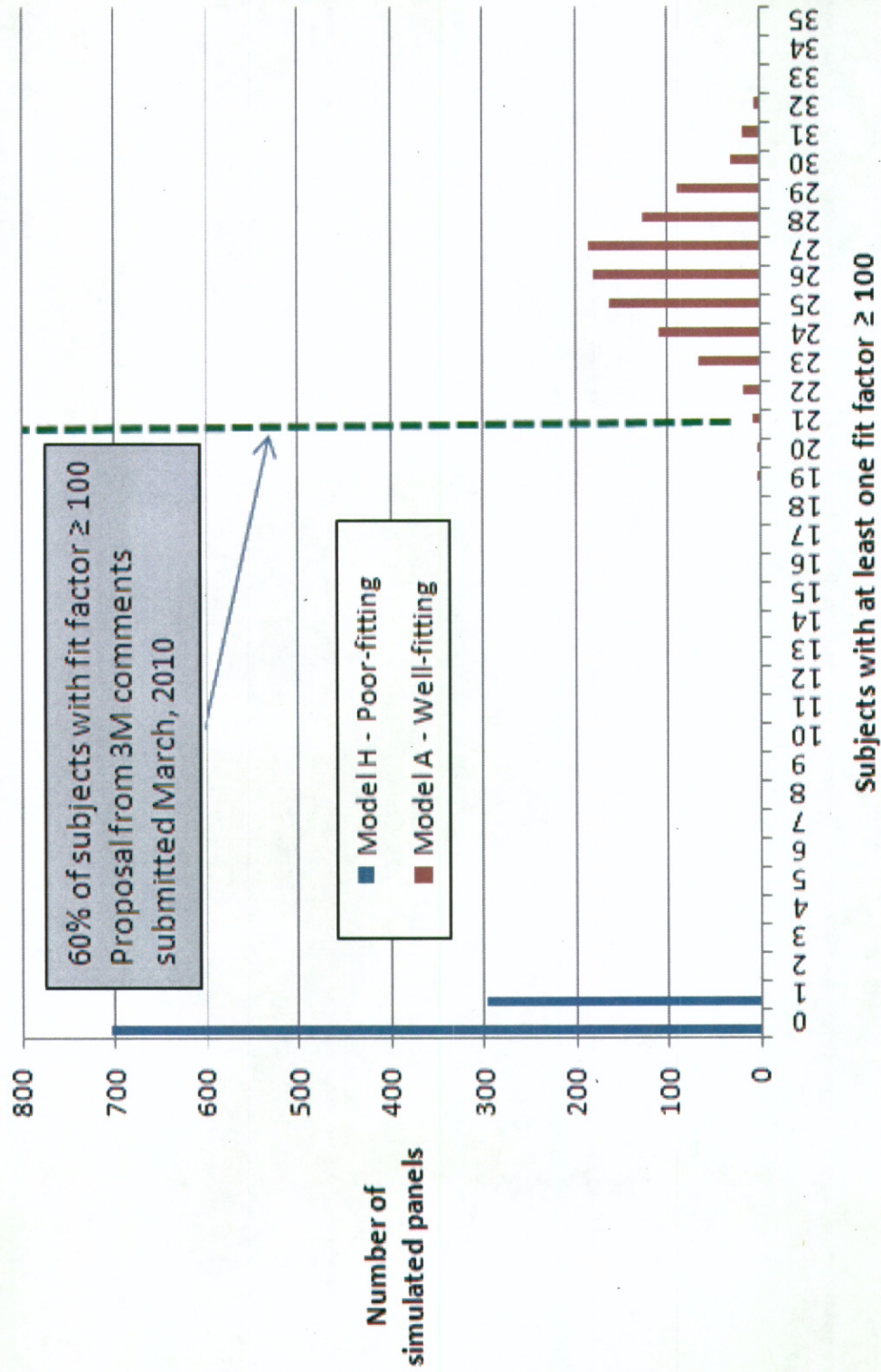
Pass Fit Factor  $\geq 50$



Subjects with at least one fit factor  $\geq 50$

# Minimum fit factor of 100

## Pass Fit Factor $\geq 100$





# Conclusions from evaluation of possible approval criteria

- Fit factor of 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

## 3M Supports a Fit Requirement as Part of Certification

- Unfortunately, the current NIOSH TIL proposal will remove well fitting devices from general industry and healthcare workplaces
- In order to meet the proposed test method, the forced redesigns of respirators would:
  - Reduce diversity among available designs
  - Reduce or eliminate respirators for “hard to fit” people
  - Eliminate respirators that fit people outside the bivariate grid

## 3M Recommendation

- Replace %TIL maximum with minimum fit factor of 50 and a 50% pass rate
- Remove “one pass per cell” requirement
- Change the UI requirement:
  - 84.175 (h) User instructions for half-mask respirators shall specify information or procedures necessary to identify the intended population or *sub-population* of users.