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From:	cecolton@mmm.com
Sent:	Tuesday, September 28, 2010 4:09 PM
To:	NIOSH Docket Office (CDC)
Subject:	HHS RIN:0920-AA33 42 CFR part 84
Attachments:	Written Comments to proposed NIOSH TIL rule.28sep10.pdf

We would like to submit the attached comments to docket 137.

Thanks,

(See attached file: Written Comments to proposed NIOSH TIL rule.28sep10.pdf)

3M

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September 28, 2010

NIOSH Docket Officer
NIOSH Docket #137,
Robert A. Taft Laboratories, MS–C34
4676 Columbia Parkway
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NIOCINDOCKET@CDC.GOV.

RE: RIN: 0920–AA33; Total Inward Leakage Requirements for Respirators: Reopening of Comment Period

3M Company Comments

Dear Docket Officer:

3M Company (**3M**), through its Occupational Health and Environmental Safety (OH&ES) Division, is a major manufacturer and supplier of respiratory protective devices throughout the world. 3M has invented, developed, manufactured and sold National Institute for Occupational Safety and Health (NIOSH) approved respirators since 1972. 3M employs experienced engineers and technical professionals for the development of respirators. Our sales people have trained and fit tested hundreds of thousands of respirator wearers throughout the world. Our technical staff has performed research on the performance of respirators and their uses, presented and published these data in numerous forums and assisted customers with the development and administration of effective respirator programs. Much of this research has been in the area of fit testing respirators resulting in the development of several new qualitative and quantitative fit test methods. In sum, we have substantial experience in all phases and applications of respiratory protection. We are pleased to provide NIOSH with our comments on the proposed rule for Total Inward Leakage Requirements, dated October 30, 2009, and related documents.

3M has always been an advocate and innovative leader in advancing the importance of fit. 3M has used quantitative fit testing for evaluating fit of half facepiece respirators, including filtering facepiece respirators, for more than 25 years. While in principle we support the idea of a fit requirement for half facepiece respirators, NIOSH's proposed rule to evaluate respirator fit as part of the certification process to address the concern that 40% of employers do not conduct fit testing is seriously flawed and not supported by 3M. 3M offers the following comments and recommendations regarding the TIL Proposed Rule and RCT-APR-STP-0068 Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators. These comments and suggestions are included with this letter.

3M appreciates the opportunity to supplement our comments and knowledge to NIOSH Docket #137.

Sincerely,

Robert A. Weber
Manager, Regulatory Affairs, Quality Assurance and Technical Service
3M Occupational Health & Environmental Safety Division

3M Comments on 42 CFR Part 84 Docket Number 137, NIOSH Proposed Rule on Total Inward Leakage Requirements for Respirators [74 *FR* 56141]

The following comments are in response to the proposed rule published in the *Federal Register* of October 30, 2009, on Total Inward Leakage (TIL) Requirements for Respirators and documents placed in NIOSH Docket #137 and additional research performed since October 30, 2009. The documents include:

- RCT-APR-STP-0068 Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators
- Comments submitted to NIOSH Dockets #036 and #137

NIOSH indicated at the public meeting of December 3, 2009, that the information in both Dockets #036 and #137 would create the record for this proposed rule making. Therefore, the following comments should be viewed as an addition to 3M's comments previously submitted to Docket #137 on March 29, 2010.

Premise of Rule

The National Institute for Occupational Health and Safety (NIOSH) states this rule is needed because they estimate that 40% of employers do not conduct fit testing and that self-employed workers are less likely to be fit tested.(1) NIOSH believes that the proposed rule will result in better fitting respirators thereby protecting these workers that are not fit tested. Even if the proposed rule could result in better fitting respirators, it will do nothing to increase the number of employers doing fit testing.

The data discussed within these and in earlier 3M comments (dated March 29, 2010) indicate that this rule will not result in better fitting respirators. In its present form, the proposed rule will eliminate most respirator models from the market including both poor- and well-fitting respirators. Even if this test were improved, it is not possible that one respirator will fit the myriad of facial profiles in the U.S. workforce. As a result, employers would still need to purchase and provide multiple respirator models to their employees in an attempt to obtain an adequate fit for its population of workers – just as employers must do today under the present rule.

NIOSH indicates in the proposed rule that certification to a fit requirement will not substitute for fit testing, respirator training, and other components of a respirator program; 3M adamantly agrees with this premise. This rule will not increase the number of respiratory protection programs and fit testing. In fact, the opposite is likely to occur because both employers and respirator users are likely to believe that this rule will certify that respirator wearers will get an adequate fit without fit testing. If there is a desire to address the problem of so few employers doing fit testing, then NIOSH must use a different approach.

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Executive Summary

3M does not support the rule as proposed in the *Federal Register, volume 74, no. 209, NIOSH Proposed Rule on Total Inward Leakage Requirements for Respirators.* This proposal does not address the issue that NIOSH has repeatedly identified as an important reason for the new fit test requirements, namely that "over 50 percent of workers and other respirator users do not have the benefit of individual fit testing, let alone a complete respiratory protection program." (1)

NIOSH takes the position that if the standard eliminated only the poor-fitting respirators from being certified, those employers that continue to violate the law would at least have respirators that fit their employees. As described in 3M's earlier comments, the proposed test procedure suffers from an acute lack of reproducibility, repeatability, and overall lack of robustness. So instead of eliminating only poor-fitting respirators, the proposed rule will also eliminate a high percentage of well-fitting respirators.

The proposed test procedure is not capable of assessing the ability of a respirator to fit a broad range of respirator wearers. Even if passing with at least one individual in every cell, the uncertainty of the predicted pass rate for users with facial sizes in any of the cells with two subjects is unacceptably large. The method proposed by NIOSH is not capable of determining performance within a cell with adequate precision and will not allow one to predict the performance of a model on a larger population of individuals that fall within a cell in which only two subjects were tested.

NIOSH's economic impact analysis is severely flawed. This is due to the incorrect conclusion as to the number respirator models adversely affected, poor assessment of the annualized sales of products affected, lack of experience with product development costs, and an incomplete consideration of the costs to end-users for re-selection of respirators. 3M estimates that the total economic impact of the proposed rule is greater than $1 billion.

Workplace fit test pass rates for currently available half-facepiece respirators demonstrate that there are a number of respirators with current technology that meet the needs of respirator users. Many of these respirators fit a high percentage of wearers. The standard as currently proposed would eliminate both well- and poor-fitting respirators, and thus does not provide a robust standard against which to develop new products and technologies.

As a result, NIOSH should withdraw the proposed rule. NIOSH should then evaluate the test procedure and conduct a thorough economic analysis of the proposed rule's impact.

Support

1. 3M and the International Safety Equipment Association (ISEA) are the only ones that have presented data of respirators tested to the proposed test procedure. If NIOSH had done due diligence in testing respirators to the rule that was actually proposed, 3M believes it would have discovered many of the shortcomings of this proposed rule prior to publication. Based on 3M and ISEA data:
   - The number of products that would be impacted by this rule has been severely underestimated.
   - The proposed procedure cannot discriminate between well- and poor-fitting respirators. This is primarily due to the large amount of panel-to-panel variability (noise) in the method.
   - The substantial amount of test variability makes it impossible for a respirator manufacturer to use pre-submission testing to determine whether a respirator will pass at NIOSH. While more testing was necessary to understand the variability of the rule that was actually proposed, interpreting the existing NIOSH benchmark testing made available to 3M indicates there is poor reproducibility.
   - The proposed test does not correlate with fit results in the field as experienced by users of existing products or NIOSH testing previously published in journal articles.[2,3] Field experience and these published studies identify well-fitting respirators that do not pass the proposed rule.
2. This proposal ignores the importance of training in achieving a good fit. A well-fitting respirator donned incorrectly will not provide protection. The connection between fit testing and training has been identified by many experts.[4]
3. Users will not be able to use face size information proposed to be required in the user instructions to save time in fit testing because the facial measurements are not correlated to fit. In addition, the face size data is next to impossible for users to obtain accurately and economically.
4. The only way to ensure a person has a respirator that fits is to perform individual fit testing as required by law. Fit testing as part of the respirator certification process will not ensure any worker will have an adequate fit or even that a worker will be provided any protection from a respirator certified under the proposed rule.

Economic Impact

3M believes NIOSH has drastically understated the economic impact of this proposed rule. NIOSH estimated that the cost of testing "would range from $8,500 to $12,000 per respiratory approval" and there would be "total testing and certification costs to manufacturers of up to $3.1 million" *(p. 56147)*.[1]

This figure radically underestimates the cost to manufacturers for each development program and it understates the likely number of re-designs that would be required. This could have been avoided if respirators had been tested to the proposed rule prior to creating these estimates rather than attempting to extrapolate information from the benchmark testing. 3M and ISEA data illustrate the error of the estimate.

While NIOSH states that "30 percent of this class [filtering facepiece and elastomeric half-facepiece respirators] have facepiece seals that did not perform adequately to achieve a fit factor of 100" *(p. 56142)*,[1] this does not represent the facts. NIOSH's own data presented at the June 2007 NIOSH/NPPTL Total Inward Leakage Public Meeting indicate that 99-100% of filtering facepieces and 70% of elastomeric facepieces would not meet the criterion of a fit factor of 100 on 75% of the 35-subject panel. The benchmark data were not collected according to the proposed test procedure and NIOSH failed to re-assess the data in reaching their conclusions. Further, NIOSH did not supply any information or context to the record. The discrepancy between NIOSH's estimate, the information presented at the public meeting, review of each respirator manufacturer's own benchmark data supplied by NIOSH, and the lack of testing performed by NIOSH according to the proposed rule motivated the respirator manufacturers to evaluate the proposed rule testing procedure.

As a result, 3M and the ISEA tested various respirators according to the proposed test procedure. This testing confirmed that a very large percentage of half-facepiece respirators would not meet the proposed test criteria of:

- Fit factor of 100 to pass
- 75% of the 35 person NIOSH bivariate panel passing
- One pass in each cell of the panel.

In other words, 3M data support the information presented by members of the National Personal Protective Technology Laboratory of NIOSH at the June 2007 Public Meeting and do not support the estimate published in the proposed rule. NIOSH has greatly underestimated the number of respirators requiring redesign and the resulting economic impact. Using the 3M and ISEA test results, one can more accurately estimate the economic impact. The NIOSH economic impact is in error for four reasons:

1. The number of respirator models estimated to be impacted is wrong.
2. Frost and Sullivan did not include the healthcare market or the market for NIOSH respirators outside the United States (US).[5]
3. NIOSH did not use accurate product development costs.
4. NIOSH did not include the impact on respirator users (unless NIOSH believed all users would quit performing fit testing and there would be no effect).

3M estimated the total economic impact by including the:

- annualized sales impact to respirator manufacturers due to existing respirator models that will not be approved under the proposed standard
- product development costs to replace the models that must be redesigned, and
- costs to the end users to follow the proposed NIOSH scheme for selecting a respirator to fit test.

The Frost and Sullivan report used by NIOSH only looked at the Canada and US industrial market. NIOSH-approved respirators sold into healthcare markets and industrial markets sold outside the US and Canada were excluded by NIOSH. Using a

more recent Frost and Sullivan report [5] and HPIS[6] data to estimate the US healthcare market, along with an estimate for NIOSH-approved respirators sold outside the US and Canada, the following economic impact analysis is more appropriate.

Annualized Sales Impact

The baseline equation for calculating the impact to the annualized sales of half-mask respirators is:

(1) (A)(B) + (C)(D) = impact to annualized sales

In this equation:

A = percentage of currently approved filtering facepieces (FFP) that will not pass the proposed rule

B = size of market of NIOSH-approved FFP

C = percentage of currently approved elastomerics that will not pass the proposed rule

D = size of market of NIOSH-approved elastomerics

Based on NIOSH's benchmark data, 3M estimates that A should be 90% and C should be 70%. Using the above data references for market size along with an estimate for the international market of 30% of the US and Canada market, we estimate the global impact to the annualized sales of NIOSH-approved half-mask respirators as follows:

[(0.90)($386.1million) + (0.70)($231.0 million)] (1+ 0.3) = **$661.9 million**

Product Development Costs

In order to calculate the costs to respirator manufacturers to re-design existing products to meet the proposed rule, the following estimated product development costs will be incurred:

(2) (E)[(F)(G)(H) + I] = cumulative cost of product re-designs

In this equation:

E = number of products that will need to be re-designed

F = cost of average employee per year

G = length of time for an average development project

H = average number of employees per development project

I = capital and supply costs for an average development project

NIOSH estimated that there would be up to 500 applications in the first two years of implementation of the proposed rule.[1] While NIOSH does not make it clear how these 500 applications would be split between FFP and elastomerics, an average of those applications for renewed approval under the proposed rule, approximately (90% + 70%)/2 = 80% of them will fail. As previously stated, the substantial amount of test

variability makes it impossible for a respirator manufacturer to use pre-submission testing to determine whether a respirator will pass at NIOSH. Therefore, (0.80)(500) = 400. So, 400 models will require re-design. Based on 40 years of respirator development, 3M estimates a redesign cost of $1.5 million (F,G,H,I combined) per model which yields an economic impact of **$600 million**.

End-user Selection Costs

As the third component that should be considered in the economic impact of the proposed rule, 3M estimates costs that would likely be incurred by the employers that would be forced to move to the few respirators that would likely pass the proposed rule or the new models as they are developed. This requires that employers will have to select new respirators resulting in the associated costs:

(5) (J)(K)0.25 hr(L) = cost to users and choosers for re-training

In this equation:

J = percentage of users that would be required to get new respirators
K = number of end-users of these products today
0.25 hr = estimate of time spent to find a new model for an employee to be fit tested with
L = estimated cost per end-user (in downtime and training equipment)

As mentioned above, an estimated 80% of respirator models will require re-design, so it is assumed that 80% of end-users will be impacted. This number represents the average of FFP and elastomeric half facepiece respirators that would likely fail the currently proposed NIOSH rule. The number of end-users (K) was defined by NIOSH[(1)] as two million.

Based on over years 30 years of measuring faces, 3M optimistically estimates that 15 minutes would be needed per employee to find the new respirator that is best for the employee based on the respirator manufacturer information provided in the user instructions.

The employee cost in wearer time off the job and the cost of the person required to spend additional time to measure and assign the facepiece to the wearer can conservatively be assumed as $75/hr burden rate and for two employees (measurer and respirator user) this is $150/ hr.

(0.80)(2 million respirator wearers)(0.25 hr)($150)/hr = **$60 million**

There is another cost related to selecting respirators where one respirator does not cover the entire panel. The employer will have to buy the necessary equipment and train people to use it.

(6) $$(M)(N)(O) + (P)(M)(N) = \text{cost for face measurer}$$

M = number of establishments required to do fit testing for respirators with sizes
N = employees trained to measure faces/establishments
O = Cost of training to learn to measure faces per person
P = Cost of calipers

The number of establishments required to do fit testing and using air purifying respirators is 264,400 based on the most recently collected data (BLS/NIOSH 2001 survey of Respirator Usage in Private Sector Firms, 2001). This includes half and full facepiece negative pressure air purifying respirators. Because it is not known how many facilities use half facepiece respirators, 3M assumes it is 50 percent. This is conservative because half facepiece respirators are more widely used than full facepiece respirators. This would make 132,200 establishments. In addition, it was assumed one person per establishment and a cost of $1000 per caliper set. It took 3M personnel one and one-half day to be trained to take the face measurements and it would cost $500 for this training. This is very conservative as there is no travel nor does it include the cost of the employee away from work. This survey also did not include healthcare.

This cost is (132,200)(1)($500) + ($1000)(132,200)(1) = **$198.1 million**

This cost will be borne by both respirator manufacturers and the respirator users and choosers. This later group is predominantly small business. The extra amount of work and cost to employers will have a negative outcome in that employers will be less likely to do fit testing prior to respirator use.

As shown, the economic impact of the proposed rule to manufacturers and customers could easily exceed $1 billion. Despite this, 3M would consider such costs tenable if they ensured increased levels of protection for workers. However, the proposed rule in its current state provides no benefit to workers yet will result in massive material, financial, and market impact. Consequently, the proposed NIOSH rule is unacceptable.

Test Procedure

RCT-APR-STP-0068 Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators is the proposed test procedure for determining whether the respirator meets the 42 CFR 84 requirement that "Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes."

To do this, a respirator of a single size or multiple sizes designed to fit facial sizes over the entire population range will be tested in the following manner:

1. 35 test subjects meeting the NIOSH Bivariate Test Panel will be selected.

2. All test subjects shall also have facial characteristics which result in being included within the Principal Components Analysis Panel, which excludes extreme facial features.

3. User Instructions for size selection shall be followed to determine consistency with NIOSH Panel cells for facial measurements.

4. Each test subject will be permitted time to make the appropriate adjustments to the facepiece until they are satisfied that they are wearing the facepiece in compliance with the manufacturer's User Instructions.

5. Each test subject shall perform a user seal check in accordance with the manufacturer's User's Instructions. Any test subject not being able to successfully perform a user seal check shall be allowed to continue the test, but the fact that a seal check could not be performed shall be noted.

6. Any test subject not receiving a pass after three tests is considered to have failed. If the subject fails and the respirator being tested has more than one size that covers the range of cells being used then the test subject can be retested using another size and the second series of tests shall be used to determine pass/fail.

7. A TIL value of 1.0 percent or less shall be achieved by at least 26 out of 35 (74%) test subjects for a respirator of a single size or of multiple sizes, designed to fit the general population of respirator users.

8. At least one test subject from each cell of the panel appropriate for the respirator being tested must obtain a passing result.

Discussion of test procedure

1. The proposed rule has problems discerning differences between well-fitting and poor-fitting respirator models. A major part of this problem is caused by variability between and within test subjects and has little to do with whether the respirator is well- or poor-fitting. It is naïve to think that with all of the human facial variability that exists, a panel size of 35 people can predict whether a respirator is well-fitting when compared to the US worker population. NIOSH questions at public meetings indicate they do not understand this point. Large between- and within-subject variability means a respirator that passes a manufacturer's pre-submission testing has a significant risk of failing the next time tested (i.e. at NIOSH) due primarily to the variability in the people making up each cell. Unfortunately, in this case failure will not mean the respirator is poor-fitting. Failure in cells with small numbers of people does not indicate that those respirators do not fit people with those facial dimensions. Based on 3M testing and evaluation of the effect of different panels, it would require a significantly larger panel to make this test robust enough for a certification standard. If the appropriate panel size is unpalatable,

then the testing criteria need to be modified in order to mitigate test method variability and more effectively discriminate between well- and poor-fitting respirators.

2. It appears that NIOSH believes that by ensuring that all members of the bivariate test panel are included within the PCA Panel, the variability of the test will be reduced by excluding people with extreme facial features. 3M testing used all of the PCA required measurements on potential panel subjects. For the studies described in these and previous comments, 3M established a test subject pool for fit testing of 323 people. Out of those 323 people, only five people were excluded from being test subjects. This is such a small percentage of the pool, excluding these people from testing would not significantly reduce the panel to panel variability. Thus, 3M believes there is no good reason to evaluate all test personnel according to the PCA panel.

3. NIOSH has proposed that the "User instructions for half-mask respirators shall specify information necessary to identify the intended population of users."[1] Additionally, NIOSH indicates that "The **applicant shall specify** in the user instructions the **face size or sizes that the respirator is intended to fit [3M emphasis]**; pursuant to this requirement, one respirator may be intended to fit all face sizes."

3M currently provides information necessary for the intended population of users to determine if 3M half-facepiece respirators fit them, but this is not done by specifying the face size or sizes that the respirator is intended to fit. As pointed out by the Institute of Medicine (IOM), a relationship between these two facial dimensions (face length and width) and respirator fit has never been established.[7] The assumption NIOSH makes is that a subject from a particular cell of the NIOSH bivariate test panel is representative of all subjects from that cell. 3M has provided to Docket #036 data that demonstrate the extreme variability in fit factors that often exist among individuals in the same cell. This variability is a sizable limitation to using facial measurements to first select a respirator model as proposed by NIOSH. This occurs because two dimensions cannot predict a three dimensional characteristic, i.e., respirator fit. Because the two dimension facial measurements from the NIOSH bivariate test panel do not consistently correlate to fit, [7] using face sizes as predictors of fit is inappropriate.

4. The idea that the panel subject can determine if they are wearing the respirator in compliance with the user instructions is nonsensical. This should be determined by the NIOSH fit tester. According to the proposed test procedure, the panel members do not undergo the same training that a worker is required to undergo by OSHA. Without appropriate training, the panel member does not immediately know if they are wearing a respirator correctly if they have only read the instructions and have received no feedback. The OSHA requirements are more thorough than the NIOSH training required for test panel members. Therefore, it would not be unexpected that fit tests conducted in a laboratory environment without the benefit of a full OSHA respiratory protection program yield lower pass rates than is observed in workplaces where full respiratory protection programs are in place. This may be one factor contributing to the different conclusions drawn from field experience and anticipated to be obtained from the proposed NIOSH test procedure.

5. The OSHA standard requires successful completion of the user seal check before being fit tested. NIOSH does not require this. This increases the chance of failure by testing the respirator on a person that the respirator does not fit or where a person did not don the respirator correctly.

6. The test protocol allows a person three tries to achieve a fit factor of 100 before calling the trial a failure. When there is a model with more than one size of facepiece, the proposed test procedure allows the test subject to try only one other size and then to try three tests in order to achieve a fit factor of 100. This assumes that there is a correlation between the respirator size and the person's facial dimensions. This has not been shown to exist. Because there is no correlation between face size and fit, the subject should be allowed to try all sizes that exist. 3M has submitted data that shows a small-medium face may fit the large facepiece better than the small when the medium does not fit.

7. NIOSH is defining a well-fitting respirator as one that fits 74% of the population as described by the bivariate face panel. First, 74% as a minimum requirement appears to be arbitrary. Second, it incorrectly assumes that every workplace is made up of people spanning the entire range covered by the NIOSH bivariate panel. On the contrary, NIOSH evaluation of anthropometric data indicates that significant differences exist between some occupational groups.[8] So, a respirator that is well fitting for construction workers may not be well fitting for healthcare workers.

The recognized authority, Edwin C. Hyatt, stated, "The approved respirators that are commercially available generally provide a good face seal if the size and shape happen to fit the individual male or female wearer."[9] Having the broadest range of respiratory products that meet a well-designed set of performance requirements is the best means to optimally provide workers with shapes that fit them. If the test is not robust the test can result in excluding these products for wearers. Whether the wearer achieves a fit is determined by two things: their skill in donning (based on training and experience) and the results of fit testing.

Hyatt also concluded that based on qualitative fit testing for a one size respirator, that the poorest fitting half mask respirator would provide satisfactory fit on approximately 60% of all the men tested. The best fitting half-mask would fit approximately 80% of the men tested. He also indicated that "the important point is that purchasing three to four approved respirator models with different facepiece shapes and sizes will provide a satisfactory fit for approximately 99% of all men tested."[9] Today's workplace has greater diversity than in the Hyatt days and thus these results may be lower today.

The fit factor of 100 is also inappropriately chosen. NIOSH has indicated that this number was chosen to be equivalent to OSHA requirements. This is inaccurate because the test method is not one of the OSHA-accepted fit test protocols in 29 CFR 1910.134. The proposed test protocol does not require the same expertise or training that is required of wearers before they are fit tested as 29 CFR 1910.134. Furthermore,

OSHA does not require one respirator model to provide everyone a fit factor of 100. OSHA requires each individual to have a respirator that provides a fit factor of 100 regardless of the model. These are very different goals.

8. NIOSH also requires at least one test subject from each cell of the panel appropriate for the respirator being tested to obtain a passing result. NIOSH believes this is necessary to indicate that a respirator is well fitting. This assumes that the proposed test is able to predict if the respirator is well fitting. It is difficult to understand what conclusions could be drawn about the fit of a respirator model on facial sizes in one cell of the panel based on testing just two subjects. The uncertainty of the predicted pass rate for users with facial sizes in any of the cells with two subjects is very large. The method proposed by NIOSH is not capable of determining performance within a cell with adequate precision and will not allow one to predict the performance of a model on a larger population of individuals that fall within a cell in which only two subjects were tested.

Differentiating between well-fitting and poor-fitting respirators

As mentioned above, data presented at the June 2007 NIOSH/NPPTL Total Inward Leakage Public Meeting indicates that essentially all FFP currently approved under 42 CFR 84 would not be approved if the proposed standard is adopted as proposed. Included in these unapproved respirators would be filtering facepiece respirators that have high fit test pass rates in the workplace.

In the proposed rule, NIOSH indicates that its intent is to remove poor-fitting products from the market. To better understand the differentiation between well- and poor-fitting respirators, 3M conducted a study of a well-fitting FFP respirator and a poor-fitting filtering facepiece respirator to determine what required pass rate and minimum fit factor would be appropriate within the proposed test procedure.

3M selected a well-fitting filtering facepiece respirator from the five models included in a survey of large respirator users conducted in early 2010. Results of this survey, which were included in 3M's previously submitted written comments, highlighted five models of respirators that had workplace fit test pass rates ranging from 80% to 100%. Model A in the survey was selected based on the high level of acceptance in the market and the high fit test pass rate reported in the survey of large respirator users (90-95%). Model A is available in one size only.

The poor-fitting filtering facepiece respirator was selected from those tested by Lawrence, *et al.*[3] Fifteen models of filtering facepiece respirators were fit tested with three different fit test methods on panels of 25 subjects spanning a range of lip lengths and face lengths. The fit test methods were the Bitrex, saccharin, and TSI N95 Companion methods. 3M selected a poor-fitting respirator from the group of six FFP which had no passing fit tests (0 passes when tested on 25 subjects) with at least one of the fit test methods used. It was assumed that a properly designed NIOSH approval test should have a very low probability of accepting one of these respirator models. The

poor-fitting filtering facepiece respirator was selected from the six models based primarily on availability. 3M designated the poor-fitting respirator as Model H. Model H is available in one size only.

Numerous comments submitted to Dockets #036 and #137 by 3M and others have pointed out the high level of variability in fit test pass rates that will occur between different panels of test subjects. In order to develop a better understanding of the impact of minimum fit factor and required panel pass rate on the rate of acceptance/approval, 3M conducted fit evaluations on three complete 35-member panels meeting all requirements of the NIOSH test procedure (RCT-APR-STP-0068 Rev 1), including the requirement to be contained within the NIOSH PCA panel.

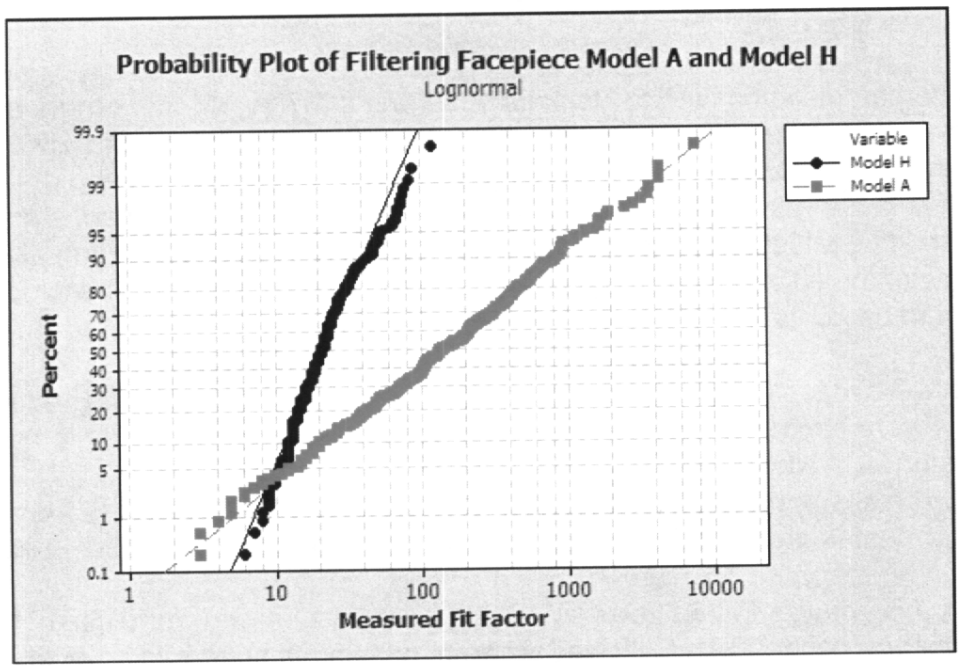
Respirators were fit tested per the NIOSH test procedure with the following exceptions:

1) Tests were conducted in a fit test chamber supplied with filtered air to provide a more uniform NaCl aerosol concentration.
2) Software developed by 3M was used to collect measured fit factors from the PortaCount instruments. This software allowed measured fit factors in excess of 200 to be recorded.
3) Each subject was tested three times with each respirator, regardless of their results on each test. This allowed different passing fit factors to be evaluated in the later analysis.
4) Subjects were allowed to sit during all exercises except the "bending at waist" exercise.

The procedure used by 3M to conduct the evaluations on respirators Model A and Model H is identical to the procedure described in ISEA's written comments to Docket #137 with the exception that ISEA required that subjects stand during all exercises in its studies.

Figure 1 shows all fit test data for the poor-fitting respirator (Model H) and the well-fitting respirator (Model A) on a lognormal probability plot. A total of 315 fit tests were conducted on each respirator model (3 panels × 35 subject per panel × 3 fit tests per subject). The figure shows a clear difference in performance between the two respirator models. While 314 tests out of 315 did not yield a fit factor greater than 100 for Model H, there were also 100 tests out of 315 that did not yield a fit factor greater than 100 for Model A. As noted above, it is not unexpected that fit tests conducted in a laboratory environment without the training provided as part of a full respiratory protection program yield lower pass rates than are observed in workplaces where full respiratory protection programs are in place. Specifically in a workplace setting, users can work with trainers/fit testers to understand how to best don and wear a particular respirator model. Individual fit factor values for all fit tests conducted on respirators Model A and Model H for this study are included in Appendix A.

Figure 1: Lognormal Probability Plot of Fit Test Data for Model A and Model H



The data set for each respirator was used to simulate the expected fraction of subjects in a 35-member panel based on the NIOSH bivariate panel that would pass various values of minimum fit factor. In the simulation process, 1000 35-subject panels were assembled randomly, without replacement, from the 105 available subjects in each data set. Each of the simulated panels met the requirements for the number of subjects in each cell of the NIOSH bivariate panel. The simulated panels were created and evaluated with a Microsoft Excel 2003 spreadsheet using Microsoft Visual Basic macros.

Minimum required fit factors of 10 to 100, in steps of 10 were evaluated. For a given respirator the same 1000 simulated 35-subject panels were used. The "one pass per cell" criterion was not included in this evaluation, since it was not expected to improve the ability to differentiate between well- and poor-fitting respirators (see following section). Figures 2 through 11 are histograms of the number of subjects passing the specified minimum fit factor.

The histograms (Figures 2 through 11) clearly show that the fit performance of a well-fitting filtering facepiece respirator (Model A) and a poor-fitting filtering facepiece respirator (Model H) can be differentiated for a minimum required fit factor between 30 and 100. A minimum required fit factor of 10 (Figure 2) does not provide any differentiation between the two respirators and a minimum required fit factor of 20 (Figure 3) has a slight overlap between the two respirators.

Applying the current proposed minimum required fit factor of 100 and that 26 subjects of 35 must have at least one fit test meeting this requirement, it can be seen in Figure 11 that the desired result of rejecting the poor-fitting respirator (Model H) is achieved with a

high degree of certainty. That is, all 1000 simulated panels for Model H fail the proposed requirements. However, it can also be seen that an undesired result occurs when utilizing NIOSH's proposed requirements; approximately ⅓ of the simulated panels for the well-fitting respirator (Model A) fail the requirements. Therefore, the current requirements (not including the "one pass per cell" requirement), cannot differentiate between the well-fitting (Model A) and poor-fitting (Model H) respirators ⅓ of the time. If the "one pass per cell" requirement is also applied, ⅔ of the simulated panels for the well-fitting respirator fail. While the minimum required fit factor of 100 separates the well- and poor-fitting respirators as evident in Figure 11, the requirement to have 26 out of 35 subjects (75%) having at least one fit test with this minimum fit factor would likely result in the well-fitting respirator failing the certification process under the proposed rule.

Based on the 3M study just described, the proposed NIOSH test should be able to discriminate between well-fitting and poor-fitting respirators if the minimum required fit factor has a value between 30 and 100 with a pass rate that is selected appropriately for the minimum required fit factor. There may be a number of poor-fitting respirators in addition to the six identified by 3M in Lawrence, *et al.*[7] It would be expected that poor-fitting respirators would show a range of fit performance between different models. Additional studies should be conducted by NIOSH to understand the expected range of fit performance for examples of well and poor-fitting respirators, so that appropriate values can be selected for minimum required fit factor and minimum pass rate. In addition, the "one pass per cell" requirement should be removed from the proposed test procedure since it will make it more likely for respirators to fail the requirements of the proposed test procedure without providing any benefits to potential users (see "One Pass per Cell," pp. 21-22).

3M proposes that a minimum fit factor of 50 be selected along with a minimum pass rate of 18 out of 35 subjects (approximately 50%). This change, along with the removal of the "one pass per cell" requirement, will provide good discrimination between well- and poor-fitting filtering facepiece respirators. With additional studies using the NIOSH-proposed test procedure, NIOSH may determine that other values for minimum required fit factor and minimum pass rate are more appropriate.

Figure 2: Histogram of Number of Subjects with at Least One Fit Factor ≥ 10 for 1000 Simulated Fit Test Panels

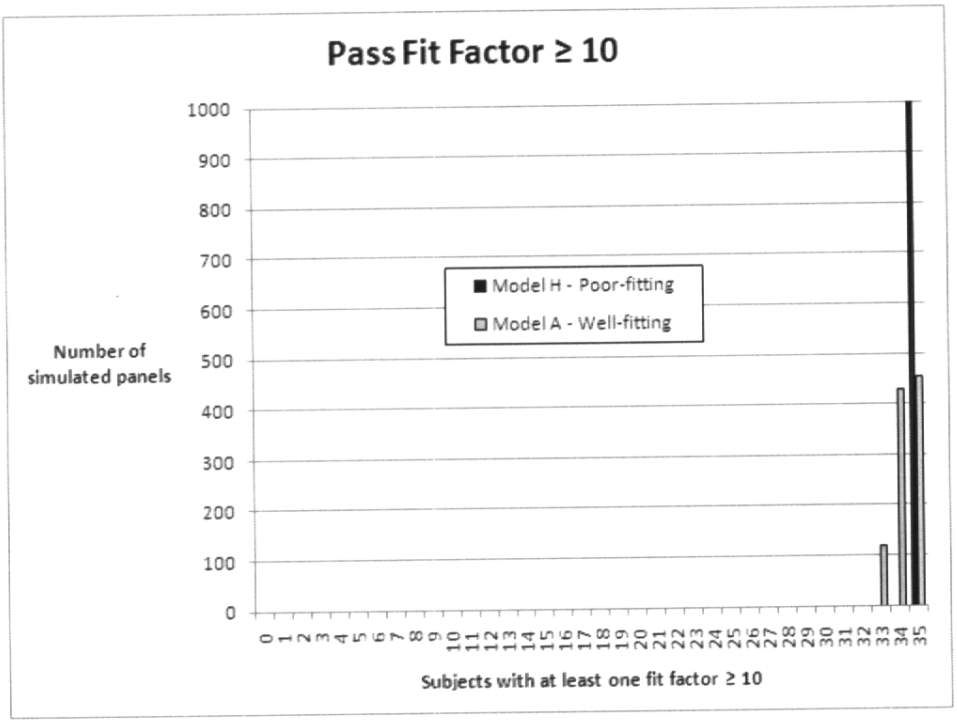


Figure 3: Histogram of Number of Subjects with at Least One Fit Factor ≥ 20 for 1000 Simulated Fit Test Panels

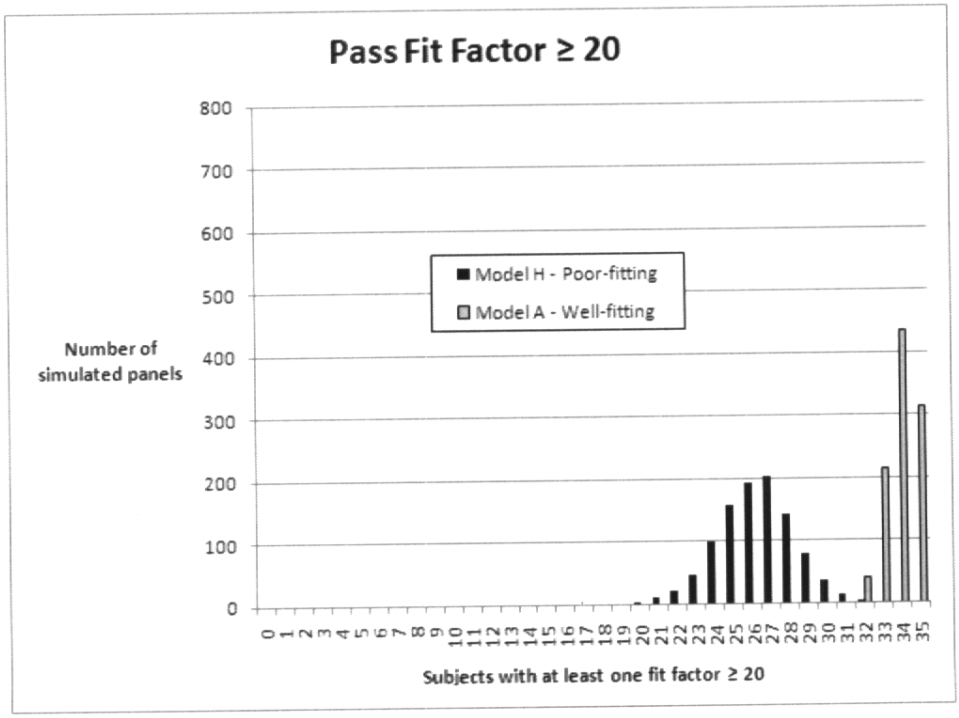


Figure 4: Histogram of Number of Subjects with at Least One Fit Factor ≥ 30 for 1000 Simulated Fit Test Panels

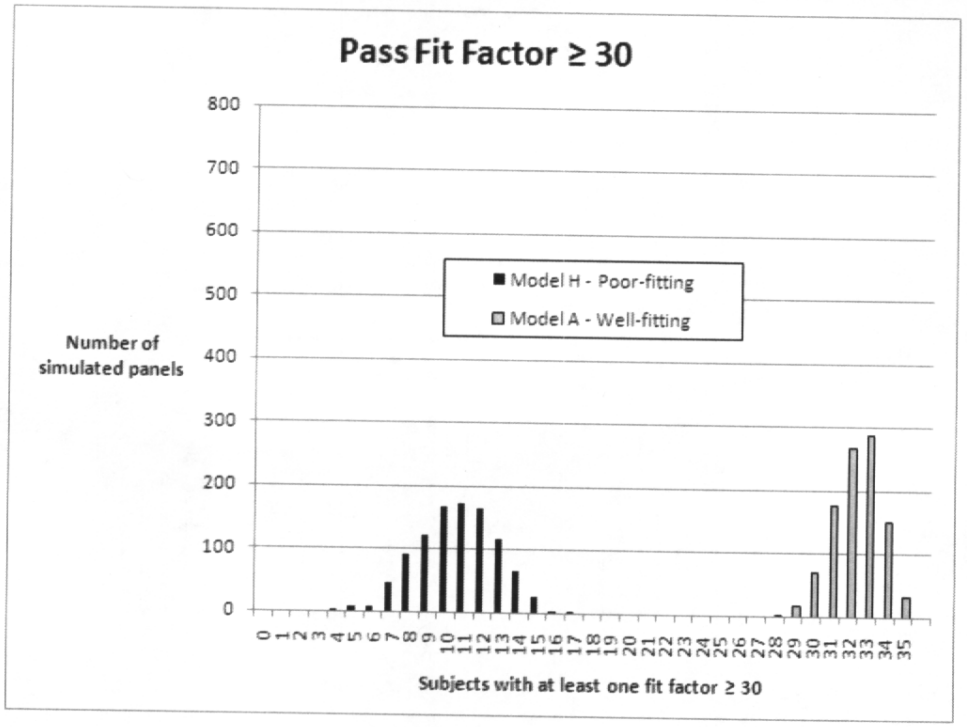


Figure 5: Histogram of Number of Subjects with at Least One Fit Factor ≥ 40 for 1000 Simulated Fit Test Panels

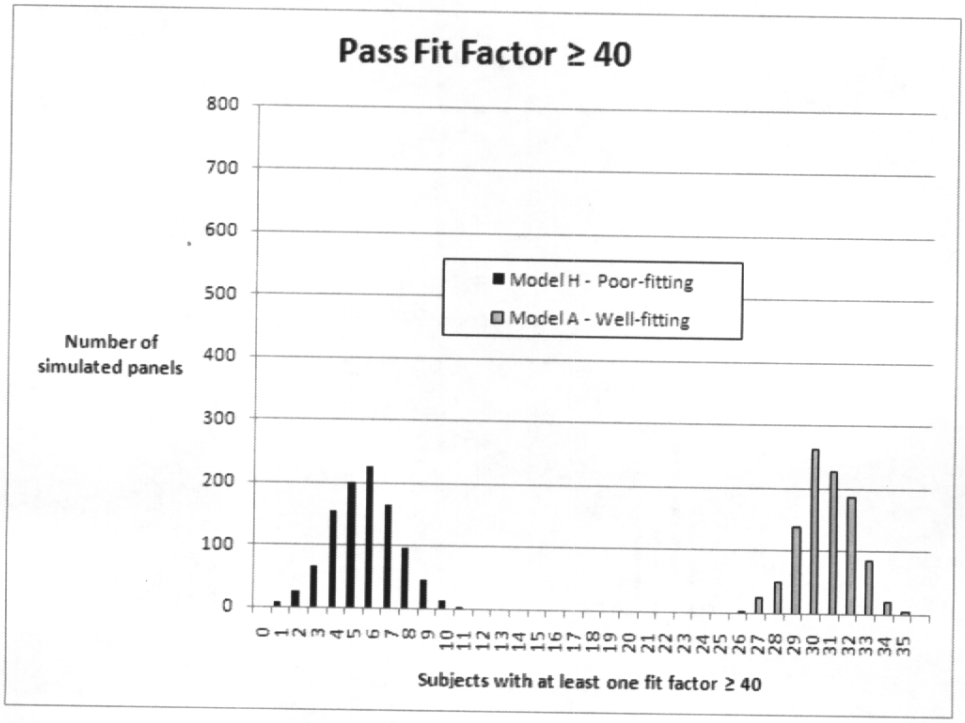


Figure 6: Histogram of Number of Subjects with at Least One Fit Factor ≥ 50 for 1000 Simulated Fit Test Panels

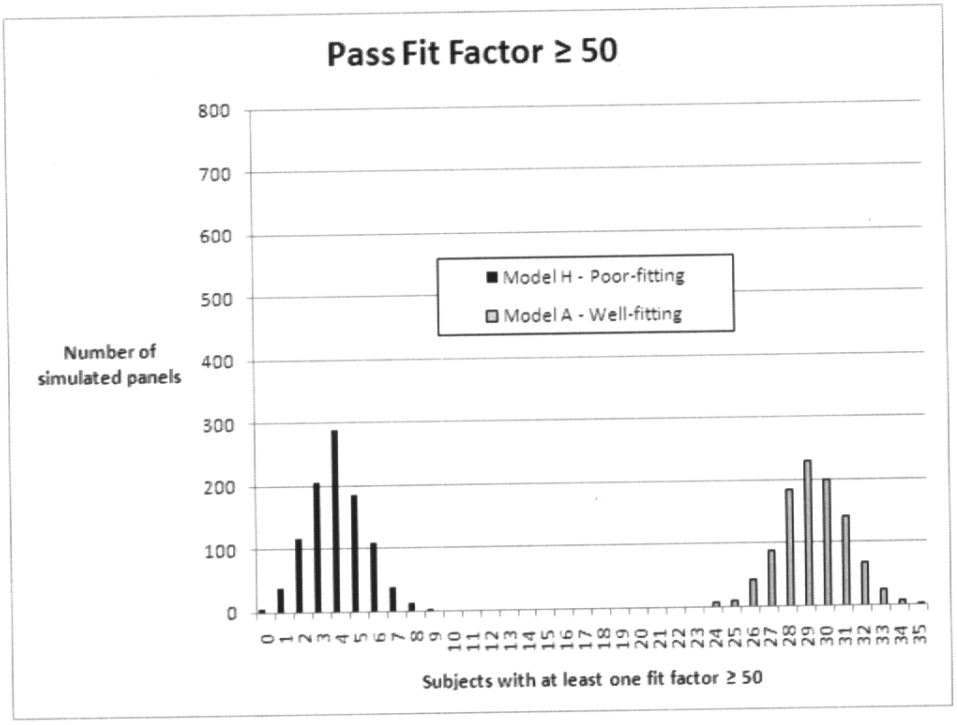


Figure 7: Histogram of Number of Subjects with at Least One Fit Factor ≥ 60 for 1000 Simulated Fit Test Panels

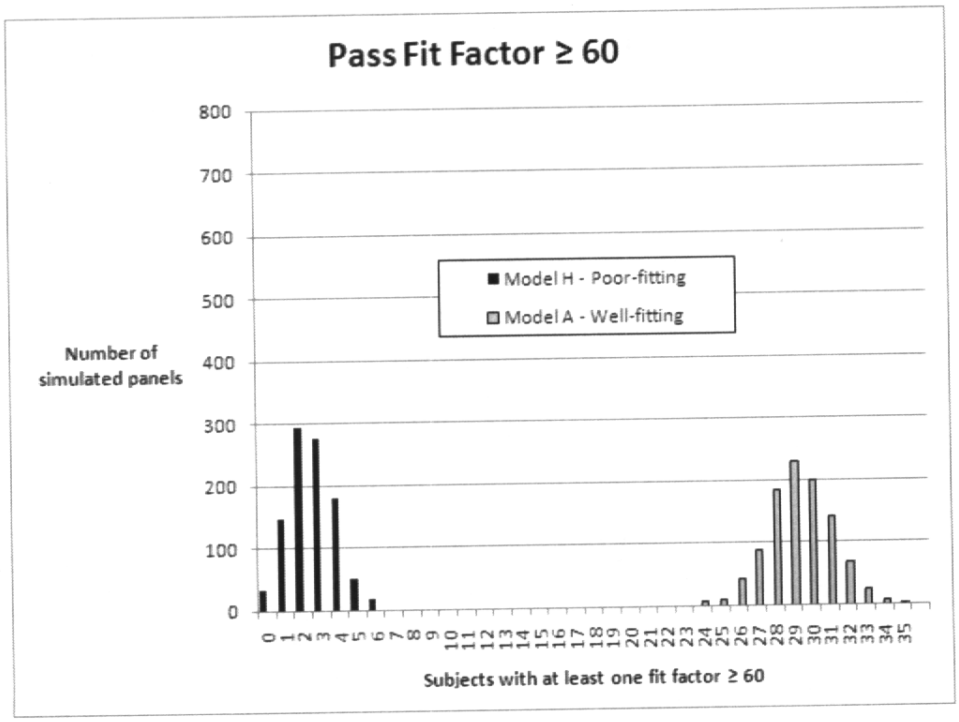


Figure 8: Histogram of Number of Subjects with at Least One Fit Factor ≥ 70 for 1000 Simulated Fit Test Panels

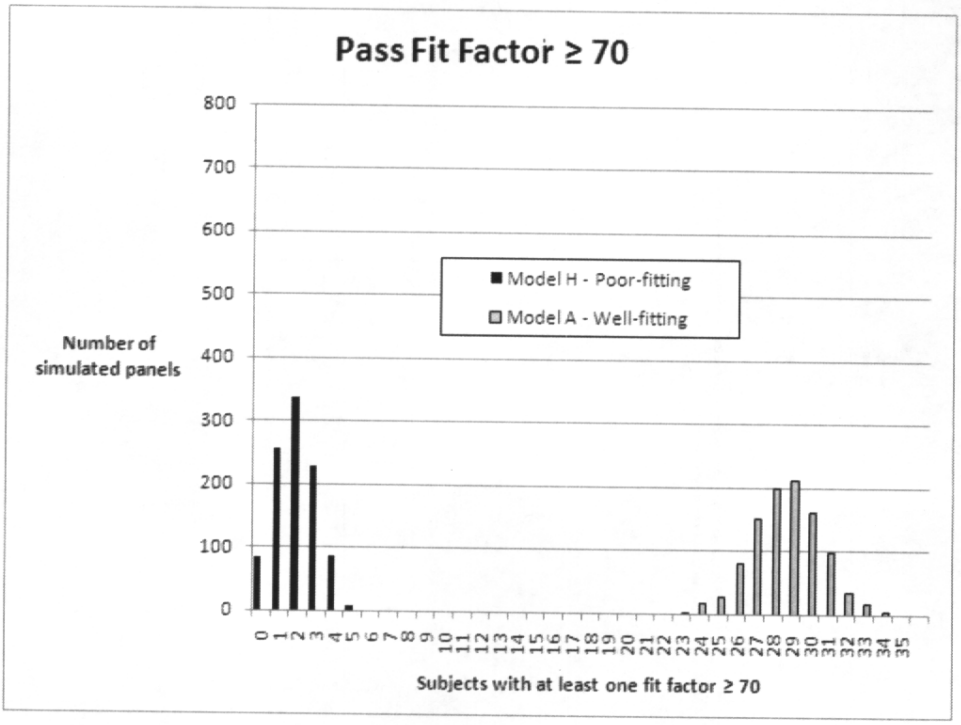


Figure 9: Histogram of Number of Subjects with at Least One Fit Factor ≥ 80 for 1000 Simulated Fit Test Panels

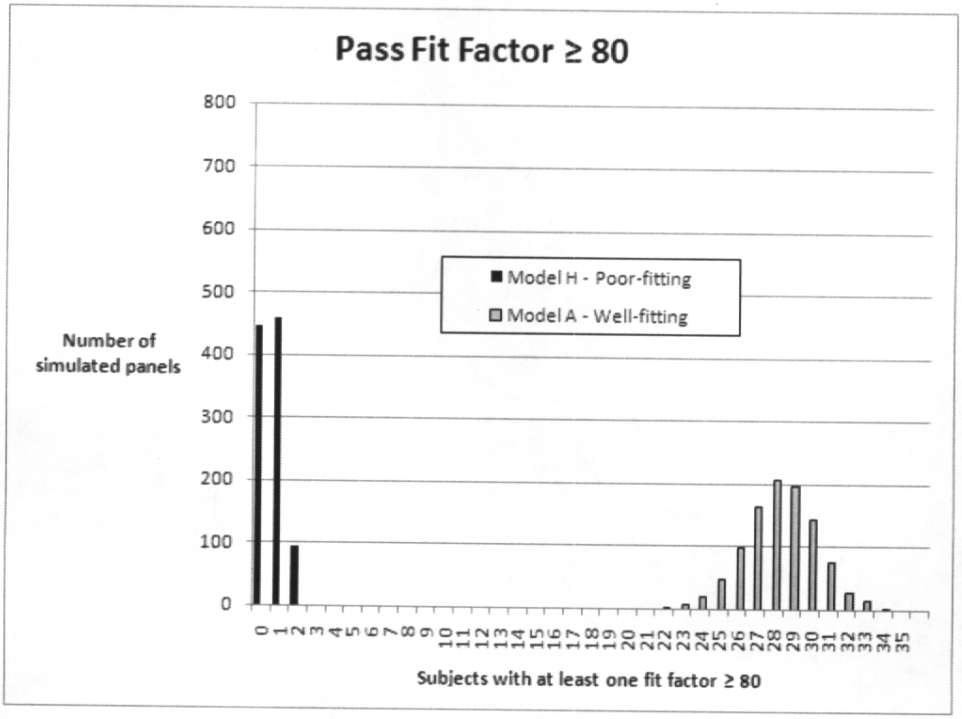


Figure 10: Histogram of Number of Subjects with at Least One Fit Factor ≥ 90 for 1000 Simulated Fit Test Panels

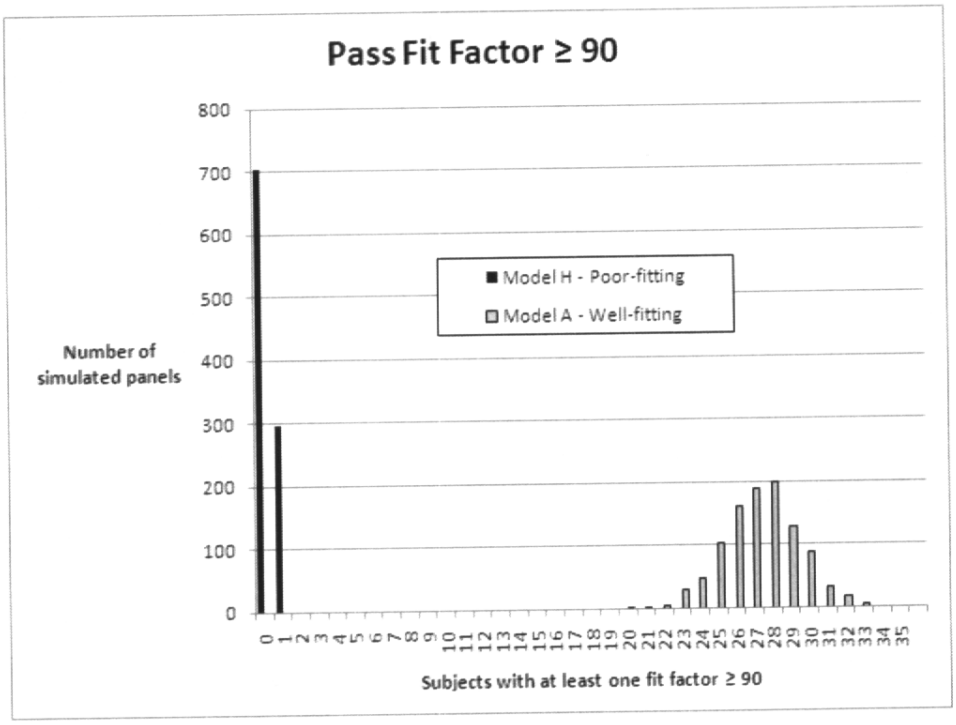
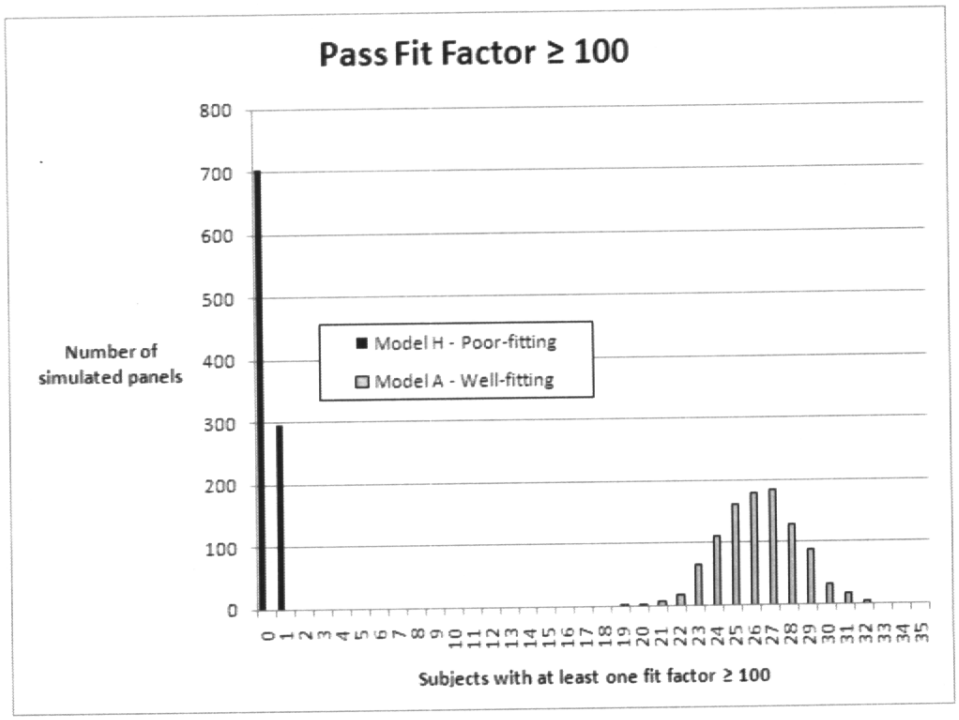


Figure 11: Histogram of Number of Subjects with at Least One Fit Factor ≥ 100 for 1000 Simulated Fit Test Panels



"One Pass per Cell"

As 3M has stated in previously submitted comments the requirement in NIOSH's proposed test procedure to have at least one passing test in each cell of the NIOSH bivariate panel will not accomplish NIOSH's objective of ensuring that approved respirators fit a wide range of facial sizes. NIOSH has provided a statistical basis for the requirement that at least 26 of the 35 subjects in a test panel would be required to have a passing result. No such basis was presented to support the "one pass per cell" requirement. If NIOSH were to conduct such an analysis on the "one pass per cell" requirement, it would most likely find that this requirement significantly increases the possibility that a particular respirator model will fail the proposed test procedure without providing a meaningful link to the ability of that model to fit a wide range of facial sizes.

NIOSH and others published a study in 2008 investigating the correlation between respirator fit and respirator fit test panel cells.[10] In the conclusion of the paper, the authors indicate that there is still "a need for individual fit testing as required in OSHA 29 CFR 1910.134" since facial size as defined by the NIOSH bivariate panel is not able to predict whether an individual can pass a fit test with a particular respirator. It is therefore surprising that NIOSH has included a requirement in the proposed test procedure that there must be at least one passing fit test in each cell of the NIOSH bivariate panel.

The "one pass per cell" requirement is not capable of reliably differentiating between respirator models that fit or do not fit users in a particular range of facial sizes. The NIOSH bivariate panel is comprised of ten cells, six of which contain two subjects each. It is difficult to understand what conclusions could be drawn about the fit of a respirator model on facial sizes in one cell of the panel based on testing just two subjects. The uncertainty of the predicted pass rate for users with facial sizes in any of the cells with two subjects is very large. If a particular respirator model fits one subject in a two-subject cell, the possible range of predicted pass rates (with 95% confidence) would be between 1% and 99%. If a respirator model fits neither subject, the possible range of predicted pass rates would be between 0% and 78%.

If it is assumed that a particular respirator model had a uniform pass rate of 80% (80% of all subjects, regardless of cell, can pass a fit test), then there would be a 22% probability that at least one of the 2-subjects cells will have two subjects which cannot pass the proposed test. The result is that even a well-fitting respirator model that fits all facial sizes uniformly will have a significant probability of failing the "one pass per cell" requirement. If NIOSH would like to attempt to predict the fit test pass rate for users having the range of facial sizes within a cell of the bivariate panel and reduce the possibility of random failures of the "one pass per cell requirement", the number of subjects within each cell of the bivariate panel must be increased substantially. This would require a significant increase in the number of subjects in the NIOSH bivariate panel, which would make it very difficult for NIOSH or manufacturers to conduct evaluations in a timely manner. Of course, this assumes that facial size as defined by the bivariate panel can predict whether an individual can pass a fit test, which has not been clearly shown.

In conclusion, the "one pass per cell" requirement contained in the current proposal provides little or no benefit to respirator users and significantly increases the probability that there will be random failures of the proposed NIOSH test procedure. For these reasons, the "one pass per cell" requirement should be removed from the proposed NIOSH test procedure.

Appendix A: Fit Test Data for Poor-Fitting Respirator

Poor-fitting filtering facepiece respirator (Model H) fit test data

Subject ID	NIOSH Bivariate Grid Cell	Factor Test 1	Fit Factor Test 2	Fit Factor Test 3
18	1	13	12	18
23	1	19	31	17
25	1	21	27	21
27	1	7	19	21
65	1	19	18	34
73	1	52	31	39
17	2	17	20	24
52	2	22	16	14
61	2	28	31	23
68	2	13	20	22
71	2	27	32	32
100	2	26	52	24
13	3	26	29	30
14	3	23	24	27
26	3	34	24	48
60	3	25	25	20
62	3	73	70	65
67	3	22	25	33
72	3	24	23	23
75	3	36	28	27
81	3	24	24	19
87	3	28	36	33
88	3	23	32	23
98	3	19	19	24
1	4	24	23	27
3	4	14	12	13
5	4	18	18	9
7	4	16	17	15
16	4	45	31	34
20	4	32	47	20
24	4	12	11	13
30	4	120	88	69
36	4	47	73	46
38	4	16	13	19
44	4	18	18	20
51	4	13	15	21
54	4	11	16	12
55	4	25	25	16
56	4	18	26	29
66	4	56	47	47
69	4	53	40	76
74	4	22	22	28
76	4	25	22	18
77	4	17	25	22
82	4	51	78	61
83	4	20	9	13
86	4	23	24	21
91	4	19	22	17
99	4	22	15	22
102	4	21	21	27
105	4	16	13	11

Subject ID	NIOSH Bivariate Grid Cell	Factor Test 1	Fit Factor Test 2	Fit Factor Test 3
12	5	13	20	16
37	5	16	18	15
39	5	51	10	48
92	5	20	16	23
94	5	35	50	68
103	5	21	31	28
15	6	23	23	18
29	6	19	8	6
42	6	21	17	23
49	6	27	22	22
59	6	14	16	15
90	6	65	83	29
2	7	13	20	19
9	7	20	27	35
10	7	18	23	23
28	7	12	22	26
31	7	14	12	16
32	7	10	23	17
33	7	9	32	39
34	7	12	12	12
35	7	9	10	14
43	7	16	15	15
45	7	20	27	27
47	7	14	8	15
48	7	24	27	23
53	7	23	27	26
57	7	9	14	14
64	7	21	14	19
70	7	36	20	35
79	7	13	12	13
84	7	19	22	22
85	7	15	13	14
93	7	39	44	11
4	8	12	13	10
22	8	16	17	22
40	8	18	24	21
46	8	26	27	13
63	8	20	15	14
78	8	26	23	20
95	8	14	11	13
96	8	13	16	20
104	8	11	15	13
6	9	25	22	23
8	9	37	32	35
11	9	19	15	22
19	9	33	41	41
58	9	23	21	12
101	9	42	51	68
21	10	10	15	19
41	10	15	18	19
50	10	13	18	18
80	10	21	16	17
89	10	31	29	19
97	10	14	16	16

Appendix B: Fit Test Data for Well-Fitting Respirator

Well-fitting filtering facepiece respirator (Model A) fit test data

Subject ID	NIOSH Bivariate Grid Cell	Fit Factor Test 1	Fit Factor Test 2	Fit Factor Test 3
11	1	10	5	3
20	1	22	15	8
21	1	36	36	26
70	1	532	105	74
80	1	488	401	567
105	1	103	101	96
19	2	423	70	157
23	2	131	135	129
47	2	398	193	193
77	2	108	66	33
84	2	438	263	82
103	2	49	20	5
4	3	184	185	118
8	3	9	12	32
24	3	273	27	22
42	3	130	129	55
49	3	107	11	100
50	3	228	143	163
65	3	1028	416	388
69	3	26	18	20
85	3	208	216	144
87	3	1297	101	691
97	3	356	36	55
101	3	356	274	102
2	4	909	1532	909
6	4	425	427	452
13	4	846	4312	2475
15	4	18	18	20
18	4	657	327	632
22	4	98	51	51
25	4	577	309	106
30	4	177	20	8
34	4	323	355	626
36	4	46	26	38
46	4	15	24	27
51	4	608	566	895
52	4	3671	220	1179
53	4	68	43	18
54	4	126	110	109
55	4	134	79	83
61	4	38	16	12
63	4	211	120	168
68	4	260	78	67
75	4	225	329	311
78	4	6	6	7
79	4	55	64	51
88	4	831	942	785
91	4	282	292	84
93	4	218	381	668
94	4	80	76	205
102	4	209	318	386

Subject ID	NIOSH Bivariate Grid Cell	Fit Factor Test 1	Fit Factor Test 2	Fit Factor Test 3
16	5	46	96	68
17	5	51	97	70
32	5	459	925	103
72	5	218	115	133
86	5	30	19	16
99	5	16	15	23
12	6	247	309	361
45	6	801	605	375
57	6	48	42	45
73	6	71	105	95
83	6	443	468	307
90	6	60	74	103
1	7	102	816	635
7	7	39	42	24
9	7	49	89	26
10	7	389	212	238
27	7	324	205	213
29	7	7453	1851	1709
33	7	737	912	1663
35	7	880	4211	2793
38	7	153	159	151
41	7	3589	1119	3246
43	7	575	556	193
44	7	206	224	260
59	7	239	302	297
62	7	140	73	221
66	7	560	437	279
71	7	40	49	109
74	7	129	149	119
76	7	34	101	39
92	7	210	206	228
95	7	190	201	118
98	7	116	69	88
14	8	4	3	5
26	8	882	927	328
28	8	86	40	14
39	8	1123	132	201
40	8	534	451	511
67	8	22	31	38
96	8	62	49	84
100	8	1636	1655	1291
104	8	189	107	138
5	9	319	477	418
31	9	244	181	100
37	9	79	166	163
48	9	112	161	132
60	9	50	70	42
81	9	1902	244	286
3	10	52	102	129
56	10	375	399	518
58	10	92	380	413
64	10	31	104	49
82	10	53	65	104
89	10	711	519	667

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