Miller, Diane M. (CDC/NIOSH/EID)

From: rkhehenberger@mmm.com
Sent: Monday, March 29, 2010 2:22 PM
To: NIOSH Docket Office (CDC)
Cc: robert.weber@mmm.com; cecolton@mmm.com
Subject: HHS RIN: 0920-AA33, 42 CFR 84
Attachments: HHS RIN 0920_AA33.3M.29mar10.pdf

Dear Docket Officer:

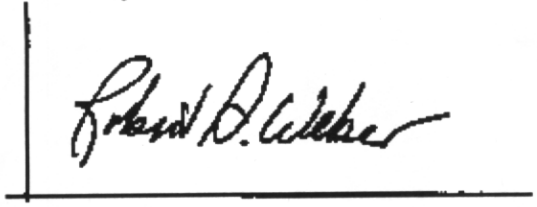
3M Company (**3M**), through its Occupational Health and Environmental Safety (OH&ES) Division, is a major manufacturer and supplier of respiratory protective devices throughout the world. 3M has invented, developed, manufactured and sold National Institute for Occupational Health and Safety (NIOSH) 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 basic 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 respirator 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 that a fit requirement be part of the certification evaluation for half facepiece respirators, NIOSH's proposed rule to evaluate respirator fit as part of the certification process as a remedy to their perception that too few employers conduct fit testing is seriously flawed and will not increase fit test compliance and will most likely reduce the percentage of employers conducting fit test. This is not supported by 3M.

3M offers the following comments and recommendations regarding the TIL Proposed Rule, RCT-APR-STP-0068 Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators, and Determination of Sample Size and Passing Criteria for Respirator Fit Test Panels. These comments and suggestions are attached in this email. Additionally, 3M is sending a hard copy of these comments via certified mail.

3M appreciates the opportunity to add our comments and knowledge to docket 137.

Sincerely,



Robert A. Weber
Manager, Regulatory Affairs, Quality Assurance and Technical Service

3M Occupational Health and Environmental Safety Division

3M Center
St. Paul, MN 55144-1000
651 733 1110

3M

March 29, 2010

NIOSH Docket Officer
NIOSH Docket #137,
Robert A. Taft Laboratories, MS–C34
4676 Columbia Parkway
Cincinnati, OH 45226.
NIOCINDOCKET@CDC.GOV.

RE: RIN: 0920–AA33; Total Inward Leakage Requirements for Respirators: Notice of Proposed Rulemaking

3M Company Comments

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3M appreciates the opportunity to add our comments and knowledge to 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 Part84 Docket Number 137, NIOSH Proposed Rule on Total Inward Leakage Requirements for Respirators

[74 *FR* 56141]

As an innovator, designer, and manufacturer of NIOSH-certified respirators since 1972 and a strong advocate for recognizing, assessing, and advancing the importance of respirator fit to the wearer's face, 3M is well acquainted with and indeed is an industry leader concerning all aspects of respirator performance, including fit. Based on this breadth of experience and global expertise, 3M is supportive of the general concept to require a minimal fit performance level as part of the certification process. This support, however, is not without several major reservations as presented below and, without appropriate revisions to the proposed rule in these areas, would result in 3M withdrawing this support.

Overall Approach to the Rule

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 Docket 137. These documents include:

- RCT-APR-STP-0068 Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators
- Determination of Sample Size and Passing Criteria for Respirator Fit Test Panels
- Comments submitted to 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.

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Introduction

3M submits that NIOSH has erred significantly concerning the definition, technical logic, and economic impact of this proposed rule. While the proposed rule is for total inward leakage, the definition of the purpose and the application of the protocol are quickly and incorrectly translated to mean fit. In the potential application of such a rule, it must be noted that improved total inward leakage is not the same as defining or improving fit. NIOSH's logic in its analysis and manipulation of the data to create technical criteria for this proposed rule is somewhat mysterious and not clear. Further, independent experiments by NIOSH, International Safety Equipment Association (ISEA), and 3M all demonstrate dramatic issues with the variability of the subject selection and the overall robustness of the proposed rule. What is more, given the lack of correlation between the proposed rule and actual field performance based on quantitative fit testing, this rule would do nothing to actually advance the stated goal of improving fit characteristics of respirator designs. Despite benchmark testing that shows a significantly high number of filtering and elastomeric facepieces would not have the requisite TIL performance as defined by their test, NIOSH nonetheless states that this proposed rule would not have a significant impact on most designs. In fact, a consequence of the proposed rule will remove well-fitting respirators from the US workforce. In determining that "this proposed rule is not economically significant," several incorrect assumptions were made in estimating revenue impact, manufacturing and development costs, and end-user impacts. Therefore, this proposed rule is wholly incongruous to streamlining the process of fit testing for employers and improving the likelihood of respirator designs passing fit tests "right out of the box."

General Comments

3M submits that NIOSH has totally missed the mark in bringing clarity and feasibility to the primary features of the proposed rule and has rather deposited confusion and ambiguity to what is expected from manufacturers in designing new, compliant products. Specifically, the proposed rule is declared to be founded on the concept of

establishing total inward leakage (TIL) requirements. The description and purpose of the proposed rule, however, appear to be dealing with the attribute of face fit, and not TIL. Any measures to improve TIL are not the same as defining or improving fit.

Definition: TIL vs. Fit Test

At the onset, it is beneficial to identify the confusion between TIL tests and fit testing. TIL, by its name, measures all sources of contaminate leakage in to the respirator such as filter penetration, face seal leakage, valve and gasket leakage, etc. A face fit test measures face seal leakage only on properly used and maintained respirators. These are two different tests that measure different attributes of respirator performance that impact design and test equipment.

The first issue is basic to establishing what this standard is proposed to accomplish. It should be pointed out that this rule creates confusion for readers due to the inconsistent use of terminology in the documents identified above. NIOSH titled this rule and past concepts as a total inward leakage requirement. However when discussing leakage measured by this proposal, NIOSH overwhelmingly uses "fit," "faceseal leakage," "fit factor" or other terms related to the fit aspect of leakage and not TIL. Because of the proposed test equipment and protocol, we believe that this requirement should be referred to as a fit requirement instead of a TIL requirement. As the ensuing comments relate to the use of this as a 'fit test,' 3M will typically use fit terminology rather than TIL for these comments. This is consistent with the original title of **§ 84.175 Half-mask facepieces, full facepieces, hoods, helmets, and mouthpieces; fit and total inward leakage (TIL); minimum requirements.** The following four points further explain why the name must be changed.

1. In previous public meetings and concepts, including the version given to ISEA members for technical review, NIOSH stated they chose the PortaCount® with Companion test equipment because it would minimize filter penetration and thus NIOSH would be evaluating respirator fit. NIOSH insists, incorrectly, on calling this TIL (total inward leakage). In the proposed rule NIOSH defines TIL as "the combination of contaminated air leaked through various potential sources including the facepiece-to-face seal, exhalation valves (if any), and gaskets (if

any) and any contaminants that have penetrated the filter." However, the test equipment chosen eliminates or at least minimizes filter penetration of 95 level particulate filters. The respirators being tested as part of a NIOSH submission are brand new and expected to be in good mechanical condition, which minimizes leakage at gaskets and valves. NIOSH performs a test that evaluates exhalation valve leakage and thus ensures this leakage is at a minimal level. Thus the only remaining source of leakage is from the face seal, which by definition makes the proposed rule a fit test.

Calling the proposed rule "TIL" will cause confusion because it conveys total performance of the product rather than the fit of the product. For example, NIOSH itself indicates that a TIL of 1% is equal to the OSHA fit factor of 100. This is true if the measurement is assessing face seal leakage only, i.e. fit testing. NIOSH further states, "the technology is identical to that in common use for measuring respirator fit..." This is recognition by NIOSH that the technology proposed for this rule is fit testing technology and not TIL.

2. The Institute of Medicine (IOM) has recognized the inconsistency of using TIL to describe fit. The IOM points out in discussing the NIOSH anthropometric panel, "that the scientific community (except NIOSH) is referring to the assessment of respirator fit as a fit test and not TIL."[1] It is best to use established terminology when talking about existing concepts.

3. TSI, the manufacturer of the test equipment, has told NIOSH that their equipment is for fit testing (see dockets 036 and 137) and does not measure TIL. 3M's experience confirms that for 95 level filters, the PortaCount® measures both filter penetration and face seal leakage whereas the PortaCount® with Companion, the equipment specified by NIOSH, only measures face seal leakage or fit factors, not TIL.

Technical Background (74 Federal Register, p.56142)

While NIOSH only summarizes the background of this rule, many of the details discussed below are pertinent as to why NIOSH should suspend action on this rule for the time being.

Though the proposed rule "has been identified as a priority among the policy making needs of the NIOSH respirator certification program," (*74 Federal Register, p.56142*) this prioritization should not accelerate the rule-making process at the sacrifice of promulgating a final rule that is capable of identifying well-performing half facepiece respirators. The history or background of getting to this proposed rule for a fit test requirement for particulate removing half facepiece respirators is a lengthy and complicated one.

For instance, NIOSH indicates in the "Background" section of the proposed rule, "....NIOSH proposed but ultimately omitted requirements for testing the performance of these respirators with respect to TIL to allow for further research on the effectiveness of TIL testing methods.[2]" This does not accurately explain the current situation. The NIOSH 1994 proposed fit test for particulate respirators with filters not intended to be replaced was an isoamyl acetate test.[3] Isoamyl acetate, however, is not an appropriate surrogate test substance for particulate respirators. This proposed paragraph required that "the respirator will be modified in such a manner that all of the air that normally would be inhaled through the inhalation port(s) is drawn through an efficient activated charcoal-filled canister or cartridge(s) without interfering with the face-contacting portion of the facepiece."[3] This typically would modify the facepiece in such a way that the proposed test would not indicate how the actual respirator would fit workers. As a result of having to modify the respirator, NIOSH stated in 1995 that, "The only means presently available to assess the fit achieved on the worker is a respirator-to-face fit test conducted on that individual with the chosen respirator."[4] While we agree that the isoamyl acetate method using modified respirators was not appropriate for testing fit during certification, we disagree that the appropriate fit testing methods did not exist at that time. Methods for fit testing existed that could eliminate the use of charcoal "surrogate" respirators during certification. In fact, 3M invented two qualitative fit test methods that have been approved by OSHA and one quantitative fit testing method that could be used for non-high efficiency filter respirators including filtering facepiece respirators.[5-7]

The primary reason 3M and other manufacturers objected to the 1994 proposal was that fit testing a respirator on a panel of people during certification does not predict an

individual's fit in the field and does not alleviate the need for individual fit testing. Despite the changes in fit testing methods and equipment, there have been no advancements in technology or science that will provide assurance that a respirator evaluated for fit during certification will assure that the respirator will fit a given worker when used in the workplace.

NIOSH identified this rulemaking as a top priority by policy makers and announced that they would begin this effort in January of 2004 at the OSHA Hearing for Assigned Protection Factors (APF). The following excerpt from the NIOSH testimony provides information on the start of this rule. NIOSH stated, "NIOSH recognizes that even though there is some uncertainty in laboratory fit-test procedures, there is a need for more testing of models in each class. NIOSH will address as a priority issue the need for future changes in the certification criteria to generate data for each respirator model. Such changes would result in additional certification tests to assure or assess the overall performance of every respirator model...NIOSH is actively developing the certification program for half-mask respirators. By focusing on this effort, NIOSH intends to minimize the time between OSHA's promulgation of the APF values and establishing protection levels through performance testing."[8]

The following is an excerpt from the follow-up questions during the OSHA APF testimony.

MR. METZLER (of NIOSH): "First of all, let me say that we feel that it is extremely important that we develop this complimentary [sic] program to OSHA's effort to undertake changes to the APF...We think that we could develop the program for half-mask air-purifying half-mask respirators probably within the year."[8]

Later in this portion of the hearings it was stated by MR. KOJOLA (of AFL-CIO): "Let us assume for a moment that there is general agreement in the respirator community that what might come out of this process, this total inward leakage test, does, in fact, do a good job of identifying good performers and poor performers of filtering facepieces. Let us assume that for a moment. However, that has not yet been done."[8]

We can only surmise that something of this high a priority that was planned to be completed in 2004 and has not yet been completed is because NIOSH wants to make

sure that they have a standard that is capable of doing what Mr. Kojola desired. However, looking at this proposal and examining the draft RCT-APR-STP-0068, the benchmark testing that was done by NIOSH, and testing done by ISEA and 3M does not indicate that this proposal will meet this expectation. We urge NIOSH to gather more data on this proposal to ensure that it is capable of doing "...a good job of identifying good performers and poor performers of filtering facepieces."[8] To do this we urge NIOSH to withdraw this proposal until more data can be gathered.

NIOSH Benchmark Testing

In the "Need for Rulemaking" section, NIOSH refers to benchmark testing of 101 respirator models that were then currently on the market, "using a test regimen similar to that being proposed in this rulemaking, to assess their TIL performance." (*74 Federal Register, p.56142*) NIOSH states in the proposal that the results of the benchmark testing is their basis for most, if not all of their conclusions. These conclusions include;

- technological impact including the number of models that would be expected to fail the proposal by not achieving a fit factor of 100 and
- economic impact of this proposal.

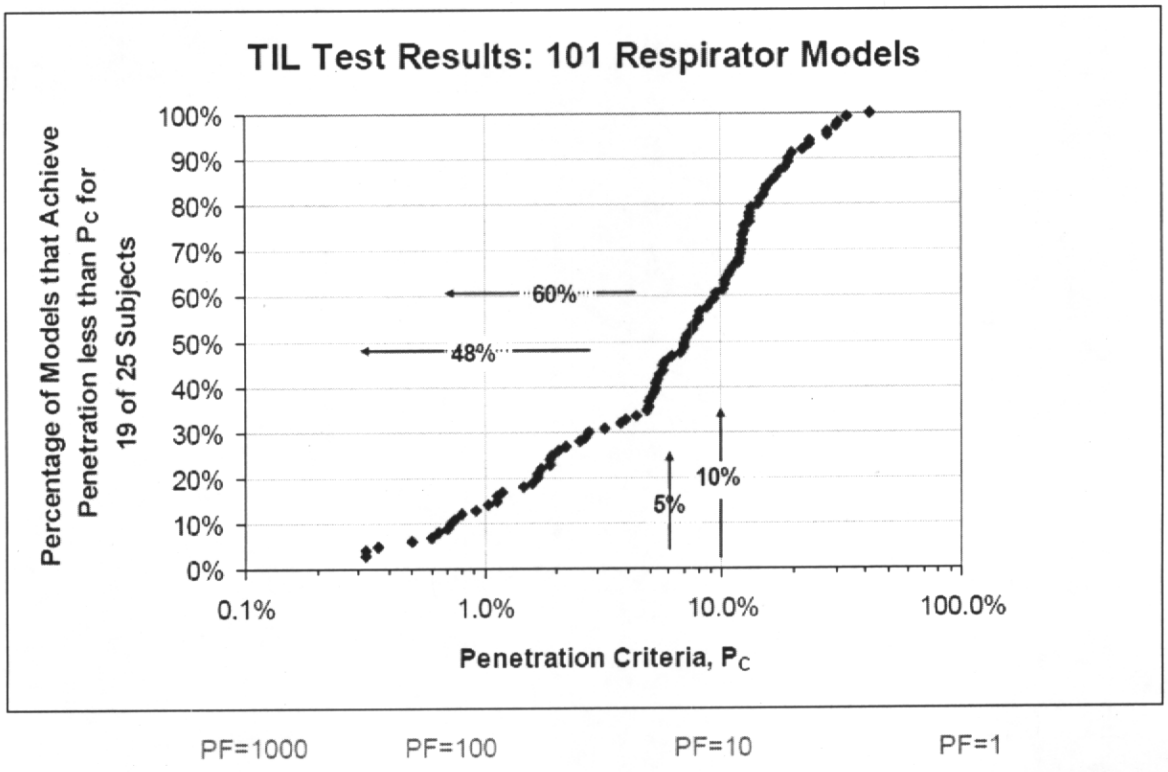
Unfortunately, NIOSH has not publicly made available these data or a summary of the data in order to understand how NIOSH reached its conclusion. NIOSH did provide data on specific manufacturer's respirator models to that manufacturer. NIOSH does not indicate how it analyzed the benchmark data. We have looked at the data collected by NIOSH on our respirators and have evaluated it to determine what the potential impact would be on our respirator models. One factor that makes it difficult to evaluate NIOSH's benchmark data is that the protocol for the benchmark was "similar" to the NIOSH proposal and not identical. Furthermore, NIOSH does not explain how it conducted its analysis of the data. Some of the test differences which will impact the statistical reliability and relevance are:

- NIOSH used a 25 person panel versus the proposed 35 person panel.
- NIOSH results include an average of three fit test trials, not one over 100.
- The NIOSH benchmark test appears not to have been evaluated for a pass in each cell of the fit panel.

- The NIOSH proposal indicates a pass/fail criterion for the respirator model of a fit factor of 100 instead of the fit factor of 20 used in the benchmark study and presentations by NIOSH.

NIOSH's own data does not support their conclusions about the impact of the proposed rule – again, some of this is speculation due to the lack of background or details of the benchmark testing itself. On June 26, 2007 at the NIOSH/NPPTL Total Inward Leakage Public Meeting, NIOSH showed the slide in Figure 1 (Docket 036).

Figure 1: TIL Test Results presented at NIOSH/NPPTL TIL Public Meeting

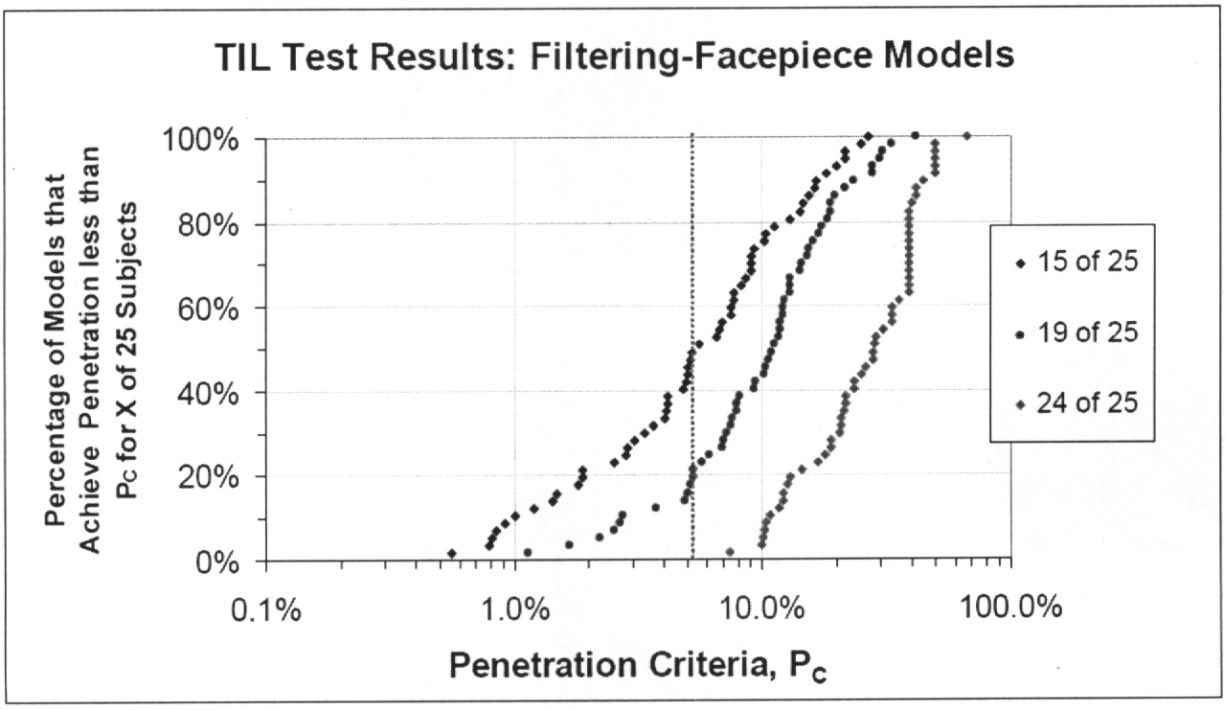


This slide indicates that using a 10% penetration criterion (fit factor of 10) resulted in 60% of the 101 tested models meeting this criterion. Using a 5% penetration criterion (fit factor of 20) 48% percent of the models tested met the criterion. Using a 1% penetration criterion (fit factor of 100), as proposed in this rule, only 15 % of the 101 models of both elastomeric and filtering facepiece half mask respirators met the criterion. This means 85% of this class of respirators have "facepiece seals that did not perform" to this criterion, not the "approximately 30 percent of this class" as stated by NIOSH (*74 Federal Register, p. 56142*). NIOSH later inexplicably concludes that, "For the leading

U.S. respirator manufacturers who obtain approvals from NIOSH, likely to represent a majority share of the current market supply of NIOSH-approved products covered by this rulemaking, NIOSH benchmark testing indicates that the new TIL requirements can be met by current products without additional development or manufacturing costs." (*74 Federal Register, p.56147*) In fact, NIOSH's own benchmark testing actually indicates that only 15% of current product would meet the requirement. Clearly, 15% does not represent the "majority share of the current market supply."

Figure 2, which is based on filtering facepieces included in the benchmarking data, allows for a more direct comparison to the proposal as it provides three different lines for different panel passing percentages for filtering facepiece respirators. If one looks at the line for 19 out of 25 (76%) of the panel passing, which is close to the 74-75% pass rate being proposed, 100% of all filtering facepiece respirators tested would be eliminated form the market at the 1% penetration criterion (fit factor of 100).

Figure 2: TIL Test Results presented at NIOSH/NPPTL TIL Public Meeting



Based on analysis of these data, the number of products needing to be redesigned is greater than the 30% mentioned by NIOSH. This will dramatically increase the time and money required to redesign the respirators that would be eliminated from the market. It

would also seriously affect the supply of respirators available to the US workforce, national and state stockpiles.

Economic Impact of the Proposed Total Inward Leakage Rule (74 Federal Register, p.56146)

3M is compelled to take issue with NIOSH's assessment that "This proposed rule is not considered economically significant, as defined in section 3(f)(i) of the executive order [12866]" *(74 Federal Register, p.56147)*. Using logic that is either unclear or incorrect, we believe NIOSH has misstated the size and percentage of the market that would be impacted by the implementation of the proposed rule. Further, their assessment of the costs of new product development, re-certifications, manufacturing impacts, and end user re-fit/re-training are significantly understated.

Size and Percentage of Market Impacted

The market research firm referenced by NIOSH (Frost and Sullivan) has reported that in 2007, the North American markets for filtering face piece and elastomeric half-face piece respirators were $386.1 million and $231.0 million, respectively.[9] In reality, while these numbers are low because they don't include health care markets nor do they take into consideration respirator use during pandemics such as the H1N1 virus, they can serve as a conservative estimate of the market size for the purposes of this discussion.

In their proposed rule, NIOSH has estimated that the cost of testing "would range from $8,500 to $12,000 per respiratory approval" and "total testing and certification costs to manufacturers of up to $3.1 million" *(74 Federal Register, p. 56147)*. This is barely the tip of the iceberg, as it radically underestimates the cost to manufacturers for each development program and the likely number of re-designs that will be required to become compliant with the proposed rule.

NIOSH states that "30 percent of this class [half-facepiece respirators] have facepiece seals that did not perform adequately to achieve a fit factor of 100" *(74 Federal Register, p. 56142)*. Therefore, a straightforward reading of the proposed rule would impact $185.1MM in annualized sales.

(30%)*($386.1MM + $231.0MM) = $185.1 MM

- $386.1MM = 2007 sales of North American filtering facepiece market
- $231.0MM = 2007 sales of North American elastomeric facepiece market

This is obviously a massive economic impact. But a deeper reading of NIOSH's own research *(figures 1 and 2)* shows that approximately 90% of filtering facepiece and 40% of elastomeric facepieces would fail the proposed testing at a required panel pass rate of 60%. Using these estimated failure rates would result in a more realistic calculation of $439.9 MM annualized impact.

(90%)*($386.1MM) + (40%)*(231.0MM) = $439.9MM

- $386.1MM = 2007 sales of North American filtering facepiece market
- $231.0MM = 2007 sales of North American elastomeric facepiece market

As demonstrated in Appendix A, the high level of variability of the test method itself makes it difficult to define an exact sales impact. So, it is reasonable to estimate an immediate economic impact range of $200-450 million in annualized revenue.

Cost of New Product Development

In addition to the revenue lost as manufacturers remove products from the market, there would be a very high cost of product development in order to create products that meet the existing needs of workers and pass the proposed TIL rule. NIOSH has estimated "applications for up to 500 approvals in the first two years of implementation of TIL requirements" *(74 Federal Register, p.56147)*. If one used the overly conservative failure rate of 30% stated by NIOSH, this would result in 150 products that would require re-design and re-submission for approval. NIOSH has calculated "design and retooling costs of $55,000 to $200,000 per model" *(74 Federal Register, p. 56147)*, which by 3M's experience is an extremely low estimate to create a high quality, well-fitting respiratory product. While it is very difficult to make a comprehensive calculation of product development costs for all companies, one could reasonably estimate 4-6 employees burdened for one year (approximately $600-900K) and additional supplies and equipment (approximately $50-150K) per development program. Some will be bigger,

some smaller, of course. But these estimates would yield an estimated $127.5 MM in additional development costs on top of the lost revenues identified above.

(150)*($750K + $100K) = $127.5MM

- $750K = average burden rate for 4-6 employees for one year
- $100K = average supplies and equipment costs

Obviously, if the failure rates demonstrated earlier in these comments were used, this economic impact could easily be doubled.

Manufacturing Impact

It is hard to imagine a scenario where hundreds of millions of dollars sales are lost from respirator manufacturers without an accompanying realization of impact to their operations. While it would not be prudent to speculate on what the impact may be, it is clear that it would affect a large number of workers. This would fall disproportionately on US factories, which are already under incredible competition from countries of low labor and facility costs. As many of these factories are located in or near small communities, this would create challenges to local US economies nationwide.

End-user Re-fit and Re-training Costs

The proposed rule would require employers (e.g. industrial and health care customers) to spend large amounts of time and money re-fitting and re-training between greater than 30% of their workforce. Size, resources, and worker requirements vary widely in this market, but it is easily foreseeable that based on lost productivity, worker salary burden rates, and costs to an employer, $100-200 could be spent on each worker. Using the NIOSH estimate that "These respirators are used by two million people," *(74 Federal Register, p. 56142)*, one quickly realizes an economic impact to employers of $90 MM.

(30%)*(2MM)*($150) = $90MM

- 30% is percentage of end-users needing re-training
- 2 MM end-users
- $150 is the estimate cost of re-training each end-user

Yet NIOSH soberly states that they do "not anticipate additional costs to consumers...as a result of the proposed TIL requirements" *(74 Federal Register, p. 56147)*.

Perhaps most concerning is the negative impact that this proposed rule would have on the very end-users that NIOSH is tasked with helping. Due to the short-comings of the proposed rule, there is no apparent benefit of ensuring that the end-user will get a better-fitting respirator. At the same time, implementation of the proposed rule would likely remove a large number of products that are providing significant safety to users today as defined by individual fit testing. In trade literature and in personal technical support, 3M strongly advocates for improved fit as measured by individual fit testing by every user. This fit testing is done to ensure optimal fit for every user and would be hampered if a product could not be used for an individual merely because they don't happen to fit into the arbitrary cells of the proposed bivariate grid. Having the broadest range of respiratory product designs that meet scientifically understood, robust testing is the best means to optimally provide workers with respirators that pass fit tests.

As discussed, the economic impact of the proposed TIL rule to manufacturers and customers could range from $200MM to greater than $500MM. Manufacturers could consider such costs tenable if the proposed rule ensured increased levels of protection for the workers.

Specific Comments on NIOSH's Technical Criteria

Comments regarding the need for rulemaking (*74 Federal Register, p. 56143*)
NIOSH states as an implication of this rule, "This process of identifying respirators that provide an adequate fit to each employee would be streamlined through NIOSH evaluation of TIL performance as proposed in this rulemaking, **using panels of test subjects representative of intended users of a particular respirator model and size**" [3M emphasis].

Bivariate Panel Summary

NIOSH has created a process for selecting subjects for the proposed TIL test based on the measurement of face length and face width. A panel of 35 subjects created with this process is intended to be representative of the distribution of face length and width of

>95% of the US adult working population. The panel is referred to as the NIOSH bivariate Respirator Fit Test Panel (NRFTP), or more simply the NIOSH bivariate panel. The NIOSH bivariate panel is composed of ten cells, each defined by a range of face length and face width measurements. The NIOSH bivariate panel requires a specific number of subjects, ranging from two to nine, in each cell. The TIL test in the proposed rule requires that: 1) at least 26 subjects in a 35-subject NIOSH bivariate panel achieve a fit factor ≥ 100, and 2) at least one subject per cell of the panel must achieve a fit factor ≥ 100.

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. For this to truly represent intended users NIOSH needs to identify the typical person meeting the measurements of each cell in order to reduce the panel-to-panel variability in this test.[1] 3M has provided data that demonstrate the extreme variability in fit factors that often exist among individuals in the same cell (docket 036). This variability is a major limitation to the benefit of this test as proposed by NIOSH. This occurs because any combination of two or more measurements of the wearer's face have still not been proven to predict respirator fit. An alternative of taking individual face measurements is to develop a set of mannequin head fixtures that are representative of a population of the people and test on said fixtures.

NIOSH also states that, "The employee is **more likely** [3M emphasis] to achieve a good fit from a respirator make that has been demonstrated through testing to achieve a specified minimum level of performance in this respect." A program to increase fit testing in the workplace would have better consequences than allowing employees to use respirators that meet the proposed NIOSH TIL requirements but have not been fit tested.

NIOSH states that, "The second implication applies to situations in which these poorly performing respirators are being used by employees and other individuals without the benefit of a complete respirator program that includes fit testing." This fails to recognize that without an OSHA compliant respirator program, training may not be complete or even occur. It will not matter how well the respirator is designed to fit if the worker is not

trained to put it on correctly. A well-fitting respirator donned incorrectly will not provide the level of protection it is capable of achieving. The connection between fit testing and training has been identified by many experts.[10]

The basis for NIOSH's position appears to be, "A recent NIOSH/Bureau of Labor Statistics (BLS) survey of respirator use among U.S. workers found that 40 percent of employers are not selecting respirators for their employees based on fit testing." This has also been stated at past public meetings and at the OSHA hearings as to why this rule became a high priority as mentioned above. Realistically, however, requiring a respirator fit requirement during certification does not address the lack of compliance with an OSHA standard. A study in the United Kingdom found that respirators that had been TIL tested on a panel of people during certification tests, but were not fit tested, only fit about 30% of the people using them in the pharmaceutical industry.[11]

We agree that lack of fit testing in the workplace poses a concern that needs to be addressed. But a more expedient and direct means to correct this issue that could have been implemented sooner than the five years already spent for a "high" priority issue would be for NIOSH to meet with OSHA to discuss ways for a joint effort to train people to properly select respirators and follow up with fit testing. This joint effort could lead to programs by OSHA for workplaces using respiratory protection to conduct fit testing and NIOSH developing tools of various sorts to help employers accomplish fit testing. This is just one example and there are certainly more alternatives that could boost the amount of fit testing being done instead of going down a path that is likely to make respirators less available and more expensive and not result in more employees being fit tested.

The third implication as stated by NIOSH "applies to the stockpiling of respirators for use in case of an influenza pandemic. During a disease outbreak, such respirators might be deployed without a respirator program and without fit testing." 3M agrees that deploying respirators and condoning their use without fit testing is a concern. But the more appropriate remedy is to ensure that the stockpile is made up of a sufficient number of respirator models and sizes so that many respirator models are available to fit a wide variety of people. Secondly, because the government is responsible for this

stockpile, the respirators should only be deployed to organizations that have complete respiratory protection programs including fit testing.

Subject Sampling (*74 Federal Register, p. 54144*)

With respect to subject sampling and panels to assess fit, NIOSH states, "It is documented in testing and agreed by reviewers that the proposed panel represents a substantial improvement over its predecessor panel and should be implemented." While 3M agrees that the Los Alamos National Laboratory (LANL) panel is in need of being updated, a point of clarification is needed. The US population appears to be larger in size and more ethnically diverse than predicted by the LANL panel, so the new panel may be more representative of these people[16]. But the LANL panel was used to attempt to select facial sizes that represented over 90 percent of the potential faces using respirators and was not proposed as a tool to design respirators. Under the proposed rule, the NIOSH bivariate test panel results in a design requirement that is not predictive of actual fit of end-users.

As pointed out by the Institute of Medicine, a relationship between the two facial dimensions used in the NIOSH bivariate panel and respirator fit has never been established.[1] As long as no correlation exists between these facial measurements and respirator facepiece sizes, using the panel to assign facepiece sizes introduces variables into the test that are not related to enhancing fit. As a result, the proposed method may reject respirators from being certified that fit an even broader range of faces than is contemplated by the NIOSH bivariate panel.

Both the LANL and NIOSH bivariate panels are attempting to use a sample of subjects in a laboratory to represent the general population of end-users. 3M has successfully placed many designs on a very large population in the real-world. This work is summarized in Table 1, in which a number of respirator users from various industries talk about the fit testing they have done with these products. No one respirator is capable of fitting everyone. The objective of a portfolio of respiratory protective products should create choices that enable the best selection of fit and features to the end-user, not pass a random group of individuals selected in a laboratory.

3M randomly contacted six different companies using filtering facepiece respirators representing a variety of industries and applications. The number of respirator users at the companies ranged from a few to several thousand. The filtering facepieces included both filter class 95 and class 100. All of the companies contacted have respiratory protection programs in place, including either qualitative or quantitative fit testing procedures. These companies were all highly satisfied with the filtering facepieces used at their sites. All the companies contacted had been using the specific models for several years and indicated their experience has been that the models fit a wide variety of face sizes, shapes, and ethnicity. Several companies indicated they use the same filtering facepiece models in areas outside the United States (e.g. Canada, Mexico).

Table 1. Summary of comments from users of filtering facepiece respirators.

			Estimated Fit Test Pass Rate for user pool				
Company	**Industry or application**	**Estimated # workers in 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%	

NIOSH published data also indicate that the same respirators models listed in this table were identified by NIOSH to be among the best of the well-fitting respirators.[12,13] In addition, workplace protection factor studies conducted on many of these same respirators indicate they provide protection above their OSHA assigned protection factor. The proposed test procedure would eliminate many products from the market that have been demonstrated by NIOSH's own data, 3M data, and end-user data to be well-fitting.

Pass/Fail Criteria (74 Federal Register, p.56150)

Fit Factor ≥ 100 Criterion

NIOSH in this proposal has established pass/fail criterion based on achieving a fit factor of 100. This is different from the concept and public meetings where NIOSH had used a fit factor of 20 as the pass/fail criterion. This dramatic five-fold increase in the criterion is not clearly or directly explained in the proposed rule. But the following statements from the *Federal Register* may serve as a partial explanation for this change.

1. "Approximately 30 percent of this class of respirators have facepiece seals that did not perform adequately to achieve a fit factor of 100 (limiting total inward leakage to no more than 1 percent), as specified by OSHA, for substantial numbers of the human subjects donning them for benchmark testing." (*74 Federal Register, p.56142*)

This statement seems to indicate that the level was chosen in part based on NIOSH's belief that most (70%) of half facepiece respirators would pass the proposed rule with the 100 criterion. Work done independently by 3M and ISEA being submitted into this docket does not support this position.

2. "NIOSH received concerns regarding the use of various testing technology and methods to evaluate TIL. The technology is identical to that in common use for measuring respirator fit and is accepted by OSHA." (*74 Federal Register, p.56143*)

This statement implies that the test equipment proposed by NIOSH for TIL is allowed by the OSHA standard, which is not true. Most importantly, OSHA does not require that TIL be measured. OSHA methods allow the use of the PortaCount with ambient aerosols for *fit testing*. However, based on our understanding and knowledge of the OSHA respiratory protection standard, 29 CFR 1910.134, along with discussions with OSHA, the PortaCount with Companion as a fit test method does not appear to be included among the OSHA accepted fit testing protocols. 29 CFR 1910.134 Appendix A, Fit testing Procedures, was published January 8, 1998 and did not mention the N95 Companion because it was not available on the market until after Appendix A was published. The N95 Companion was not available on the market until after Appendix A was published according to TSI information.

In April 1998 OSHA published corrections to the federal Register copy of the Respiratory Protection standard. One of the corrections was in the condensation nuclei counter quantitative fit test protocol in which the requirement in paragraph (a)(1) that a high-efficiency filter be fitted was revised to allow for the fit testing of additional types of filters as appropriate. It reads, "(1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction." (*63 Federal Register, p.20098*) TSI has indicated that this correction was to allow for the PortaCount with Companion. For OSHA to accept the PortaCount with Companion, a study or publication would have to have been conducted by a national laboratory or published in a peer reviewed journal confirming that N95 companion is accurate and reliable. This has never happened. NIOSH needs to provide information from OSHA that the PortaCount with Companion is included in 29 CFR 1910.134 Appendix A before making this statement.

3. "The maximum allowable leakage is now equivalent to the fit test criteria required by OSHA for this type of respirator." (*74 Federal Register, p.56144*)

This statement indicates that the fit factor of 100 obtained with the PortaCount with Companion is equivalent to a fit factor of 100 obtained by one of the OSHA-accepted fit test protocols. 3M is not aware of any basis to support this position. No known or published study has been performed that correlates or compares the PortaCount with Companion fit test method with any of the OSHA accepted methods. Furthermore, all of the OSHA accepted fit test protocols were compared and determined to be equivalent to the generated aerosol protocol. Studies have been published or conducted by national laboratories and determined that all of the procedures are as accurate and reliable as the generated aerosol method. Until this similar validation is completed using the PortaCount with Companion, there is no scientific basis that the 100 fit factor calculated by the PortaCount with Companion is equivalent to a 100 fit factor determined by another OSHA accepted protocol. Furthermore, OSHA does not require a respirator to provide everyone with a fit factor of 100, only the person that is assigned to wear that

half facepiece respirator. Hence selecting a fit factor of 100 as the pass/fail criterion reflect an arbitrary decision rather than one that is based on science.

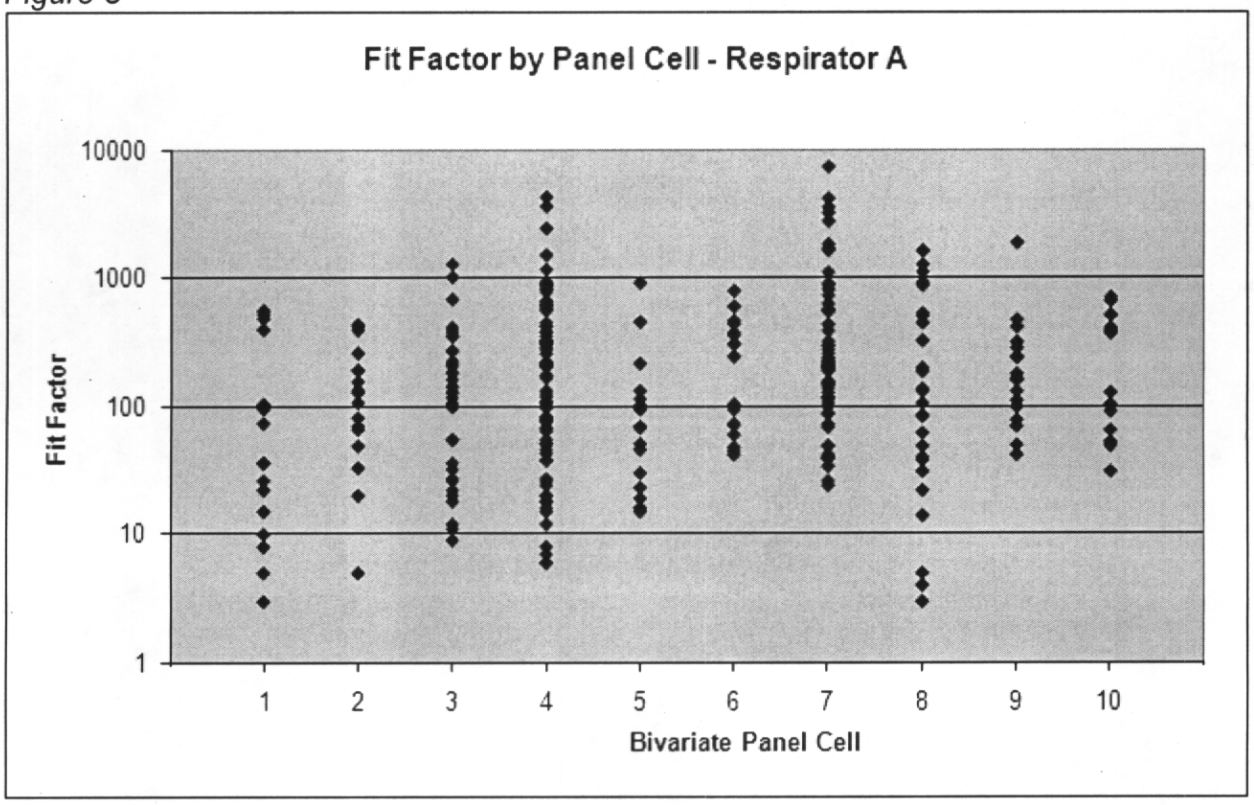
4. "The standards have been designed statistically to identify and pass with high accuracy (greater than 90 percent probability) those respirators that provide adequate TIL performance to the large majority of intended users (in the range of 80 to 90 percent of intended users) while failing with near certainty (greater than 99 percent probability) those respirators that do not provide adequate TIL performance to a majority (50 percent or more) of intended users. Adequate TIL performance is a TIL value of 1.0, equivalent to a fit factor of 100, which is the level of performance for these respirators specified by OSHA." (*74 Federal Register, p.56144*)

As stated above, there is no evidence to indicate that this fit factor is equivalent to the level required by OSHA.

One per Cell Criterion

This proposal requires respirators fit a large variety of facial shapes and sizes. 3M supports this requirement. Based on fit testing results of large numbers of subjects, our data indicate filtering facepiece respirators are capable of fitting subjects in every cell of the NIOSH bivariate panel. Figure 3 shows the distribution of individual fit values versus NIOSH bivariate panel cell for 105 subjects tested three times each on a well-accepted 3M filtering-facepiece respirator. The respirator fits some subjects in each panel cell well (fit factor $\geq$ 100) and does not fit other subjects in the same cells as well (fit factor < 100).

Figure 3



However, based on the proposed small sample sizes of 35 people the proposed test procedure is unable to demonstrate that any particular respirator model satisfactorily fits a large variety of facial shapes and sizes (see table 2). We believe this is due to the small number of subjects tested coupled with the wide variability in fit among subjects in the same cell. In the cell sizes that represent a small fraction of the likely end-user population, there are only two test subjects and given the large variability between subjects, the chances of failing are higher in these cells.

Table 2: 3M Laboratory Testing Based on the Proposed NIOSH TIL Rule

Product	Mean Fit Factor	Passes (# out of 35)	Pass Rate	1 pass in each cell?	Pass NIOSH TIL Test?
Model A	167	27	77%	Yes	Yes
Model B	153	29	83%	Yes	Yes
Model C	358	30	86%	No (10)	No
Model D	527	29	83%	Yes	Yes
Model E	209	25	71%	Yes	No

The proposed test method requires a pass in every cell of the NIOSH bivariate test panel, either with one respirator that is tested over the entire panel or one model with various sizes to be tested over the entire panel. Data collected as specified in this proposal and RCT-APR-STP-0068 Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators indicates that few respirator panels of 35 subjects will have a pass in every cell primarily due to the test design as opposed to the respirator design (*see Technical Annex: Study Two Summary of Results, Table A1*).

If the proposed rule is not changed, manufacturers will end up designing respirators to meet the NIOSH bivariate test panel instead of the wearer population. As they do so, it will reduce the likelihood of a respirator being able to fit someone outside of the panel as indicated by performing a required fit test. Those industries with smaller workers will typically have fewer respirator choices available to them. In addition, the variability in design between manufacturers will decrease. As the diversity in design decreases it will be more difficult for employers to find respirators for the "hard to fit" wearers.

Practical Considerations for Pass/Fail Percentages

A pioneer in face fit measurement, Hyatt[14] reported that his experience, based on a single facepiece size design using qualitative fit testing, indicated that the best fitting half facepiece respirator fit approximately 80% of all men tested. He also stated that the

poorest fitting half facepiece respirator provided a satisfactory fit on 60% of the men tested. This indicates that a well-fitting respirator would be in the range of 60-80% of those tested. Based on Hyatt's choice of language, his results may have been from testing done on males only. We would expect that if this testing were to include females, the testing may indicate lower percentages for all three categories.

Comments on Summary of Proposed Rule (74 Federal Register, p.56144)
The original intent of 42 CFR 84 is not changed by this proposal. Paragraph 84.175 (a) remains the same, "Half-mask facepieces and full facepieces shall be designed and constructed to fit persons with various facial shapes and sizes either:

(1) By providing more than one facepiece size; or

(2) By providing one facepiece size which will fit varying facial shapes and sizes."

Complying with these provisions is ambiguous.

Paragraph 84.175(h) is also new and, in 3M's opinion, very problematic. It states, "User instructions for half-mask respirators shall specify information necessary to identify the intended population of users:

(1) The **applicant shall specify** [3M emphasis] in the user instructions **the face size or sizes** [3M emphasis] that the respirator is intended to fit; pursuant to this requirement, one respirator may be intended to fit all face sizes; and..."

We interpret this paragraph to require the respirator manufacturer to indicate the size of the face that a specific model or facepiece size is to fit. If only one model is made in that model this certification would imply that it is designed to fit all the sizes of the NIOSH bivariate test panel. We have stated in comments to Docket 036 and at the December 3, 2010 public meeting why this is problematic. The proposal on p. 56144 makes it clear that "It [paragraph (h)] would require the user instructions of a half mask respirator to specify the intended users of the respirator, **by facial size** [3M emphasis], if applicable, and by other descriptive information as might be necessary for respirators designed for specific subpopulations, ..." It does not say by facial size or by other descriptive means.

As a manufacturer, 3M believes that:

- By specifying the face size the respirator is to fit or

- Implying that one size fits all when tested on the entire NIOSH bivariate test panel

we are creating a product performance claim and perhaps an implied warranty.

This claim would in effect say that if your face fits in to the size indicated by the two measurements specified in the user instructions, this respirator fits you. This implies fit testing is not needed, thus reducing individual fit testing (the opposite effect desired to be achieved by this proposal) and giving a false sense of security to the wearer that the respirator properly fits them.

Moreover, if this requirement were to come to fruition, it will make worksite fit testing procedures more complicated. This proposal will require that all employers acquire calipers, learn how to use them, measure facial dimensions of each wearer, determine the panel cells each respirator wearer fits into, and acquire respirators for those panel cells if they elect to select respirators in accordance with the information NIOSH may require manufacturers to place on packaging. The employer will also need to update the written Respiratory Protection Program to reflect all these changes. In 3M's opinion, neither the employer nor the respirator wearers will benefit from any of these new requirements because after doing all of this, if the data shows that after performing individual fit testing there will still be end-users that the respirator does not fit, which will require the selection of a different respirator model.

Because the two dimension facial measurements from the NIOSH bivariate test panel do not consistently correlate to fit,[1] using these face sizes as predictors of fit is inappropriate. 3M supplied data and information to docket 036 demonstrates that the proposed measurements do not correlate to an acceptable fit. Due to the large variability of human facial features, it is unlikely that a correlation between cell number and respirator size can ever be established. For example, the anthropometric measurements used to establish the NIOSH bivariate fit test panel are based on measurements between boney anatomical landmarks. Aging and significant changes in weight are recognized as affecting respirator fit, but neither change the distance between anatomical landmarks. As a result, each cell has an infinite set of face shapes,

which makes individual user fit testing the only way to determine which respirator model and size is appropriate for each worker.

Based on comments from the 2007 public meeting and stated in the proposed rule, "All test subjects shall also have facial characteristics which result in being included within the Principal Components Analysis Panel, which excludes extreme facial features." (*RCT-APR-STP-0068, p.2*) NIOSH may believe that this will eliminate the variability between members of a cell of the NIOSH bivariate test panel. The fit test panel data 3M supplied to the docket 036 and the December 3, 2010 public meeting did not change by eliminating those panel members with extreme facial features. Our experience from conducting the studies to evaluate the NIOSH proposal indicates that out of 272 subjects meeting the bivariate requirements only four have been excluded by the PCA panel. NIOSH did not provide any data to support the use of the PCA panel to eliminate "extreme facial features."

There is insufficient data in the docket to support the proposed rule. To support this conclusion, 3M has:

- reviewed the NIOSH benchmark data on our respirators,
- conducted a study evaluating our respirators to the proposed test protocol, and
- participated as a member company in an ISEA study.

The results of the ISEA study are being submitted to docket 137. Hence 3M has much more data than NIOSH has publicly disclosed for evaluating the impact of this rule.

NIOSH Questions and 3M Responses (*74 Federal Register, p.56145*)

In addition to general comments, NIOSH specifically invited public comment on specific questions. NIOSH indicated there are several critical factors that the public should consider in providing such comments:

1. What percentage of the intended user population should be able to achieve adequate TIL performance for the respirator to be approved by NIOSH?

NIOSH has proposed that 75 percent or higher should be able to achieve such performance. This performance level is based on the design and statistical considerations presented above in this General Discussion section; essentially, using

this 75 percent testing parameter would provide strong assurance (90 percent probability) that testing identifies for approval respirators fitting the large majority—80 to 90 percent—of intended users, while rejecting with near certainty (99 percent probability) respirators that fit only a minority—less than 50 percent—of intended users.

3M response: Again, note that NIOSH is using this proposed rule as a fit test and not a TIL test. 3M maintains that initial and annual qualitative / quantitative fit testing should be done by every end-user, as it is the only means of ensuring fit performance. Therefore, the premise of NIOSH's own question on total inward leakage is incongruous. Regardless of the chosen target of "percentage of the intended user population…to achieve adequate TIL performance," no statistical manipulation will ensure that such "testing identifies for approval respirators fitting the large majority." TIL testing by regulators does nothing to enable, ensure, or improve the likelihood of respirator fit. We believe due to the many limitations of this test procedure, 60% of the NIOSH bivariate panel should achieve an adequate fit. Any higher percentage requirement will certainly eliminate some well-fitting respirators from the market place.

2. As the percentage of the intended user population capable of achieving adequate TIL performance from a respirator declines, at what point, if any, should NIOSH set the limit to be nearly certain (e.g., 99 percent or higher probability) that the respirator would not be approved?

NIOSH has proposed that a respirator should be rejected with near certainty if it does not provide adequate TIL performance to at least a majority (50 percent or greater) of intended users. NIOSH believes this is a reasonable standard for defining the performance of a poorly fitting respirator that should not be approved.

3M response: Even if NIOSH were to remove language that incorrectly equates TIL and fit, the TIL performance as measured by the proposed rule is highly variable between subjects. Given the inherent variability demonstrated in comments from 3M and the ISEA, at its best the proposed TIL rule could do little more than screen out the very weak respirator models. Therefore, a pass rate of at most 60% (20/35) of the intended user population should have to achieve adequate TIL performance for

the respirator to be approved by NIOSH (assuming the removal of the 'one per cell' criterion). This number means that any product being placed in the market would minimally have an adequate fit for the three most populous cells of the panel (3,4,7). While this does not ensure fit for an individual end-user, it may help rule out particularly weak designs with respect to poor fit.

3. How many test subjects should be included in the testing, considering the fact that testing accuracy increases with the number of test subjects, but that the cost of testing also increases with the number of test subjects? Do the numbers of subjects proposed by NIOSH (15 to 35 test subjects, as specified under § 84.175(i)(4)) reflect an appropriate balance between limiting manufacturer testing costs and providing sufficiently accurate results?

What level of testing cost is supportable, in the view of manufacturers? Would manufacturers prefer a higher numbers of test subjects and associated higher costs, to reduce further the likelihood that a respirator with adequate TIL performance is denied by chance?

3M response: The statistical analyses conducted by 3M and ISEA demonstrate that a significantly large number of test subjects would be necessary to assure "sufficiently accurate results." While NIOSH correctly notes "that the cost of testing also increases with the number of test subjects," it is far more costly for a manufacturer to be forced to re-develop a respirator due to incorrect conclusions from a poor test result than to run a larger test panel.

The results of 3M's large subject pool testing and the subsequent statistical analysis show that there are two issues to be considered in answering the question of sample size: 1) the overall pass rate and 2) the value of the 'one per cell' criterion. Assuming that the 60% passing rate suggested above is used, 3M would make the following recommendations.

1. The between-subject variability of a market-proven, well-fitting respirator shows that the inclusion of a 'one per cell' criterion inappropriately biases the panel results toward cells with a small set of subjects (1,2,5,6,9,10). Indeed, a respirator with a very high pass rate of 86% still failed a 35 subject panel

because two of the five failures came from the same cell. Therefore, if the 'one per cell' criterion were included and the relative proportions between cells kept consistent, a panel of no less than 105 subjects would be necessary to build some statistical confidence that the between-subject variability is not leading to incorrect test results on a respirator design.

2. As the inclusion of the 'one per cell' criterion has not been clearly explained and its presumed value questionable, if it were dropped from the proposed rule, demonstrating a 60% subject pass rate over a panel size of 35 subjects would reflect an appropriate balance between cost and confidence in the fit results.
3. A third option could be used as a potential compromise between larger panel sizes and higher likelihood of accurate "TIL" results. If the 'one per cell' criterion is not removed, NIOSH could selectively increase the subject size in any given cell up to three times the original cell requirements. As long as the overall pass rate does not go below 60%, it would be reasonable to include extra subjects in a specific panel cell if this is the only reason that a respirator model does not achieve adequate TIL performance during the initial panel of 35. This would enable a level of confidence that the respirator will achieve adequate TIL for a majority of users (>60%) while also allowing a level of confidence that it will achieve adequate TIL for a broad variety of faces (one per cell).

To be clear, 3M's position is that any panel size of the current proposed TIL rule would be onerous to manufacturers. This is not due to the cost of the panels; rather it is unacceptable because TIL results do not ensure the enhanced fit for end-users.

Effective Date (*74 Federal Register, p.56149*)

NIOSH has encouraged the public to comment on the proposed implementation schedule and any related issues. Some specific issues for comment include the following:

1. Do manufacturers believe they can meet the proposed TIL performance standards and testing requirements and provide adequate product supply to meet anticipated market demand within the proposed 3-year deadline?

3M Response: Given the lack of reliability of the test method in the proposed rule, it would be exceptionally difficult to determine the overall number of respirator models that would need to be re-designed. Probability estimates run from a conservative 30% (NIOSH) to a more realistic 95% (3M and ISEA) of filtering facepiece respirator models failing the criteria of the current incarnation of the TIL rule. The following compliance steps could reasonably be predicted:

- First, all designs would have to re-submitted to NIOSH in order to determine whether they have adequate TIL performance as established in any final rule. Given the high subject-to-subject variability (*see Appendix A*), and thus panel variability, no manufacturer would have assurance that their design would pass the NIOSH criteria unless it was actually tested by NIOSH's panels. This step would take several months, particularly as NIOSH would be inundated with submissions during this initial period. This would likely expend 3-6 months of development time for each respirator model.
- Once a failure is announced to a manufacturer, possible options include: 1) a straightforward material change, 2) a modification of the design or process requiring no capital expenditures, 3) a complete re-design requiring significant product development and manufacturing input. Such programs could take from six months to several years to complete.
- Whatever option is chosen by the manufacturer, after they have completed their changes they would have to re-submit for NIOSH approval again. Once again, this could take 3-6 months. Timelines will be exacerbated by the fact that with the highly variable nature of the proposed test it would be nearly impossible for a manufacturer to gain certainty prior to submission that a design would have adequate TIL performance for NIOSH approval. Therefore, the entire process may require multiple iterations as designs are created, tested internally, submitted for NIOSH testing, and then re-designed, re-tested, re-submitted, etc.
- As one of the most likely causes of any failure of the proposed NIOSH rule is due to the subject-to-subject variability, it would be extremely difficult to know if the test data actually shows inadequate respirator performance or a difference in the panel selection.

No two designs or product development processes are alike, so it is extremely difficult to estimate the period of time to implement this proposal. But if even one half of the models on the market would require re-design, a 3-year deadline to modify all half facepiece models would be very difficult to manage. Given the inherent variability of the test, it is much more likely that manufacturers with many designs that protect large and varied categories of end-users would need 5-8 years to entirely re-fit their portfolios in order to comply with the proposed rule.

2. Would any parties affected by this proposed rule incur an exceptional and unsupportable financial or other burden as a consequence of the proposed 3-year limit on the sale and distribution by approval holders of respirators certified under the current requirements (which omit TIL standards and testing)?

3M Response: Nearly all parties impacted by this proposed rule would incur an exceptional financial and/or other burden as a consequence of a 3-year limit. First, as noted in 3M's economic impact statement, annual revenues for all respiratory protective equipment (RPE) manufacturers would be dramatically decreased as currently used, well-fitting respirators would likely need to be removed from the market before re-designs are entirely complete. If a time limit as short as three years were implemented, this would require all RPE manufacturers to rapidly and dramatically shift significant laboratory and manufacturing resources to re-design products that would meet the proposed rule criteria. A shift in resources would likely also impact the employment structure in American manufacturing facilities as respiratory companies have to shift financial resources to product development activities and away from the plant. This would also impact the local economies that are supported by these facilities.

Implementation of the proposed NIOSH TIL rule over the next three years would limit the choices for respiratory protection for current users, as many designs will need to be pulled from the market because they do not have adequate TIL performance – even if they are established, well-fitting respirator products. Companies that coordinate safety programs for their workers will in many cases have to re-invest in fit testing and training, as many of the current products will either be pulled from the

market or re-designed. This will cost them both money invested directly in the training programs, lost time by workers, and reduced productivity in many sectors of the economy. Unfortunately, the substantial costs incurred for this proposed rule would necessarily be shared through the entire supply chain, from the respiratory manufacturer to the purchasing customers.

At the same time, this replacement of resources will prevent RPE manufacturers from developing new and better products to meet the needs of the end-users, including products that would actually enhance fit. Should another pandemic occur during the time period of the new rule implementation and current products not being available to the market, it would significantly limit the availability of certified respiratory protection products to the general population.

Governments and other holders of stockpiles would also be impacted as the products in which they have invested may no longer meet the requirements of the NIOSH approval.

3. Would a different implementation schedule be better justified in terms of balancing the public health, practical, and economic benefits of removing from the market NIOSH-approved respirators with inadequate TIL performance against the public health, practical, and economic benefits of ensuring that an adequate supply of NIOSH-approved respirators remains constantly available?

Please describe the advantages and disadvantages of extending or contracting the implementation schedule.

3M Response: As it is currently proposed, it would be hard to imagine a significantly better implementation schedule for something as variable and ineffective as this rule. However, a few recommendations for consideration would include:

- Grandfather in all current designs holding NIOSH approvals with demonstrated levels of fit. 3M would be open to working with NIOSH and industrial collaborators to further define this topic. Penalizing RPE manufacturers for designs in the market that are accepted by users would not be logical for this particular proposed rule. If a fit proposal were created that improved the

likelihood of better fit and was robust enough to withstand scientific scrutiny, then a different type of implementation schedule might be appropriate.

- While allowing existing respirator models to stay in the market unencumbered, new respirator designs and submissions will require compliance with a modified proposed rule (for example, 60% pass rate, TIL ≤ 5%, no 'one per cell' criterion). These proposed changes would meet NIOSH's stated objective of excluding poor respirator models from the market, is consistent with the earlier proposals for the actual TIL value, and removes the unexplained criterion that exacerbates the between-subject variability of the proposed rule.
- The proposed rule with the suggested modifications could be initiated in concert with a re-invigorated fit testing compliance and enforcement activity. As an example, an employer is given the option to complete a fit test criteria for products that they use already instead of requiring a NIOSH approval with the proposed TIL rule. This would have the benefit of keeping most of the acknowledged, well-fitting respirators on the market and available.
- Remove the proposed rule from consideration and use the next three years to focus on developing an effective and robust test method that drives all companies toward designing and selling respiratory protection that provides genuinely better fit for end-users.

4. Are other factors that have not been identified by NIOSH important to deciding an appropriate implementation schedule?

3M Response: At this time, 3M does not have any further comments on an appropriate implementation schedule.

RCT-APR-STP-0068 Total Inward Leakage Test for Half-mask Air-purifying Particulate Respirators

Because the bivariate measurements are not correlated with achieving an acceptable fit, we believe the test protocol must be changed in how it instructs one to select a respirator size from a model that has multiple sizes after failing to pass a fit test with the first size selected. It currently says, "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." Because there is no correlation between size and fit, one can not ensure what size the next selection should be. It also implies that out of three or five sizes, only one additional size can be selected. We believe if the second size fails all sizes must be tried until they are exhausted or there is a pass.

Summary

In principle, we support the idea to evaluate respirator fit as part of the certification process, but based on the above comments 3M does not support the TIL concept as proposed. Further, this proposal will not solve the problem that NIOSH has repeatedly identified as an important reason for the TIL program, namely, that less than all employers conduct fit testing of their respirator users. Because this is a user's issue, 3M suggests that resources should be spent on informing the user of the importance of individual fit tests. The solution is not a new NIOSH test but rather reinforcing the importance of conducting individual fit tests and ensuring training for proper donning and use. Based on the proposed rule's statistical weakness, lack of reproducibility and repeatability, and overall lack of robustness, NIOSH should withdraw the proposed rule.

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Appendix A: Technical Annex

In order to determine the performance of NIOSH's proposed TIL test procedure 3M recently conducted tests on a number of different well-fitting 3M filtering facepiece respirators in accordance with that procedure.

Study One: 35 Subject Panel Conducted on Five Separate Respirator Designs

The objective of the first study was to assess a single panel example of assessing five well-fitting 3M filtering facepiece respirators (determined via high percent pass rates when fit tested on actual wearers in the field) by means of NIOSH TIL test method RCT-APR-STP-0068. For this study, a single subject pool of 35 subjects was selected according to the NIOSH bivariate panel and PCA compliant; with a separate subject pool being drawn for each of five distinct 3M filtering facepiece respirator models. The results were then used to give an example of the proposed rule's effect on these filtering facepieces.

Study Two: 105 Subject Panel on Single Respirator Design

In the second test conducted by 3M, three complete panels of 35 subjects selected from the NIOSH bivariate panel were tested with samples from the same manufacturing lot of a well-fitting 3M filtering facepiece respirator (respirator A) per the NIOSH-proposed TIL test procedure. The data from the fit tests were then used to generate 1000 simulated 35-subject panels via a bootstrap technique. Each simulated panel was created from a random sample of 35 subjects meeting the requirements of the NIOSH bivariate panel. Sampling for each panel was done without replacement (data for the same user was not used twice in a simulated panel). NIOSH's TIL pass/fail criteria were then applied to the fit test results for each of the 1000 simulated panels.

Study Three: 35 Subject Panel Repeated Three Times on Single Respirator Design

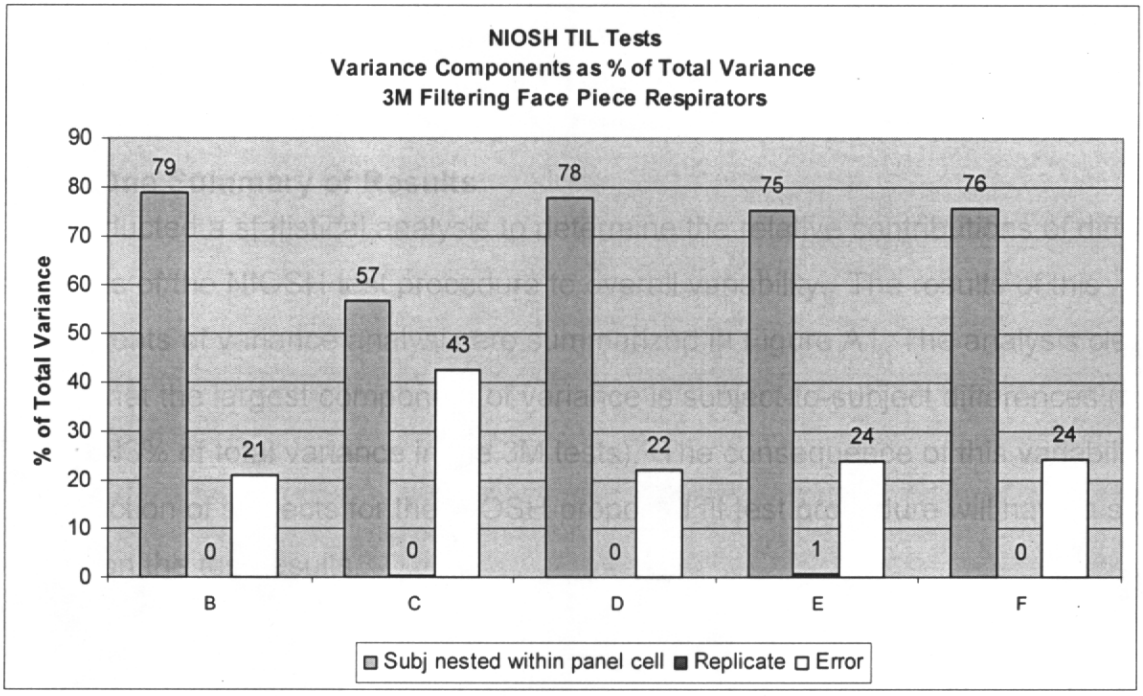
The objective of the third study was to isolate the variability when the proposed NIOSH TIL rule was conducted on the same subjects on multiple occasions. For this study, a single subject pool of 35 subjects was selected according to the NIOSH bivariate panel. These subjects conducted testing according to the proposed rule on three separate

occasions utilizing a new respirator of the same design and from the same manufactured lot number on each occasion.

Study One Summary of Results

3M conducted a statistical analysis to determine the relative contributions of different elements of the NIOSH test procedure to overall variability. The results of this components of variance analysis are summarized in Figure A1. The analysis clearly shows that the largest component of variance is subject-to-subject differences (from 57% to 83% of total variance in the 3M tests). The consequence of this variability is that the selection of subjects for the NIOSH-proposed fit test procedure will have a strong impact on the test results.

Figure A1 – Components of variance analysis for five well-accepted 3M filtering facepiece respirators



Study Two Summary of Results

The results of the application of the pass/fail criteria to the simulated panels are shown in Table A1. The overall pass rate (fit factor ≥ 100 or TIL ≤ 1%) for all 105 subjects was 75%. Therefore, it is not surprising that the requirement to have 26 of 35 subjects have

a TIL ≤ 1% was met 655 times in 1000 simulated panels (~66%). However, what is surprising is that the requirement to have at least one subject pass in each cell of the NIOSH bivariate panel was met only 463 times in 1000 simulated panels (~46%). When these two criteria are used in combination, only 369 out of 1000 panels (~37%) met the requirements of the proposed rule.

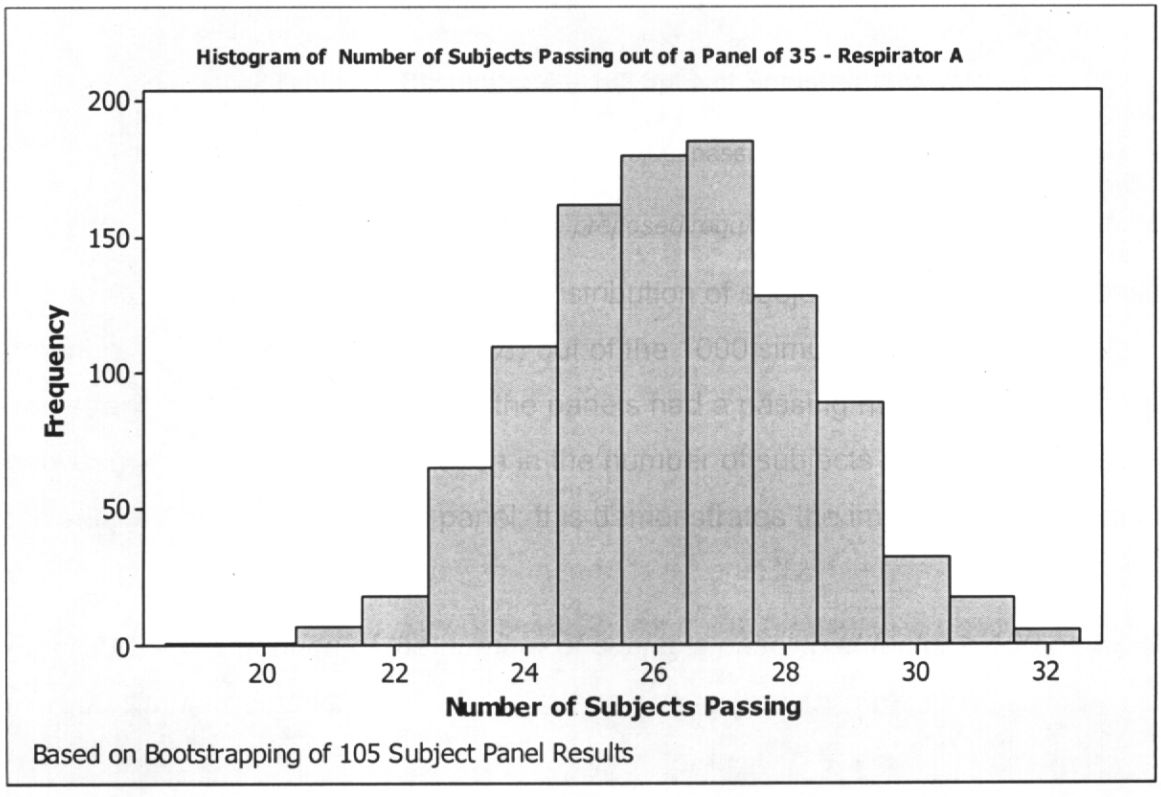
Table A1- Respirator A – 105 Subject Bootstrap Analysis

Number of panels with 26 out of 35 subjects passing	655 out of 1000
Number of panels meeting at least one subject passing per cell	463 out of 1000
Number of panels passing both criteria	369 out of 1000

Note: 79 out of total 105 subjects met the proposed requirement of TIL ≤ 1% in the overall panel

Figure A2 is a histogram showing the distribution of subjects passing the TIL pass/fail criterion (fit factor ≥ 100 or TIL ≤ 1%) out of the 1000 simulated panels generated in the bootstrap study. Ninety percent of the panels had a passing number of subjects ranging between 23 and 29. Wide variation in the number of subjects passing is due solely to the subjects selected for each panel; this demonstrates the impact of subject-to-subject variability.

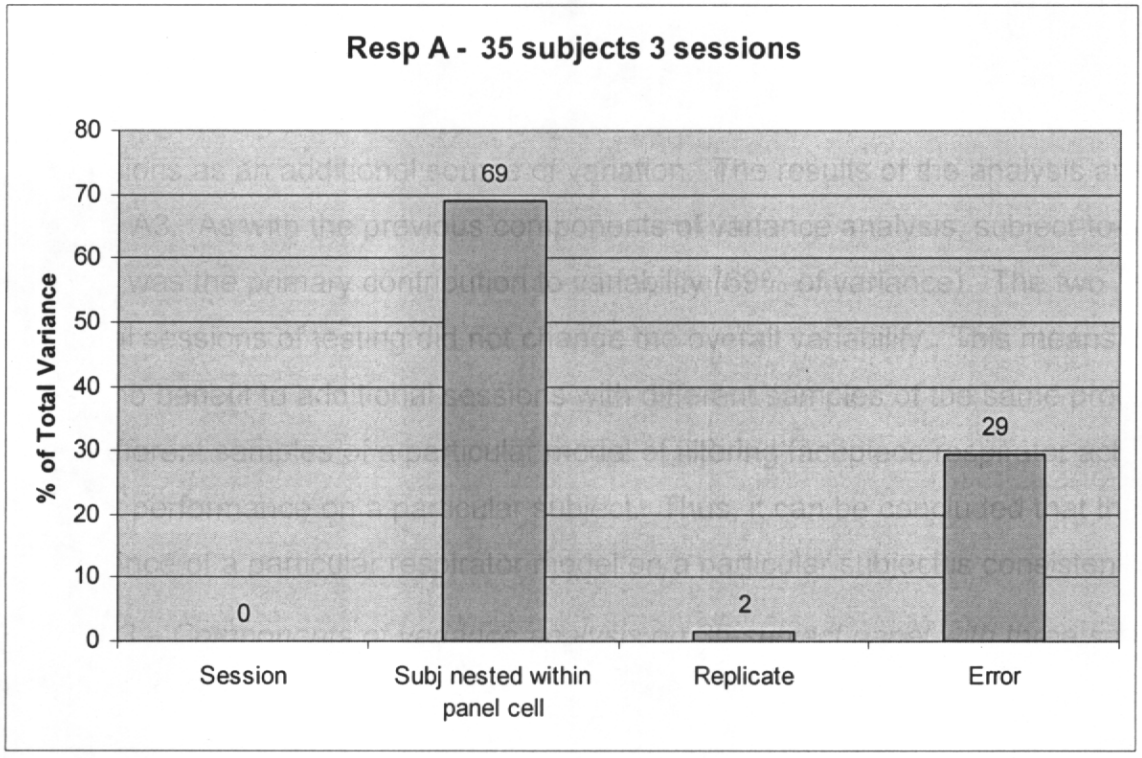
Figure A2 – Distribution of the number of subjects passing fit factor ≥ 100 or TIL ≤ 1% in 1000 simulated panels



Study Three Summary of Results

A components of variance analysis was conducted on study three, adding the repeat test sessions as an additional source of variation. The results of the analysis are shown in Figure A3. As with the previous components of variance analysis, subject-to-subject variation was the primary contribution to variability (69% of variance). The two additional sessions of testing did not change the overall variability. This means that there is no benefit to additional sessions with different samples of the same product. Three different samples of a particular model of filtering facepiece respirator achieved similar fit performance on a particular subject. Thus, it can be concluded that the fit performance of a particular respirator model on a particular subject is consistent.

Figure A3 – Components of variance analysis on 35-subject panel with three separate sessions on a single model of 3M filtering facepiece respirator



Therefore, if NIOSH wishes to overcome the limitations imposed by the large amount of subject-to-subject variability, the only solution is to increase the panel size. There is minimal benefit to be gained from conducting repeated tests with a smaller group of subjects.

Summary Comments

"One pass per cell" criterion

After reviewing the analysis of 3M tests conducted in accordance with NIOSH's proposed TIL test, 3M determined that the requirement to have at least one subject pass a TIL test in each panel cell has two major shortcomings. First, it overweights the impact of the six cells in the NIOSH bivariate panel which contribute two subjects each to the NIOSH TIL panel. These six cells represent one-third of the total subjects in the 35-member NIOSH panel. The remaining two-thirds of the subjects in the panel are contained in the remaining four panel cells. Second, for each cell with two subjects, there are only two independent trials, since the three tests (replicates) conducted on each subject are not independent, as discussed earlier. The impact of the "one pass per cell" requirement was not included in NIOSH's consideration of the impact of the rule change on consumer and producer risk in the white paper provided by NIOSH.[15]

The one per cell requirement does not benefit end-users since the requirement to pass at least one TIL test per panel cell has little predictive power for fit test pass rates in the workplace. This can clearly be seen in Table A2, in which it is assumed that each of the two-subject panel cells has up to six independent TIL tests (three per subject) and fit test results for an end-user can be predicted by their cell in the NIOSH bivariate panel. 3M considers both assumptions to be overly optimistic from an end-user protection perspective. The analysis in Table A2 is based on a uniform TIL pass rate within a panel cell and the binomial distribution.[15]

Table A2 – Predicted TIL % pass rate based on a uniform TIL pass rate in a NIOSH panel cell with 2 subjects

TIL tests passed out of TIL tests conducted	Subject 1 passed on	Subject 2 passed on	Predicted pass rate	Lower 90% conf limit	Upper 90% conf limit
1 pass out of 6 tests	3rd test	No Pass	17%	1%	58%
2 passes out of 6 tests	3rd test	3rd test	33%	6%	73%
1 pass out of 5 tests	2nd test	No Pass	20%	1%	66%
2 passes out of 5 tests	2nd test	3rd test	40%	8%	81%
1 pass out of 4 tests	1st test	No Pass	25%	1%	75%
2 passes out of 4 tests	1st or 2nd test	3rd or 2nd test	50%	10%	90%
2 passes out of 3 tests	1st test	2nd test	67%	14%	98%
2 passes out of 2 tests	1st test	1st test	100%	32%	100%

The range of predicted fit test pass rate for the portion of the general worker population sharing the same cell in the NIOSH bivariate panel cell is large. For one pass out of six trials, the 90% confidence limits for TIL pass rate are 1% to 58%. The remaining entries in Table A2 correspond the remaining ways in which at least one passing TIL test could be achieved in a single two-subject cell of the NIOSH bivariate panel. So, for each two-subject cell meeting the "one-pass" requirement, a passing result predicts a fit test pass rate for the general worker population with face sizes falling into that cell of the bivariate panel of between 17% and 100% with 90% confidence limits between 1% and 100%.

In addition to the negligible benefit to end-users of the "one pass per cell" requirement, it significantly increases the probability that a product passing the 26 out of 35 subject requirement will not be approved. This is clearly shown in Study 1 (see Table A1). Out of 1000 simulated panels, 66% of the panels pass the 26 passes out of 35 requirement, while only 37% of the panels pass the "one pass per cell" requirement. In summary, the

"one pass per cell" requirement would make it harder to obtain approval under NIOSH's proposed rule and provides no benefit to potential users of an approved product.

Use of PCA panel

The NIOSH test procedure for Total Inward Leakage (TIL) includes two panels. The first is the NIOSH bivariate panel which is used to construct the 35-member panels used in the TIL test. The bivariate panel is discussed at length in 3M's comments to the NIOSH proposed rule. The second panel in the NIOSH TIL test procedure is referred to as the Principal Component Analysis (PCA) panel. The sole purpose of the PCA panel in the TIL test procedure is to exclude unusual face shapes or sizes from a 35-member TIL panel.

In constructing the PCA panel, NIOSH first identified ten anthropometric dimensions as possibly being best correlated with fit. A PCA on those ten measurements resulted in the creation of two new variables (PCA1 and PCA2), which are linear combinations of the ten measurements. According to the publication describing the creation of the PCA panel, the ten anthropometric measurements were selected based on identifying which measurements out of a larger group that would best be correlated with respirator fit.[16] Rather astonishingly, however, the principal component analysis used to create the new variables did not utilize any fit test data. Although the PCA conducted by NIOSH may provide a better definition of face size and shape through the variables PCA1 and PCA2, there is no reason to believe that the variables are connected in any meaningful way to respirator fit. Unfortunately, a good understanding of how various facial dimensions affect the fit of a respirator does not exist. Although the fit test panels proposed in the NIOSH test protocol cover 97.7% of the US workforce in terms of facial dimensions, this does not translate clearly into statements about respirator fit.

3M acknowledges that NIOSH's updated bivariate panel is beneficial in ensuring that a representative distribution of face sizes is included in 35-subject TIL panels. 3M sees less benefit from the use of the PCA panel as specified in NIOSH's TIL test method. In 3M's evaluations, only four subjects out of a pool of 272 were excluded as outliers through the use of the PCA panel. Based on this and the fact that there is no clear reason why the PCA panel should be connected with respirator fit, 3M concludes that

the use of the PCA panel will have little, if any, impact on the variability of TIL test results. However, in accordance with NIOSH's TIL test method, 3M did exclude the four "outlier" test subjects from all tests described in this document.